FUNDAMENTAL REVIEW OF THE GENERIC DRUGS MARKET

A Report Prepared by OXERA

on behalf of the Department of Health

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Abbreviations

AO	assembly-only
API	Association of Parallel Importers
AWP	average wholesale price (US)
BGMA	British Generic Manufacturers Association
BNF	British National Formulary
EC	European Community
EDI	electronic data interchange
EGA	European Generics Association
EU	European Union
FDA	Food and Drugs Administration (US)
GP	general practitioner
GPO	group purchasing organisations (US)
HCFA	Health Care Financing Administration (US)
IDN	integrated delivery network (US)
IT	information technology
KNMP	Koninklijke Nederlandse Maatschappij ter bevordering van de Pharmacie
LBS	London Business School
MCA	Medicines Control Agency
MMC	Monopolies and Mergers Commission (now the Competition Commission)
MRA	mutual recognition authorisation
MRP	mutual recognition procedure
NIC	net ingredient cost
NHS	National Health Service
OECD	Organization of Economic Cooperation and Development
OFGEM	Office of Gas and Electricity Markets
OGC	Office of Government Commerce
OTC	over the counter

PASA	Purchasing and Supplies Authority
PCA	Prescription Cost Analysis
PHARMAC	Pharmaceutical Management Agency Ltd of New Zealand
PI	parallel importer/import
PPA	Prescriptions Pricing Authority
PPO	Preferred provider organisation
PPRS	Pharmaceutical Price Regulation Scheme
PSNC	Pharmaceutical Services Negotiating Committee
R&D	research and development
ROC	return on capital
RPSGB	Royal Pharmaceutical Society of Great Britain
WACC	weighted-average cost of capital
PBM	pharmacy benefit manager
HMO	health maintenance organisation
DRG	Diagnostic Related Group

Executive Summary

OXERA was commissioned by the Department of Health to undertake a fundamental review of the supply and distribution of generic medicines. This review arose from the Department's concerns about the generic medicines market in the UK, and, in particular, the significant price rises in an unusually high proportion of generic drugs during 1999. The aim of the review was to provide the Department with remedial and radical options for reforming the existing market structure and government procurement arrangements, in order to deliver the Department's objectives, which are to:

- maintain, and improve, the current quality of service to patients;
- minimise the costs of the distribution networks, subject to service-level and quality requirements;
- reimburse pharmacists as closely as possible for what they actually pay for the medicines they dispense under the National Health Service;
- ensure transparent prices;
- support a competitive pharmaceutical market; and
- secure value for money for the NHS.

This is a public-domain version of OXERA's study, which was in two phases. Phase I of the review provided a detailed examination of the industry and then outlined a range of remedial and radical options. Two of these options required further analysis, and were examined in more detail in Phase II of the review. The material remains in the form that was presented to the Department at the time. Phase I was written in January 2000; Phase II in summer 2000.

The generic pharmaceutical sector has undergone significant changes over the last decade—changes that have put significant pressure on the NHS's procurement policies. Perhaps one of the more surprising outcomes from the study was the number of years that the system has served the government's interests, delivering reductions in the drugs bill for generics. Given the focus on generic prescription as a means of delivering substantial headroom in the NHS budget, it is crucial that the supply chain for generics functions effectively. Enhancing the competitiveness of UK generic manufacturing is a central element of this. It is through dynamic generic entry that the costs of branded drugs are lowered once off patent. Setting in place a framework to encourage this activity will deliver strong public-interest benefits. The study examined the current system, highlighting any weaknesses, and suggested policy options that could be considered to enable the government's objectives to be more closely met.

Six key industry characteristics should be borne in mind when considering likely developments that will influence the success or failure of any reforms to the generic drugs supply chain:

- the inherent security-of-supply risks for drugs where the number of licence-holders is low;
- an increasingly internationalised manufacturing base;
- an increasing focus on the profitability of individual drugs;
- vertical integration in the supply chain;
- the role of IT; and

- the role of community pharmacy.

It is important to bear in mind that medicines for which there are a small number of licence-holders are problematic under any system. Any reforms to industry arrangements should seek to ameliorate this situation where it occurs and protect against any supply problems that could arise.

The pattern of UK generic manufacturing ownership has changed significantly in the last ten years, moving towards large international generic manufacturers, with subsidiaries in up to 15 countries worldwide. As European mutual recognition procedure (MRP) is established, the gains from supplying a broad European market are increasing, as new drugs come off patent. As mutual recognition of manufacturing sites also grows, the cost of cross-border supply is falling.

The effect of this could be to make NHS demand a much less central part of the business of these companies. It also makes it more likely that foreign suppliers will wish to enter the UK market. As long as this foreign supply is forthcoming, then risks of supply failures should be lessened. There may be a convergence of prices for some products across European markets, as arbitrage may remove price differentials. Overall supply costs may fall, as manufacturers can benefit from substantial economies of scale if they are supplying a market across four or five major European countries. As penetration of generic prescribing and dispensing grows across France, Germany and Italy, for example, the potential industry growth rates are large.

Accompanying this broader international perspective, and contributing to pressures to equalise prices across countries, is a closer attention to the margins earned on individual drugs. Inevitably, this will involve a reassessment of portfolios and a likely cessation of production of drugs with poor long-term performance.

Looking at patterns of consolidation and integration elsewhere in the supply chain, the main UK national wholesalers are all part of pan-European integrated companies. Generic distributors are also developing further European links. At the pharmacy level, the trend towards large chains, integrated or independent, continues. Vertical integration is a key tool in ensuring supply stability (for wholesalers) or demand stability (for manufacturers or wholesalers) in an increasingly open market.

Phase I

This phase of the review analysed the functioning of the generic drugs supply chain, and established a set of critically assessed policy options for the supply and distribution of medicines.

The major weaknesses in the current system for supply and distribution of generic drugs were found to be:

- a lack of information on supply conditions and shortages throughout the chain;
- vertical integration, which makes the NHS's reliance on pharmacists as contractors problematic;

- perverse incentives in the then current reimbursement scheme, leading to, in particular, increased discounting on list prices and artificial inflation of the Category A Drug Tariff price;
- supply instability in times of shortage affected by actions of short-line wholesalers (although these participants also perform a useful competitive function);
- the absence of workable and enforceable supply contracts;
- licensing controls, which appear to be a barrier to entry in manufacturing and contribute to a fragmentation of a global market into many smaller national markets for some presentations;
- returns may be higher than might be expected for some elements of the supply chain.

The options for reform considered in this report fell into six categories.

- 'Do nothing', except perhaps attempt to recoup any returns in 1999 of those in the supply chain that are considered excessive.

- Reform the reimbursement system by:

  – expanding the Drug Tariff basket to include the other large manufacturer, the third national full-line wholesaler, as well as some larger short-liners;
  – removing Category D;
  – reforming the Discount Inquiry, in particular by designing different inquiries for independent and for integrated pharmacies.

- Improve transparency through various types of information requests:

  – requiring price and volume information from manufacturers and wholesalers;
  – making better use of endorsement information;
  – IT solutions.

- Reform the licensing regime for manufacturers, to facilitate entry.

- Enforce vertical separation between integrated wholesalers and pharmacies.

- Use centralised purchasing by the NHS, either for all drugs, or for those in shortage.

The table below summarises how successful each of the proposed changes is likely to be in achieving the objectives of the Department—ie, whether their effect on the then current position would be an improvement (↑), no change, or detrimental (↓).

Effect on the Department's objectives

	Quality of service	Minimise distribution costs	Reimburse closely	Transparent prices	Competitive pharmaceutical market	Value for money
Expand Drug Tariff basket	no change	no change	↑	↑	no change	no change
Remove Category D	↓	no change	↓	↑	↑	↑
Reform Discount Inquiry	no change	↓	↑	↑	no change	↑
Improve information	↑	↓	↑	↑	↑	↑
IT systems	↑	↓ (short-run) ↑ (long-run)	↑	↑	no change	↑
Licence changes	↑	no change	no change	no change	↑	↑
Vertical separation	↑?	↓	↑	↑	?	↑
Centralised purchasing	↑	↓	↑	↑	↑?	↑
Centralised purchasing of drugs in shortage	↑	↓	↑	↑	↑?	↑

In the table below, each option is assessed for whether the identified weakness is addressed (✓) or not (X), or goes part-way towards it (assist).

Effect on the weaknesses of the current system

	NHS's purchasing power used?	Improves performance monitoring	Enhances competitive manufacturing sector	Improves reimbursement
Expand Drug Tariff	X	✓	X	✓
Remove Category D	X	X	X	X
Reform Discount Inquiry	X	✓	X	✓
Improve information	X	✓	X	✓
IT systems	assist	✓	assist	✓
Licence changes	✓ (indirectly)	X	✓	X
Vertical separation	✓	✓	X	✓
Centralised purchasing	✓	✓	✓	✓
Centralised purchasing of drugs in shortage	✓	✓	✓	✓

If radical solutions are pursued to restore a successful procurement strategy to the NHS, it is important to realise that such solutions take time. Some short-term changes could be instituted to ameliorate the major weaknesses in the current structure, such as:

- expanding the Drug Tariff basket;
- removing Category D;
- making minor licence changes, to enhance import entry;
- instituting information requests; and
- reforming the Discount Inquiry.

With the longer term in mind, either a decentralised or a centralised approach could be pursued to enhance the NHS's buyer power. In both cases, a more competitive manufacturing sector should be encouraged. Additionally, an integrated, open-standard IT system could be of major benefit.

A decentralised approach would include the following policy options:

- some form of vertical separation;
- major licence changes;
- investment in integrated, open-standard IT systems.

A centralised approach would include the following options:

- centralised purchasing through competitive tender;
- major licence changes;
- investment in integrated, open standard IT systems.

More remedial options are those that would not alter any of the major structural features of the market, and would therefore include:

- expanding the Drug Tariff basket;
- removing Category D;
- reforming the Discount Inquiry;
- establishing information obligations or integrated IT system;
- centralised purchasing of stocks in shortage;
- licensing reforms.

Almost all these options could be implemented independently of the others, and would improve some aspect of the system for supplying drugs to the NHS. The next phase of the fundamental review was to examine these options in more detail where necessary.

Phase II

The five key proposals for change made in Phase I of the review were to:

- reform the reimbursement system;
- improve information flows in the industry;
- consider structural change (vertical separation) to the industry;
- facilitate entry, particularly to manufacturing;
- explore centralised purchasing options.

The last two of the proposed options were examined in more detail in Phase II. After examining the range of options presented in Phase I of the report, the Department of Health considered that these two alternatives required further investigation before any consultation process or policy decision could proceed.

Enhancing competition in generic manufacturing

The report considered methods that might be employed to increase competition in the UK generics market. The level of involvement by foreign manufacturers in the UK was assessed, and found to be relatively low, with the exception of entry through the acquisition of existing UK generic manufacturers. The likely causes of this limited involvement in the UK are found to be a combination of the maturity of the UK market, opportunities elsewhere in the world, and the time taken to gain UK product licences, which particularly affects firms wishing to enter the market quickly.

One method of speeding up the licence-approval process would be to acquire existing UK licences from other manufacturers that no longer need them, through the licence-transfer process. However, in the Phase I report, this was not identified by manufacturers as a frequently used entry route. Examination of a sample of licence-transfer data from the Medicines Control Agency (MCA) confirmed this.

To attempt to increase the level of competition in the UK generics market, a number of remedies are recommended. These are divided between those that would be 'ideal', but which could only be implemented in the long term, and those that could be introduced in the short to medium term.

The 'ideal' remedies are as follows.

- Investigate the extension of mutual recognition, both the MRP for product licences and mutual recognition authorisation (MRA) arrangements for manufacturing sites. MRP could be changed so that it applies retrospectively to all off-patent drugs, and MRP could be agreed with non-European Union (EU) countries. MRA negotiations could be extended to countries such as India and Iceland.
- Highlight that a bibliographic application can be made under Directive 65/65, even when the initial branded product has been removed from the market.[1] Consider the nomination of a generic drug as the reference drug for this situation. The aim is to ensure the possibility of new suppliers for drugs that have been off-patent for a long period.
- Modify the MCA's existing fast-track drug application procedures to apply them to drugs in shortage or those with few existing licences.
- Publicise more widely the possibility of 'piggyback' entry into all generic drugs, where a new licence is issued that is an exact copy of an existing generic.

The practical remedies are as follows.

[1] Council Directive 65/65/ EEC of January 26th 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products. The directive states that a generic must be equivalent to a product that has been authorised for at least ten years.

- Establish a secondary market for licences, which may be as informal or as extensive as necessary, and could be run by the Department or the MCA.
- Introduce an active market-monitoring role for the MCA, which would involve monitoring the level of licences available for all generics, and attempting to identify potential shortages before they occur. This could be linked to market management, where the Department or the MCA takes steps to rectify the problems identified.
- Reduce the time taken by the MCA in approving licence transfers, possibly by reclassifying a change of ownership as a simple licence variation.
- Introduce status-of-production reports for all UK generic licence-holders so that the level of drug production can be monitored, thereby aiding detection of potential shortages.

Many of these remedies rely on the MCA as the lead institution. The remit of the MCA is currently interpreted in a relatively narrow, clinically based manner, when compared to similar organisations, such as the US Food and Drugs Administration (FDA). It may therefore be important to revise the scope of the MCA's role to include, as an objective, the promotion of the competitive supply of drugs.

The case for centralised purchasing through tendering

Centralised purchasing through tendering of generic drugs by the NHS has many advantages, and would resolve some of the problems of the current system that were identified in Phase I. Tendering would:

- facilitate greater use of the power of the NHS as the single buyer of generic drugs, thereby securing lower prices;
- make prices paid to manufacturers transparent. Information on the prices of drugs that are tendered would therefore no longer need to be obtained through the Discount Inquiry with pharmacies, nor through an inquiry into prices of vertically integrated wholesale–pharmacy groups;
- in combination with adequate demand forecasting (which this report shows is feasible), give manufacturers certainty over demand, which would help to bring total production into line with total demand, and thereby reduce costs;
- if appropriately designed, facilitate new entry into the market, thereby increasing or preserving competition;
- remove adverse incentives to hoard stocks at any stage in the supply chain, reducing the likelihood of both 'true' supply shortages and 'artificial' shortages through speculative hoarding;
- reduce price fluctuations, thereby making total NHS expenditure on generic drugs more predictable;
- in combination with enforceable penalty clauses in the supply contracts, impose an obligation on the manufacturer to supply the drugs that are contracted for, thereby improving security of supply;
- remove the need for the trading activities of pharmacists, thereby increasing the emphasis on pharmacists' advisory and other healthcare-related functions.

The introduction of centralised tendering also has potential disadvantages. The options for tendering presented in this report are designed to seek to obviate these disadvantages

and risks as much as possible. They draw on auction theory, on the experience of other countries and other sectors, and on the interviews with industry sources and the NHS Purchasing and Supply Agency (PASA), as described in the report.

The main potential disadvantage of tendering is that it may increase the likelihood of market concentration, as tendering rounds are repeated over time. Furthermore, any form of tendering may facilitate market sharing, collusion or bid rigging. (Tenders can be set up so as to minimise incentives to collude, but collusion can never be ruled out completely, and the NHS will have to rely on the Competition Act 1998.) A further potential disadvantage of tendering is that price is generally the key selection criterion. Bidders should therefore also be required to meet other criteria to demonstrate that their bids are serious and that they can guarantee supply.

The introduction of tendering would dampen the commodity nature of the market. Further, bypass of the system should not be allowed; otherwise, the NHS could not make demand commitments, and incentives to participate in the tender would be undermined. This bypass would come from manufacturers (branded or generic) that are unsuccessful in the tender, or those that had chosen not to bid.

Four options for tendering are presented below: full tendering, partial tendering; tendering for buffer stocks; and tendering framework agreements. For the first two options, there is detailed discussion of the required distribution and reimbursement arrangements.

Tendering options 1 and 2: full and partial tendering of generic drugs

Tendering option 1 involves the tendering of all generic drugs. Option 2 involves tendering of a limited number of generic drugs. The tendering scheme presented is the same for both options, and makes the prices of individual preparations explicit and transparent, preventing cross-subsidies or loss-leading on some drugs. Tendering for each preparation also creates greater opportunities for different suppliers remaining in the market for the same chemical entity.

The scheme proposed involves staggered tendering of two-year contracts, with total demand for a preparation divided into six tranches. Auction theory and experience in other countries and industries (described in the report) suggest that sealed-bid, first-price auctions are an appropriate method for the tenders.

The scheme would work as follows. First, for each individual preparation tendered, total demand over the next two years would be forecast. Then, every four months, one-sixth of total demand is put out for tender, and the winning bidder is awarded a two-year contract for supply of that tranche. Hence, during each period of four months, total demand is supplied out of the six tranches (although not necessarily by six different suppliers). The scheme is somewhat similar to the staggered tendering for framework agreements in the hospital sector, but without regional separation between the tranches.

There are lead times of four months between the announcement of the tender and the award of the contract, and another four months between the award and the start of the contract. The quantity contracted for each two-year tranche should not be supplied in full at the start of the contract, but spread over time to meet demand patterns. Variations to the scheme are possible (*ex ante*), as the six tranches, the four-month staggering and the

two-year contracts are not definitive figures. These should be discussed in consultation with the industry. It might, for example, be appropriate to have more, or fewer, tranches in some products.

The staggered-tendering approach presented above has several advantages:

- by splitting total demand into six tranches and limiting the duration of each supply contract to two years, the NHS is not making excessive use of its buyer power, thereby reducing incentives for suppliers to make 'desperate' bids or to collude;
- a two-year contract is long enough to give demand security to the winning supplier, allowing for economies of scale and efficient planning of production;
- each supplier has the opportunity to enter or re-enter the market every four months, reducing market exit and increasing entry opportunities;
- manufacturers have flexibility in planning their product portfolio, as all drugs included in the list come up for tender every four months;
- staggered tendering is less prone to collusion than tendering the entire market at once, every two years (although, clearly, collusion remains a threat at all times); and
- the NHS can adjust for supply problems or unexpected demand changes every four months, and can monitor market developments.

Tenders should be open to all manufacturers, both UK-based and foreign, and generic and branded. The tenders should also be open to short-liners with an assured supply source, and to full-line wholesalers.

All bidders should be required to meet certain criteria to show that they can provide a reliable source of supply. To make this screening of bidders more efficient, a pre-selection process could be set up, through which bidders could qualify for several rounds of tendering.

Some restrictions should be imposed on participation by suppliers of other tranches of the same preparation. One possibility is to limit each individual supplier to a maximum of five tranches. As such, one tranche would always be reserved for a competitor. Overprotection of entrants to preserve competition may be counterproductive, and it might be necessary to tailor such measures, depending on the number of potential bidders in a particular tender.

Full versus partial tendering

Partial tendering has some advantages over full tendering. It would be easier to administer. Tendering drugs that are only infrequently prescribed may be inefficient. It is easier to set up a pilot scheme for only a limited number of drugs. With partial tendering, the NHS can still rely on the existing supply-chain competition for those drugs that are not tendered. Possible criteria for selecting those drugs that are tendered are examined in the report.

Contracting and payment under tendering options 1 and 2

In the proposed scheme, each tranche supplier should be paid the price bid in the tender (if the same supplier wins different tranches at different prices, this supplier should be paid a weighted average price). The problem with having different prices for different tranches is that this creates opportunities for arbitrage between the tranches by

wholesalers and pharmacists. Such arbitrage has benefits in the current commodity-type generic drugs market, but would no longer be desirable once tendering is introduced because it makes it more difficult for the NHS to commit to a certain demand volume.

Three options for distribution of tendered drugs

The report presents three options for arranging distribution of the drugs tendered under full or partial tendering.

Distribution option 1 would basically preserve the existing distribution system, in that any wholesaler could order the tendered drug from any of the six tranche suppliers. The disadvantage is that wholesalers still have incentives to prefer particular suppliers if prices differ across the six tranches.

Under *distribution option 2*, a 'designated distributor' would take care of delivery of the drugs tendered for. A single distributor could be designated for the six tranches, or each tranche supplier could have a different distributor. The NHS could contract out, or put out for tender, the function of designated distributor. Alternatively, tranche suppliers could negotiate the distribution arrangements themselves, and these could form part of the original bid in the tender. The main disadvantage is that distribution-chain efficiency may be lost.

Distribution option 3 includes the creation of a clearing house (perhaps the Prescription Pricing Authority, PPA). Any wholesaler can distribute any product, but orders must be placed at the clearing house, which then assigns them to one of the six tranches, ensuring that, on aggregate, sufficient demand is allocated to each of the tranches. This prevents arbitrage by wholesalers, while preserving distribution efficiency. It also allows the clearing house to monitor product flows from each tranche, which can be used for payment to suppliers. The clearing house should deliver monitoring and distribution efficiencies, but may be costly to establish.

Under any arrangement, wholesalers can no longer make use of trading opportunities in the tendered generics, but can still earn a distribution fee. If the designated-distributor option is chosen, this fee can be negotiated with the NHS or with the winning tranche suppliers. Under the other two options where any wholesaler can distribute, the NHS should determine a single distribution fee for each tendered preparation. A major advantage of per-item distribution fees over an ad-valorem fee is that arbitrage incentives are reduced.

Under distribution options 1 and 3, there is still scope for some competition between wholesalers in selling to pharmacists, although the upper bound of discounts would be the fixed distribution fee, since the tranche supplier's price is fixed.

Advantages and disadvantages of the three distribution options

	Option 1: Any wholesaler	Option 2: Designated distributor	Option 3: Clearing house
Prevents arbitrage between tranche suppliers, allowing NHS to make demand commitments	No	Yes	Yes
Allows efficient monitoring of product flows from tranches	No	Yes	Yes
Maintains efficiencies of current distribution structure	Yes	No	Yes
Avoids vertically integrated wholesalers and pharmacists having to deal with competitors	Yes	No	Yes
Allows distribution to be part of bid in supply tender	No	Yes	No
Avoids creation of new government agency	Yes	Yes	No

Three options for reimbursement of tendered drugs

There are three options for pharmacy reimbursement of tendered drugs, with different implications for payment flows throughout the chain.

Under *reimbursement option 1*, the NHS pays the tranche supplier the tender price directly after delivery of the product into the distribution chain. This implies that neither the distributors nor the pharmacists 'own' the product, minimising arbitrage by wholesalers and pharmacists. The disadvantage is that wholesalers and pharmacists may have incentives to hold excessive stocks, or to smuggle products abroad (although this would be theft, and might be prevented through policing and standardisation of 'NHS-branded' packs). One solution would be an IT system that allows the monitoring of tendered products throughout the chain, from manufacturing to dispensing.

Pharmacists have to pay wholesalers the distribution fee, which will to some extent limit incentives to hold excessive stocks. The NHS reimburses the distribution fee to the pharmacist after a product has been dispensed.

Under *reimbursement option 2*, wholesalers and pharmacists would pay for the product, similar to the current system, except that the product price and distribution are fixed. After dispensing, the NHS reimburses the tender price plus distribution fee to the pharmacist.

This reduces incentives to hold excessive stocks or smuggle products abroad. Another advantage is that the NHS would pay for the products at the end of the chain (ie, after they are dispensed), instead of paying the tranche suppliers up front, as under reimbursement option 1. The main disadvantage of reimbursement option 2 is that wholesalers and pharmacists still have incentives to prefer some tranche suppliers over others. If this option were to be implemented, then arbitrage could be prevented at the distribution level of the chain (through using designated distributors or a central clearing house, and setting per-item rather than ad-valorem distribution fees).

Under *reimbursement option 3*, the possibility of price differentials among the tranche suppliers of a certain preparation is maintained, but the NHS would set a single price to be paid by wholesalers and pharmacists for that preparation. The difference between this

single price and the price of each tranche supplier agreed in the tender is settled directly between the NHS and each tranche supplier.

The single price for a tendered preparation would function as a Drug Tariff price. For example, a new 'Drug Tariff Category T' could be introduced, listing the prices set by the NHS for each of the tendered preparations. The difference with existing Drug Tariff prices is that the Category T price is the price paid by *wholesalers* to the tranche suppliers. Pharmacists, in turn, pay the wholesalers the Category T price plus the predetermined distribution fee. The NHS then reimburses pharmacists the Category T price plus the distribution fee. This simplifies reimbursement, while preserving the beneficial effects of staggering prices over time.

In principle, the precise level of the Category T price is irrelevant, since any differences with the agreed tender prices are settled with the tranche suppliers. However, it is important to set the Category T price *below* the lowest agreed tender price. Otherwise, tranche suppliers, wholesalers and pharmacists would have an incentive to bypass the tendering contract. It is suggested that the Category T price should be set at 60% of the lowest of the six tranche prices.

Advantages and disadvantages of the three reimbursement options

	Option 1: Distribution fee only	Option 2: Full tender price	Option 3: Category T price
Prevents arbitrage between tranche suppliers, allowing the NHS to make demand commitments	Yes	No	Yes
Reduces the likelihood of bypass via non-winning suppliers and PI	Yes	No	Yes (partly)
Reduces likelihood of excessive stock holding and smuggling products abroad	No	Yes	Yes (partly)
Allows the NHS to pay for drugs after dispensing	No	Yes	Yes (if settlement is delayed)
Gives the NHS the option not to reveal winning tender prices	Yes	No	Yes
Reimbursement prices can be announced in the Drug Tariff, thereby providing clarity to pharmacists	Yes, but only distribution fee, so may look unfamiliar	Yes, but different prices for different tranches may cause confusion	Yes
Transitional problems are only one-off	Yes	Yes	No
Follows the principle that each player is paid after delivery	Yes	Yes	Yes (if settlement is immediate)

Tendering option 3: tendering for buffer stocks

Tendering for buffer stocks is aimed specifically at meeting the Department's objective to prevent shortages and to maintain price stability. It can be implemented leaving the current supply system intact, or in combination with the full or partial tendering options.

The NHS would tender for the supply of, say, two months' supply of certain preparations, to be kept and managed by the NHS as a buffer stock. To guarantee sufficient shelf life, the buffer stock has to be put gradually into the market and then replenished, so that

tenders would be required continually, but for relatively small volumes after the initial acquisition.

In case of a shortage—still signalled via the Pharmaceutical Services Negotiating Committee (PSNC) and the PPA—the NHS can supply its stocks into the market at the prevailing Drug Tariff price, or at the contract price it obtained in the tender. This gives a breathing space of two months for the supply chain to resolve any manufacturing problems. The supply from the buffer stock could be combined with rationing, to ensure that the drug is evenly distributed across the country. An additional advantage of buffer stock tendering is that it could be used as a means to retain different suppliers in the market, or to assist a new entrant.

The whole process needs to be actively managed by the NHS, requiring significant market knowledge from the buffer stock manager. Providing a continual supply into the open market involves price risks, and other players may strategically anticipate the buffer supply. As with exchange-rate intervention, the buffer stock only works for temporary shortages, not for serious shocks. The call on the buffer stocks would be extremely rapid in the case of a shock, and so, during those two months, the NHS would need actively to encourage entry. Once the buffer stock is exhausted, the market price is likely to jump again, and players may have an incentive to delay (re-)entry until this happens. Finally, and perhaps most importantly, holding buffer stocks is expensive, as it implies up-front investments, opportunity costs of working capital and appropriate warehouse facilities.

Tendering option 4: tendering for framework agreements

The fourth tendering option is similar to the existing hospital scheme. It involves tendering for framework arrangements with manufacturers, which wholesalers and pharmacists have the option to use for the purchase of their drugs. Manufacturers bid to become the framework arrangement supplier. Effectively, the framework price will function as the maximum price that any wholesaler or manufacturer can charge to pharmacists for that drug. It is therefore also the maximum reimbursement price paid by the NHS. In this sense, the option is also similar to the short-term arrangements implemented by the Department.

However, bidding for framework arrangements may not be attractive to manufacturers since they receive no volume commitment from the NHS. In fact, the framework agreement is similar to a financial instrument called an ‘American call option’ (pharmacists have the option, but not the obligation, to buy the product at the specified price from the framework supplier). The NHS would therefore have to pay an option premium to the framework supplier.

Setting up a pilot for staggered tendering

The report discusses in detail the setting up of a pilot for the staggered-tendering scheme, which would initially involve a small number of drugs, tendered nationwide. Criteria for selecting products for the pilot might include predictability, volume, cost, recent problems, number of licence-holders, and availability of therapeutic alternatives. An indicative example of a candidate list of drugs that could be tendered is given in the report.

Impact on the supply chain

The response of those manufacturers already active in the UK market to the suggestion of any form of centralised purchasing through competitive tendering has been uniformly negative. The response of some foreign manufacturers was more encouraging, perhaps because they see an opportunity therein.

The impact of tendering on manufacturers' entry and exit decisions is key to the dynamic success of centralised purchasing. The proposed structure establishes a number of protections to ensure that monopolisation is unlikely, or, where it exists, that the NHS's exposure to price and security risks is minimised. With regard to the production risks, the proposed staggered-tendering design should mitigate this problem as well.

If the introduction of competitive tendering is successful, prices *paid* by the NHS for generics should fall. The impact on manufacturers' prices is less clear. Manufacturers state that their factory-gate prices are very low and highly competitive, but that excessive margins are being taken elsewhere in the chain. If this is the case, then manufacturers may benefit from tendering, since there are cost benefits to be captured (eg, lower risk, an ability to negotiate better contracts with active-ingredient suppliers, better production scheduling to exploit economies of scale) and tender prices will reflect actual costs. Managed tendering should not drive prices to unfeasibly low levels.

The role of wholesalers in the distribution of generic drugs would change significantly under a centralised tendering arrangement. Wholesaling would be reduced to mainly a distribution function, given that the price is set through the tendering process. This is similar to existing agency arrangements with manufacturers, and to the role that wholesalers play in the USA. Given that generics are only a small part of the full-liners' business by volume (and even smaller by value), they profess to be not very concerned about this non-core segment.

Distribution option 2 is likely to have the greatest impact on distribution costs. Successful distributors would then have to deliver to all pharmacies in the country, which is likely to affect the network required. It also means that tied pharmacies would receive deliveries from other wholesalers. Wholesalers may also face increased competition from logistics companies, or pre-wholesalers, which team up with manufacturers to offer full manufacture and distribution services to the NHS. Under distribution options 1 or 3, where the pharmacist chooses the wholesaler for a particular drug, there will be incentives for wholesalers to encourage pharmacists to concentrate orders through volume discounts. Given the structure of wholesaling, this has beneficial economies of scale. Under these arrangements, the effects on full-line wholesalers would not be substantial.

For specialist generic distributors, the implications are greater. Currently they play a potentially useful role by bringing new sources of supply of drugs into the market. Those short-liners with product licences would have the option to participate in the tenders. The proposed tendering arrangement is designed to encourage these players to continue to have a role in the market. Since some specialist distributors already contract with their suppliers for up to five years, with penalty clauses in the case of default, it seems feasible for them to play a role. Other short-liners would not bid in a tender, although they could still aim to distribute generics under distribution options 1 or 3.

For pharmacists, the financial impact of tendering will be different, depending on which strategy is being pursued in the existing market. Trading pharmacists may see a significant drop in income. Non-trading pharmacists may benefit, as existing pressures towards consolidation, driven by commercialisation, are alleviated. They may see a financial impact, but it is unlikely to be of the same proportion as that for a trading pharmacist. Assessing the appropriate level of remuneration for pharmacists is outside the scope of this report.

Pharmacists will benefit from the extra time saved from not having to search for low-priced generic drugs. This will enable them to spend more time on patient care, and play an increased role in the community as a healthcare resource between the doctor and patient.

Impact on government

The introduction of tendering could have significant resource implications for the NHS. It leads to direct costs to, and increased risks for, the NHS. However, tendering would also deliver lower prices, enhanced transparency and increased information.

Direct costs of the proposed tendering systems include administrative costs, IT costs and labour costs. The costs of establishing the centralised clearing system required for distribution option 3 could be significant.

The other major cost from the introduction of tendering is the potential for a major supply disruption. First, there may be a significant cost impact on the NHS as it seeks to find replacement supply at short notice and at a substantial premium to the tender price. Second, shortages may occur, jeopardising quality of service to patients. However, the proposed tender scheme is designed to protect the system from disruption. In the event of any disruption, financial costs should be passed through to the defaulting supplier.

It is also important to estimate the expected benefits from tendering, although these are hard to quantify. Estimated savings through generic drugs tendering in New Zealand are 15–20%. Savings as a result of tendering by the NHS Hospital Domestic Services range between 18% and 48%. Experience from other industries and countries, discussed in the report, suggest that savings through tendering may be substantial, especially in combination with the development of an on-line system for tendering and possibly distribution management.

A comparison between the prices achieved in New Zealand tendering exercises with those in the primary and secondary sectors of the NHS suggests that expectations of savings in the region of 10% on factory-gate prices are not unreasonable. However, it should be noted that New Zealand is a much smaller market than the UK, and is well integrated with the nearby larger Australian market. This lessens the supply risks they face.

If it is assumed that supply-chain margins are not currently substantial and manufacturing is competitive, then savings around £30m are generated. Medium-range assumptions suggest savings in the region of £100m. This assumes that 80% by value of drugs dispensed in the UK are tendered within the first year.

Alternative solutions

In Phase I, a number of remedial options were raised, under the following three headings:

- reform reimbursement;
- request information;
- enforce vertical separation.

The issue is whether these can, at lower cost, deliver similar outcomes to that of tendering, in terms of transparency. In the short run, the answer is likely to be 'yes', but there are two difficulties. First, these changes may not be robust to structural changes in the industry in the future. Second, the Department may find itself having to judge appropriate cost levels in wholesaling and manufacturing.

A successfully functioning, competitive tendering scheme meets five of the six key objectives of the government. It will:

- reimburse pharmacists closely for what they pay for medicines dispensed under the NHS;
- ensure price transparency;
- maintain and improve the current quality of service to patients;
- support a competitive pharmaceutical market;
- secure value for money for the NHS.

These are achieved through:

- increased security of supply and a less volatile market;
- price transparency;
- purchasing arrangements that are robust to market structure changes;
- cost-reflective prices.

The sixth objective—the minimisation of distribution costs—may not be a feature of the tendering system.

Considerable benefits may arise from the introduction of centralised purchasing, in the form of substantial reductions in the prices of generic drugs supplied to the community.

Against these benefits, the risks of this radical change must be set, and are as follows:

- it could be expensive to introduce;
- complex organisation is required and significant market expertise is required of the tendering authority;
- substantial price reductions may not be forthcoming;
- supply failures may occur and could be difficult to resolve without a market mechanism in place.

The tables below summarise the risks and opportunities that are presented by each of the options for reform to procurement arrangements.

Risks and opportunities of full tendering

Option	Risks	Opportunities
Full tendering system	Supply disruptions Centralised market management difficult Complex system to administer for all drugs Some demand forecasting required Arbitrage may occur between tranches if prices differ, or between countries	Lower, and less volatile, prices Entry assistance Good understanding of supply conditions Transparency Scale economies in production Staggered contracts allow demand flexing over time
Partial tendering system	Similar to full tendering May need to establish most of the infrastructure for full tendering, even to run it partially	Basic pilot approach starting with a few manageable drugs Allows adjustment if/when difficulties are found Gives an option to pull out without committing substantial resources Threat of moving from competitive market to tendering may be a powerful constraint on behaviour

Risks and opportunities of alternative tendering options

Option	Risks	Opportunities
Buffer-stock tendering	Costly to hold stocks Management of the stock difficult Supply into the market may be costly if spot price lower than contract price In the event of a disruption, there may be incentives for suppliers to wait until the buffer stocks have run out before resupplying	Good insurance against supply disruptions Entry-assistance method
Framework agreements	Without output contract, price that is bid can be meaningless Complex to set up and complex for manufacturers to bid for. Conceivably there could be no bidders	Option framework may be good solution for call-off requirements Competitive market still exists alongside agreements
Information obligations	Short-term solution Supply chain manages to obscure true prices under new information obligations No improvement in cost of drugs to the NHS	Less costly to implement Existing market arrangements continue
Vertical separation	Serious resistance to such a substantial intervention in industry structure Informal links are formed, although officially separated Loss of the true efficiencies that provided the original incentive for the integration Still strong incentives to hide true market information from NHS	Transparent prices Independent contractors will have incentives to negotiate good prices from suppliers

1. Introduction

OXERA was commissioned to undertake a fundamental review of generic medicines, announced by the Department of Health to the Health Select Committee in November 1999. The review arose from the Department's concerns regarding the supply and distribution of generic medicines in the UK, and, in particular, the significant price rises during 1999 in an unusually high proportion of generic drugs.

OXERA was commissioned to carry out a wide survey of the industry, and to consider whether the existing market structure and government procurement arrangements are adequate to deliver the Department's objectives, which are to:

- maintain, and improve, the current quality of service to patients;
- minimise the costs of the distribution networks, subject to service-level and quality requirements;
- reimburse pharmacists as closely as possible for what they actually pay for the medicines they dispense under the NHS;
- ensure transparent prices;
- support a competitive pharmaceutical market; and
- secure value for money for the NHS.

The events of 1999 have revealed, at best, an underlying instability in the current system; at worst, the problems experienced may suggest the need for a fundamental overhaul of the system. The objective of the fundamental review is to deliver an assessment of whether remedial or radical changes are necessary, and to offer options for both. The remit of the review is to find a solution that will have long-run durability, through being flexible and robust to major structural change in the industry.

The generic pharmaceutical sector has undergone significant changes over the last decade—changes that have put significant pressure on the NHS's procurement policies. Perhaps one of the more surprising outcomes from this study is the number of years that the system has served the government's interests, delivering reductions in the drugs bill for generics. Given the focus on generic prescription as a means of delivering substantial headroom in the NHS medicines budget, it is crucial that the supply chain for generics functions effectively. This study examines the current system, highlighting any weaknesses, and suggesting policy options that could be considered to meet more closely the government's objectives.

There are six key industry characteristics which should be borne in mind when considering likely developments that will influence the success or failure of any reforms to the generic drugs supply chain:

- the inherent security-of-supply risks for drugs where the number of licence-holders is low;
- an increasingly internationalised manufacturing base;
- an increasing focus on the profitability of individual drugs;
- vertical integration in the supply chain;
- the role of IT; and
- the role of community pharmacy.

It is important to bear in mind that medicines for which there are a small number of licence-holders are problematic under any system. Analysis by the Department has shown that around 40 of the top 200 generic drugs have three or fewer licence-holders. Difficulties of ensuring vaccine supplies have been problematic, partly because of the very concentrated supply of these products. Any reforms should seek to ameliorate this situation and protect against any supply problems that could arise.

The pattern of UK generic manufacturing ownership has changed significantly in the last ten years. Generic houses used to be offshoots of the major research-based companies. Gradually, they have been sold off from the branded sector, remaining independent for some time, and now most have been purchased by large international generic manufacturers. The main UK suppliers are now owned by Ivax (US, Norton), Teva (Israel, APS), Alpharma (US, Cox) and Merck (Germany, Generics UK). Most of these generic houses have subsidiaries in up to 15 countries worldwide.

This internationalisation is a relatively new phenomenon. As European MRP is established, the gains from supplying a broad European market are increasing, as new drugs come off patent. As mutual recognition of manufacturing sites also grows, the cost of cross-border supply is falling. At present, it appears that, for some manufacturing sites, a large proportion of output is destined for one main market. However, looking forward, many of the players describe a market with long production runs that are supplied into a range of markets (for instance, the USA, France, Germany and the UK).

The effect of this would be to make NHS demand a much less central part of the business of these companies. It also makes it more likely that foreign suppliers will wish to enter the UK market. As long as this foreign supply is forthcoming, then risks of supply failures should be lessened. There may be a convergence of prices for some products across European markets, as arbitrage should remove price differentials. Overall supply costs may fall, as manufacturers can benefit from substantial economies of scale if they are supplying a market across four or five major European countries. As penetration of generic prescribing and dispensing grows across France, Germany and Italy, for example, the potential industry growth rates are large.

Accompanying this broader international perspective, and contributing to pressures to equalise prices across countries, is a closer attention to the margins earned on individual drugs. Parent companies can consider whether to supply a particular batch run into, say, the UK market or France. If returns are much higher in France then suppliers will switch into that market until returns fall to levels similar to those in other countries. To make these trade-offs, the companies need to understand the direct and fully allocated costs of each drug they produce. Discussions with some UK manufacturers certainly suggest that portfolios are being reassessed, with a view to identifying drugs with poor long-term performance.

Looking at patterns of consolidation and integration elsewhere in the supply chain, the main UK national wholesalers are all part of pan-European integrated companies. Five or six UK small wholesalers have been acquired in the last year. Generic distributors are also developing further European links. At the pharmacy level, the trend towards large chains, integrated or independent, continues, with the supermarkets emerging as important players in this area. Plans for a new superstore, or major refurbishment to a superstore, will usually include a pharmacy.

Most companies in the UK market monitor the optimal structure for the sector. Most wholesalers have pharmacy interests; many of which are substantial. Manufacturers too may be considering integrating downstream into pharmacy. Vertical integration is a key tool in ensuring supply stability (for wholesalers) or demand stability (for manufacturers or wholesalers) in an increasingly open market.

The scope for IT to affect the medicines supply chain is substantial. Examination of supply chains elsewhere, such as the supermarkets or the book industry, indicates that automation can yield many advantages. It is not always easy to predict the impact of such changes; nonetheless, the role of the government, the wholesaler and the pharmacist could all be considerably affected by innovative IT solutions.

The role of community pharmacy in the NHS is also a crucial part of the context of this study. Pharmacists play an important role in NHS–patient contacts, and could play a more significant role. The importance of their role as drug purchasers needs to be balanced against other possible uses of their time. General practitioners (GPs) do face overall budget constraints for pharmaceutical prescribing. However, there is no direct mechanism through which a GP takes the price of a particular drug into account when making a prescribing decision.

1.1 Phase I

Phase I of this study gives an overview of the industry and sets out a range of policy options.

The shortages in 1999 and budget over-runs have pointed up four core problems in the current system:

- pharmacists may not be the best agents of the government's purchasing power;
- the government has no mechanism to monitor performance in the supply chain;
- there is poor coordination in the supply chain, particularly in the short term;
- perverse incentives are a feature of current reimbursement policy.

Section 2 sets out these key messages that emerged from the examination of the industry, including a picture of where the value lies in the supply chain and an analysis of the profitability of the different players. In addition, three appendices give in-depth descriptions of the three key sectors of the industry: manufacturing, wholesaling and pharmacy. Appendix 10 details the companies that provided information for the analysis.

Sections 4 to 8 present the range of options to alleviate the problems identified in the current system (including a discussion of the option of 'doing nothing').

Five key forms of change are proposed, and OXERA recommended that these should be investigated further:

- reform the reimbursement system;
- improve information flows in the industry;
- facilitate entry, particularly to manufacturing;
- consider structural change to the industry;

- explore centralised purchasing options.

The more radical reforms discussed in this report entail a major shift from a decentralised system, where much of the downward pressure on prices is delivered through short-liners and PIs, to a more centralised system, where the government's buyer power enables it to negotiate good deals with the large suppliers. It is noted that any obligation to provide more information may also increase pressures to consolidate.

To judge any new policy option, two important questions need to be addressed.

- How well does the policy achieve the stated objectives, as compared with the status quo?
- How well does it resolve the identified weaknesses?

These questions are addressed in section 9, where the options are drawn together into a suite of reforms going forward—short-term versus long-term, centralised versus decentralised—and assessed against the key objectives. This sets the scene for Phase II.

1.2 PHASE II

Phase II of the fundamental review looks in more detail at two of the options proposed in Phase I:

- encouraging greater competition in the generic drugs industry, especially in manufacturing; and
- developing proposals for centralised purchasing through competitive tendering as a way of making use of the NHS's buyer power, and ensuring a competitive market, greater transparency, stability of supply, and best value to the NHS.

After examining the range of options presented in Phase I of the report, the Department of Health considered that these two alternatives required further investigation before any consultation process or policy decision could proceed.

Against the background described in Phase I, this phase of the project gives a detailed critical analysis of possible licence changes and competitive tendering. It draws on substantial primary research, through interviewing existing and potential industry participants, and investigating industry arrangements in a number of other countries.

The licensing changes proposed in the more detailed, second-stage examination are designed to signal when difficulties arise, not just in the actual number of licences for a given product, but in the number of *active* licence-holders. They also attempt to facilitate entry by players active elsewhere in the UK market, or in other developed country markets.

As will be seen, the proposed tendering procedure is designed to ensure that monopolisation does not occur—ie, that licence-holders do not drop out of the market as tendering proceeds. For particular drugs where there are already very limited numbers of suppliers, the existing market price may be above costs. In theory, this provides a signal

for entry. In this situation, tendering is unlikely to lead to a higher price, and may assist smaller new entrants, perhaps by reserving a slice of the UK market for them.

Phase II of the report is structured as follows.

- Section 10 investigates entry conditions for the UK market, discussing patterns of foreign entry and licence-transfer behaviour. It proposes a range of changes to licensing that may facilitate entry for any particular generic drug.

- Sections 11 to 16 focus on centralised purchasing through competitive tendering.

  – Section 11 examines the theoretical advantages of tendering and the lessons for tender design from auction theory. It also looks at the practical experience of the NHS PASA in tendering for hospital framework agreements.
  – Section 12 lays out the proposed arrangements for a full tendering scheme, covering the form of the tender process and the role each element of the chain would play. Three options for managing the distribution of the generic drugs are proposed, and three reimbursement options are also outlined. A partial tendering scheme is presented to enable a focus on the high-volume or high-value drugs.
  – Sections 13 and 14 examine other options that still feature competitive tendering in some form: purchasing of buffer stocks; and framework agreements along the lines of the existing hospital arrangements, respectively.
  – Section 15 outlines a pilot for the partial competitive tendering scheme, and Section 16 assesses the impact of the proposed tendering arrangements on manufacturers, wholesalers, pharmacists and the government.

- Section 17 draws together all the recommendations from the second phase and assesses them critically against the Department's objectives.
- The appendices cover drug purchasing arrangements in the USA, New Zealand, and the Netherlands, and tendering experience in the hospitals and in other industries.
- Appendix 10 provides a list of interviewee and information sources.

PHASE I

2. Key Findings of the Industry Analysis

This section presents a summary of the key findings and conclusions from the investigation of the sector.

2.1 The 1999 shortages

Most industry players confirm the Department's view that the initial problems in the generics industry arose from a set of supply shocks, including the closure of Regent in December 1998, the relocation overseas of manufacturing facilities by Norton and APS, and the introduction of patient packs. These shocks have occurred sequentially, prolonging the disturbance to the market.

In addition, the industry's perception is that the negative impact of these shocks has been exacerbated by three factors:

- a demand-side response;
- the reimbursement system (ie, the Drug Tariff);
- limited capacity on the supply side.

Each is discussed in more depth below.

Accepting the explanation provided to OXERA of the functioning of the supply and distribution chain, it follows that, for products in shortage, it now takes more product to fill the chain than it did before the shocks mentioned above. This does not necessarily imply speculative hoarding, although it is consistent with it. Part of this demand-side effect is explained by rational behaviour on the part of pharmacists, who order more drugs, given the extra costs and the potential loss of customers resulting from a drug becoming difficult to acquire.

The peculiarities of the determination of Category D of the Drug Tariff have amplified the instability. Category D is an element of the reimbursement system designed to secure that patients are supplied even when drugs are in shortage, by protecting pharmacies in the short term from price increases. Drugs are moved into Category D when there is a defined level of shortage, such that pharmacists may not be able to purchase it at the Category A price. In the longer term, price increases would normally feed through into the Category A price, which is updated monthly.

However, it is difficult to identify whether:

- there is a true shortage of a drug;
- the stockholding rules are outdated; or
- the drug is being held somewhere in the chain, and is not being picked up by the standard stock inquiries of PSNC and the PPA.

Most pharmacists and their representatives reported that there were actually few true shortages—ie, the product could always be found, although often at higher prices—although there is some regional variation on this.

The financial benefits of trading in a Category D drug, once it is in short supply, encourage speculative behaviour. Those players not part of the basket of suppliers are free to hold a product if they suspect there will be supply problems. However, according to OXERA's understanding of the functioning of the supply chain, it is less likely that the market speculators (variously referred to by other market participants as short-liners, traders or 'non-serious players') can *create* drug shortages through stockpiling. The amount of product they would need to store and finance in order to create a shortage, as opposed to benefit from an existing shortage, is large. Rather, some market players profit from moving ahead of the rest of the market when shortage problems arise (and, indeed, exacerbate the problem at this point).

Most industry participants regard the supply problems at the manufacturing end as the cause of the shortage. Many manufacturers have had large back-order books and have been running plant at maximum capacity. The question is why manufacturers do not invest in more capacity, and why there is not more entry at the manufacturing level. There are (at least) four possible answers:

- the returns may be too low, given the risks faced (although profitability figures, discussed in more detail below, do not suggest that manufacturers are earning low returns);
- manufacturers are strategically restricting capacity, feasible because of entry barriers;
- the size of the required investment increment is large, leading to long periods of out-of-equilibrium behaviour;
- entry is difficult owing to licence requirements.

All industry participants have commented on patient packs. There is significant criticism of the government in not managing the process well. Pharmacists have experienced problems because patient packs were not listed in the Drug Tariff initially, and they have also complained about space limitations. Manufacturers have invested in new machinery, but have not always judged capacity appropriately. Wholesalers have generally had few problems adjusting warehousing and delivery processes to accommodate patient packs. Both wholesalers and manufacturers state that the unit costs of production and wholesaling are higher for patient packs.

However, industry players at all levels, including pharmacists, also see the benefits of an overall move to patient packs. The patient-pack problem is basically a transitional issue, with some one-off adjustment costs, and a new long-run equilibrium pack price. The length of time for the transition to be complete is uncertain.

With regard to which parties have profited from the turmoil in the market, all interviewees indicated others in the chain. Manufacturers, short-liners and some pharmacists may have profited from the price shocks. The national full-line wholesalers claim to have lost money (partly through their affiliated pharmacy chains), and to have suffered from significant customer dissatisfaction at poor service levels. Additionally, it is claimed that salaried pharmacists in pharmacy chains do not have the same incentives (as owner-managers) to be careful about endorsement; hence money is lost on Category D drug purchases.

Profits have followed the stock, with the result that those who manage to obtain access to, or produce, drugs in shortage will make money in such circumstances. It is not clear whether a few players have made considerable amounts of money, or whether many players have made a few gains. Many of those interviewed pointed to the great number of companies with a wholesale licence being able to engage in speculative activities. From this, it might be concluded that there could be a situation where lots of players make a few gains.

2.2 The current situation for hospitals

Hospitals have faced similar problems of shortages. To some extent, these are closely related to the problems in the community pharmacy sector. First, although hospitals usually contract directly with the manufacturers, these contracts can be suspended relatively easily if a manufacturer has production difficulties, or if it can obtain a higher price elsewhere (eg, in the community pharmacy sector). The manufacturer pays some penalty (normally the difference between the agreed price and the price the NHS is forced to pay). This picture is consistent with what the full-line wholesalers have reported; namely that manufacturers are reluctant to engage in supply contracts with their regular clients.

Second, most products for which there is a contract between hospitals and manufacturers are distributed via the full-line wholesalers. Their automated inventory systems do not distinguish between products for hospitals and those for community pharmacies (although there are 'hospital-only' products). In addition, their ordering systems work on a 'first-ordered, first-served' basis. Therefore, shortages in the community pharmacy sector may also leave the hospitals without products. This is not effectively prevented by penalty mechanisms in the contracts between hospitals and manufacturer, as the wholesalers have reported that no penalties have been passed on to them by the manufacturers.

The hospitals' situation does differ in one important respect from that in the community pharmacy. The combination of centralised procurement (at the regional level, and with regions influencing each other through the four months' rotation in procurement) and formularies (allowing substitution between branded drugs as well as between branded and generics) implies that the hospitals are using their buyer power. This enables them to secure lower prices.

However, a downside to this, as perceived by the NHS, is that too much buyer power might have been exerted, driving prices down too far and 'squeezing' suppliers out of the market. For several drugs, only one supplier to the hospitals remained, making hospitals vulnerable to supply shocks and price increases, particularly since (re-)entry into the market for these products by other manufacturers may not provide sufficient protection, as these other manufacturers may have let their product licence expire.

2.3 Industry ownership patterns

Industry ownership linkages show that most of the major wholesalers have few manufacturing interests, and most manufacturers have few wholesaling interests, although some do have sales forces. Most wholesalers, regardless of size, have some pharmacy interest. Manufacturing is increasingly global, with very few UK-based manufacturers remaining. Large wholesalers are increasingly European in nature, and integrate with

retail pharmacies to the extent allowed by the law in each country. Alliance UniChem makes use of virtual chains and buying groups in countries where legislation requires pharmacies to remain independent. Manufacturers have considered increased integration, particularly into pharmacy.

Vertical integration of wholesalers and pharmacies significantly undermines the effectiveness of the contractor relationship between the government and pharmacies. By presenting high transfer prices to the PPA for the goods bought by the wholesale arm and sold to the retail arm, any profits could be held in the wholesale part of the business. Wholesalers maintain that they make very low margins in this business (although on substantial turnover). These issues are discussed further below.

2.4 Entry barriers

For a manufacturer/supplier, different entry options can be considered. The key requirement to enter the UK market is a UK (or UK-recognised) product licence. Having acquired this, a supplier can enter as:

- a new start-up manufacturer;
- an existing manufacturer producing a new drug;
- a new supplier into the UK market.

The most likely source of new entry into the UK market is the third of these—for example, overseas producers supplying into the UK market from foreign production facilities. There are growing global generic manufacturers, such as Teva in Israel and Ranbaxy in India, which own firms in, and produce for, many countries around the world (including the UK). These large firms should in principle be able to obtain licences relatively easily, as they often already manufacture the drugs for other markets. The only further requirement is to have an EU-based importing agent that is the legal holder of the product licence. This agent need be no more than an office. Overseas producers also make use of more relaxed patent laws around the globe to bring new generic drugs to market faster than is possible in the UK.

While entry as a traditional manufacturer into the UK market may appear relatively costly, and entry into the production of a new drug may appear to involve moderate investment, the possibility of contract manufacture significantly widens entry possibilities. There is an increasing number of global generics corporations that could swiftly begin production for the UK, provided they have access to production facilities in a UK-licensed plant, and to a UK product licence for the drug. It would appear from this that entry and exit barriers should not be substantial in this market. Nevertheless, actual entry is low. Section 6 explores this in greater depth.

Entry at the full-line wholesaling level is difficult owing to economies of scale, although Phoenix recently entered as a third national full-line wholesaler by acquiring several regional full-liners.

Entry as a short-line wholesaler is easy, however. There are currently more than 1,000 wholesalers with a licence from the MCA to trade in prescription-only medicines. These include pharmacies, pharmacy chains and pharmacy buying groups, as well as wholesalers and parallel importers (PIs). The range of activities undertaken by these

players varies from pure brokerage, through importation, to acquisition of a product licence and contract manufacture. It is difficult to pigeonhole these players; they perform the useful function of providing flexibility in the system, putting competitive pressure on the other market participants; however, in times of shortages, they may also enhance instability through speculation.

2.5 The value chain in generics

Confidential information supplied to OXERA during the study enabled us to indicate to the Department a range for shares of NHS generic drug purchase revenues accruing to the key participants in the supply chain in 1998. This information cannot, however, be published.

2.6 Profitability analysis

The profitability analysis described in this section of the report was carried out in order to address the following questions.

- How does profitability within the sector compare to that in other sectors of the economy?
- Are rates of return in the sector consistent with a competitive market?

This type of analysis is typically undertaken when competition issues are being investigated in order to assess whether returns are higher than would be expected in a fully competitive market. The results of the analysis would give a general picture of the sector, and would, together with other information, be used to determine whether further, more detailed, analysis was warranted. Clearly, investigations by competition authorities benefit from the right to access detailed, confidential data from the companies under investigation—although analysis of comparator sectors typically uses the same methods as presented here (ie, it is based on published accounts). As OXERA's analysis is based solely on published annual accounts, a number of caveats should be raised.

- Many of these companies have only been in existence for a few years and, hence, there is a danger that they are not being observed over a full business cycle.
- The distinction between, for example, shortliners and assembly-only (AO) licence-holders may be arbitrary.
- Some generic manufacturers produce branded drugs as well as generics (this is particularly important for CP Pharmaceuticals and Norton). This analysis does not distinguish these two sales streams.
- UK 'manufacturers' may simply import finished or part-finished product from a second company within the same group structure. In this case, the UK company would have a very low capital base, and the real costs of production would only show up in the accounts if the transfer price within the group were similar to the relevant market price.
- UK and export business cannot always be separately identified.

Despite these concerns, this analysis is a useful step in attempting to understand the level of competition through the generic drug supply chain.

A more detailed examination, highlighting both methodological aspects and company-specific patterns, is described in appendix 5.

2.6.1 Methodology

To address these questions, data was gathered for the period since 1990, with a view to showing profitability measurements over different business cycles for the following groups of companies. Appendix 5.11 lists the companies in full:

- manufacturers of generic drugs (nine firms);
- full-line wholesalers (13 firms);
- short-line wholesalers (11 firms);
- AO licensees (12 firms);
- four samples of comparators:
  - the three major R&D drugs firms listed on the London Stock Exchange (Glaxo Wellcome, SmithKline Beecham, and AstraZeneca);
  - eight firms described as distributors in the London Business School (LBS) Risk Measurement Service (which provides stock-market information on all publicly quoted companies on the London Stock Exchange);
  - nine firms from the same listing described as food and drug retailers; and
  - nine firms described as food processors.

The split into short-liners and AO licensees is fairly arbitrary. There are more than 800 wholesaler licence-holders, so a sample of these was selected. 'Short-liners' were selected as Association of Parallel Importers (API) members. These are the well-known short-liners in the market. Four of these do hold AO licences. 'AO licensees' as a group were highlighted as they import product into the country and, hence, must hold product licences, although much of this is likely to be branded parallel imports (PIs). All but two also hold wholesaling licences, and could therefore also be included as short-liners.

The tables below show the summary results of the profitability analysis (details are described in appendix 5). It is important to emphasise that interpretation of these tables is subject to the qualifications at 2.6 above.

Table 2.1: Manufacturers of generic drugs (nine firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	47	123	155	121	255	280	352	441	236	
UK turnover (£m)	39	107	135	109	227	250	305	381	201	
Gross profit (%)	30	33	37	32	37	46	40	37	38	**37**
Operating profit (%)	6	8	9	9	9	10	13	16	9	**10**
Return on capital (%)	25	36	25	41	24	24	28	38	22	**29**

Note: At the time of writing, Norton had not filed accounts for 1998 at Companies House, which explains the lower-than-average industry turnover in 1998.
Source: Companies House and OXERA calculations.

Table 2.2: Full-line wholesalers (13 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	938	1,146	1,379	1,479	2,969	3,255	3,449	3,943	7,595	
UK turnover (£m)	933	1,137	1,367	1,462	2,950	3,229	3,429	3,939	7,573	
Gross profit (%)	7	11	10	10	9	10	10	11	8	9
Operating profit (%)	2	2	2	2	3	3	3	3	3	2
Return on capital (%)	25	18	28	22	27	23	31	29	48	28

Source: Companies House and OXERA calculations.

Table 2.3: Short-line wholesalers (11 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
Turnover (£m)	18	86	146	179	293	384	456	618	477	36	
UK turnover (£m)	18	71	127	157	262	334	410	580	438	36	
Gross profit (%)	7	8	10	10	9	8	10	12	11	25	9
Operating profit (%)	4	3	4	4	4	4	5	7	4	10	4
Return on capital (%)	28	38	44	39	48	33	38	53	40	65	40

Source: Companies House and OXERA calculations.

Table 2.4: AO licensees (12 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	7	31	38	65	69	93	112	229	245	
UK turnover (£m)	7	30	38	63	67	90	110	223	242	
Gross profit (%)	31	21	24	27	30	29	24	21	17	25
Operating profit (%)	11	9	9	4	8	5	5	5	5	7
Return on capital (%)	18	42	41	20	34	14	14	24	40	27

Source: Companies House and OXERA calculations.

Table 2.5: Summary comparison of average profitability measures

	Weighted-average cost of capital (%)	Gross profit (%)	Operating profit (%)	Return on capital employed (%)	Ratio of market to book value
R&D drug companies	8	66	27	32	4
Distributors	8	27	7	20	1
Food and drug retailers	7	12	6	18	2
Food processors	8	18	5	13	2

Source: Datastream and OXERA calculations.

1.1.1 Results

The following patterns can be identified from the above tables. These figures are all subject to the qualifications at 2.6 above.

- Table 2.1 shows that manufacturers of generic drugs have exhibited rates of return on capital (ROC) between 21.7% (1998) and 40.7% (1993). The average over the period was 29%. Their gross profit margin averaged 36.7% over the period and the

average operating profit margin was 9.9%. In terms of time variation, there is no apparent correlation between the ROC and the business cycle throughout the period analysed. This may suggest that manufacturers of generic drugs may have low systematic risks (in a capital asset pricing model sense)—ie, they have low costs of capital. Cross-sectional variation in ROC is low.

- Full-line wholesalers' gross profit margins (see Table 2.2) averaged 9.4% over the period analysed and the operating profit margin was 2.4%. Such businesses are significantly less capital-intensive than manufacturers (and thus the ROC measure is less informative of the performance of the wholesalers); the average ROC over the period was 27.8%.

- Short-line manufacturers showed higher profitability than full-line wholesalers on an operating profit margin basis (4.2%), but were similar on a gross profit margin basis (9%) (shown in Table 2.3).

- AO licensees showed significantly higher gross profit (23.5%) and operating profit (6.8%) margins than the other wholesalers (as reported in Table 2.4).

1.1.2 Interpretation

To ascertain the comparative performance of the sets of companies mentioned above, the same ratios were calculated for other manufacturers, wholesalers and drug companies. Furthermore, the weighted-average cost of capital (WACC) was calculated over the period for the manufacturers so that a comparison could be drawn between their ROC and the WACC during the whole period (see Table 2.5 for the results).

The following conclusions can be drawn.

Manufacturers

Subject to the qualifications at 2.6, the average ROC for the generics manufacturers (around 29%) appears considerably higher than the comparator WACC (approximately 10%) over the 1990s (see Table A5.5) and only slightly lower than the average ROC for R&D pharmaceutical companies (32%).

Three qualifications may be significant:

- intangibles are not included;
- in companies with complicated ownership structures, assets may not be held in the company where profit is taken;
- many of the companies engage in non-generic drug manufacture and export drugs.

There may be market-valued intangibles that were not included in the book asset valuations used in the calculations. This may lead to an underestimation of the asset values of those businesses, and an overestimation of the rates of return. Therefore, the extent to which these intangibles may exist was estimated. If companies in those sectors are under strong competitive pressures then the difference between the market valuation and the book valuation can be accounted for by intangibles. Table 2.5 shows that, for food processors, food and drug retailers and other distributors, intangibles lie in the range

0.5 to 1 times book values. Assuming that manufacturers of generic drugs have the same extent of intangibles, the ROC-adjusted figure over the period for the manufacturers would be reduced from 29% to, say, a range of 15–20%. This is still above the benchmark cost of capital of 10%.

Companies may have put in place cost-allocation rules whereby a share of the assets is not included in the accounts of the drug-manufacturing business, but are instead included in the group accounts. There is no systematic way of correcting for this potential deficiency of the quality of the data. It is therefore useful to rely on other ratios for the manufacturers and compare them with other sectors, which are assumed to be competitive. As noted above, gross margins in manufacturing have averaged approximately 37% over the period. Table 2.5 above shows that gross margins for food processors averaged 17% over the same period; for food and drug retailers the ratio was approximately 12%; and for distributors the ratio was 27%. R&D-intensive drug companies have displayed significantly higher margins.

On an operating profit basis, the margins were 10% for the manufacturers of generic drugs, compared with margins of between 5.2 and 6.8% for food processors, distributors, and food and drug retailers. Therefore, leaving the R&D-intensive companies aside, where the business risks are unlikely to be viewed as comparable with the risks in manufacturing generic drugs, there is still evidence of high profits for the latter group.

Some of the generic manufacturers have other business areas, including producing branded drugs or patented delivery-system products. To the extent that higher returns are earned on these parts of the business, earnings on generics will be lower. However, a number of the companies are almost solely generic houses (Generics UK, Cox) and their profitability levels are relatively high.

To summarise, there is some evidence to suggest that manufacturers of generic drugs have enjoyed relatively high levels of profits. This conclusion needs to be qualified by the limitations to the analysis at 2.6 above.

Wholesalers

Evidence from gross and operating margins shows that neither full-liners nor short-liners have higher margins than the sample of comparators described in Table 2.5. The sub-sample of wholesalers with AO licences has enjoyed significantly higher margins than the full- and short-line wholesalers.[2] This is a further indication that access to product licences for import into the UK market may lead to higher profitability. For AO licence-holders, these gains may arise from PIs of branded drugs, or generic imports.

Similar caveats apply to these numbers: the initial split into AO holders and others is arbitrary; the structures of the holding companies mean that costs and profits of a given activity may be allocated in different locations within the group, and they deal in a wide range of products. Branded products, whether UK-supplied or PIs, are a more important part of drug wholesaling businesses than generics. Returns on these will dominate aggregate figures, and are likely to mask profitability levels on generics alone.

[2] Four of the main short-liners also hold AO licences.

In sum, the profitability analysis indicates that those players which manufacture or import products into the UK drug market show higher returns than comparator estimates of costs of capital. In addition, these returns appear stable, although for some companies there is only data for a limited number of years. One potential explanation is an entry barrier associated with product licence-holding. Wholesalers do not show profitability out of line with comparators, although short-line wholesaling does have higher levels of operating profits. However, profits on generics may be masked by returns on branded drugs that form the bulk of wholesalers' turnover.

This analysis does not include 1999 data, as this was not available at the time of writing. Hence, these high returns are *before* the shortages occurred.

1.2 Pharmacy purchasing incentives

The underlying rationale of the yardstick[3] regulation provided by the Drug Tariff works well, at least to the extent that it became clear from the interviews that pharmacists feel under pressure to be looking for low prices. In addition, wholesalers and manufacturers are aware of the need to beat this tariff to gain business.

The Discount Inquiry, normally held yearly (although not held in 1999) to determine the level of claw-back, is an incentive for good buying practice. However, it may also mean that pharmacists are dissuaded from dispensing some of the more expensive branded drugs. The longer-term effect may well be to encourage trading behaviour by pharmacists and to drive out those who are not commercially minded. This is because there are significant financial benefits to good management of purchasing.

1.3 Service to patients

An additional concern relates to service standards for patients. Shortages could have various impacts on patient care, including:

- potentially harmful health implications;
- an increase in 'owings' (prescriptions only partially filled), requiring more frequent trips to the pharmacy;
- a lower quality of service (no continuity in dispensing), while fully meeting prescription requirements.

Most pharmacists say that there has been no point at which a patient has not been supplied with an appropriate drug, although significant amounts of time and effort have been expended in the process. A number of pharmacists have liaised with GPs to prescribe a different therapeutic drug with similar properties that is not in shortage, where such substitutes are available.

Many pharmacists and their representatives say that continuity in dispensing is an important aspect of service to patients. Constantly changing the source of supply for a generic drug is perceived to cause confusion, particularly for chronic conditions, and may lessen the effectiveness of the treatment. Some pharmacists say they prefer to ensure

[3] A yardstick incentive mechanism is one where an agent is judged against the performance of all its peers, and its performance is an element of the target for other agents.

continuity in dispensing to patients, but they are unlikely to be fully reimbursed for this practice. In times of shortage, continuity in dispensing is the first casualty.

1.4 Conclusions

Key features of the industry structure that have emerged from the interview stage of the study are highlighted here. The structure of the industry is changing, and these changes must be taken into account when assessing how:

- the current system provides incentives to the industry participants to behave in a certain way;
- the pressures on the current system have changed since it was first implemented; and
- the pressures on the system will change in future, if the current trends continue.

The following trends have been apparent in recent years.

- **Vertical integration**—vertical integration between wholesalers and pharmacies is increasing: two of the three national full-line wholesalers, AAH and UniChem, are affiliated with large chains of retail pharmacies. The third, Phoenix, also owns some smaller chains of pharmacies. The vertically integrated chains have been expanding at the expense of independent pharmacies. Furthermore, it could be expected that increased regulatory pressure on margins at the manufacturing end of the supply chain would cause manufacturers to think about integrating with the downstream parts of the chain, in order to preserve margins overall. Such vertical integration could take the form of ownership links, but also agency-type arrangements that allow manufacturers to sell directly to pharmacists, and where wholesalers simply act as distributors (but do not own the product).

- **Concentration**—horizontal concentration is increasing at the wholesale and pharmacy level, and, to a lesser extent, at the manufacturing level. For example, Phoenix has consolidated a number of regional, full-line wholesalers. At the pharmacy level, the number of small independent pharmacies is declining.

- **Geography of markets**—there is increasing consolidation and integration at both European and global level, with all three national wholesalers, as well as most of the large manufacturers, owned by large pharmaceutical groups outside the UK. Furthermore, although national markets for generic drugs are still distinct, owing to differences in industry regulation, healthcare systems, and licensing requirements, these distinctions are becoming less sharp, as regulatory and licensing bodies increasingly recognise each other, and licensing of foreign manufacturers of drugs for import becomes easier.

- **Agency schemes**—in the generic sector, manufacturers are increasingly using agency agreements with full-line wholesalers through which they fulfil orders acquired from pharmacies by their sales teams. These agreements are used by manufacturers of both generic and branded drugs. This means that an increasing proportion of generic drugs will be distributed through the full-line wholesalers.

- **Commercialisation of pharmacies**—pharmacists are put under pressure by the operation of the reimbursement system to find the lowest prices, rather than simply ordering drugs always from the same supplier. The longer-term effect may be to encourage trading behaviour by pharmacists and to drive out those who are not commercially minded.

- **On-line ordering**—there is already a significant use by pharmacies of on-line ordering from wholesalers. This allows more efficient exchange of information on supply and stock conditions. However, there is scope for increasing the use of on-line information systems between wholesalers and manufacturers, and to track a prescription from the GP's surgery through a pharmacy and to the PPA.

In light of the market structure, and the changes identified above, a number of weaknesses can be identified in the current system for the supply and distribution of generic drugs. The reforms proposed in the following sections will be judged against how well they alleviate these weaknesses.

- A noticeable feature of the pharmaceutical supply chain is the absence of workable and enforceable supply contracts, particularly in the case of generic products. This is the case for contracts between manufacturers and wholesalers, and between manufacturers and hospitals. Manufacturers seem reluctant to enter into such supply obligations with wholesalers, but report wholesalers to be similarly reluctant. This feature may be explained by the commodity nature of the generic market. It may be part of the reason why demand and supply are poorly coordinated and why there appear to be limited incentives for long-run investment in manufacturing.

- An underlying issue is whether generic drugs can be described as commodities. They have many attributes of commodities: they are unbranded, homogeneous, and easy to produce. However, licensing restrictions mean that there can be shortages in a particular drug in a particular country, although that therapeutic form may be manufactured and supplied in many places in the world. The time lag involved in licensing a new source of a drug may contribute to a fragmentation of a global market into many smaller national markets.

- Another feature is the lack of information on supply conditions and shortages throughout the chain, making it hard for manufacturers to plan production to meet short-term demand, and imposing costs on pharmacies and on the government when supply is short. This uncertainty and unpredictability in short-term demand at intermediate points in the supply chain is in sharp contrast with the (normally) stable and predictable aggregate demand from patients. In addition, this dearth of information makes it very difficult for the NHS to monitor the performance of its procurement system.

- Vertical integration and consolidation trends suggest that pharmacies may be increasingly less price-sensitive. Although the incentive to purchase keenly may remain elsewhere in the chain, current reimbursement techniques mean that the NHS does not benefit from these gains. The government's purchasing power could be better harnessed.

- As a corollary to this, some incentives in the current reimbursement scheme are perverse. Increased discounting on list prices is observed, artificially inflating the Category A Drug Tariff price, and putting extra pressure on the Discount Inquiry. Rebate schemes, including free product, have the effect of obscuring real prices from the NHS. High levels of claw-back that may be called for at the next Inquiry may be unpopular with the pharmacy sector.

- Short-line wholesalers may aggravate supply instability in times of shortage by reacting to, and taking advantage of, the ability of pharmacies to pay elevated prices when products are in short supply. However, these participants also perform the useful function of identifying new, cheaper, sources of supply, and driving prices down at other times.

- The transition to patient packs has not been smooth, partly owing to the lack of certainty about the transition. The industry emphasises that the government could have made this more certain by establishing clear rules from the outset. However, it may also be that the manufacturers underestimated the costs, the time of switching to patient packs, and the packaging capacity required.

2. Performance of the Current System

The performance of the current system—and the policy options for changing the system, proposed in the following sections—should be judged against the stated objectives of the Department of Health, which are to:

- maintain, and improve, the current quality of service to patients;
- minimise the costs of the distribution networks, subject to service-level and quality requirements;
- reimburse pharmacists as closely as possible for what they actually pay for the medicines they dispense under the NHS;
- ensure transparent prices;
- support a competitive pharmaceutical market; and
- secure value for money for the NHS.

In order to judge any recommended change, a benchmark is required; hence, this section examines to what extent these objectives are fulfilled under the current system. It also discusses the policy option of 'doing nothing' (ie, leaving the system unchanged, in the expectation that market developments—such as the decrease in the number of Category D products, re-entry of Regent, and the increase in APS's capacity once its Hungarian plant is fully operational—will eventually solve the shortage problems).

2.1 Quality of service to patients

2.1.1 Patient preferences

OXERA has not analysed in detail what patients actually want from their drug system, as this was beyond the scope of the review. The Department has provided some evidence on patient preferences from a number of surveys.

A survey performed in 1991 by Aston University and MEL Research for the Department of Health revealed that, overall, patients rated the *speed of dispensing* as the single most important reason for choosing the pharmacy they use (for high users, this was the second most important factor).[4] However, the survey also found that *convenience factor*s, such as location, are more important overall than service quality in determining which pharmacy to use.

Another survey, performed in 1996 by BMRB International for the Royal Pharmaceutical Society of Great Britain (RPSGB),[5] found that the speed of dispensing was given a relatively low score as a main reason for choosing a pharmacy (3% for repeat prescriptions, 4% for one-off prescriptions), but that location factors predominated (77% and 78% respectively). However, slow or busy service was reported as one of the three main reasons for deliberately avoiding a particular pharmacy (along with the staff and a poor range of stock), although only around 5% of respondents claimed to have deliberately avoided a pharmacy at all.

[4] Aston University/MEL Research for the Department of Health (1991), 'Consumer Expectations of Community Pharmaceutical Services', December.
[5] BRMB International Ltd (1996), 'Community Pharmacy: The Choice Is Yours', prepared for the RPSGB.

Finally, a survey in 1996 by the University of Manchester for a local health authority recorded a generally high level of satisfaction with the level of community pharmaceutical services at the time.[6]

In addition, it is often said that patients prefer to be prescribed the same company's drug (for example, when a chronic condition is being treated), and that they value receiving adequate information on the drugs they are taking.

2.1.2 Regulation of quality of service

The NHS Pharmaceutical Services Regulations establish minimum levels of quality and speed of service to patients. These are reflected in the Terms of Service, the arrangement with the local health authority under which the pharmacy is allowed to provide pharmaceutical services. Principally, pharmacies must supply any prescribed drug, and supply must be made 'with reasonable promptness'. If a drug cannot be supplied on the spot, pharmacies must give an estimate of when they will be available (although they are not bound by that estimate).

The terms of service also establish the minimum number of servicing hours (normally 30 per week) and provide for the possibility of service outside normal working hours. Moreover, the terms of service contain requirements related to professional standards, and the obligation to have in place a system for the investigation of complaints about the service provided to patients.

Quality of service is further enhanced by the RPSGB's Code of Ethics and its Standards of Good Professional Practice (although it has yet to be tested whether breaches of these standards would be sufficient to constitute the serious misconduct required for a pharmacist to be 'struck off').

Pharmacists must dispense exactly what is prescribed. They must 'round' products in calendar packs, or those which are otherwise indivisible to the nearest whole pack, unless, in their opinion, the prescriber wanted it dispensed exactly. If the prescriber has omitted the quantity, strength or dosage of a drug, the pharmacist may use professional judgement to dispense no more than five days' supply of a suitable drug.

If a prescription is written using the brand name, the pharmacist must dispense the brand. If it is written generically, the pharmacist may choose which company's drug to use. This possibility of substitution between different manufacturers of the same generic drug reduces the likelihood of shortages of that drug. It also allows the pharmacy to choose the supplier with the lowest price, thereby reducing the overall pharmaceutical bill for the NHS (which is another objective of the Department). However, it does not satisfy patients who prefer to be prescribed the same company's drug when a chronic condition is being treated.

As seen above, patients value the convenience of location of pharmacies, yet the establishment of a pharmacy in a certain area is restricted. Specifically, a pharmacist applying to the local health authority for admittance must show that a new pharmacy is necessary or desirable for the adequate provision of pharmaceutical services in the area.

[6] Pharmacy Practice Research Resource Centre, University of Manchester (1996), 'An Assessment of Need for Community Pharmaceutical Services in Dorset', October, prepared for the Dorset Health Authority.

According to a report by the Monopolies and Mergers Commission (MMC, now the Competition Commission), in 1991–92, the Department justified this policy to:

> ensure a cost-effective system of distribution and to reduce the practice of 'leap-frogging', whereby new pharmacies would be opened close to a doctor's practice when a site became available whether or not there was a need for an additional pharmacy.[7]

2.1.3 Service performance

Overall, pharmacists offer patients a 'reasonably prompt' service (ie, they can dispense any drug within a short time period). This is made possible by a distribution network where pharmacists are supplied two or three times a day by full-line wholesalers which carry the entire range of drugs. In addition, pharmacists can obtain drugs, usually at lower prices, from short-line wholesalers. Service levels may be lower from these players, but often include daily deliveries. Increasing horizontal integration between pharmacies, and vertical integration between pharmacies and wholesalers (and perhaps manufacturers), will also improve the pharmacies' abilities to obtain products.

From the interviews, it followed that, even during the current situation of shortages, there have been very few instances in which a patient's product needs could not be fulfilled (although this may have occurred more frequently in some regions than in others). This is partly due to Category D, which is designed to secure the supply to patients by ensuring that pharmacists are reimbursed fairly when they cannot purchase a drug in shortage at the Drug Tariff price. Pharmacists often manage to get hold of products that are in shortage by trying different suppliers, and Category D allows them to pay the higher price. Alternatively, they may dispense the branded equivalent of the product in shortage.

However, even without Category D, pharmacists often manage to satisfy the patients' needs through other means.

- Most pharmacists interviewed emphasised that their main concern during the 1999 shortages was to ensure that they could supply patients, not whether they were going to be reimbursed for the drugs at the price paid. Therefore, they would often simply buy the drug at whatever price they could acquire it, whether it was in Category D or not.

- Many pharmacists had increased the number of owings, effectively rationing available stocks.

- Pharmacists, particularly those working in chains that do not have purchasing or trading authority, often barter with other nearby pharmacies. Some reported that this had increased during shortages, and others that it had decreased because colleagues were protecting stocks.

- In the particular case of the Bendrofluazide 2.5mg shortage, pharmacists had been splitting 5mg tablets in half, or directing patients to do this.

[7] MMC (1997), 'UniChem plc/Lloyds Chemist plc and Gehe AG/Lloyds Chemists plc', p. 102.

- A number of pharmacists, particularly those working with nearby surgeries, had discussed shortages with GPs, with the result that prescribing patterns changed. Different presentations or alternative therapeutic drugs would be prescribed.

While these actions have prevented a strong decline in service levels during the shortages, patient satisfaction is likely to have diminished for a number of reasons. For example, the use of owings means that patients have to return to the pharmacy more frequently, and the change in prescribing patterns by GPs affects patients who prefer to be prescribed the same presentation of a drug.

Finally, OXERA has little evidence to judge whether the move to patient packs improves quality of service to patients. On the one hand, patients are better informed, both through the leaflets in each pack and because pharmacists have more time available to give information. Patients may also prefer drugs presented in packs. On the other hand, the lack of coordination between the number of tablets prescribed and manufacturers' pack sizes often means that pharmacists are having to split and cut packs, removing most of the time-saving advantages of patient packs. A solution would be to enhance such coordination, or to give pharmacists more flexibility to dispense pack sizes different from those prescribed. Furthermore, the absence of any bulk packs is problematic for supplies for nursing homes and managed-dose systems. For such systems, pharmacists have to take pills out of blister packs and place them inside new dispensing devices, which they claim is a costly and time-consuming activity.

In conclusion, the overall quality of service to patients appears to be reasonably high. Even with the current shortages, pharmacists appear to have done their utmost to ensure that patients were dispensed drugs appropriately. Without formal evidence on patient satisfaction, it is hard to estimate the extent to which the efforts of pharmacists have prevented patients' satisfaction from falling.

2.2 Costs of the distribution networks

Minimising the costs of the distribution networks, subject to service-level and quality requirements, is one of the objectives of the Department. The pharmaceutical distribution system in the UK is effective and reasonably modern. As mentioned above, pharmacies are offered two or three deliveries a day by their full-line wholesalers. It is these full-line wholesalers which make the high level of service to patients by pharmacies possible, by ensuring that any drug in the British National Formulary (BNF) is available in a reasonable time. The full-line wholesalers face competitive pressures from short-liners and from each other, particularly since the entry of Phoenix.

Full-line wholesaling requires a very costly infrastructure for storage and distribution, as well as large investments in stocks of infrequently prescribed drugs in order to offer the full range of products. Delivery two or three times a day makes pharmaceutical wholesaling more costly than other wholesaling activities (although supermarkets may face similar challenges), leading to economies of scale in full-line pharmaceutical wholesaling. The three national full-liners belong to larger European pharmaceutical wholesale groups, and each has just completed investments in the expansion and automation of warehouses in the UK. The economies of scale require handling large volumes, which the full-liners assure through:

- vertical integration with pharmacies;
- volume discounts to pharmacies above some threshold sales level—effectively inducing pharmacies to use only one full-liner as a primary wholesaler;
- other services to pharmacies in exchange for certain exclusivity, such as IT systems and financing schemes.

UniChem and AAH have automated warehouses and their systems allow accurate stock checks. Both report a very high proportion of ordering by pharmacies as now on-line. However, there is scope for increasing use of on-line information systems, particularly between wholesalers and manufacturers.

To assess whether the costs of the current distribution networks are low or high would require benchmarking against networks in other countries or against distribution networks in other sectors, such as supermarkets.

Overall, the current pharmaceutical distribution networks give good service, but also have some important weaknesses.

- There is an insufficient flow of information on supply conditions and shortages throughout the distribution chain. This makes it hard for manufacturers to plan production to meet short-term demand, and imposes costs on pharmacists and on the government when supply is short. This uncertainty and unpredictability in short-term demand at intermediate points in the supply chain is in sharp contrast with the stable and predictable aggregate demand from patients.

- Short-line wholesalers may aggravate supply instability in times of shortage by reacting to, and taking advantage of, the ability of pharmacies to pay elevated prices when products are in short supply. However, these participants also perform the useful function of identifying new, cheaper, sources of supply, and driving prices down.

- Any such benchmarking would be difficult, to the extent that institutional arrangements and levels of service differ.

- Even though the hospital sector and the community pharmacy sector each procure their drugs separately, both make use of the same distribution networks (ie, those of the full-line wholesalers). This is, in principle, efficient practice, since it prevents costly duplication of networks. However, the full-line wholesalers' automated inventory systems do not necessarily distinguish between products for hospitals and those for the community pharmacies. In addition, their ordering systems work on a 'first-ordered, first-served' basis. As a result, shortages in the community pharmacy sector may also leave the hospitals without products. This is not effectively prevented by penalty mechanisms in the contracts between hospitals and manufacturers, as the wholesalers have reported that no penalties have been passed on to them by the manufacturers.

2.3 Reimbursing pharmacists what they paid

The Department of Health seeks to reimburse pharmacists as closely as possible for what they actually pay for the medicines they dispense under the NHS. This is different from the Department's other objective (discussed further below) of securing value for money for the NHS by giving pharmacists incentives to obtain drugs at the lowest possible price.

The current reimbursement system is designed to fulfil both objectives simultaneously, although a trade-off must be made.

- Instead of reimbursing pharmacists exactly the amount they paid, reimbursement is at the Drug Tariff Category A price, which is an average market price. In addition, a discount is clawed back from the pharmacists, which is again an average, as determined by the Discount Inquiry. Thus, pharmacists who obtain lower prices or higher discounts from suppliers than the average will make a profit, while those who pay higher prices or receive lower discounts from suppliers will make a loss.

- For drugs that are in shortage and enter into Category D, pharmacists are reimbursed the price they actually pay (minus the standard claw-back), no matter how high. Here, the objective of reimbursing pharmacists fairly—as well as giving patients quality of service—is given priority over the objective of securing value for money.

The question is whether the Drug Tariff and the Discount Inquiry actually do reflect closely the prices paid by pharmacists.

There are strong indications that the Drug Tariff prices are higher than the actual market prices. The Drug Tariff (specifically Category A) is based on a basket of only a limited number of suppliers (ie, UniChem and AAH, the two main national full-line wholesalers, and Norton, Cox and APS, the three manufacturers). As such, it is unlikely to be representative of the market price. The basket excludes the newly established national full-liner, Phoenix, as well as the remaining regional full-liners (although the latter only have a small overall market share). The basket also excludes the other three large generic manufacturers (ie, Generics UK, CP Pharmaceuticals and Lagap), the first having a higher turnover than both Cox and APS. Most importantly, however, the Drug Tariff does not account for the fact that pharmacists obtain a substantial part of their generic drugs (perhaps up to 40–50%) from the short-liners.

According to the PSNC, few pharmacists have actually complained that they cannot obtain drugs at the Drug Tariff prices. It interprets this to mean that the Drug Tariff is representative. A different interpretation would be that pharmacists do not complain because they always manage to obtain prices below the Drug Tariff.

Nonetheless, the fact that Drug Tariff prices exceed those actually paid by pharmacists is not necessarily problematic since the difference should in principle be clawed back through the Discount Inquiry. However, even this average discount determined in the Discount Inquiry is at best only a rough estimate of the actual discounts offered.

- The Discount Inquiry is held at most on a yearly basis, and did not take place during 1999. Moreover, it only addresses sales during one specific month. This chosen month may not be representative for the 12 or more following months.

- Boots, which does its own wholesaling (and some manufacturing), effectively does not contribute to the Discount Inquiry since it cannot provide a meaningful transfer price between its wholesale and retail arms. Other large suppliers have stated that they do not participate either. The more widespread such exceptions are, the less representative the Discount Inquiry becomes.

- Likewise, the growing importance of vertical integration between wholesalers and pharmacies makes asking pharmacies for the prices paid to wholesalers increasingly meaningless. As is well established in theory, vertically integrated companies can easily shift profits from one part of the chain to another, depending on their objectives. In pharmaceuticals, the integrated chains may offer their pharmacies lower discounts, in order to reduce the claw-back, while keeping profits upstream.

- A further source of discount has been uncovered in Category D drugs. Once a drug is in Category D, the brand can be dispensed and the pharmacist is reimbursed at the PPRS price, as with any branded drug still on patent, and gains the discount negotiated with the branded supplier. A supplier with access to a 'true' generic alternative has an incentive to 'list' it at a price close to the branded price, and then offer discounts on this price. This is so that the pharmacist has a similar 'discount reward' whether the branded or generic drug is dispensed against the Category D prescription.

However, pharmacists may not always endorse properly, either by mistake, or because of lack of time or understanding of the system. This often happens when dispensing Category D products (but also, for example, may occur when the patient is exempted from the £5.90 charge[8]). When pharmacists endorse correctly, they may not always include all relevant information. Some of the costs of Category D are involuntarily borne by the pharmacists instead of the NHS. Again, no evidence is available to estimate these costs. It is also possible that the reverse occurs, and incorrect endorsement is a burden on the NHS.

In all, theoretically, there should be a high number of pharmacists who cannot 'beat' the average reimbursement price and therefore incur losses. However, there is little evidence on individual pharmacy returns from NHS prescriptions. Many pharmacists do complain that they have been forced to seek better prices because of the claw-back, which suggests that the yardstick incentive does work.

2.4 Transparent prices

The objective of ensuring transparent prices has three elements:

[8] By default, the PPA assumes that the pharmacist has charged the £5.90.

- transparency assists the NHS in assessing the performance of its procurement system;
- the NHS needs to know what the prices in the market are in order to determine the appropriate reimbursement prices;
- price transparency throughout the supply and distribution chain enhances the efficient functioning of the chain, by sending the correct price signals whenever there are discrepancies between supply and demand, and by reducing the costs to market participants of searching for the lowest price. By contrast, price transparency in a concentrated market may facilitate collusion.

From the previous section it is clear that the prices pharmacists pay to wholesalers are far from transparent. The NHS has even less information on the prices that the wholesalers pay to the manufacturers. The latter will become increasingly important, given the vertical integration between wholesalers and pharmacies.

In the supply and distribution chain, there is a large group of short-liners, including pharmacies and pharmacy chains, which actively seek arbitrage opportunities and react swiftly to changes in demand and supply conditions. For this group, there are significant rewards for predicting price movements accurately, and, hence, they invest time and effort in identifying prices. For the full-line wholesalers, prices are also reasonably transparent, since their buyer teams continually shop around for the cheapest available supply source (even buying drugs from specialist generic distributors in times of shortages). The prices charged by full-liners are transparent because they usually sell at their list prices, with standard discounts.

However, as mentioned earlier, there is an insufficient flow of information on supply conditions and shortages throughout the distribution chain. Manufacturers do not respond swiftly to shortages. Short-line wholesalers may aggravate supply instability in times of shortage by reacting to, and taking advantage of, the ability of pharmacies to pay elevated prices when products are in short supply. Thus, price signals do not function properly in the sense of giving manufacturers timely warnings on shortages.

2.5 Competitive pharmaceutical market

A competitive market is one with a large number of buyers and sellers, no barriers to entry or exit, and prices reflecting production costs (ie, no excessive profits are made). The degree of competition of the UK generic drugs differs at each of the stages of the production and distribution chain.

2.5.1 Manufacturing

The extent of competitiveness in generic manufacturing is not clear—there is conflicting evidence. There are six large manufacturers (excluding Regent) and a number of smaller ones based within, or focusing on, the UK market. In addition, there are many foreign firms that supply into the UK market through importers and/or agents. The exact position of imported products within the generic supply chain in the UK remains unclear, although the majority of imports seem to enter the market through small firms with wholesale import licences that may also be classified as short-line wholesalers.

For the rest of the report, the term ‘UK manufacturers’ applies to those firms with manufacturing facilities in the UK, or those for which the UK is their primary market.

Other firms supplying generics into the UK market—but which do not produce in, or primarily for, the UK—are referred to as overseas manufacturers or importers.

The study has identified several possibilities for entry, by either a start-up manufacturer, an existing manufacturer producing a new drug, or a new supplier into the UK market. The possibility of contract manufacture (from UK or overseas manufacturers on behalf of a product licence-holder) further widens entry opportunities. The most likely source of new entry into the UK market is from overseas producers, contracting into the UK market. There are growing global generic manufacturers, such as Teva in Israel and Ranbaxy in India, which both own firms in, and produce for, many countries around the world, including the UK.

However, there has been little major entry or exit in the past decade, and the generic manufacturers do not appear to be earning low returns, as discussed above.[9] This is not consistent with a fully competitive market. Major barriers are the acquisition of UK product licences and the fact that licence variations can take up to three months, thereby hindering rapid entry to take advantage of short-term shortages. This is further discussed in section 6.

2.5.2 Wholesaling

Economies of scale inhibit the development of a fully competitive wholesale market since there is room for only a limited number of full-line wholesalers. Nevertheless, Phoenix entered as a third national full-line wholesaler, next to AAH and UniChem, and competition is expected to become fiercer as a result.

In addition, the full-line wholesalers face significant competitive pressure from the short-liners, particularly in some of the most profitable branded drugs (which the short-liners obtain through PIs) and in generics. There are many short-liners and entry is easy, as witnessed by the fact that there are, at present, more than 1,000 wholesalers with a relevant licence. This picture of a competitive wholesale market is consistent with the evidence on profitability given in section 2.6. Full-line wholesalers make relatively low returns. The short-liners analysed do not make particularly high returns on average (although there may be important exceptions).

2.5.3 Retailing

There are about 12,000 pharmacies in the UK. There is an increasing tendency towards horizontal integration, with only 6,411 pharmacies (53% of the total) still belonging to chains of five or fewer shops. In addition to Boots, which is fully vertically integrated, the other two largest pharmacy chains are owned by the major national full-line wholesalers.

There are also entry barriers. An entrant must convince the local health authority of the need for an additional pharmacy in that area, or else purchase an existing contract. Larger pharmacy chains, and supermarkets, such as Tesco, overcome this barrier by simply acquiring an existing pharmacy in the area. Independent pharmacists have fewer resources to enter the market this way, further inducing the tendency towards integration.

[9] For some product lines, there has been marked entry.

2.5.4 Demand side

On the demand side, the generic drugs market is not competitive, in the sense that the NHS is the only buyer. A market with a single buyer and many suppliers—called a 'monopsony'—can produce the same inefficiencies as a market with many buyers and a monopoly supplier (although, of course, it benefits the buyer, in this case the NHS, through lower prices). However, the monopsony or buyer power of the NHS is limited for several reasons.

- In the primary-care sector, the NHS does not procure centrally, but rather completely 'fragments' its buyer power by using many pharmacists as its contractors. These pharmacists negotiate with their suppliers individually, and, together, do not have the same buyer power as the NHS if it were to negotiate as a whole. This contrasts with the hospital sector. Here, the combination of centralised procurement (at the regional level, and with regions influencing each other through the four months' rotation in procurement) and formularies (allowing substitution between branded drugs as well as between branded and generics) implies that the hospitals are using their buyer power.

- The NHS cannot obtain low prices in the same way as a traditional monopsonist can—ie, by reducing demand (in the same way as a monopolist increases price by reducing supply). This is because the NHS must fulfil every patient's needs, and cannot afford to buy too little of a product and risk shortages. In economic terms, the NHS demand for drugs is price-inelastic, which reduces its buyer power.

2.6 Value for money for the NHS

Securing value for money for the NHS is implicit in the other five objectives of the Department. Overall, patients are probably getting a reasonable quality of service from pharmacies, and, while many pharmacists do complain that they have to seek better prices because of the claw-back, this suggests that the yardstick incentive does work.

Higher up in the chain, relatively high levels of profits are made, particularly by manufacturers and AO licence-holders. This implies that the NHS is currently not getting all the value for money it could from the system, and suggests that the role of pharmacy needs to be examined.

2.7 The option of 'doing nothing'

In its Memorandum for the Health Select Committee of November 1999, the Department stated that:

> For decades the NHS has relied on the market for the supply of generic medicines. The assumption—and, to date, the experience—has been that a competitive market in the supply of generic medicines delivers the NHS continuity of supply and reasonable prices, ie, overall value for money for the NHS.

Generic prices in the UK dropped in real terms by 25% between 1994 and 1998, and have been relatively lower than in other countries. More importantly, the *use* of generics is very high in the UK, thus significantly reducing the total drugs bill compared to other countries that still mainly use branded drugs.

Therefore, once the effects of the supply shocks that triggered the shortage problem—ie, the closure of Regent, the relocation overseas by Norton and APS, and the introduction of patient packs—have been overcome, the situation could return to normal, and the current system could give the NHS value for money again. There are indeed signs that the shortage problem is diminishing—the number of Category D drugs has decreased significantly—as expected by many of the industry players interviewed by OXERA. Thus, one of the policy options for the Department would be to 'do nothing'.

The option of 'doing nothing' to the system could be combined with some form of claw-back from the industry of 1999 profits, if it becomes apparent that the shortages led to profits significantly higher than normal. Once the accounting data of the manufacturers and wholesalers for 1999 becomes available, the need and the level of the claw-back could be determined. On the other hand, such a claw-back will be perceived as an *ex-post* change to the rules of the game, which may distort incentives to invest further in the generic drugs sector.

The developments in 1999 have demonstrated that the current system absorbs supply shocks unsatisfactorily. In addition, as outlined in sections 3.1 to 3.6 and summarised in Table 9.1 below, not all the Department's objectives are fully satisfied under the current system. Therefore, 'doing nothing' is not the most appropriate solution. Alternative options are explored in the following chapters.

3. Reforms to Pharmacy Reimbursement

The study of the supply and distribution of generic drugs in the UK has pointed out a number of perverse incentives in the current reimbursement system, despite the effectiveness of the underlying yardstick benchmarking. OXERA proposes the following three policy options to modify the reimbursement system itself:

- expand the Drug Tariff basket to include more manufacturers and wholesalers, and change the weighting method;
- abolish Category D;
- reform the Discount Inquiry.

These are explained fully in this section. The first and third of these options could, in principle, both be implemented individually. The second option should ideally be implemented in combination with the first, and/or with some of the options outlined in the following sections. Alternatively, a new mode of contracting could be designed, whereby pharmacists play little role in the NHS purchasing strategy. Such centralised purchasing is discussed in section 8 and more fully in sections 11–16; if fully implemented, this could obviate the need for reimbursement.

3.1 Expansion of the Drug Tariff basket

As noted in section 3.3, there are indications that the Drug Tariff prices are higher than the actual market prices. The Drug Tariff (specifically Category A) is based on a basket of only a limited number suppliers (ie, UniChem and AAH, the two main national full-line wholesalers, and Norton, Cox and APS, the three manufacturers). As such, it is unlikely to be representative of the market price. It excludes the newly established national full-liner, Phoenix, as well as the remaining regional full-liners (although the latter have a small overall market share). The basket also excludes the other three large manufacturers (ie, Generics UK, CP Pharmaceuticals and Lagap), the first having a larger turnover than both Cox and APS. Most importantly, the Drug Tariff does not account for the fact that pharmacists obtain a substantial part of their generic drugs (perhaps up to 40–50%) from the short-liners.

Expanding the Drug Tariff basket would lead to more representative Category A prices. The basket should at least include the third national full-line wholesaler, Phoenix, as well as the other three large manufacturers (ie, Generics UK, CP Pharmaceuticals and Lagap). The PPA has said that it would be relatively straightforward to include these companies. It would have to ask all these suppliers for their price lists, something that already happens for Category D purposes.

Ideally, the Drug Tariff basket should also include short-liners, since these are a major provider of generics to pharmacies. However, there are problems with including the short-liners:

- they only supply a limited range of drugs, and their product offerings may vary regularly in accordance with changing profit opportunities;
- their product availability and supply conditions may vary between regions (depending on where they have depots).

The first is not a serious constraint. Short-liners' prices would only affect prices where they held stocks of the product. In addition, some larger short-liners do offer a wide range of generic drugs and even delivery once or twice a day. For example, at least one 'short-liner' apparently stocks the full-line generics (1,200 products) and offers delivery twice a day. A second short-liner can deliver one or two times a day in the five regions where it has a depot, and uses couriers for overnight delivery in other areas. Including these and other short-liners in the basket is therefore feasible.

The second is more problematic, and is the reason that even regional wholesalers are not currently included. Constructing a different Drug Tariff for each region would not be feasible. Thus, either short-liners should be left out of the Drug Tariff, even though this makes Category A prices less representative, or they should be included, and no compensation should be made for the fact that some pharmacies may not have access to stocks at the reported prices.

Expanding the basket—whether by including only Phoenix and the three manufacturers, or by including some short-liners as well—has the following advantages:

- Drug Tariff prices for Category A drugs would better approximate the actual market prices paid by pharmacists;

- Category D would be triggered less frequently, since the PSNC's and PPA's stock inquiries would cover a greater number of Category A suppliers. Of course, Category D should not be triggered in the new system simply because one of the basket suppliers has insufficient stock, as could happen in the current system. Instead, provided that a certain minimum number of basket suppliers have sufficient stock, Category D would not be triggered;

- higher prices resulting from genuine shortages would be reflected more quickly in the Category A prices;

- suppliers in the basket have less incentive to hoard.

The cheaper prices that pharmacists receive from short-liners and the discounts offered by manufacturers and full-liners would still have to be captured through the Discount Inquiry, as under the current system. The stocks of products in shortage held by short-liners, and thus overlooked in current stock inquiries, could be discovered through sales information requirements.

As to the feasibility of this option, the PPA has affirmed that expanding the basket would be a straightforward exercise. In addition, it said that, in principle, it would also be possible to perform stock checks with the basket suppliers *before* they are included in the weighting for any specific drug. Clearly, this would have resource implications. This could prevent the inclusion of basket suppliers which do not have the specific product available for that month but have not taken it off their price list. At present, the PPA only performs stock checks for Category D drugs, and then only on a voluntary basis.

In addition (or as an alternative) to expanding the basket of Category A suppliers, a different weighting system could be introduced. Rather than taking a weighted average of all the basket suppliers that offer the product, the Category A price could be taken as the

average of the lowest three prices offered in any month. The name of the three suppliers with the lowest price should also be mentioned explicitly in the Drug Tariff. This introduces an incentive for every basket supplier to belong to the bottom three.[10] It does necessitate each supplier providing accurate price and stock-level information each month. Whether the bottom-three suppliers actually have sufficient stock has to be checked, otherwise the basket price would be too harsh on pharmacists.

3.2 Removal of Category D

Category D has been designed to secure the supply to patients by ensuring that pharmacists are reimbursed fairly when they cannot purchase a drug in shortage at the Drug Tariff price. Pharmacists often manage to get hold of products that are in shortage by trying different suppliers, or they dispense the equivalent branded drug, and Category D allows to them to be reimbursed for higher prices. Another useful function of Category D has been to signal to manufacturers that there are shortages.

However, Category D has not functioned satisfactorily, and it creates a number of adverse incentives, which destabilise prices.

- By design, once a product is in Category D, pharmacists no longer have an incentive to search for the lowest price.
- The financial benefits of trading in a Category D drug encourage speculative behaviour. Those players not part of the basket of suppliers, particularly short-liners but also manufacturers, are free to hold a product if they suspect there will be supply problems, knowing that this stock holding is not part of the Category D assessment.
- There is an incentive to dispense the brand, or to purchase from suppliers that inflate generic list prices and offer discounts.
- By means of the practices (discussed above) of dual price lists and of vertically integrated wholesalers always endorsing the most expensive version of a Category D drug, pharmacies profit from Category D at the expense of the NHS.

Therefore, one of the policy options is to remove Category D completely. This would eliminate the financial benefits throughout the chain of speculative trading in Category D drugs, while keeping the yardstick mechanism for pharmacies intact at all times, including in times of shortage. The effect of supply shocks, such as those that occurred at the end of 1998 and early 1999, would be mitigated.

The major disadvantage is, of course, that patients may not be supplied in times of shortage because pharmacies cannot find the product at a reasonable price. Alternatively, pharmacists who do supply the patient may be penalised for buying the drug at a higher price than the Drug Tariff price. In addition, Category D would no longer function as a mechanism for signalling shortages to manufacturers.

However, these disadvantages could be overcome by removing Category D in combination with some of the other options presented in this report.

[10] This mechanism is somewhat similar to that used by the European Commission to determine 'best current practice' telephone interconnection charges in the EU. Best current practice is defined by the three member states with the lowest charges. The European Commission publishes this information regularly.

- As noted earlier, in times of shortage pharmacists have resorted to several measures that mitigate the effects of the shortage, such as owings, bartering with nearby pharmacies, or discussions with GPs to seek changes in prescribing practice. These have the beneficial effect of further reducing the effectiveness of hoarding.

- If the Drug Tariff basket is expanded, the absence of Category D will be less severe. First, the Drug Tariff price will be more representative of the actual market price, and any price increase caused by shortages will eventually (after a month) be reflected in an increase in the Drug Tariff. Second, stocks of products in apparent shortage will be checked for with more suppliers, meaning that Category D will be triggered less frequently. Third, the number of companies with an incentive to hoard drugs in shortage is reduced.

- For drugs in real shortage, a mechanism could be devised to replace Category D whereby the Department of Health (through the PPA or another agency) would take over responsibility from pharmacists to search for, and acquire, the product. This option is discussed in detail in section 8.

3.3 Changes to the Discount Inquiry

3.3.1 Changes in discounting practice

The aim of the Discount Inquiry is to 'claw back' from pharmacies all discounts to the PPRS and Drug Tariff prices at which reimbursement is made. The key problem for the Discount Inquiry is the vertically integrated chains. More radical options for this underlying problem are discussed in section 7. Here, options to improve the Discount Inquiry that would suit the current industry structure are outlined.

The main proposal is to accept the different ownership structures in the industry and to design different claw-back solutions to match them. In addition, it is important to be clear about the source of discounts and to ensure that the Discount Inquiry questionnaire is designed to identify them. There are three different ownership structures:

- independent pharmacies, perhaps with a large number of stores or participating in a buyer group;
- wholesalers, which supply their own retail pharmacies and other pharmacies;
- Boots, which supplies only its own retail outlets.

Discounts can arise from two basic sources:

- purchasing at a better price than is reflected in the list prices of the basket suppliers. This 'better price' could be offered by an alternative supplier or as a discount from the basket suppliers' list price;
- negotiating a better deal on the wholesaling/distribution part of the service.

It is likely that the first of these will result in greater discounts than the second. As consolidation continues at the pharmacy level, more centralised purchasing occurs. The guaranteed dispensing volume significantly enhances the bargaining power of the

pharmacy group. The current Discount Inquiry seeks information at a pharmacy level, to compensate appropriately for the fact that pharmacies with smaller turnover will incur higher costs in drug supply. It is this that enables integrated chains (and even the supermarkets) to argue that the prices they would report for their smaller stores would not be comparable with those of small independents. By doing this, the additional discounts arising from the buyer power of these larger groups are not captured by the NHS. The proposed changes focus on identifying this 'discount' explicitly.

The particular discount practices that are prevalent in the industry are:

- PIs for branded drugs (supplied by full- and short-line wholesalers);
- volume discounts offered by main full-line wholesalers, to encourage consolidation of purchasing. These discounts apply to all drugs and other products supplied by full-liners;
- lower prices for generics from suppliers not included in the Drug Tariff;
- additional discounts and rebate schemes operated by manufacturers, smaller wholesalers and buying groups to encourage pharmacists to consolidate purchasing. Rebates can include cash-back or free product;
- as a pharmacist is supposed to be reimbursed exactly for any Category D drug, no product-specific discounting should be possible, although these purchases would contribute towards any volume discount. However, there is evidence of (sometimes significant) differentials between list prices and market prices for Category D drugs from some suppliers. This suggests a potentially new source of discount for the Discount Inquiry.

3.3.2 Inquiry for independent pharmacies

The main structure and workings of the Discount Inquiry would not change for pharmacies remaining independent of wholesalers. The change would be in focusing on the key margin that the Discount Inquiry is trying to identify—the difference between a pharmacy's actual expenditure on all drugs purchased and the amount reimbursed by the PPA for drugs.

During interviews for this study, most independent pharmacists said they could not, or did not, undertake this calculation. This is because of the difficulty in tracking the price at which a drug was purchased (possibly some time before dispensing) and that at which it was reimbursed (up to three months after dispensing). All claimed not to look at this metric of purchasing skill, even on an annual basis. While the complexities of the Drug Tariff may make it difficult for pharmacies to keep track of purchases, it is not surprising that pharmacists would protect this information, as it is a clear signal for the appropriate level of claw-back.

A move towards an annual Discount Inquiry on the total actually paid for drugs dispensed would undoubtedly require different systems to be put in place by pharmacists to track stock value more closely. However, it does not seem too much to expect a pharmacy chain to be able to answer the question, 'How much did you pay for your drugs last year?' Any IT system (discussed in section 5) which tracked information through the chain would enhance this process. More detailed information on suppliers, volume-related discounts, proportion of 'true' generics dispensed, and use of PIs could all be ascertained. However, to achieve this using the current system of looking through

invoices is extremely time-consuming and leads to long lags in the process. Until computerised systems are in place, it may be better to use the Discount Inquiry to look at the overall total margin and not the details. Other ways of obtaining such information are discussed in section 5.

The margin would be determined at company, not individual pharmacy, level. Hence, for example, all Tesco stores would be assumed to have gained the average margin for the company as a whole. Since most supermarkets use a full-line wholesaler to supply them, they are no different from any chain of independent pharmacies. Claw-back would be set for different turnover bands as at present, but would be based on total turnover for pharmacies that are commonly owned—the same claw-back would apply whether the turnover occurred in one store, or across ten small ones, if they were owned by one company. This would ensure that the buyer power of larger groups would be captured by the Discount Inquiry.

An additional reform might be that discounts are calculated at an individual pharmacy or company level. The entirety of the discovered discount is not clawed back, but 30%, say, remains with the pharmacy to ensure that the incentive for good purchasing remains. This option, which is similar to the system in the Netherlands, requires detailed information to be examined for each pharmacy (or chain) in the country. Under a complete revamp of the IT support for drug purchasing, such a scheme might be feasible.

3.3.3 Inquiry for integrated wholesalers

If the Discount Inquiry is to tackle integrated businesses, it is very difficult to avoid addressing the issue of an appropriate return (or margin or fee) for the wholesale business. The issue of the costs and benefits of vertical integration and how to deal with it are discussed in section 7. Here, two basic ways of capturing the 'true' price of drugs for pharmacies integrated with wholesalers are explored.

The first option is to use the discounts discovered from analysing the independent sector as a proxy for the integrated chains. This assumes that wholesalers would offer similar deals to their own pharmacies, whether or not they are integrated; what determines the discount is the turnover of the chain as a whole. This is basically the current approach. It is not robust to further integration since it requires a dynamic representative independent sector to produce a sensible benchmark. It may also not be robust to new ways of delivering discounts.

Second, the integrated chains can be asked for information on actual purchase prices of drugs. Subsequently, some estimate of an appropriate margin on this price for wholesale and distribution is added to form an estimate of the transfer price from wholesale to retail business.

- Prices at which drugs were supplied to wholesalers, weighted by volumes, should be provided on a monthly or annual basis. This is the key piece of information that is currently not used by the Discount Inquiry.

- To this price needs to be added the costs of distribution. Information on 'allowed' margins from contracts between manufacturers and wholesalers could be used. Currently there are a number of schemes where the wholesaler acts as an agent, including the PPRS. Generally the margin is of the order of 15% for generics. It

would be important to ensure that such clauses were not inflated for the Inquiry, with discounts offered subsequently.

- Alternatively, a full formal assessment of the wholesaler's costs could be undertaken to give a view on the appropriate margin. It could be similar to a five-year regulatory price control, setting the margin for some period of time. A yardstick control could be employed (using the costs of the others as a benchmark for one firm), as there are three large integrated companies.

Combinations of the above could be used, depending on the size of the wholesaler. Short-liners with significant pharmacy interest could be included in the process.

3.3.4 Inquiry for Boots

Many of the same issues arise with Boots as with the integrated wholesalers; however, there is a difference. Boots is not a full-line drugs wholesaler. It only carries 4,000 lines, and uses a full-line supplier as its secondary supplier. It has its own distribution system, which is used for a wide range of retail products. Dispensing brings customers in and establishes a trustworthy reputation. This leads to different economies of scale and scope from the full-liners. It is this that has led to difficulties in including Boots in the Discount Inquiry.

As with the integrated chain, Boots could be asked to disclose information on actual purchase prices of drugs, and the distribution margin identified as appropriate for the integrated chains could be applied to Boots' purchase costs.

3.3.5 Summary

The costs of a Discount Inquiry designed to give a better estimate of the costs of distribution could be large. The benefits depend on the value of the hidden information of the price at which wholesalers buy directly from manufacturers. If wholesalers were structuring transfer prices so that profits were taken upstream, this should be apparent in operating profit margins. For the full-liners, these are not very high, although generics are a very small part of turnover.

Such an Inquiry could yield significant information about prices and the value chain in the industry. As such, it would have numerous beneficial effects, including enhancing price transparency, minimising distribution costs, improving the reimbursement system, and increasing the competitiveness of the market. However, many of these objectives can be achieved by other options; a more modest change to the Discount Inquiry may be sensible at the first stage.

4. Improving Information Flows

The main problem hindering the Department's efforts to reimburse pharmacists as closely as possible is the failure to achieve transparent prices. The lack of information available to the NHS also hinders its ability to monitor procurement effectively. At no stage in the supply chain are the actual prices paid visible to the Department, and this renders accurate reimbursement practically impossible. By design, there are those who gain from the system, and it appears that, despite its complexity, pharmacists do not have a coherent position on desired reforms to the current mechanism, although most said that they thought the reimbursement system was flawed. Many claim not to know whether they are actually reimbursed accurately. This could suggest that it is rare for pharmacists to make significant losses from the existing system.

In order to improve the performance of the existing, or any reformed, reimbursement system, the level and accuracy of the information acquired by the Department or its agencies must be significantly improved. Under any market regime where firms are remunerated (even indirectly) by the prices they declare, they will have an incentive to declare incorrectly. The most direct way to improve the quality and accuracy of information is to compel firms to provide the information, and have an auditing mechanism to deter cheating.

Therefore, OXERA proposes three policy options that would improve the flow of information:

- information requirements on licence-holders;
- better use of endorsement information;
- IT solutions.

4.1 Information requirements on licence-holders

Information would be requested from each product and wholesaling licence-holder. The key data that is needed in order to monitor the market is on prices and stock. The objective of any new system would be to make this information as accurate and timely as possible.

- Price data should be provided by both manufacturers and wholesalers on a monthly basis.
- Selling and purchasing prices for full- and short-line wholesalers should be provided on a monthly basis.
- Manufacturers' selling prices to wholesalers, direct to retail, and to other manufacturers should be provided.
- Manufacturers should provide monthly average information on their stock levels, and the quantity of sales and production during the month.
- Wholesalers should provide end-of-month stock levels, volume of sales and purchases during the month.

By obtaining this information, the Department would be able to monitor more accurately from month to month the stock position of drugs, and to pinpoint potential shortages as they arise. While the Department would ideally request this information for all drugs,

such requirements may be unduly onerous on wholesalers and manufacturers. Instead data on the top 200 or 500 generics only may be demanded. In addition, it is worth noting that most wholesalers told OXERA that they do not calculate or keep some of the information on bought and sold prices. In requesting data in a set form, the Department may therefore be defining the way in which wholesalers operate their systems. While this may not necessarily be negative, it should be borne in mind when determining the exact information requirements.

Both the price and stock information should be auditable (ie, the Department or the PPA would have the right randomly to check any information provided by firms). The firms themselves would have to give an agreement to allow free and unhindered access to inspectors in order to carry out this audit procedure.

The main cost implication of this option is in the analysis and monitoring of the data on the Department's side. If the current paper-based approach remains, this could involve extra personnel at the PPA headquarters to input data into a database, and analyse it, and a larger field team to carry out random checks on the firms. However, depending on the extensiveness of the data, this team could remain small, maybe two or three people. The key issue is whether all the full-line wholesalers' price details should be analysed.

It is expected that more accurate information provision will improve the performance of the reimbursement system, in whatever form. Therefore the benefits of introducing this option may outweigh the costs.

The above ignores the issue of how companies might be compelled to provide the required information to the Department. The obvious mechanism would be inclusion in the wholesale or manufacturing licence provisions. It is not clear whether this would be a practicable option, or whether the measure could be introduced through other instruments available to the Department.

4.2 Better use of endorsement information

Another option is to obtain information about pharmacies' sources of supply through the endorsement prescriptions. Pharmacists should be required (and trained) to fill in prescriptions properly, including, for each drug dispensed, the manufacturer, the supplier and the price paid (although to provide the price paid could be problematic as a result of the wholesalers' discount structures).

The PPA would collate this endorsement information. Of course, the information is backward-looking and cannot therefore be used to monitor stocks or predict shortages. However, it would allow the Department to examine, in times of shortages and price increases, where, and via whom, the product comes out of the supply chain into the pharmacies. In this way, the Department could pinpoint any suppliers that might be responsible for hoarding or price spikes. If price data was included, the information would also be used to check how representative the Drug Tariff prices are, as an alternative mechanism for the Discount Inquiry.

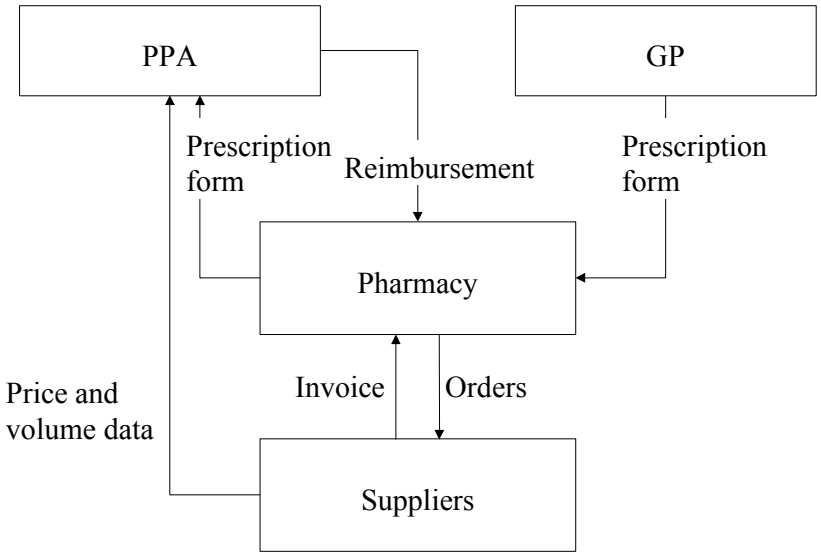
Better use of endorsement information would be significantly facilitated by automatic endorsement, one of the IT solutions explored further below.

4.3 IT solutions

At present there is scope in the generic medicines supply chain in primary care for improvements in terms of technology. Automated ordering is a feature of the established full-line wholesalers, but other, mainly short-line, wholesalers and manufacturers do not use such systems widely. Invoicing is generally not automated, making it difficult to value stockholding accurately. The PPA is a huge, paper-based operation for reimbursing prescriptions, which operates in arrears and does not allow for easy analysis of dispensing patterns. Thus, there would be benefits to automating the process in some way.

Figure 5.1 shows the information flows that could be automated. Currently only the ordering link between pharmacy and suppliers is partially automated, mostly with proprietary systems. Below the other elements of IT automation are discussed. It is crucial that any platform used by industry participants has an *open standard* in order to maximise the benefits.

Figure 5.1: IT information flows



It seems that it would be worthwhile to investigate the costs and benefits in implementing one or more of the following options, which are listed in terms of increasing complexity. The operation of some of the options depends on the introduction of earlier ones:

- automated PPA payment system;
- electronic prescription;
- on-line data delivery from manufacturers and wholesalers;
- automated stock replenishment from wholesalers, manufacturers or central purchaser;
- barcode tracking of products for price and dispensing.

5. Lowering Entry Barriers into Manufacturing

A crucial part of the industry picture has been the lack of response from manufacturers and importers to the 1999 supply shortages and price rises (in terms of new entry or increased capacity). Short-liners may have speculated through hoarding some drugs, but this strategy is only successful when alternative supply is not forthcoming in response to the price signals. The remedies discussed here aim to reduce entry barriers in the supply of drugs to the UK market by facilitating the acquisition of licences.

5.1 Licensing

Any firm wishing to supply the UK market must have a valid UK product licence and manufacture at an MCA-approved site. To obtain the product licence, the bioequivalence and other clinical tests must be presented to the MCA. In addition, the holder of the product licence must be registered within the EU. Thus, non-EU manufacturers supplying into the UK must have, at the very least, an agent established inside the EU to hold the licence; often this is no more than an office. The manufacturing premises themselves will be inspected by the MCA to ensure that they meet the requirements of Good Manufacturing Practice before the product licence is awarded.

The research that is used to acquire the product licence must relate to the particular product to be manufactured, but does not have to have been generated specifically for the UK licence. Bioequivalence and clinical trials carried out to gain a licence elsewhere can be used to acquire a product licence in the UK, so long as the data is provided in full and the tests required by the MCA are met. Licensing costs can therefore be reduced by using the same experiments for product licences in a number of countries.

However, the requirements of the different national licensing authorities often affect the ease with which test data is transferable. Every county requires bioequivalence against the reference drug appropriate for its country. As patented drugs were historically often registered with different characteristics in different markets, this can require repeating the bioequivalence test for each market. Many national authorities attempt to encourage cross-licensing by minimising the differences between countries' generic specifications, although it is likely that this is still the most expensive part of the testing programme.

Other differences also exist; the USA demands only one batch of stability tests to be carried out on new generic drugs, while the EU requires three. Manufacturers with a US parent company have said that this impedes them from benefiting from their parent company's research; it would incur additional cost and delay in achieving the US licence that would not be necessary for the US market. Consequently, synergies from global firms are much reduced.

Importers of generics medicines into the UK from outside the EU must have a wholesale import licence from the MCA. This stipulates that every batch of imported products must be re-tested for compliance with the product licence once it has arrived in the EU.

An AO licence allows the holder only to repackage products, either to break bulk containers or change the packs in which the product will be sold. It is not necessary for an importer to hold an AO licence if they do not repackage the drugs once they have been imported. In this instance, the importer would sell the drugs to a manufacturer, wholesaler or retailer in the same form as they were imported. In practice, however, the majority of

importers hold AO licences (around 70% of AO licences are held by firms with wholesale licences).

In addition, the MCA referred to 'virtual wholesalers', which do not actually own any wholesaling premises. Instead, the operators negotiate access to another firm's licensed site, and the wholesaler's own facilities may be little more than an office. The wholesaler never takes delivery and, in effect, brokers a deal with a purchaser, which arranges distribution, or the wholesaler contracts a distributor to deliver the product. In order to register another firm's site, the virtual wholesaler would need no more than a written agreement from the site owner. There are also firms, such as Healthcare Logistics, which specialise in providing warehousing and distribution services to third parties, without seeming to be involved in dealing in generics themselves.

There are therefore certain barriers to imports of generic drugs, the principal one being obtaining a UK product licence. Having obtained such a licence, it does not appear difficult to import generic drugs. The key to improving the opportunity for imported generic drugs to play a part in the UK market appears to be related to the product licence.[11] It is not desirable on public-health grounds to reduce the standards for achieving a licence (even if EU legislation did not prohibit this strategy), and the MCA seems to be efficient at its licensing operation, suggesting that there would be few gains from focusing on the licensing infrastructure. One possible improvement to the licensing would be a fast-tracking option at the MCA for amendments to product licences for generic drugs that are in shortage.

There are essentially two options that could be pursued, which are not mutually exclusive:

- improve (and stimulate) the secondary market for product licences; and
- achieve MRPs where possible.

One of the problems is both the cost and length of time that it takes to acquire a new product licence. One option for addressing this could be to formalise the secondary market in product licences. Although such a market already exists, it appears to be on a relatively informal basis.

In order to improve trade in licences, a clearing house for trading licences could be set up. Firms wishing to sell a licence would notify the clearing house of the details of the licence, and an auction could then be held at the end of each month, and publicised throughout the industry.

It might also be beneficial to stimulate the market, as trading appears infrequent at present, and to address the problem of licence hoarding (ie, firms acquire licences and then decide not to produce for strategic or other less competitive reasons). While firms ought to be allowed commercial discretion over whether they wish to produce, it is in the Department's interest to have as many producers of generics as is economically feasible. Therefore, a 'use-it-or-lose-it' type of clause could be included in the licence. If a firm

[11] This need not be active participation. If imports are readily available, given sufficient profit opportunity, the threat of entry will have a constraining effect on the existing market players.

does not produce under a product licence during a predetermined period, for instance 12 consecutive months, then the firm must offer the licence for transfer.[12] This type of arrangement is used in many markets where licensing determines output—for example, in wireless telecommunications. However, clearly this change to the licensing rules would require detailed further investigation to weigh the costs and benefits.

For both manufacturing and product licences, national authorities are increasingly working together to achieve mutually acceptable procedures. The UK authorities, particularly the MCA, could press the EU to introduce mutual recognition of manufacturers for non-European countries whose licensing procedures meet European standards. The EU already has MRA agreements with Australia and New Zealand for manufacturing licences. Other countries may be recognised soon.

An MRP system for generic product licences exists within Europe, along the lines of that which operates for new branded drugs. It would be beneficial for use of this system to be encouraged.[13]

OXERA understands that up to three-quarters of the cost of developing a generic can be in achieving country-specific bioequivalence. This cost would be reduced or saved altogether if product MRP were also agreed. New branded drugs increasingly have pan-European product licences, as they are supplied into a number of European countries. Therefore, when they come off patent, generic equivalents will also have European applicability.

Overall, improving the availability of product licences should increase the number of possible suppliers, making shortages less frequent. This will improve the service to patients and enhance the competitive market in the supply of generics. In particular, more constant price pressures would be expected.

5.2 Roche–Bolar for the UK

At present, most development of new generic products has been moved abroad, out of the UK. The prime reason for this is the opportunities offered by the Roche–Bolar, or similar, patent provisions available in countries such as the USA, Canada or Israel. The Department is well aware of the benefits provided by Roche-Bolar systems, so they will not be discussed further here.

As a result of the availability of earlier product development overseas, the trend is for UK firms to become more similar to Lagap in their organisational structure. That is, the UK branch becomes no more than an agency operation for manufacturing facilities overseas. Even now, the only major generics firms with UK manufacturing capacity are CP Pharmaceuticals, Generics UK and Cox; the others, such as APS, Norton and Ranbaxy, control overseas plant from head offices in the UK.

The Department ought to be mindful of these developments and trends when considering the security of supply of UK generic drugs. Many suggest that the margins in the UK

[12] The reserve price would then be a certain percentage below the expected price for such a product licence on the open market. This price would effectively become the residual value of the licence.

[13] Since this report was written, the MCA has indicated that 25% of licence applications received during 2000 made use of the European MRP system.

generic drugs industry are the smallest in the world. Furthermore, as the generics market becomes increasingly global, firms may turn away from the UK if it is not considered their home market. This trend will be exacerbated by MRP provisions, and could, indeed, be a downside of widening product licence recognition.

In order to ensure security of supply and to develop the UK as a base for European or global generics manufacturers, the Department could consider the introduction of a Roche-Bolar-type provision into UK patent law. This would have to be negotiated at the European level, so could not be considered a short-term measure. In addition, it would cause considerable friction with the proprietary drugs companies in the UK. However, these companies do not at present benefit from the stricter EU laws anyway, as new generics are already developed overseas and imported.

6. Options for Changing Retail Industry Structure

6.1 The problem of vertical integration for the current system

The success of the NHS's objective of 'value for money' in drug supply depends on the price sensitivity of its contractors, the pharmacists. The yardstick benchmark of the Drug Tariff and the averaged claw-back from the Discount Inquiry provide incentives for any pharmacist to beat the average. This then feeds through into prices and claw-back in the next period, ratcheting down the costs of drug supply. Against this design, a number of structural changes have occurred. Between 1990 and 1999, the number of independent pharmacies (chains of five pharmacies or fewer) fell by over 20%, to 6,411. While small independents still predominate, there is an increasing number of managed pharmacies operated by salaried or locum pharmacists.

The twin pressures of integration and consolidation reflect underlying economies of scale and scope. One person buying for a number of stores can exert more buyer power on the relatively small number of drug suppliers. A wholesaler can negotiate better deals on supply with guaranteed dispensing through its own chain. The key to profitable wholesaling is volume—purchase by a wholesaler of its retail customers ensures this underlying volume. Delivery networks can be designed on the basis of a core, stable demand. Such changes may well reflect sensible responses to the competitive pressures in the market-place. However, they can have a negative impact on the success of the government's procurement objectives.

Wholesalers' interests do not match those of the government. There will always be pressure to structure reporting such that prices seem high to the downstream business. Wholesalers may not offer the same discount to integrated pharmacies as to independent ones. As pharmacists build buyer power, their interests may diverge from those of the government, and pharmacists' skills in strategically hiding discount activities are likely to grow as the returns also grow. Pharmacist trading is an indicator of this activity.

How should the NHS address this problem? There are three options:

- do not change the structure, but rather devise different claw-back mechanisms based on specific Discount Inquiries for vertically integrated chains—an option discussed in section 4.3 above;
- reverse the trend, and enhance the independence of pharmacy. This could go as far as enforced disposal of pharmacies owned by companies with wholesale interests. This separate structure is standard practice in much of Europe;
- change the method of procurement, recognising that pharmacists are not sufficiently price-sensitive. Centralised purchasing is discussed in detail in the next section.

The second option is scoped out here. It should be emphasised that a careful assessment of the costs and benefits of vertical integration should be considered before any major structural changes are implemented. If there are underlying benefits to vertical integration, then separation may not be successful, as commercial pressures will find ways to circumvent the rules.

6.2 Vertical separation or ring-fencing

The issue of regulating vertically integrated businesses has occupied the minds of most of the UK sectoral regulators; however, in those cases, the underlying issue was slightly different. The outcome in gas, electricity, telecommunications, rail and now water has been the attempt to separate out the natural monopoly component of the chain and regulate that, but allow competition to develop elsewhere in the chain. In the supply chain being analysed here, the reason for the separation is different—wholesaling is not a natural monopoly business. However, the means of achieving separation should draw on experience elsewhere. There are three, increasingly separate, forms:

- accounting separation;
- ring-fencing;
- full divestment.

Accounting separation refers to a requirement to allocate costs between integrated businesses according to clearly specified rules. These rules are designed to produce efficient transfer prices between the businesses to ensure that unintegrated downstream firms are not disadvantaged when they purchase access to the upstream business's services. Such rules have been used extensively to set interconnection prices for many network businesses. For example, the European Commission has published guidelines on accounting separation for telecommunications operators in Europe.

Ring-fencing goes further, recognising that, despite such guidelines, there remains a significant information advantage in the integrated firm. Accounting separation rules can be adhered to, and yet there can still be evidence of inefficient transfer prices (usually in the form of a margin squeeze). The UK Office of Gas and Electricity Markets (OFGEM) is consulting on revisions to current ring-fencing arrangements put in place in response to increasing foreign ownership. These revisions are now necessary because electricity distribution and supply licences must be separately owned. These arrangements are designed to ensure that the network businesses meet their licence obligations, including investment in safety and service standards. Of most relevance to the current discussion is the obligation to conduct all transactions with affiliated companies on an arm's-length basis and on normal commercial terms. Any infringements of ring-fencing obligations (which include information provision) give the regulator the power to prevent dividends being paid.

The final form of vertical separation is to require full divestment. The decision on whether to require full vertical separation between the wholesale and retail parts of integrated businesses depends on where the costs of integration are seen to be. If it is in the dulling of the price sensitivity of the pharmacists, then divestment is the only solution. If it is believed that, in the integrated businesses, wholesalers do purchase keenly and the real problem is that this purchasing activity is not transparent in the current system, then a more regulated system of transfer prices could achieve the objective of value for money.

7. Centralised Purchasing

In the primary-care sector, the NHS does not procure centrally, but rather 'fragments' its buyer power by using a large number of pharmacists as its contractors. These pharmacists negotiate with their suppliers individually, and, together, do not have the same buyer power as the NHS would have if it were to negotiate as a whole.

This contrasts with the hospital sector, where the combination of centralised procurement (at the regional level, and with regions influencing each other through the four months' rotation in procurement) and formularies (allowing substitution between branded drugs as well as between branded and generics) implies that hospitals are using their buyer power.

The NHS could reduce the drugs bill (achieve value for money) by exercising its buyer power in the primary-care sector as well. This could lessen the importance of, or remove the need for, the reimbursement system, and would make the market significantly more transparent. Using buyer power in the primary-care sector would also remove price volatility from the system, which is important for a sector where meeting budget constraints is crucial.

This section describes several mechanisms through which buyer power could be exercised. In section 8.1, centralised purchasing for all drugs is explored, focusing on the different solutions to coordinating delivery and ensuring secure supply. Section 8.2 discusses centralised purchasing only for drugs that are in shortage, which could be implemented while preserving a decentralised procurement system.

7.1 Centralised purchasing of all drugs

To focus the purchasing power of the NHS, some form of centralised purchasing for community pharmacy could be considered. Rather than using the fragmented buyer power of pharmacy against the several manufacturers and wholesalers, the NHS could design a set of tenders for community pharmacy demands for generic drugs. The other role pharmacy plays in being the NHS contractors is ensuring the drugs are where they need to be. It can be harder to negotiate distribution centrally, and much of this section discusses the role wholesalers should play in a centralised purchasing system. In particular, the important role that full-liners play in ensuring that all BNF drugs are available should not be discounted.

At its root, centralised purchasing cannot resolve any underlying barriers to supply; however, it could provide manufacturers some security of demand and could be used by the government to encourage new entrants. In theory, manufacturers should be able to structure production optimally in response to receipt of a tender, and hence reduce the frequency of shortages.

It has been suggested that the shortages experienced through 1999 were driven by an underlying market price that currently does not reward manufacturers for the inherent risks of the business. While the profitability analysis does not confirm such a view, if this view were correct, it would imply that a trade-off would have to be made between the level and the volatility of prices. In other words, the NHS may need to limit to a certain extent the exercise of its buyer power in order to protect supply.

If this radical change were to be implemented, a number of issues would have to be resolved:

- where does the contracting take place within the NHS (eg, at the Primary Care Group, health authority, or regional level)?
- will tenders be open to both manufacturers and wholesalers?
- skilled purchasing teams will be required at whichever level has been determined;
- should contracts be set up for all drugs, or would this be too unwieldy?
- if there is regional discrepancy between prices, and does this create incentives for arbitrage?

The nature of the tenders is discussed below, together with their structure and scope, and to whom they would be open. The implications for pharmacy reimbursement are explored for the different contractual arrangements, with an examination of how secure supply could be maintained. Other issues raised above are considered in more detail in Phase II of the fundamental review.

7.1.1 Structure of the contract

Each tender contract must specify:

- price, and acceptable price variability in the contract period;
- duration of contract;
- quantity to be supplied, and acceptable variability;
- service levels—the extent of the tenderer's obligation to deliver the drugs;
- exclusivity—whether the other suppliers will also be able to supply pharmacists/NHS drug requirements;
- clear penalties for non-compliance.

The government must also choose with whom it is prepared to contract (manufacturers, full-line and/or short-line wholesalers, importers), and the range of drugs for which it is contracting. Different players could feature in the tender process for different drugs.

Option 1—Tender with manufacturer also responsible for distribution

Assume that the government contracts directly with a manufacturer for a specific drug, or basket of drugs. The contract specifies price, volume and service levels, including delivery to any community pharmacy in a given region. The manufacturer then contracts with a distributor (full-line wholesaler, short-liner, or just distributor) to provide delivery services for a given contract region. Pharmacists have to place orders directly with manufacturers—the contract may require on-line ordering systems in order to facilitate pharmacy use. Alternatively, pharmacists could place orders with the distributor or wholesaler with which the manufacturer has the arrangement, which then coordinates stockholdings and delivery schedules for that region. IT solutions discussed in section 5.3 would facilitate this process.

Will this minimise the costs of distribution? At present, full-line wholesalers are set up to offer the whole of a pharmacy's requirements, and they give preferential discounts to achieve this. By splitting up the market into particular drugs, the economies of scale achieved by the current full-liners could be undermined. It is to this level of the chain that

the government's objective of ensuring that every drug on the BNF is available in a timely fashion is delegated.

The system described above might lead to the demise of the full-liner, as high-volume products could be supplied by smaller distributors. It is certainly likely to lead to less cross-subsidisation, with less frequently prescribed products bearing a larger proportion of the fixed costs of the full-liners' business. It may also lead to pressure on the multiple-times-a-day delivery service, potentially affecting patient waiting times. On the other hand, it should be recalled that the full-liners currently have only around 25–30% of the generics market, so the impact of this type of tendering on their profitability may not be so marked.

The effect of this solution could be that a pharmacy may have several deliveries a day, dependent on how each manufacturer structures the distribution side of its NHS community contract. If such an outcome were to emerge, this may indicate that the fixed costs of distribution are not that high, and any extra costs incurred here are offset by the savings made through centralised purchasing. For example, the bookstore chain, Waterstone's, has up to seven deliveries each day to the average branch, precisely because each supplier (publisher) uses a different distribution network. Books do not require specialised storage or delivery, and distribution is therefore undertaken by a range of players, including speciality book distributors and general distributors, such as TNT and Securicor. However, even in the generics market, there are a number of logistics firms that operate in a similar market niche.

Option 2—Agency-type schemes

Under this option pharmacists would use the wholesaler of their choice for each drug, as is currently the case. The NHS contracts with the manufacturer for a price for the drug, plus a wholesaler fee or margin for delivery. The drug should appear in all full-line (or short-line) wholesalers' price lists at the contracted price plus a fee.

The extent to which pharmacies consolidate purchases under such arrangements would give a good indication of the true economies of scale in wholesaling.

Option 3—Fully open tender

A further option is to open the tendering process to wholesalers as well, including short-liners. Full-line wholesalers have the distribution side of the contract organised, but cannot currently guarantee access to the drugs. This option would require, in turn, long-run contracts with manufacturers. The success of such tenders would depend crucially on this link, and could lead to vertical integration between manufacturers and wholesalers. The larger short-liners often provide once-a-day delivery guarantees and have access to generic drugs from UK manufacturers or foreign imports. Again, secure supply could be of concern when contracting with them.

The appropriate level at which to sign the contract depends on whether the main sticking point is the production of the drug or the coordination of distribution. At present, production is more problematic than distribution, and more security may arise from the government contracting with the manufacturer. In theory, whether the government signs a contract with the manufacturer or a wholesaler should not make a difference—all problems of default should be dealt with through matching penalty clauses. However, one or other side may have more success enforcing such penalties.

7.1.2 Role of pharmacy

Under some structures of a centralised system, there would no longer be a need for reimbursement or a Discount Inquiry. This would be a significant advantage of such a scheme. Below, each of the three options outlined above is discussed with regard to its implications for reimbursement.

Option 1 and no reimbursement

Assume that the drug has been tendered out to three different manufacturers. The pharmacist looks up the prescribed generic in the Drug Tariff and sees the three manufacturer, their designated wholesalers and the agreed NHS price. The pharmacist orders stock from any or all of them. When a prescription is submitted, the pharmacist dispenses one of the stock and endorses the prescription appropriately (mentioning manufacturer and wholesaler). This process could be automated, as nearly every prescription will be endorsed. A fully integrated IT system would clearly complement this option. Endorsement is important because it is the only way that the NHS can check whether the contract is being fulfilled. Prescriptions are despatched (in either paper or electronic format) and the PPA has settlement accounts with all the contracted manufacturers and wholesalers. All wholesalers receive a margin on the contracted revenue, or a fixed fee.

There is no incentive for pharmacists to hold stock appropriately, as the manufacturer and wholesaler bear the costs between ordering and dispensing, and dispensing and PPA reimbursement. A more timely reimbursement cycle could mitigate this problem. This is likely to affect the price of the contract.

Option 1 and retain reimbursement

Again, assume that the drug has been tendered out to three different manufacturers. The pharmacist chooses the manufacturer/wholesaler combination and, once the stock is received, the pharmacist pays the invoice. Once dispensed, the pharmacist endorses the manufacturer and/or wholesaler as appropriate and receives the contract price. There may be incentives for the wholesaler to offer discounts on the NHS price, as there are currently under the PPRS; hence pharmacists may be reimbursed more than they pay. A Discount Inquiry would be required to identify this gap.

The problem here is that if an alternative, cheaper, short-term source came on the market through a short-liner, then pharmacists would have the incentive to purchase these. The NHS would have to mandate that it will only reimburse stocks from its core manufacturers, and, as above, every prescription would need to be endorsed, although there would only be one reimbursement price.

Option 2 and retain reimbursement

Under this option, the pharmacist trades with a preferred supplier, although this could change from drug to drug. It could include short-liners, provided they have access to the manufacturers' stocks.

This gives the same incentives for wholesaling discounts as in the PPRS, as effectively this is a similar system. Instead of a price determined by profit control, there is a contract price, with a similar agreed margin for wholesaling. Wholesalers will be tempted to offer some of this margin to pharmacists to ensure that their turnover remains high. This would imply that, as above, there will still be a role for the Discount Inquiry, unless

reimbursement is changed so that no such discount is allowable. Paying volume-related margins (reducing, as volumes increase) could be considered, although this is likely to be very complicated to implement.

Option 3 and no reimbursement

If the contract is signed directly with a wholesaler, then there is no need for reimbursement. The pharmacist orders the drug from the designated wholesaler, and the wholesaler is paid when the drug is dispensed. Again, the pharmacist does not pay for inefficient stockholding choices, so the wholesaler may develop schemes to encourage pharmacies to hold stock sensibly. Increased vertical integration is one obvious solution, and integrated computer systems would also help.

In all the above cases, the manufacturer or wholesaler would make any gains from sourcing drugs cheaply through a grey import market. The contracted supplier could have market power as the sole purchaser of alternative supplies of drugs if there is excess supply. Equally, if there is a UK shortage, then the contracted supplier may have to pay high prices on the open market to secure the stocks to meet its contractual obligations. Thus, clawing back the upside of such volatility is not sensible, as the NHS will impose severe penalties if the contractor defaults during the downside. Part of the price of the tender is that the contractor will be bearing this risk and not the NHS. Good contracting and tendering practice should lessen the problem, with clear clauses on acceptable price variability and the option to split the market where volume is large.

7.1.3 Contract defaults and supply security

The few instances of formal contracting that exist are characterised by a lack of enforced penalties when there is a default. Manufacturers claim that they make deliveries to wholesalers, which then do not deliver to pharmacies or hospitals. Wholesalers maintain that manufacturers do not meet delivery quotas. Part of the difficulty is that full-line wholesalers claim that their systems do not allow them to earmark stock from a manufacturer to a particular hospital or pharmacy. The optimal outcome for the NHS is that manufacturers and wholesalers negotiate this between themselves, to ensure that contracts are fulfilled, and pay penalties for default. This may require some change to wholesalers' systems.

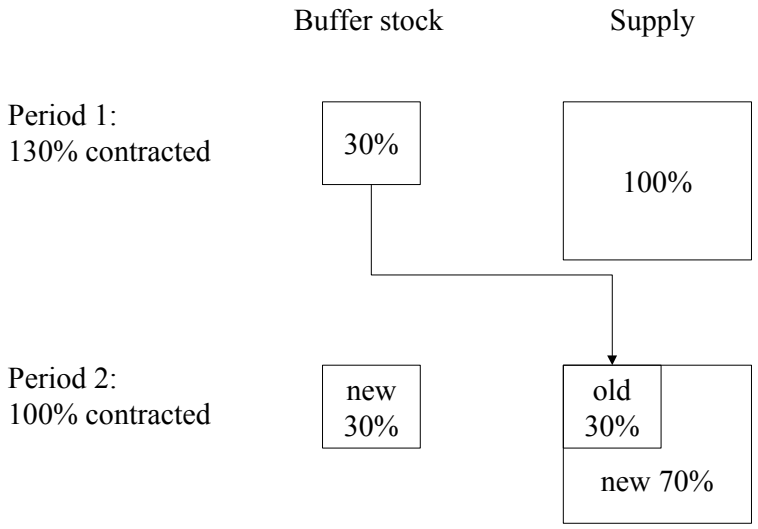
The payment of financial penalties to compensate the NHS when there is a default on a contract is only of partial comfort. As has been found in the hospital sector, problems arise when there is no supply of the drug, at any price. While most of the supply difficulties during 1999 the community pharmacy sector do not appear to have been characterised by such a complete lack of availability, a move to centralised purchasing (depending on the design) may lead to such problems. More concentrated manufacture may increase the vulnerability in the NHS to actual shortage if one designated manufacturer has difficulties delivering.

A number of solutions could be considered. First, the design of the initial tender can ameliorate these problems. No one manufacturer should be given the contract for the entire NHS market—it could be divided regionally, or a forecast total could simply be split into three or four tenders. Given the prevalence of contract manufacture, it would be crucial to ascertain whether each part of the tender is being supplied from different manufacturing plant. Depending on the number of product licence-holders and the economies of scale in production, more than one of the tenders could be awarded to the

same tenderer. This should also limit the scope for market sharing between existing players.

In addition, the first tender could be deliberately inflated to provide protection against shortage if one of the suppliers defaults. This would create a rolling buffer stock, controlled by the NHS. Thus, an extra 30% (or other proportion to be determined) is contracted initially and, if not required, is cycled into supply in the next period, with 70% of the next period's production. The other 30% forms the buffer for the next period (as illustrated in Figure 8.1). Tender periods would have to match use-by dates of the drugs, and hence may differ across drugs. Some losses are likely to occur, but significant security could be achieved with this system.

Figure 8.1: Rolling buffer stock



Further detailed study of a tendering option would analyse optimal auction design to induce truthful revelation of costs and to limit the scope for collusion—one option is that the lowest three win, and are paid the price bid, or highest of the three prices. The possibility of market sharing should be considered as part of any design, and mechanisms built in to dissuade this. In addition, if prices are differentiated regionally, it should be noted that there may be scope for arbitrage.

Despite the buffer stock, the proposed tender design will not necessarily protect against shortage for those products where there are three or fewer product licences. At present there are over 30 such products. It is conceivable that setting up such a tendering process may encourage more entry into these products; however, a solution must be designed for situations where few product licence-holders remain.

In the case where there is only one active producer that tenders for the entirety of the NHS market, and no other producer enters the competition, a secondary tender could be conducted. There would be a tender for a secondary supplier contract, which would involve holding a dormant licence, but with the facility to commence production within a contracted period, say one month. A fixed price would be paid to the provider of this

service. Once it begins production, it would be at the previously contracted price, or that price plus a margin, to be specified in the secondary supplier contract.

The only remaining issue would be where the original default was due to a problem with the supply of the active ingredient, where this supply was itself monopolised. Then a secondary supplier is likely to face the same problem. Situations of this type may call for more extensive buffering and a recognition of possible shortages.

7.1.4 Difficulties

Such complicated tendering would be a heavy burden for NHS Executive for all generic drugs. A hybrid could be used where there is centralised purchasing by drug for the most frequently prescribed drugs. It would be a matter of judgement whether this included, say, the top 200 or 500 generic drugs. For the remainder of the infrequently prescribed drugs, each pharmacist could be left to source these themselves—probably through the full-liner infrastructure. This would then require the existing reimbursement infrastructure to set prices for this tail of drugs. Alternatively, the government could award the regional full-line residual contract, requiring the chosen party to supply all residual demand to a given set of pharmacies. How this would match with the economics of full-line wholesaling needs to be carefully thought through, as it may put pressure on the unsuccessful wholesalers.

The feasibility and stability of this contracting must be carefully considered. One of the key questions when examining the UK market as it currently stands is: why do manufacturers and wholesalers not sign more long-term contracts? Such contracts should:

- lower the risks of the manufacturer because of difficulty forecasting own demand;
- reduce production costs by allowing long production runs;
- reduce shortages.

The lack of existing contracts suggests that there are strong incentives to default from such contracts once they are written. From the wholesalers' perspective, if a cheaper drug source comes along, then they want to renegotiate, or not take the contracted output. From the manufacturers' perspective, if a buyer comes along who is willing to pay a higher price, they want to supply at the higher price. These are standard risks in long-term contracting, and various clauses could be written in to protect both sides and to ensure that the contract is resilient to market pressures. However, both sides do 'pay' something in flexibility for the reduced risk. Penalty clauses need to be carefully constructed and exercised if default occurs. Such penalties should be financial in nature in the first instance, but could also include revoking or transferring licences.

In addition, the contract must withstand production difficulties; an entire batch may be discarded, because of a production problem, or there may be a shortage in an active ingredient. There should be no incentive to supply the UK market with sub-standard products; the extensive testing that accompanies licensing should ensure this. Penalty clauses should not excuse these types of production failures—manufacturers should include such penalties in contracts with active-ingredient suppliers.

If it embarks on negotiated deals with a set of manufacturers, the NHS will face such difficulties. In addition, the changed nature of relationships would have a significant impact on the industry structure. It is difficult to predict exactly how all the players would

respond. It is possible that large full-line wholesalers would come to dominate, and that they would integrate upstream to be able to schedule production. Short-term, flexible production is not likely to be a feature, as the nature of such long-term contracts is to remove the power of short-run changes.

It is also important that this change does effectively enhance the NHS's buyer power. As discussed in section 3, the NHS is not a true monopsonist, since it must fulfil the drug demand each year. A set of coordinated suppliers could share out the NHS market, colluding on price and tender offerings. This may be worsened because only players with access to large quantities of drugs could be active participants in the tendering process; hence, short-liners and small importers will be marginalised, and will no longer provide a competitive discipline on manufacturers, as they do now. The government could try to use the tenders to encourage new entrants, say foreign producers; however, it will always be important to ensure secure supply and effective penalties for default.

7.2 Centralised purchasing of drugs in shortage

Rather than instituting a major change to centralised purchasing, the NHS could focus this option on the main weaknesses in the current system—price volatility and uncoordinated supply in the face of shortage. It should be emphasised that this means that the NHS still bears the risks of, and hence the price volatility associated with, such shortages; however, it may be able to manage the situation better.

Under the current system, when a product goes into shortage, Category D is triggered. The major disadvantages of Category D have been outlined in section 4.2 above. Category D is designed to secure the supply to patients by ensuring that pharmacists are reimbursed fairly when they cannot purchase a drug in shortage at the Drug Tariff price. However, even if a drug is in Category D, the pharmacists still often have to contact several suppliers in order to obtain the product, and then must spend time to endorse properly.

From the Department's point of view, this is also unsatisfactory. A product in Category D is normally supplied (if at all) by only a small number of manufacturers and/or wholesalers, and required by a large number of pharmacies, who would basically be willing to pay any price for the drug (since they will be reimbursed anyway). This provides a clear incentive for the suppliers with Category D drugs to raise prices.

A possible solution would be for the Department to take over the responsibility and risk from the pharmacists of looking for drugs in Category D and purchase them centrally. This could be done through the PPA, or through a purchasing agency, comparable to the NHS Supplies Authority. The agency would then provide (through full-line wholesalers) the pharmacists with the product free of charge. (Alternatively, it could charge them the price it negotiated and reimburse at that price later.)

This would have the following advantages.

- There would still be an incentive to negotiate low prices from suppliers for Category D, since it is the Department itself that does the purchasing. Under the current system, this incentive is lost.

- The centralised agency would have greater buyer power and different incentives than the individual pharmacists over the suppliers that have Category D products in stock, which should result in lower prices than at present. Despite this, if only one supplier has supplies of an essential drug, then it would still be able to charge high prices.

- Suppliers would have fewer incentives to hoard Category D products, since they would only be able to sell them to the purchasing agency. For the reasons mentioned above, they would not be able to extract the same high prices from the agency as they can now from the individual pharmacists. In addition, by selling to the agency, they would 'expose' themselves to the government (ie, they would not be able to engage in speculative trading without being noticed by the Department, as occurs under the current system).

- The purchasing agency would be better placed to ration products that are in serious shortage, for example, by supplying only a limited amount of the drug to each region (and providing information to the public on where they can obtain the product). At present, the distribution of Category D drugs over regions may be random since it depends on which pharmacists are quickest to find the drug.

With this option, a number of issues have to be addressed.

- The conditions on which the central purchasing agency starts to operate need to be established. In principle, this could be the same conditions that currently trigger Category D (ie, a situation of shortage signalled by the pharmacies and then checked by the PSNC and the PPA).

- The purchasing agency must possess sufficient resources and information to find out promptly which suppliers have the product available. This may be difficult, but the rationale for this option is that the agency would, in any case, be better placed to perform this function than pharmacists. The agency would even have greater access to information if licence-holders were required to provide information on their commercial operations regularly, an option described in section 6.1.

- The price at which the purchasing agency would acquire the drugs has to be established. The agency could negotiate a price with each supplier individually. Alternatively, if enough information on total supply were available, the agency could determine a price that would be paid to all suppliers. With both methods, prices paid by the agency would reflect demand and supply conditions, but should be lower than current Category D prices, given the agency's greater buyer power.

- Distribution to the pharmacies has to be arranged, especially if the purchasing agency is to be used as a rationing device between regions. It would be better to use the existing distribution networks rather than creating a new network for the purchasing agency. If sufficient information on demand conditions is available (as might be the case, since pharmacies would contact the agency for their product

needs), then the agency could arrange for direct delivery by the supplier to certain pharmacies. Alternatively, the full-line wholesalers could be used as distribution agents, similar to the function they currently perform under manufacturer direct-sale schemes, such as Norton Advantage.

Finally, the risk of speculation must be reduced. The price that the purchasing agency will pay for drugs in shortage is likely to be higher than the Drug Tariff price (although lower than current Category D prices). There is therefore still some risk of speculative hoarding by suppliers in order to create shortages and trigger the central purchasing conditions. However, as explained above, the incentives to speculate are lower with centralised purchasing than under the current system.

Thus, the Department would have to explain clearly to all market players that products in shortage could only be sold to the purchasing agency, and could no longer be sold at any price directly to pharmacies. The Department should consider implementing this option in combination with some of the other options presented in this report that reduce the risk of speculation, particularly the expansion of the Drug Tariff basket (section 4.1) and the improvement of information flows (section 5).

8. Conclusions from Phase I

The current system has been successful in delivering reductions in generic prices. However, in the past, as difficulties have arisen, the minimal monitoring available because of the highly decentralised form means that unpicking the underlying drivers of the problems is complex. Any proposed reform not only needs to address the determined weaknesses of the system, but also to be robust to the potentially quite major changes afoot in the sector, which include consolidation, integration, and NHS restructuring. Further study of these options is necessary to address fully how the proposed reforms sit in this wider context. Within all this flux, the NHS has one core tool that it can use—its buyer power. The analysis of the existing situation suggests that this power has not been fully brought to bear in the current system.

Despite the competitive pressure on prices from pharmacists seeking better generic deals, manufacturers and some parts of the wholesaling sector have managed to sustain rates of return that appear higher than estimates of their cost of capital. This suggests that the NHS's buyer power has not been marshalled well against these suppliers by pharmacists. The reforms suggested here all focus on preserving the competitive aspect of this market, rather than regulating the manufacturers directly. There are three key reasons for this.

- The main entry barrier identified is licensing. The fundamental characteristics of the market are of a commodity-type product where there is no underlying reason for an uncompetitive outcome. This is different from the branded sector, where the patent system effectively gives each company a set of monopolies.

- Price or rate-of-return regulation is likely to limit the benefits arising from a properly functioning competitive market, which include timely production and reduced production costs.

- On a practical note, it is difficult to define the boundary of manufacturing. Are AO licence-holders manufacturers? The problematic nature of identifying these players is indicative of the positive pressures from potential competitive suppliers. This should signal the inappropriateness of formal rate-of-return regulation.

8.1 Proposed options for reform

The reforms proposed fall into six categories.

- **Do nothing**, except perhaps attempt to recoup 1999 returns of any market participant considered excessive.

- **Reform the reimbursement system**—expand the Drug Tariff basket, remove Category D, and reform the Discount Inquiry.

- **Improve transparency** through various types of information requests.

- **Reform the licensing regime**.

- **Enforce vertical separation**.

- **Use centralised purchasing**, either for all drugs, or for those in shortage.

Table 9.1 shows how well the proposed reforms meet the Department's objectives, and Table 9.2 shows how they redress the identified weaknesses.

Table 9.1 summarises, for each of the proposed reforms, its effect on the current position as to whether it has improved (↑), there has been no change, or it has worsened(↓). The question marks indicate that the effect on the current position can go either way and the net effect is not entirely certain.

Table 9.1: The effect of the reforms on the Department's objectives

	Quality of service	Minimise distribution costs	Reimburse closely	Transparent prices	Competitive pharmaceutical market	Value for money
Expand Drug Tariff basket	no change	no change	↑	↑	no change	no change
Remove Category D	↓	no change	↓	↑	↑	↑
Reform the Discount Inquiry	no change	↓	↑	↑	no change	↑
Improving Information	↑	↓	↑	↑	↑	↑
IT systems	↑	↓ (short run) ↑ (long run)	↑	↑	no change	↑
Licence changes	↑	no change	no change	no change	↑	↑
Vertical separation	↑?	↓	↑	↑	?	↑
Centralised purchasing	↑	↓	↑	↑	↑?	↑
Centralised purchasing of drugs in shortage	↑	↓	↑	↑	↑?	↑

Looking at the objectives, a number of points stand out, as follows.

- Under most proposed reforms, patient service should improve.
- In none of the proposed reforms do the costs of distribution fall, at least in the short run. This is because any increase in information or tracking of drugs will impose costs on distribution, as well as elsewhere in the chain. Similarly, where claw-back is made more effective, this is usually at the expense of the wholesalers.
- Most of the proposed reforms improve transparency, reimbursement and value for money.
- Improving the competitiveness of the pharmaceutical market is not clearly achieved. This is partly because of the broad nature of the objective. A reform that

makes the demand side more price-responsive, contributing to a more efficient market mechanism, may have a negative impact elsewhere in the chain. For example, enforced vertical separation removes the benefits of vertical integration, and centralised purchasing may make it harder for new players to enter the manufacturing market because of the scale required to participate in a government tender. Balancing such trade-offs will be an important part of implementing any change to this sector.

- There is an underlying tension between value for money and minimising costs. Many of the options relate to improving information and transparency. The costs of these must be borne by the supply chain—the assumption that value for money increases depends on the benefits in terms of better prices for the NHS being higher than the cost of collecting the information. This detailed trade-off must be examined prior to implementation.

In Table 9.2, each option is assessed as to whether the weakness is addressed (✓) or not (X), or goes part-way towards it (assist). In some cases, the effectiveness of a reform is influenced by the way it is implemented, or by interactions with other reforms. These are discussed in more detail below.

Table 9.2: How the reforms address the sector's weaknesses

	NHS's purchasing power utilised?	Improves performance monitoring	Enhances competitive manufacturing sector	Improves reimbursement
Do nothing	X	X	X	X
Expand Drug Tariff	X	✓	X	✓
Remove Category D	X	X	X	X
Reform Discount Inquiry	X	✓	X	✓
Improve information	X	✓	X	✓
IT systems	assist	✓	assist	✓
Licence changes	✓ (indirectly)	X	✓	X
Vertical separation	✓	✓	X	✓
Centralised purchasing	✓	✓	✓	✓
Centralised purchasing of drugs in shortage	✓	✓	✓	✓

- A number of reforms address the weaknesses of performance monitoring and reimbursement incentives, and some of these changes would be more successful than others in achieving these objectives.
- Removing Category D does not really affect the four identified key weaknesses; it improves the competitiveness of the market by removing the incentive to hoard and it enhances value for money.
- To make better use of the NHS's purchasing power, only radical options are likely to make a real difference. A decentralised option (vertical separation) and a centralised option (tendering) are both suggested.

Enhancing the competitiveness of the manufacturing industry can be seen as key. It is from here that the true long-term gains from generic drugs spring. Manufacturers develop new generic drugs that undercut branded drugs as they come off patent. Two solutions are proposed, depending on the perceived source of underlying problems in manufacturing:

- if entry barriers are high and are preventing entry then the solution is to change the licensing system to facilitate new entry into drug production;
- if information difficulties mean that manufacturers have problems planning production, more transparent systems could enhance contracting, and centralised purchasing means that the government monitors supply balances more closely.

Given the high rates of return in manufacturing, it seems that there is scope for lowering entry barriers. Neglecting to do this may have negative effects on other options. The centralised purchasing option would work best when there is a competitive supply market. If entry barriers are significant, the NHS would have to be careful that collusive behaviour by suppliers did not result in continued high prices. One possibility is that the NHS could allocate tenders with a view to encouraging new entry.

1.1 The way forward

The reforms can be thought of in two ways: short-term versus long-term, and radical versus remedial.

Distinguishing between short- and long-term essentially implies that radical solutions are required to restore a successful procurement strategy to the NHS. However, as such solutions take time, some short-term changes can be instituted to ameliorate the major weaknesses in the current structure. The short-term reforms that could be considered are:

- expanding the Drug Tariff basket;
- removing Category D;
- making minor licence changes, to enhance import entry;
- instituting information requests;
- reforming the Discount Inquiry.

All these options basically improve the NHS's ability to monitor performance, and remove the worst incentives in the reimbursement system. They particularly attain the objectives of transparency and value for money within the current system.

With the longer term in mind, a decentralised or a centralised approach could be pursued to enhance the NHS's buyer power. In either case, a more competitive manufacturing sector should be encouraged. In addition, an integrated, open standard IT system could be of major benefit.

The decentralised approach would include the following policy options:

- some form of vertical separation;
- major licence changes;
- investment in integrated, open-standard IT systems.

Alongside these, it is important to ensure that the reimbursement system and the Discount Inquiry are well designed, since pharmacies remain the agents of the government's procurement strategy. Vertical separation ensures that transparency between wholesale and retail is restored, in theory removing many of the problems apparent in the current system.

One difficulty with relying on this mechanism is the possibility of 'virtual' integration, circumventing the restrictions on ownership. Many European countries require independence at the pharmacy level. Wholesalers suggest that virtual integrated chains are set up through purchasing groups and other mechanisms. If the underlying economics of the industry lead to strong pressures for integration, then any procurement strategy relying on independent pharmacies will face significant problems.

The centralised approach would include the following options:

- centralised purchasing through competitive tender;
- major licence changes;
- investment in integrated, open-standard IT systems.

Under this approach, there is less reliance on reimbursement and discount claw-back to deliver the NHS value for money, since the tendering process is designed to achieve this. Ensuring efficient distribution may require that reimbursement is still necessary—an integrated IT system can simplify the process significantly. It is recommended that a more competitive manufacturing industry be encouraged as part of this option, but this may take time to establish. Consequently the tendering option needs to be carefully structured, given the extant manufacturing industry and its possible market power, to ensure that the NHS does obtain access to cheaper medicines.

Effectively, the long-term solutions described above are the radical options for reforming NHS procurement. More remedial options would not alter any of the major structural features of the market and would therefore involve:

- expanding the Drug Tariff basket;
- removing Category D;
- reforming the Discount Inquiry;
- information obligations or an integrated IT system;
- centralised purchasing of stocks in shortage;
- reforming licensing.

Here the picture is as follows: improve the reimbursement system to remove perverse incentives; improve the competitiveness of manufacturing; increase information flows to enhance monitoring, but assume that the current role of pharmacists is adequate to deliver competitive pressures on suppliers. The nature of the Discount Inquiry reform would stop short of regulating wholesale prices, but would use a market-based marker for setting reasonable wholesale margins. It is still within the range of a suite of remedial options for the government to step in for products in serious shortage. The problem with leaving reforms at this remedial level is that the significant gains to the NHS are likely to be kept hidden within wholesalers and large pharmacy chains, or will be expensive to identify.

Almost all of these options could be implemented independently of the others and would improve some aspect of the supply system for drugs to the NHS. Phase II explores some of these options in more detail.

PHASE II

After assessing the recommendations from Phase I of the fundamental review, the Department decided that further study was required for two of the key options. Without such additional investigation, it would not be possible to determine the appropriate course of action for consultation and implementation.

Hence the second phase of the review has two main focuses:

- to explore the extent to which licensing is a key barrier to entry in the UK, and suggest ways of enhancing competitiveness.
- to propose in detail a possible framework for centralised purchasing through competitive tender.

Section 10 addresses the first issue and sections 11 through 16 describe a number of alternative options for tendering. Section 17 concludes the second phase of the report, critically analysing the suggested options.

2. Enhancing Competition in Generic Manufacturing

One of the key conclusions from Phase I was that increasing the level of competitive entry in the UK generics manufacturing market would improve supply-chain efficiency. Two aspects were identified as worthy of further investigation: why foreign manufacturers (those without major supply operations within the UK) do not appear to export significant product volumes to the UK; and whether the system for licence alterations could be improved to stimulate a secondary market in licences.

Although many foreign producers supply some volumes or reduced product lines into the UK via agents (often the generic distributors), there is little evidence of systematic large-scale supply into the UK from overseas. The principal route of entry to date has been via acquisition. While there are clear pressures for extensive foreign acquisition by the major international players, owing to the globalisation forces in generic supply, it is not clear why there would not be brisk trade by other foreign players into the competitive UK market. The objective of the investigation was therefore to establish why this alternative route for foreign supply appears limited; whether licensing was a key barrier to this activity; and how the position could be improved.

In particular, while it is feasible to transfer licences between suppliers, the extent of this activity appeared to be limited. Licence transfers could facilitate supply of products into the UK from players whose main base is elsewhere. This part of the investigation therefore also focused on establishing the actual level of licence transfers, the attitude of manufacturers towards transfers, and improvements that could be made to facilitate transfer.

In considering these two areas, it should be borne in mind that the regulatory environment within the UK is largely determined not by the UK itself, but by the European Commission. Many of the more significant changes that might be made to the licensing regime might therefore only be feasible through European negotiation. Accordingly, the recommendations in section 10.4 are separated between those that are feasible in the short to medium term by the UK acting unilaterally, and those that must be agreed and implemented through EC processes, which are necessarily more long-term.

The structure of this section of the report is as follows. The next sub-section considers foreign entry into the UK. Section 10.2 analyses the data provided by the MCA (via the Department) on the level and nature of licence-transfer activity in the UK. This includes summary details of all licences, and changes to them, for 26 drugs. Section 10.3 considers firms' experiences of trading licences. Recommendations that follow from this preceding analysis are presented in section 10.4.

2.1 Foreign entry

The principal entry route into the UK in the last few years has been through acquisition. This has occurred as large R&D companies withdrew from generics supply, selling their UK manufacturing operations. Through the 1990s, therefore, there has been a change in the ownership structure of UK generics manufacturers, from large R&D pharmaceutical firms to large international generics firms. In effect, the trend of close coordination between R&D companies and generics, through generic subsidiaries, was reversed, and the two became polarised again.

Firms, such as IVAX (Norton), Teva (APS), Merck (G(UK)) and Alpharma (Cox), have all entered in this fashion. However, now that all large and medium-sized generic manufacturers have been acquired, new foreign players in the UK have been limited. Only Ranbaxy (from India) has set up operations of any size in the UK; it is also in the process of establishing a production facility. Other manufacturers, considered below, have supplied limited ranges or small volumes through import specialists, such as Lagap, or wholesale distributors, such as Waymade. Overall, other than direct investment through acquisition, foreign involvement in the UK market does not appear to be extensive, although there are signs that it is slowly increasing.

The developments in ownership structure of UK manufacturers mirror wider trends, with large global manufacturers developing a presence in the main world markets. These players choose their markets of operation based on maximising return from their global portfolio, and are not constrained to one country of operation or supply, as traditional domestic suppliers were. They are often able to acquire licences in many countries using the same basic bioequivalence research, and, in theory, can direct their generic output to those areas that generate the greatest return. These acquisition strategies are based on broad long-term goals, including a diversified portfolio with experience of lower- and higher-margin markets.

In a commodity-based market, such as the UK generics market, it would also be expected that a significant number of foreign players would supply into the market on a more arm's-length basis. One of the propositions advanced by the British Generic Manufacturers Association and other generic manufacturers is that the UK is a fundamentally unattractive market in global terms because of low prices, and correspondingly low returns. This is said to account for the relatively low level of trading activity by foreign firms in the UK market. International drug price comparisons are extremely difficult for several reasons, but this is particularly so in the generics market, where accurate price information is hard to obtain. It is therefore problematic to compare returns between countries.

However, there are other explanations for low foreign trading involvement in the UK, rather than (or in addition to) low returns: high barriers to entry (including poor

information), and disinterest from foreign firms. Disinterest from foreign firms could arise if foreign generic drug markets are not yet at equilibrium, so that firms are growing as fast as they can in their home markets and have no spare capacity for investment elsewhere.

Barriers to entry could arise from informational difficulties. Indeed, two of the foreign manufacturers contacted mentioned licensing and information as the main difficulties in supplying limited numbers of drugs into the UK market. Of greatest importance to both firms was having staff running their UK office who had wide-ranging contacts within the UK industry.

This stage of the investigation has therefore focused on establishing the reasons for the apparently low level of foreign involvement at a trading level (as opposed to acquisition) in the UK.

In addition to those firms already involved in the UK through acquisition, there are a number of global generics firms that are considering producing, or have begun to produce, for the UK. Taro Pharmaceuticals, which has operations in the USA, Canada and Israel, began to supply the UK through Lagap, but found that its volumes remained low. It is now setting up a UK operation to supply limited lines of its own drugs and some from other manufacturers, as well as seeking to gain 'piggyback' licences for the UK.[14] Taro views its efforts to expand its UK product portfolio as having been hindered by the time taken to obtain licences, although it perceives the UK as a potential gateway to Europe.

Ratiopharm is a large German manufacturer with over 2,500 product lines, which also operates in the USA, Canada and several European markets. It has decided to enter the UK and launched in August 2000, initially with a limited range of only ten product lines.

Stada is another German generics and research-based manufacturer with interests throughout Europe, and in Asia and North Africa, that has been considering entering the UK market. Stada usually arranges supply or distribution links with local firms before establishing its own subsidiaries. In 2000, it announced a joint venture with Dowelhurst to market generic drugs in the UK. Stada has purchased an Irish manufacturer and is considering entry into the USA by acquisition.

Given this background, it is helpful to understand the perceptions of the UK market from overseas, particularly the relative returns available. If UK margins are low by global standards, and the flexible production hypothesis is correct in practice, then a low (and declining) level of foreign involvement would be expected in the UK market. However, production may not be as flexible as mooted by the 'global generic firm' paradigm, and there may be other reasons which explain the limited UK supply by overseas firms.

No overwhelming or consistent view of the UK market has emerged from the various overseas contacts made. In particular, those manufacturers in the USA that were not already supplying into the UK did not appear to have a strong perception of UK market

[14] 'Piggybacking' allows the applicant to replicate exactly an existing manufacturer's product licence. As the new licence would be identical to that on which it piggybacks, the new licence owner would be constrained to having the drug produced at the original manufacturing site (unless it undertook further licence variations).

conditions. Britain is seen as a mature market in terms of generic supply and the level of generic penetration. This contrasts with other national markets, where generics are still increasing fairly quickly as a proportion of total drugs dispensed, and which potentially offer more opportunities to new entrants. For instance, one manufacturer stated that, ahead of the UK, it would consider other European markets that are only just opening up to generic supply, especially France and Italy. Many of the companies contacted were, not surprisingly, not forthcoming about their underlying strategic objectives.

Growth of domestic markets was also a key factor in limiting the spread of some US manufacturers; they are currently at full capacity meeting their US demand and so have little incentive to expand overseas.

Some manufacturers did confirm that margins in the UK were lower than elsewhere, and that this influenced their entry decision. However, others suggested that lower margins were not a primary reason for failure to enter, and cited other factors, such as licence requirements and distribution difficulties. For instance, it may be difficult for a new entrant to sell its product without a dedicated sales force. In addition, the time taken to obtain a licence was a major factor in constraining entry at times of shortage. A Dutch manufacturer told us that it had been considering supplying the UK with Category D products during 1999. However, the time taken to obtain a licence, even though the manufacturer had a product licence for the Netherlands, increased the risk that the short-term effect would have rectified itself by the time it was able to supply. This dissuaded the firm from entering the UK market.

2.2 Licensing activity

The MCA provided licensing data for 26 drug preparations which showed all the licences that had existed since each drug came off patent, and the changes of ownership that have occurred. Thus the data showed which firm had initially applied for any licence, and, if it had subsequently transferred it, to which firm and when. The data also showed whether licences had been transferred or simply cancelled. Volume data (ie, whether licences were active) was not included, as the MCA does not require this information from licence-holders.

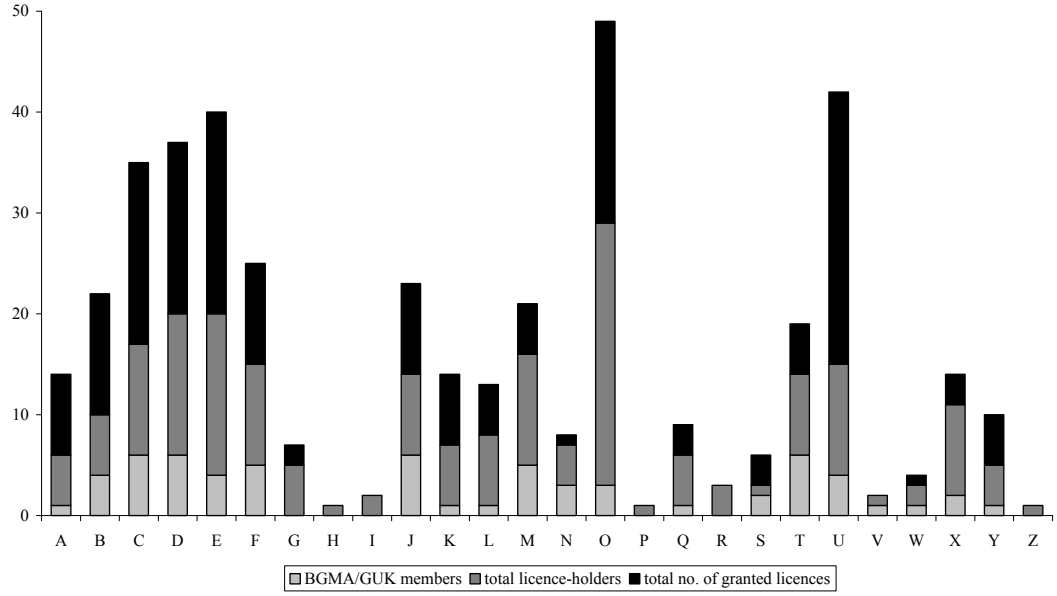
The preparations for which data was provided were a broad mix, including dry-powder tablets, liquids, creams, injections, inhalations, and eye drops. Only one preparation was included for each drug, and the number of prescriptions dispensed for that particular preparation was obtained from the Office of National Statistics and the Department of Health.[15] The drug names have been removed in order to protect confidentiality.

There was considerable variation in the number of existing licences, and the level of transfer activity. As can be seen in Figure 10.1, there was a very wide spread in the number of valid licences, with three drugs having only one licence, and some having 20 or more potential manufacturers. For each drug, the column in the figure indicates the number of licence-holders as well as the number of licences registered to those holders. The difference arises because manufacturers sometimes have several licences as a result

[15] Office of National Statistics and the Department of Health (1999), 'Prescription Cost Analysis' (henceforth referred to as the PCA).

of takeover activity. There may also be licence duplicates for manufacture at a different site or for another customer.[16]

Figure 10.1: Numbers and profile of licences for a selection of drugs

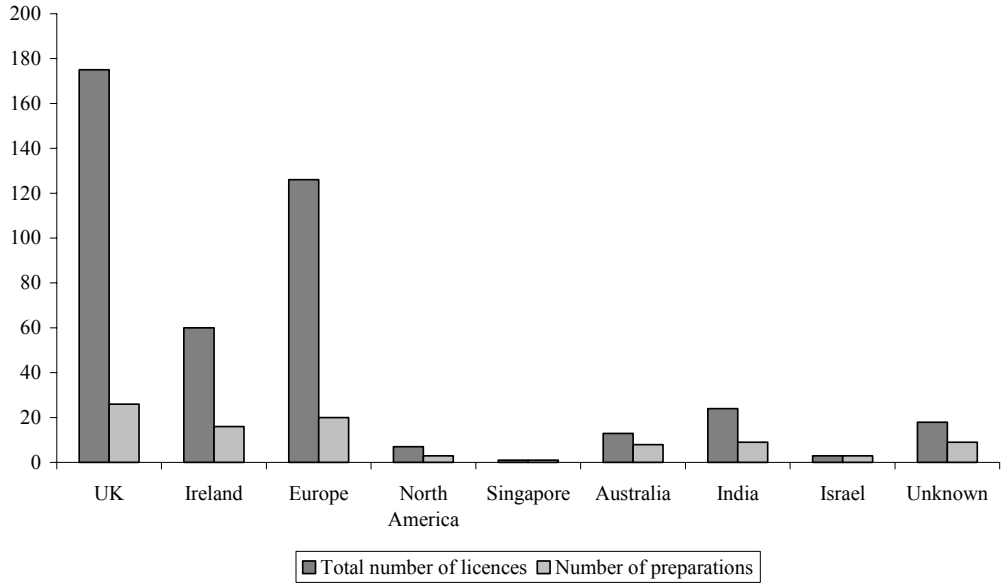


Source: OXERA analysis of MCA data.

The licence-holders have been classified into BGMA members (plus GUK, which is a UK-based manufacturer, but is not a member of the BGMA), or 'others' (which could be either branded suppliers, small manufacturers or overseas suppliers). The location of production facilities is also recorded in the licence, and Figure 10.2 shows the number of licences, and of preparations to which those licences relate, for all the geographic areas covered in the sample.

[16] In particular, this may relate to manufacturers that arrange cross-supply contracts.

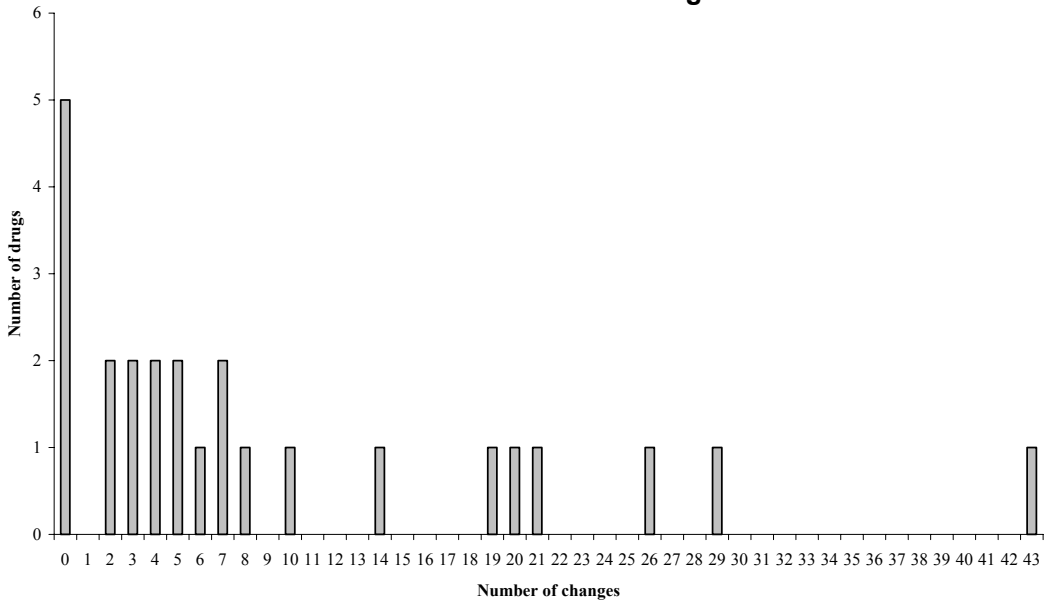
Figure 10.2: Geographic spread of manufacturing sites for a selection of drugs



Note: 'Unknown' refers to country locations that were unknown by the MCA system owing to incompatibility between the existing data program and its predecessor.
Source: OXERA analysis of MCA data.

On average, there have been 11 licence changes for each drug since it came off patent (which is a period of more than ten years for all but one of the preparations analysed). However, this is a heavily skewed picture, and, as shown in Figure 10.3, the majority of preparations have had fewer changes than average, with 18 having less than eight—for five of these preparations there have been no licence changes.

Figure 10.3: Incidence of changes in licensing, transfers and cancellations for a selection of drugs



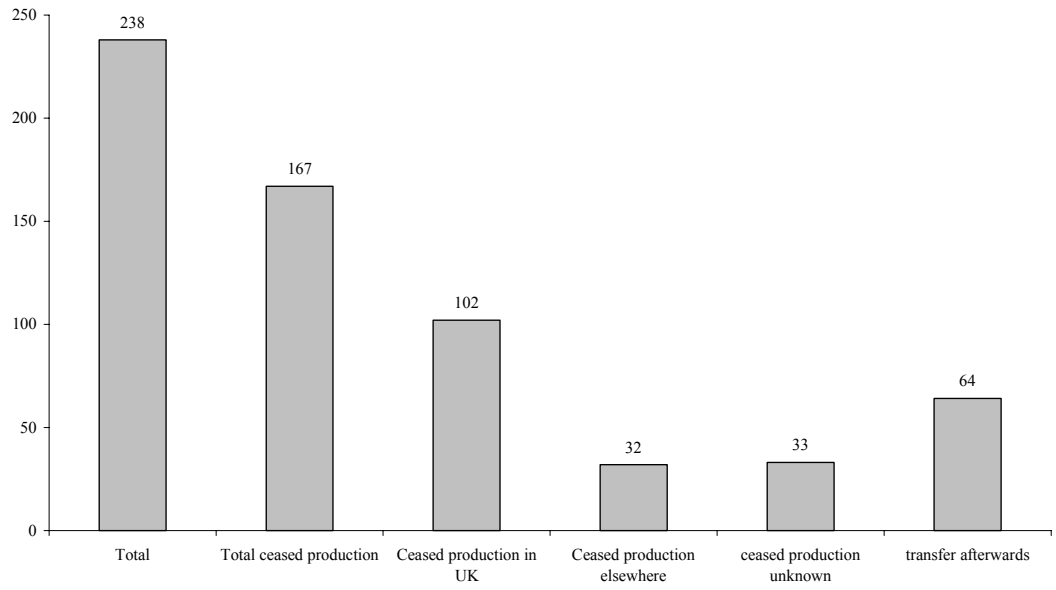
Source: OXERA analysis of MCA data.

The majority of licence changes (about 80%) are cancellations rather than transfers. The cancellations indicate that firms have allowed a licence to expire instead of selling it to another manufacturer. Figure 10.4 gives a breakdown of the type of licence changes that have occurred, and, where relevant, the area where production has ceased. The total cancellations figure also includes transfers. This is because, to transfer a licence, the existing one is first cancelled, and then transferred to another player.

Further analysis reveals that the majority of transfers occurred in relation to a complete takeover by one firm of another, rather than the transfer of individual licences. For example, Norton acquired a number of licences from Medevale in 1994, but this related to Norton's acquisition of Medevale itself, rather than acquiring a few product licences. On the whole, from this sample of drugs, there is little evidence of licences having been acquired by foreign manufacturers or new entrants as a means of commencing production in the UK. Full details of the transfer data are included in appendix 1.[17]

[17] Since July 2000, MCA reports that licence trading activity has increased and there are greater numbers of non-UK generic licence-holders.

Figure 10.4: Breakdown of cancelled licences



Note: The total number of cancelled licences does not match the sum of total ceases in production and total transfers. This is because some cancellations were made by a company which retained another existing licence for that product in the same country.
Source: OXERA analysis of MCA data.

Overall, even this limited data suggests that licence transfers are not a popular route for either reducing a manufacturer's product licence portfolio, or for facilitating new entry into the UK. There are a number of reasons for the low level of licence-transfer activity, and these are explored below.

2.3 Trading licences

Alterations or changes to licences are processed in accordance with European regulations. Alterations are classified as either Type I or Type II. Type I are minor changes, such as altering the manufacturing site, and the European regulations require that they are dealt with within 30 days—although, in practice, 84% are approved in less than 20 days. Licence variations that involve changing the manufacturing site would typically be approved more quickly if the new site had already been inspected or approved in relation to another application. Type II changes are more complicated alterations, often relating to the pharmaceutical side of the generic preparation. The official European regulation time for these is 90 days, but, again, the majority (85%) are done in less than 60 days. These target times are all net of 'clock-stopping'.[18] The MCA may sometimes have to ask applicants for additional data, which will delay consideration of the licence application. These delays can range from days to, on occasion, several years.

[18] Clock-stopping refers to the practice of the MCA when there is insufficient information in the original application. The clock is stopped from the point at which the MCA requests additional information until it is provided by the prospective licensee.

In addition, manufacturers can apply for a change of ownership, or for a completely new licence (an abridged new drug application), of which there are two types. A change of ownership of a licence, other than through corporate takeover, must be registered and treated separately from other variations to the licence. Approval of a change of ownership takes between four and six weeks.

The easiest way of obtaining a new product licence is to apply for a piggyback licence.[19] Piggyback applications take around three months to gain approval.

The other type of new licence application is the standard abridged form, where the applicant carries out its own research work (or sub-contracts it to a specialist research firm), developing an essentially similar generic equivalent to an originator product (ie, a new generic brand). These forms of licence take considerably longer than any of the above, both to prepare for the application, and in the approval process.

The change of ownership requirements and timeframe do not appear particularly onerous, or likely to deter licence-transfer activity significantly. It is reasonable to conclude that there are other reasons why so few licences are actually sold on by manufacturers.

Manufacturers confirmed that the licence-variation procedure did not deter them from transferring licences, and many had experience of it in the process of acquisition of other generics firms. Nonetheless, they were unwilling to sell licences to rivals, even when they no longer manufactured a product and had no intention of doing so in the future. This is because the ownership of a licence for a particular drug increases the leverage for that manufacturer in negotiating the price for supply from a rival manufacturer. The ability to self-supply a drug is the most effective and credible threat with which to negotiate supply terms from another manufacturer. Without a product licence, the firm seeking supply would need another potential source of the product, or it would be unable to negotiate the best terms from a supplier. As described in Phase I, cross-supply arrangements of this sort between manufacturers are very common in the UK generics market.

It is the prevalence of these cross-supply arrangements, and the benefits from holding on to licences, which may explain in part the limited number of licence transfers. Most manufacturers will hold their licences until they need to be renewed (there is an annual service charge for licences), regardless of whether they are producing. At the point of renewal, a manufacturer will decide whether to retain each of its licences, and, if not, will allow them to lapse (this is counted as a cancellation in the licence data).

Furthermore, even if a manufacturer or other licence-holder did decide to sell a product licence, there is at present no established forum for selling existing product licences, and the little transfer activity that does occur is through private arrangements. Notwithstanding the reluctance of manufacturers to sell their licences, a formal secondary market might encourage licence sales. In particular, it may be clear to a UK-based firm whom it would need to approach to obtain a product licence, but this information may not be available to firms outside the UK.

[19] 'Piggybacking' allows the applicant to replicate exactly an existing manufacturer's product licence. As the new licence would be identical to that on which it piggybacks, the new licence owner would be constrained to having the drug produced at the original manufacturing site (unless it undertook further licence variations).

Some manufacturers have considered selling a number of product licences, but have not pursued the idea. In part this was because of the effort needed to find a company to purchase the licences. The lack of an obvious source of information on licences available for transfer is an explanation for why so few overseas manufacturers appear to be using this route to enter the market.

2.4 Recommendations

From the foregoing analysis a number of recommendations arise, which cover many aspects of the licensing system within the UK. Some of those considered below address issues that were raised in the Phase I report and which were not further investigated in Phase II. Owing to the interface between the UK licensing regime and policy, and European regulation, some of the optimal changes may be feasible only in the long term, if at all. Two sets of recommendations are therefore presented: the ideal licence changes; and a second set of practical changes, which recognise the limitations of UK unilateral action.

2.4.1 Ideal changes

The ideal changes to the licensing regime would be as follows:

- expansion of countries approved under mutual recognition;
- use of 'bibliographic' applications for new licences for old products, or else adoption of one specific generic drug formulation as the reference product when the original brand is withdrawn;
- entry by duplication of existing generic drugs;
- the establishment of fast-track approvals procedure for drugs in shortage or with very few suppliers.

Increased mutual recognition

One of the problems identified in the UK market is the difficulty faced by foreign firms in switching their supply to the UK, especially in times of shortage. A straightforward method of overcoming licence entry barriers would be to expand MRP. There are two forms of mutual recognition that could be expanded: the product licence MRP system and MRA arrangements for manufacturing sites.

An expansion of the product licence MRP programme to include non-EU nations would significantly reduce the time and costs involved in entering the UK market from overseas. In particular, the time taken to enter would be reduced because suppliers would not need to have existing generic chemical entities approved by the MCA. While such a measure needs to be negotiated at the European level, the MCA could still play an active role in collaborating with other national licensing bodies, and contacting potential host countries, such as the USA, Canada or Israel.

Greater use of MRP may also lower entry costs, as potential suppliers would not have to invest in altering an existing product to take account of any UK-specific attributes of the branded product. Entrants would similarly pay reduced licence fees to the MCA. Overall, MRP is likely to encourage short-term or transitory entry that is particularly important in times of shortage, and the possibility of this entry would act as a constraining force on incumbents in the market.

MRA arrangements are effectively a bilateral agreement between the UK (or EU) and a third-party host country to recognise each other's inspections of manufacturing sites. At present, outside the EU, MRA is limited to manufacturing sites, and is negotiated centrally by the EU. Only Australia and New Zealand have MRA arrangements with the EU. Agreement with Canada has been delayed, and agreement with the USA is expected eventually. No others are scheduled, but this could be reconsidered.

A further spin-off might be easier entry for UK manufacturers to other global markets. If it becomes straightforward to export from the UK to the EU, and to an increasing number of countries outside the EU, the UK might become a more attractive environment for global manufacturers. Existing operations could be more flexible in the areas to which they supply, and other firms could set up plants in the UK in response to the more streamlined regulatory environment.

Another method for boosting the UK generics industry, and for repatriating some of the R&D activity that has been moved overseas, would be the introduction of Roche–Bolar-type regulations. Most manufacturers in the UK actually develop new generic equivalents outside the UK, in countries where they are allowed, through Roche–Bolar provisions, to begin development before the end of the patent term. For example, major UK manufacturers supply Fluoxatine on contract from a manufacturer in Iceland. This manufacturer was able to carry out the bioequivalence research in advance, and now has 2–3-year production agreements in place. Both existing manufacturers and new entrants might be attracted to the UK if this restriction were relaxed in accordance with those elsewhere in the world. This would also have to be negotiated at the European level.

Reference generic drugs

A future problem highlighted in the first stage of the report was possible difficulties with licensing new generic drugs, should the original branded drug already have been discontinued. This could lead to older drugs facing a falling number of suppliers with no possibility of new entry.

Directive 65/65 states that a generic must be equivalent to a product that has been authorised for at least ten years; this has been interpreted as meaning an original branded product, as generics do not have sufficient clinical data in their application. The MCA states that it should be possible to make a 'bibliographic' application if the original product has been withdrawn—however, this procedure has not yet been tested practically.

In the USA the FDA has overcome a similar problem by nominating a particular generic to be the new 'reference' drug, so that new entrants prove essential similarity to that, rather than to the brand which is no longer available. In the UK, the direct copying of one licence by a new entrant is already possible through piggyback licence applications. However, this requires the permission of the original licence owner and creates an exact duplicate licence, rather than allowing essential similarity which could involve, for instance, different active-ingredient suppliers or excipients.

Entry by generic duplication

This would allow manufacturers to enter through duplicating an existing generic product without having to demonstrate bioequivalence. This differs from the current piggyback scheme because it would allow licences to be granted for sites other than the existing one, but the licences would otherwise be identical.

It does not appear that potential entrants, especially foreign firms, are aware of the possibilities for piggyback licensing. It may therefore be in the public interest for the availability of the process to be publicised more widely within the global generics industry.

The objective of such a remedy would be to increase the availability of R&D of generic drugs, and could lead to the sale of 'recipes' for generics. The costs of entry would be reduced to firms not undertaking the primary development. Manufacturers carrying out could sell their formula, and thereby increase the likelihood of fully recouping their research costs.

There are already some firms and web sites that facilitate the sale of research information and licensing opportunities. On-line services and CD-ROMs have been developed for companies to exchange licensing and R&D information on the Internet or via some intermediary. Web sites also offer variations on this theme (for example, www.pharmalicensing.com and www.pharmaexchange.com). Pharmaexchange is a deal-making service where firms can register to browse or post their offers for free, but any contacts which result in a deal arising from use of the web site are subject to a commission payable to Pharmaexchange. There is also an option for more active involvement of Pharmaexchange, which can mediate a deal with a third party and provide various support services, also in return for a commission.

Pharmalicensing's site, however, is more of a bulletin board, where advertisers of licences and research pay to have their company 'profiled' on the web site. Along with the profile, the firms are entitled to post a limited number of advertisements. Pharmalicensing does not appear to become involved in deals arising from visitors to its site, and the revenues appear to be fee- rather than commission-based.

IMS Health, an information solutions firm servicing the pharmaceutical industry, has developed an on-line database service and CD-ROM for subscribing companies. These databases are used to monitor the development, efficacy and status of pharmaceuticals, from early clinical testing through to launch. They also allow licensing opportunities to be browsed, and these are categorised by the area of the industry in which they are offered.

Data is gathered through direct contact with manufacturers and research organisations. The data appraises both the scientific and commercial aspects of drug development, and are searchable by a number of variables, including product, company, and country. These on-line databases facilitate communication between firms, which improves information within the market as a whole, especially allowing firms to target partners for joint ventures and licensing, or to assess R&D portfolios for investment and acquisition purposes.

Fast-track approvals

A further method of increasing the speed of foreign entry at a time of shortage would be through a fast-track approval process for manufacturers producing the drugs that are in shortage. The MCA already has such a process, which is applied to two particular categories of drugs: those that treat a rare or new condition (eg, CJD); or when there is a shortage of vaccines, especially for children. In general, the MCA will only apply the

fast-track prioritisation for a clinical need. Additionally, it could actively solicit licence applications for drugs in shortage or where few UK licences are active.

The MCA was asked for its opinion on applying the procedure to drugs that were in shortage, or with few licences, and it felt that this was not an appropriate use of the process. Its particular concern was that fast-tracking should not be used simply because the NHS did not wish to purchase drugs from the existing suppliers in the market, or at the prevailing prices.

The process for implementing this remedy therefore already exists. However, there would need to be a change in the MCA approach, to include wider public-health criteria for implementing the fast-track procedure, rather than the current purely clinical focus.

Associated with such a change in the use of fast-tracking could be a more active monitoring role for the MCA in determining potential bottlenecks in generic supply. This proposal is developed in more detail in the practical remedies below.

2.4.2 Practical changes

The remedies suggested above may be difficult to implement in the short to medium term for a variety of reasons. However, the recommendations offer a potential guide to future negotiating strategies and goals.

A number of other remedies, more practical in the short term, have also been formulated. These could be introduced in the short to medium term, and ought to be feasible without European involvement. The practical recommendations are as follows:

- reduce the time for licence transfers;
- create an organised licence-trading facility;
- introduce status-of-production reports from manufacturers;
- establish a market-monitoring role for the MCA/the Department of Health.

Reduction in transfer time

Although the MCA currently beats its own time guidelines for the approval of changes in licence ownership, it may be possible to reduce the time taken even further. This could be achieved by giving ownership changes a higher priority. At present, changes of licence ownership take longer than other licence variations.

As has already been noted, reducing the time taken to acquire a licence for the UK market would improve the accessibility of the UK, and encourage foreign entry. This entry does not actually have to take place in order to affect prices—so long as it is *potentially* feasible, this will act as a price constraint on incumbents. These changes would effectively make the UK generic market more contestable.

Formal secondary licence market

There is evidence to suggest that one of the reasons for the low level of licence-transfer activity at present is the absence of a formal secondary market. If such a market, or environment in which licences could be traded, were established, it would be significantly easier for firms (either entrants or established players) wishing to acquire a particular product licence to do so.

To facilitate licence transfers, the most important factor is information provision: potential buyers need to be aware of the licences available, and sellers need to advertise the licences they wish to sell. Therefore the 'market' need only be a forum for information exchange, which could be as simple or as complex as desired. In particular, it could be coordinated by the MCA via a web site or other medium.

The MCA does not envisage its role as including the operation of a licence market in any form, but did mention that it coordinates trading opportunities in other areas. One of its main concerns was that it might not be able to recoup any costs that were incurred in setting up or running the market; however, this could be overcome through charging commission or fees. The commercial web sites and other facilities in the generic duplication remedy above could provide models for the operation of such a market.

The MCA suggested that trade bodies, such as the BGMA or European Generics Association (EGA), might be more interested in establishing a trading arena. However, there may be a conflict of interest between members of trade (or similar) bodies and the objectives of a secondary licence market.

Market monitoring

In the USA, the FDA's remit includes an obligation to monitor the market and take action if there is any indication of likely shortages or potential problems resulting from a scarcity of licences for particular drugs. This market-monitoring activity consists of monitoring the media and trade publications for news either of shortages, production problems, or intentions to exit the market. One of the remedial strategies employed by the FDA is to encourage smaller suppliers to increase production volumes or obtain a specific licence where there is an opportunity. In addition, the FDA may prioritise licence applications to speed them up if there are shortages, and it is also able to grant emergency licences on a much shorter timescale than a standard licence application. In this way, the FDA manages the market with as little intervention as possible.

Such an approach could be adopted in the UK, with either the MCA or the Department having responsibility for monitoring the market. Similar actions to those used by the FDA could be employed, especially where drugs are identified with only a few existing licence-holders. This would function to remove informational barriers to entry; new entrants could also be given access to a fast-track procedure (subject to safety constraints).

The sponsorship of new entry, or other forms of active entry encouragement, could be operated in combination with, and facilitated by, any tendering regime that was implemented. This has been one of the most successful features of the New Zealand tendering exercise, where the previous manufacturers' duopoly has been broken by entry encouraged through the tendering process.

The MCA stated that it did not consider either market monitoring or actively facilitating entry as within its current remit, and would not therefore be willing to undertake this activity.

Production status reports

One of the requirements on licence-holders in the USA is to report to the FDA the annual production volumes for each of their licences. They also have to inform the FDA if they

do not produce under any licence for more than six months. The annual production returns are included as part of an annual report that all manufacturers must submit to the FDA.

It would aid the monitoring and market-management function if similar production volume returns and non-production information could be incorporated into UK licence requirements. This would significantly improve transparency in the market from a regulatory point of view, which would be especially valuable if a centralised purchasing option is not introduced. The MCA or the Department would have much greater information with which to manage the market where necessary, and to attempt to reduce shortages and price volatility.

An alternative mechanism by which this information could be obtained is through the Health Act 1999. The Department is already requiring similar information provision as part of its short-term measures, and it may be possible to use the same statutory powers to enforce reporting requirements.

MCA objectives

Through discussions with the MCA, it has become clear that the role it has been expected to perform is different from that of the FDA in terms of generic medicines, particularly in relation to the management of the market. The MCA works on a clinical basis, and applies its rules and regulations only insofar as they apply to clinical issues. The FDA, in contrast, has a much wider role—for example, in monitoring whether there are sufficient producers to allow the supply of generic drugs at a reasonable price, and taking action if this is not the case.

However, these different approaches appear to stem from different interpretations of their respective remits, rather than from a fundamental difference in institutional structure. As can be seen from the mission statements reproduced below, both the FDA and MCA have, in principle, very similar roles (with the exception of the FDA's specific mission to promote regulatory harmonisation). It is the interpretation of these roles that differs so widely.

FDA Mission

1. To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
2. With respect to such products, protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labelled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labelled, and; public health and safety are protected from electronic product radiation;
3. Participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonise regulatory requirements, and achieve appropriate reciprocal arrangements; and,
4. As determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors and retailers of regulated products.

Source: www.fda.gov/ope/FY00plan

MCA Mission Statement

To promote and safeguard public health through ensuring appropriate standards of safety, quality and efficacy of all medicines in the UK market. Also, to apply other relevant controls and provide information which will contribute to the safe and effective use of medicines.

Source: www.open.gov.uk.mca/activity.htm.

The MCA has considerable information and data, especially on licences, which are not currently used in a market-monitoring function. Even relatively straightforward analysis, such as that contained in section 10.2 above, would significantly increase the amount of information on the generics market available to government. It is therefore recommended that the Department discusses with the MCA broadening the interpretation of the MCA's remit, along the lines of that of the FDA. In doing so, reference would have to be made to the MCA's Trading Fund Order, which imposes constraints on the type of activities that the MCA may undertake.

1. The Case for Centralised Purchasing through Tendering

The second aspect of Phase II of the review is to provide detailed recommendations on the introduction of central purchasing through competitive tendering. This is done over the next six sections.

This section outlines the advantages and the potential disadvantages of tendering (sections 11.1 and 11.3), which should all be taken into consideration when designing a tendering system. Section 11.2 explains that demand for each drug is reasonably predictable, which is important in making the tendering process smooth. The tendering options presented in sections 12 to 14 seek to maximise the advantages and minimise the disadvantages signalled in this section. Section 15 outlines a possible pilot scheme and section 16 analyses the potential impact of the proposed scheme.

1.1 Advantages of tendering

Centralised purchasing through tendering of generic drugs by the NHS has many advantages, as outlined below. Tendering would resolve some of the problems of the current system that were identified in Phase I.

Tendering would:

- facilitate greater use of the power of the NHS as the sole buyer of generic drugs, thereby securing lower prices;
- make prices paid to manufacturers (and other suppliers) transparent, so that information on the prices of drugs that are tendered would no longer need to be obtained through the Discount Inquiry with pharmacies, or through an inquiry into prices of vertically integrated wholesale–pharmacy groups;
- in combination with adequate demand forecasting, give manufacturers (and other suppliers) certainty over demand, which would facilitate bringing total production (and supply from other sources) into line with total demand;
- if appropriately designed, facilitate new entry into the market, thereby fostering competition;
- remove perverse incentives to hoard stocks at any point in the supply chain, reducing the likelihood of both actual supply shortages and 'artificial' shortages through speculative hoarding;
- reduce price fluctuations, thereby making total NHS expenditure on generic drugs more predictable;
- in combination with enforceable penalty clauses in supply contracts, impose an obligation on the manufacturer (or other supplier) to supply the drugs that are contracted for, thereby reducing risks to security of supply;
- reduce the trading activities of pharmacists, thereby increasing the emphasis on pharmacists' advisory and other healthcare-related functions.

Each of these advantages is discussed further below.

1.1.1 Exploiting buyer power

In the primary-care sector, the NHS does not procure centrally, but rather 'fragments' its buyer power by using a very large number of pharmacists as its contractors. These pharmacists negotiate with their suppliers individually, and, together, do not have the

same buyer power as the NHS would have were it to negotiate (tender) as a whole. (Although the pharmacists' buyer power overall has been increasing owing to horizontal and vertical integration; a trend discussed in Phase I of this report.)

In Phase I, it was signalled that the NHS cannot obtain low prices in the same way as a traditional monopsonist can—ie, by reducing demand (in the same way as a monopolist increases price by reducing supply). This is because the NHS must fulfil every patient's needs, and cannot afford to buy too little of a product and risk shortages. In economic terms, the NHS demand for drugs is price-inelastic, which reduces its buyer power.

Nevertheless, it is still likely that the mere volume demanded by the NHS would lead to significantly lower prices than those obtained by the pharmacies because of production efficiencies. This is certainly the experience in the secondary-care sector, although the lower prices for drugs to hospitals may have other explanations, as discussed elsewhere in this report. Price reductions have also been obtained in other countries where some form of centralised purchasing or tendering of drugs is used, such as the USA and New Zealand (see appendices 6, 7 and 9), and in other industries that use tendering. An estimate of the savings made through centralised tendering is presented in section 16.

In some countries there is also increasing emphasis on exploiting buyer power to reduce drugs prices. For example, in the Netherlands, policy reforms are aimed at exploiting the buyer power of the health insurers in the procurement of drugs from manufacturers. Another aim of these reforms is to make prices paid to manufacturers more transparent, which would also be achieved through centralised purchasing by the NHS, as mentioned in the second bullet point above.

It should be noted that buyer power can be exploited excessively, potentially causing inefficiency and security-of-supply problems. This is discussed below.

1.1.2 Making prices transparent

As noted in Phase I of this report, prices paid by pharmacists to wholesalers and manufacturers are far from transparent. The Drug Tariff prices (minus claw-back) are unlikely to be representative of market prices, for a number of reasons.

- The Drug Tariff is based on a basket of only a limited number of suppliers (two national full-line wholesalers and three manufacturers), and does not account for the fact that pharmacists obtain a substantial part of their generic drugs (perhaps up to 40–50%) from short-liners.

- Second, suppliers to pharmacies compete on discounts on their list prices. The Discount Inquiry (on which the claw-back percentage is based) is at best only a rough estimate of the actual discounts. This is because it is held infrequently, covers only one specific month, and excludes chains, such as Boots, which cannot provide a meaningful transfer price between wholesale and retail arms.

- The growing importance of vertical integration between wholesalers and pharmacies distorts the prices revealed by pharmacists, reducing the value of the information obtained through the Discount Inquiry. The three national full-line wholesalers are affiliated with large chains of retail pharmacies. Pharmacists also increasingly set up joint buying groups that function as wholesalers. These

vertically integrated players can manipulate internal-transfer charges from retail to wholesale without affecting total profit, in order to inflate reimbursement prices. The Discount Inquiry should then ideally look at the prices paid by the vertically integrated wholesalers to the manufacturers, although these prices are even less transparent.

Centralised purchasing would lead to transparency of the price paid to the manufacturer (or other supplier) that is awarded the contract after the tender. All pharmacists would be reimbursed at this price (plus a distribution fee). Of course, the appropriate distribution margin would have to be determined, but this would be much more transparent than the margins currently earned at different levels of the distribution chain.

1.1.3 Balancing supply and demand

As signalled in Phase I of this report, there is only a limited flow of information on supply conditions and shortages throughout the distribution chain. Manufacturers do not respond swiftly to shortages, and they often do not know whether price increases reflect:

- 'true' supply shortages (likely to be long-lived), in which case it would make sense to increase production; or
- 'artificial' supply shortages through hoarding (which would be short-lived), in which case increasing production would be risky.

Short-line wholesalers may aggravate supply instability in times of shortage by reacting to, and taking advantage of, the ability of pharmacies to pay elevated prices when products are in short supply. Thus, price signals do not function properly in the sense of giving manufacturers timely and efficient signals of 'true' shortages.

In addition, Phase I of this report signalled that a noticeable feature of the pharmaceutical supply chain is the absence of workable and enforceable supply contracts for generic products. This is the case for contracts between manufacturers and wholesalers, and between manufacturers and hospitals. Manufacturers seem reluctant to enter into such supply obligations with wholesalers as they prefer to remain free to sell to the highest bidder at any time. Likewise, wholesalers prefer to remain free to purchase from the cheapest supplier at any time. This feature may be part of the reason why demand and supply are poorly coordinated.

This unstable supply situation seems unnecessary because total (end-user) demand for each drug is relatively predictable, as further discussed in section 12.2. In principle, therefore, manufacturers should be able to make reasonable forecasts of total market demand (and estimate their own achievable market share of this demand). Centralised purchasing gives individual suppliers certainty about the demand they will face for the duration of the supply contract. This facilitates bringing total production (and supply from other sources) into line with total demand, reducing the likelihood of 'true' supply shortages. It also allows manufacturers to set up longer (and therefore more efficient) production runs.

1.1.4 Facilitating entry

The tendering system, if appropriately designed, could be used to facilitate entry into the market, thus fostering competition. (However, an inappropriate tendering system may

have the opposite effect and lead to market exit, as discussed in section 12.3.) By giving individual suppliers certainty over the total demand they will face for the duration of the supply contract, tendering could make the UK market more attractive to potential entrants, especially foreign manufacturers.

The experience of generic drugs tendering in New Zealand is encouraging in this respect (see appendix 9). Several tenders have been won by traders (short-liners) with a foreign supply source that had previously not been active in the New Zealand market.

The New Zealand tendering authority, Pharmaceutical Management Agency Ltd of New Zealand (PARMAC), goes further—it explicitly allows bids from manufacturers or traders that do not yet have the relevant product licence. If the lowest bid in the tenders comes from an unlicensed supplier, the authority would delay the award of the contract and speed up the licensing process.

1.1.5 Removing incentives to hoard

Because prices paid to suppliers (and margins paid for distribution) are fixed and transparent under centralised purchasing, players at different levels of the distribution chain would no longer have incentives to hoard products in anticipation of price increases. In fact, the supplier that is awarded the contract would probably make distribution arrangements with only one or a few wholesalers (either full- or short-line) for delivery of the drug. This would increase transparency of where products are in the distribution chain at any point in time. As a result, 'artificial' shortages owing to hoarding of products would occur less frequently.

1.1.6 Reducing price fluctuation

In addition to making prices lower and more transparent, centralised purchasing would also reduce price fluctuations. This is because the supply contracts would be awarded for a reasonably long period of time, and supply prices would be (mostly) fixed for the duration of the contract.

Some flexibility in terms of prices responding to short-term changes in market conditions would be lost. However, as described above, some price fluctuations that have occurred do not constitute 'efficient' price signals anyway—and there are few fundamental drivers of short-term cost changes in this market. More stable prices are desirable from the point of view of NHS budgeting, as they make total expenditure on generic drugs more predictable. Stable prices may also reduce uncertainty for potential entrants into the market. However, the tendering options presented in sections 12–14 would still allow for some price variability to reflect real changes in underlying market conditions.

1.1.7 Imposing supply obligations

Imposing effective supply obligations in contracts has proved particularly difficult in the pharmaceutical sector. In Phase I of this report, it was signalled that the few instances of formal contracting that exist in the generic drugs market (eg, between manufacturers and wholesalers in the context of an agency scheme or a supply contract to hospitals) have been characterised by an unwillingness to accept blame when there is a default.

Awarding a supply contract after centralised tendering gives the NHS an instrument to impose effective obligations to supply on the manufacturers (or other suppliers) that are awarded a contract. Each contract should contain enforceable penalty clauses to deal with

cases of defaulting. Currently, the NHS has no such instrument in the community sector, and the NHS and pharmacies bear (almost) all the risk of shortages. With centralised purchasing, the risk of shortage would be reduced, although the NHS would still be responsible for the supply to pharmacies.

The penalty clauses should, however, allow an appropriate amount of flexibility for the supplier in case of changes to market conditions beyond the control of any of the contracting parties.

1.1.8 Trading by pharmacists

As also discussed in the Phase I report, pharmacists are put under pressure by the operation of the reimbursement system to find the lowest prices, rather than simply ordering drugs from a single wholesaler. Clear indications exist already that the longer-term effect is to encourage trading behaviour by pharmacists and to drive out those pharmacists who are not commercially minded. Centralised purchasing would reverse this trend, since it takes away trading risks (as well as trading opportunities) from the pharmacies—ie, the NHS would take over the role of finding the lowest price for the community. This would create more space for the pharmacist's traditional role as provider of healthcare and professional advice.

1.2 Lessons from auction theory and practice

The advantages (as well as possible disadvantages) of tendering also follow from auction theory and from experience with tendering in other countries and industries.

Most importantly, a key benefit of tenders over bilateral contracts is the ability to design a mechanism which induces bidders (in this case, the manufacturers) to reveal voluntarily to the NHS accurate information about their costs and their valuation of the product being auctioned. In economic terms, truthful cost revelation is a 'dominant strategy' for bidders in an auction.

Auction theory further suggests that the NHS tenders should be in the form of *first-price sealed-bid* auctions, in which bidders provide a secret bid to the NHS. The lowest price bid is the winning price, and will also be the price actually paid to the winning manufacturer. First-price sealed-bid auctions are widely used in practice.

Finally, from the experience with tendering in other sectors, examined in appendix 8, it becomes clear that tenders can provide even greater benefits when used in combination with the development of sophisticated IT systems.

1.3 Predictability of demand as a prerequisite for tendering

This section shows that demand for drugs is reasonably predictable, which is a crucial requirement for any tendering option to function. Factors that influence short-term changes in demand include:

- a change in prescribing behaviour (as a new drug is introduced, or a new use is found for an existing drug);
- epidemics; and
- seasonal incidence of illness.

In addition, in the longer term, demand is also driven by population growth.

To illustrate predictability for the purposes of contracting, historic demand data for ten preparations were obtained from the Department. Figure 11.1*a* and *b* show quarterly demand over the period 1995–99.

Figure 11.1*a*: Quarterly demand, 1995–99

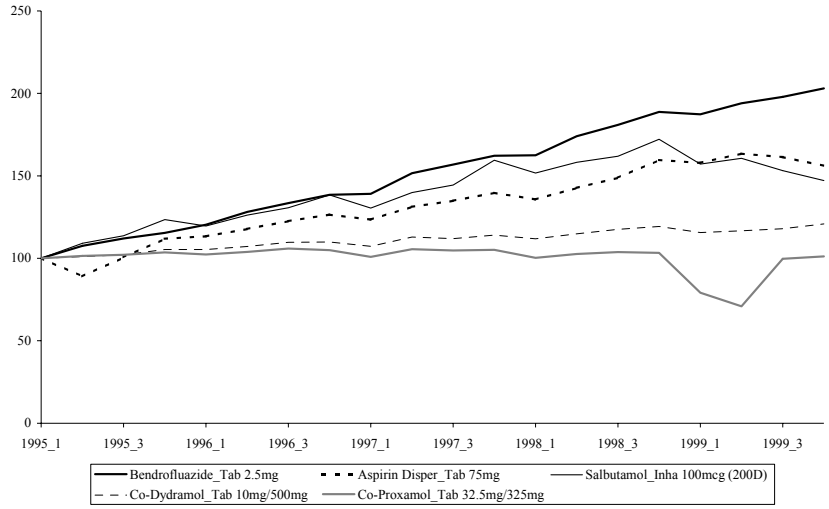
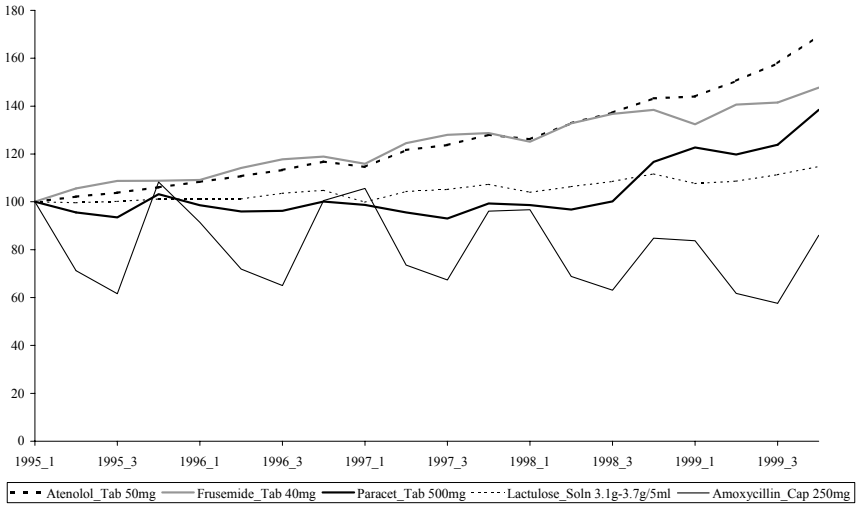


Figure 11.1*b*: Quarterly demand, 1995–99



Note: Demand for all ten drugs normalised to 100 at the beginning of 1995.
Source: Department of Health, Statistics Division, and OXERA calculations.

The most obvious trend is that demand usually increases through time. It can also be seen that demand for Amoxycillin is seasonal, and that there was a shortage of Co-Proxamol towards the end of 1999.

To demonstrate predictability of demand, a simple model was constructed where a prediction of future demand for quarters $n + 3$ to $n + 8$ was assumed to be a linear combination of historic demand in quarters $n - 3$ to n. This model was used to predict demand for the ten drugs in Figure 11.1 for 1998 and 1999. The percentage differences between actual and predicted demand are shown in Figure 11.2*a* and *b*.

Figure 11.2*a*: Predictability of demand

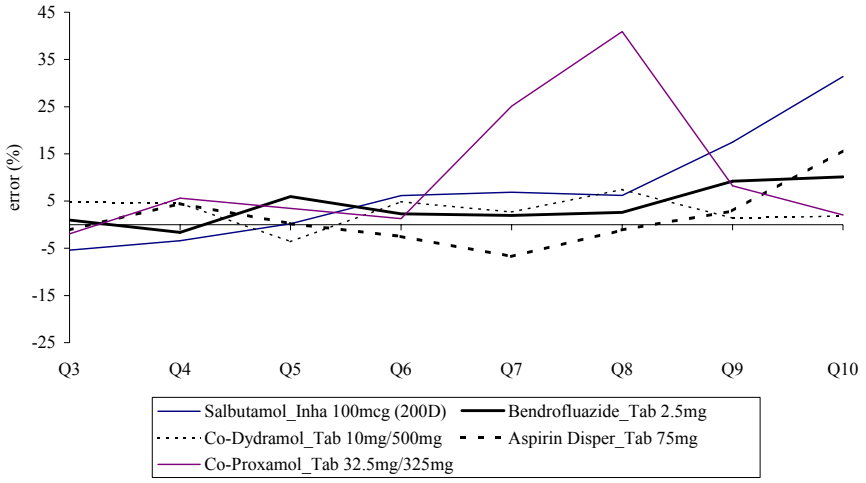
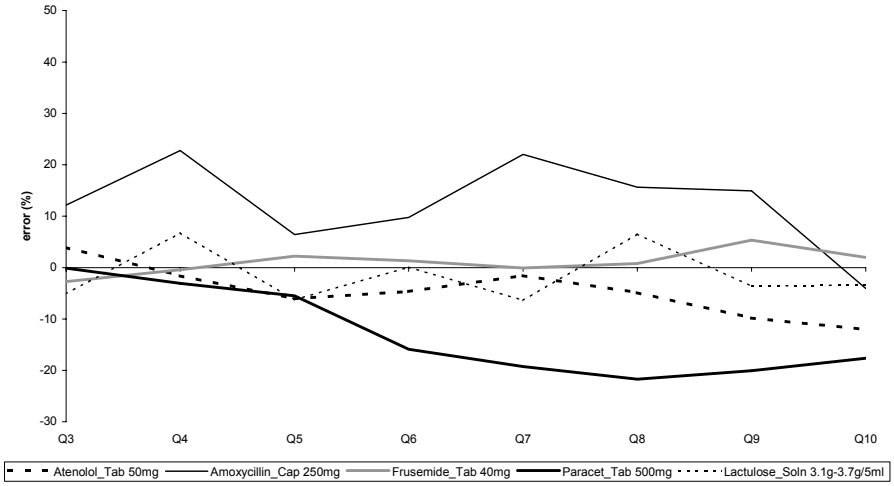


Figure 11.2*b*: Predictability of demand



Source: OXERA calculations.

Such a prediction could be made when the tendering process begins, and would cover the two-year period of the tender.

These results come from an unsophisticated regression, yet show that demand for most drugs is easily predictable within ±10%, at least 18 months ahead. It would be possible to obtain more accurate predictions with more sophisticated modelling and through the use of a longer series of historic demand data.

In section 13, a tendering scheme is proposed that starts with forecasts of demand of each of the tendered drugs for the following two years. It has been shown that such two-year forecasts can reasonably be made. However, the proposed scheme involves staggered tendering over four-month periods. As explained in further detail in section 13, this allows for additional flexibility and demand adjustments every four months, thereby making the scheme less vulnerable to potential forecasting mistakes.

1.4 Potential disadvantages of tendering

The introduction of centralised tendering also has some potential disadvantages and risks, as has become clear from auction theory, the experience of other countries and other sectors, and the interviews with industry sources and the NHS PASA. These are discussed below. The options for tendering presented in this report are designed to seek to obviate these disadvantages and risks as much as possible.

The main potential disadvantage of tendering is that it may increase the likelihood of market concentration as tendering rounds are repeated over time. This occurs when the same suppliers keep winning contracts for a certain drug, discouraging other suppliers from continuing to bid for that drug, and perhaps encouraging them to let their product licence expire altogether. This risk has been emphasised by all of the industry sources interviewed.

Similarly, the NHS PASA has signalled a common pattern for several drugs, whereby tendering drives the price down rapidly once a drug comes off patent, after which many suppliers exit the market and the price increases again (although usually not all the way up to the original branded price). However, no firm evidence has been produced.

Furthermore, any form of tendering may facilitate market sharing, collusion or bid rigging. Tenders can be set up so as to minimise incentives to collude—and the tendering options presented in this report seek to do this—but collusion can never be ruled out completely. To prevent collusion in its tenders, the NHS will have to rely on the Competition Act 1998, which is a powerful tool, as it provides for wide investigative powers for the Office of Fair Trading (including the possibility of ‘dawn raids’) and harsh penalties for collusion. Tacit collusion (coordinated behaviour without a formal cartel agreement) is also prohibited under the Act.

A further potential disadvantage of tendering is that, under public procurement rules, price is generally the key criterion. There may be concerns about the reliability of supply of the cheapest producer, or that low prices now may lead to high prices in the future. The tendering process needs to be structured to minimise these problems. In particular, bidders should meet certain selection criteria to demonstrate that their bids are serious and that they can guarantee supply.

Centralised tendering also has an important impact on each level of the supply chain, possibly affecting certain parts of the chain that are currently performing satisfactorily. Section 16 presents a more detailed impact analysis of tendering, also addressing the effects on each level of the chain. Here, it is worth mentioning the following potential disadvantages.

- The introduction of tendering would dampen the commodity nature of the market. As discussed in Phase I of this report, the commodity nature has delivered important benefits as well as costs to the NHS. It has allowed players at different levels of the chain, such as the short-liners, to exploit commercial opportunities and put competitive pressure on other players. Under a tendering system, the competition is focused only on the initial supply negotiation (ie, when suppliers make their bid). Once these winning suppliers deliver the product to the NHS (into the distribution chain), there is no further competition. In the existing system, competition occurs throughout the chain.

- If a drug is tendered for, all units of that drug dispensed should come from the contracted suppliers. Otherwise, the NHS could not make demand commitments, and incentives to participate in the tender would be undermined. Bypass could come from UK-based supply sources that did not win the tender. In principle this could be prevented by declaring it illegal. However, some of the options of tendering discussed in section 12 are designed to limit the risk of bypass at any rate. Bypass could also come from foreign sources (although these are expected to be limited for generics, especially if the tender leads to a competitively low price).[20] European Commission rules normally do not allow countries to restrict free movement of goods, but may do so if the tender procedure itself is in accordance with the EU public procurement rules.

- For the same reason, own-label generic products would disappear. Boots is likely to be particularly affected by such a rule. AAH and some of the manufacturers 'brand' their range. This branding may also have value through some form of quality assurance, and, through these branded ranges, pharmacists can give patients the same drugs for repeat prescriptions. Lack of this type of continuity was highlighted as a problem in the shortages experienced in 1999. As a remedy, tendering could enforce homogeneity through NHS livery and pill specifications. The 'NHS' brand would then have to meet public concerns over quality, just as the own-label brands currently seem to do.

[20] Operating the scheme may be particularly problematic if it does not include Scotland and Wales. Integration of pharmacy and distribution across the whole of the UK would make it very difficult to prevent England-only preparations being supplied elsewhere in the UK, if the tender price was lower than the market price.

2. Tendering Options 1 and 2: Full and Partial Tendering of Generic Drugs

This section describes the options of full and partial tendering of generic drugs. Both options use preparation-by-preparation tendering, rather than tendering of product baskets, so the mechanism described in this section applies to both options. The differences between full tendering (ie, of all generic preparations) and partial tendering (of a limited number of generic preparations) are discussed at the end of the section.

2.1 Preparation-by-preparation tendering

The advantage of a form of *product-by-product tendering* is that it makes the prices of individual drugs explicit and transparent.[21] Furthermore, if *product baskets* were tendered, bidders might have incentives to cross-subsidise or loss-lead on some drugs in the basket, in order to win the supply of the whole basket. Currently UK manufacturers often use such cross-subsidies in order to offer a full range of drugs, in particular, to full-line wholesalers. However, it might be preferable to make the prices of individual drugs explicit and transparent, as this would allow supply conditions for each individual drug to be monitored, and make new entry at the individual-drug level easier.

A further question is whether tenders should be for individual chemical entities or for each different preparation of every chemical entity. Tendering for each preparation creates greater opportunities for different suppliers remaining in the market for the same chemical entity, thereby reducing the likelihood of monopolies and increasing security of supply. In New Zealand, generic drugs are tendered preparation by preparation, although bundled bids for different preparations of the same chemical entity are allowed.

In several other industries, tenders and auctions are also organised on a product-by-product basis, even if the auctioneer buys (sells) many different products simultaneously, and the bidders sell (buy) many different products simultaneously. For example, in the US spectrum auctions, different regional spectrum licences were auctioned simultaneously, but separately. Bidders were free to form different bundles of regional licences, but they had to win each regional licence separately. Likewise, generic manufacturers would be free to form different product portfolios, but they would have to win each product tender separately.

The disadvantage of preparation-by-preparation tendering is that some economies of scope in production (eg, between tablets of different strengths) or in contracting with raw-material suppliers may be lost. However, manufacturers can still bid for each of the preparations of a certain chemical entity, and then benefit from economies of scope.[22]

Product-by-product tendering might imply an administrative burden, particularly if every generic drug preparation is tendered for. In 1999, around 4,650 different generic preparations were dispensed in the community sector. The burden will be less under partial tendering—ie, when a limited number of drugs are tendered for. Nevertheless, in

[21] Here product-by-product refers to the generic term for any tendering where each product is specified separately. The specific terminology for pharmaceuticals is preparation-by-preparation, and this is used where relevant.

[22] One option would be to allow a manufacturer to make a lower-priced, joint bid for two preparations of the same chemical entity that come up for tender at the same time, in addition to separate bids at a higher price. However, this might again create opportunities for undesirable loss-leading, and is therefore not recommendable.

the hospital sector, the framework agreements for drugs are also tendered on a product-by-product basis (see appendix 3), and the NHS PASA does not consider the administrative burden to be excessive. The PHATE system of the NHS PASA reports that around 14,400 different tendered framework agreements are currently in place for different drugs for the different regions. The administrative burden of organising tenders for individual drugs may also be significantly reduced through some form of on-line bidding system.

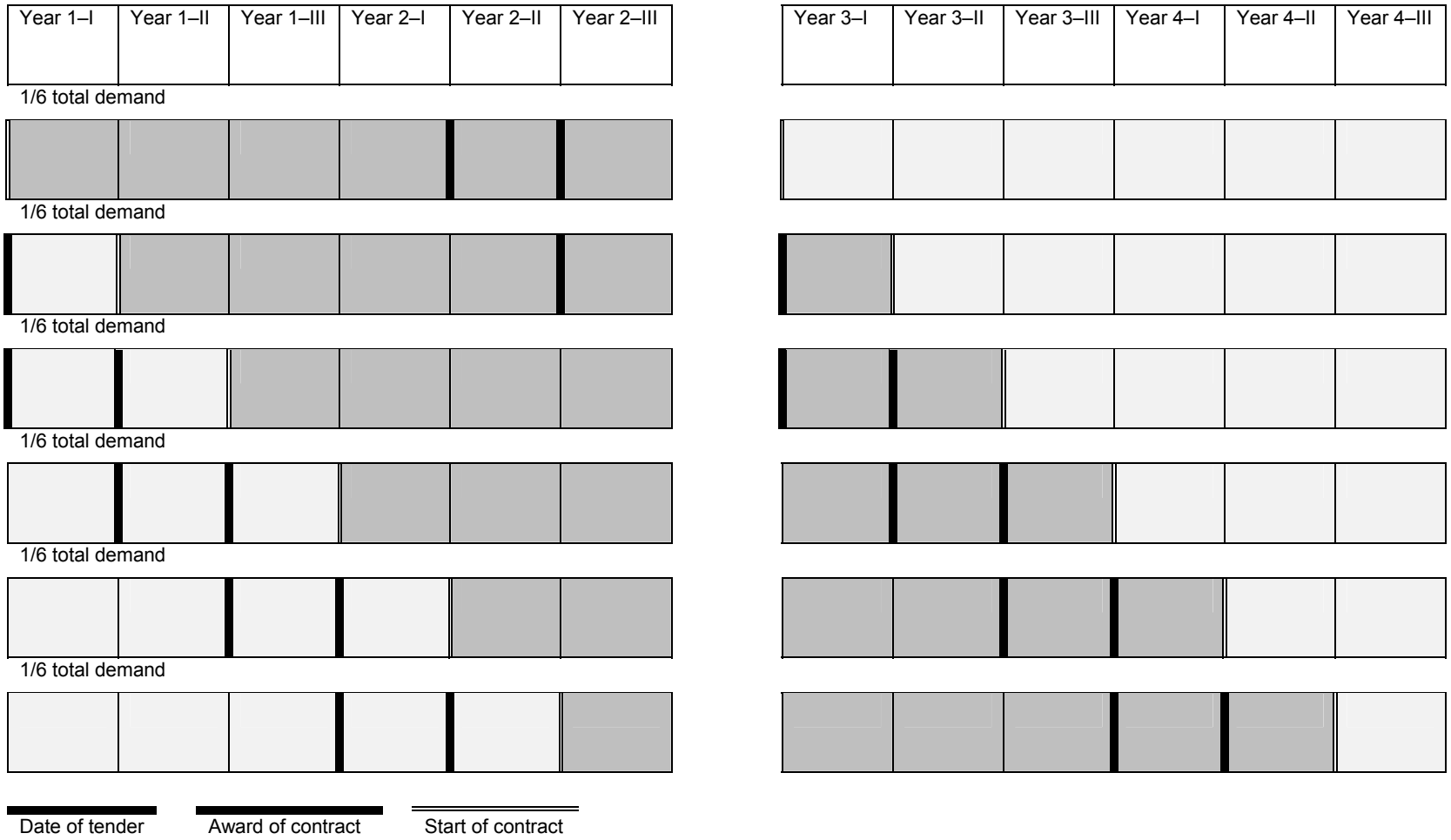
The NHS PASA mentioned that, ten years ago, in one region the NHS did tender a basket of 50 old and infrequently prescribed drugs, for which it wished to reduce the number of suppliers from 12 to around three. Each bidder could indicate its individual-product preferences. This method might also be applied for the rump of old and infrequently supplied drugs in the community sector. However, the NHS hospital sector has since moved away from tendering product baskets.

2.2 Staggered-tendering scheme

The scheme proposed involves staggered tendering. Figure 12.1 illustrates what this scheme would look like for each individual drug (preparation) that is put out to tender. Hence, for each preparation tendered, there is a separate scheme, as in Figure 12.1. Horizontally, the figure is divided into 12 blocks representing consecutive four-month periods over a total of four years (although the figure could, in principle, continue indefinitely). Vertically, the figure is divided into six tranches (excluding the top row, which indicates the time dimension). Each of these tranches represents one-sixth of the total demand for the drug in question.

The scheme would work as follows. First, for each individual preparation tendered, total demand over the next two years must be forecast. Then, every four months, one-sixth of total demand is put out for tender, and the winning bidder is awarded a two-year contract for supply of that tranche. Hence, during each period of four months, total demand is supplied out of the six tranches (although not necessarily by six different suppliers, as discussed below).

Figure 12.1: Staggered tendering for an individual drug (tendering options 1 and 2)



The scheme is somewhat similar to the staggered tendering for framework agreements in the hospital sector, which also involves six tranches of demand (ie, the six regions), a four-month tendering cycle for all the tranches, and two-year tendering cycles for the individual tranches. The main difference is that, in the scheme proposed for the community, there is no regional separation between the six tranches, as this is not considered feasible. The potential problems related to arbitrage that result from using non-geographical tranches in the community sector are addressed below.

The scheme of six tranches, four-month staggering and two-year contracts presented in Figure 12.1 has certain advantages, as discussed in the next section. However, they are by no means definite figures. For individual drugs, there may be variations to the scheme in terms of lead times, number of tranches, or length of contract. This depends on the specific characteristics of each drug. For example, if total demand for a product is low, or economies of scale in production are significant, then dividing demand into six tranches and tendering every four months may not be efficient.

However, too much variety across the schemes for the different drugs may be confusing and difficult to administer. Furthermore, once a specific scheme is chosen for a drug, the NHS should commit to that scheme in order to provide assurance to bidders that *ex-ante* rules will be respected *ex post*.

In the scheme shown in Figure 12.1, there is a lead time of four months between the date (announcement) of the tender and the actual award of the contract. Some time is required to evaluate all the bids and determine the winner. However, if some form of on-line auctioning is used, the bidders make sealed bids, and as the procedure becomes more familiar, this time might be significantly shorter than four months. The European Commission procurement rules also require a certain minimum lead time between the announcement of the tender and the award of the contract. In the NHS PASA framework agreement tenders for hospitals, the invitation to tender is published in week 1; tender offers are received by week 11; and the announcement of the winner is made by week 20. Thus, this amounts to a total lead time of roughly five months (there is a further lead time of four weeks between the announcement of the winner and the start of the contract).

In the scheme proposed here, there is also a lead time of four months between the award of the contract and the start of the contract. Interviews with manufacturers made clear that a significant lead time is required. Four months is roughly the time it may take a manufacturer that already has the required product licence to start up production of a drug that it is not currently producing. (This lead time may of course vary; manufacturers have mentioned required lead times between three and six months, depending on how recently they last produced the drug in question.)

The quantity contracted for each two-year tranche should not be supplied in full at the start of the contract, as this would be infeasible for the NHS and the distribution chain, as well as for the manufacturer. Rather, the two-year supply must be spread over time to meet demand patterns. Hence, if there are no seasonal patterns in demand, the manufacturer would roughly produce the same quantity each month for two years. The manufacturer may, for internal reasons, choose to concentrate production of the two-year supply, for example, in certain months of each year, but it should be required to guarantee that each product delivered has a minimum shelf life.

A1.1 Advantages of staggered tendering

The staggered-tendering approach presented above has several advantages.

First, by splitting up total demand into six tranches and limiting the duration of each supply contract to two years, the NHS is not making excessive use of its buyer power. The NHS would be likely to obtain a much lower supply price if it organised, say, a single tender for the full demand of a certain drug for the next four years. However, such excessive use of buyer power would almost certainly be counterproductive. It would lead to the formation of monopolies, as the losing bidders would find it difficult to re-enter the market after four years when the current contract expires. For the same reason, bidders would be forced to make 'desperate' bids—perhaps even offering prices below cost—in order to stay in the market. Suppliers would also have greater incentives to collude to seek to divide the market between them. Winning bidders in the New Zealand generic drugs tenders have become the sole supplier of certain drugs, for a period of around three years. Whether this will lead to monopoly problems still remains to be seen (see appendix 9).

On the other hand, a two-year contract appears to be long enough to give demand certainty to the winning supplier, allowing for economies of scale and efficient planning of production. Interviews with foreign manufacturers further suggest that such longer-term demand commitments make entry into the UK market more attractive (of course, potential foreign entrants will still have to win the tender).

It should be noted that six tranches has not been determined as theoretically optimal, and four or five might equally preserve competition. However, a market with six equally sized suppliers is usually considered competitive.[23] Furthermore, the experience of Boots shows that tendering one-sixth of the total market at the same time is manageable, both for the NHS and for the bidders.[24] A further consideration on tranche size is that a single tranche should be a manageable size for a smaller entrant to come into the market. One-sixth is likely to satisfy this for most of the market, while one-fourth may not.

Another advantage is that the staggered approach allows each supplier the opportunity to enter or re-enter the market every four months. This reduces market exit by bidders that have lost one tender, as they will have the chance to try again four months later. It also increases opportunities for new entrants into the UK market, which would otherwise have to wait for long periods (eg, two years) until the product in question came up for tender again.

Also, if the staggered approach is applied across all preparations that are tendered for, manufacturers will have the required flexibility in planning their product portfolio, as all drugs come up for tender every four months. One of the main arguments of the generic manufacturers against tendering is that they will have difficulties planning production because they do not know beforehand which products they will have to produce (ie,

[23] For example, the Horizontal Merger Guidelines 1997 of the US Department of Justice and the Federal Trade Commission state that mergers in markets with a Herfindahl concentration index of 1,800 or lower are approved without further detailed analysis because such a market is competitive. A Herfindahl value of 1,800 obtains in markets with five or six, roughly equally sized, competitors.

[24] Boots has a market share in generics of approximately 13% , so slightly lower than one-sixth of the market, and tenders for its supply of the major generic drugs.

which tenders they win). This would perhaps be the case if all drugs were put out for tender at the same time for a long period. However, under the staggered approach, such difficulties are mitigated.

The alternative to the staggered approach is tendering the six tranches at the same time, every two years. However, this is likely to be more prone to collusion or market sharing (although collusion of course remains a threat at all times, especially because these are repeated tenders where, in one round, bidders can signal information to each other for future rounds).[25] It would arguably be easier for suppliers to divide the tranches between them in a simultaneous tender where several bidders can win a tranche.

A suggested alternative for simultaneous tendering is to divide demand into unequally sized tranches, for example, three tranches of 60%, 30% and 10%, respectively. This might induce more aggressive bidding for the larger tranche. However, the problem of the price differences between tranches (discussed in more detail in section 12.4 below) would be even greater than with equally sized tranches. In particular, the tender for the 60% tranche would likely result in a lower price than the other two, owing to economies of scale. Furthermore, it is not necessary to impose beforehand a market structure of 60%–30%–10% market shares. Market forces themselves, through the tendering process, might lead to such a structure. For example, if one supplier wins three tranches, one wins two, and a third wins one, then the market structure would be 50%–33%–17%, but this would be a market-determined outcome.

With the staggered approach, (collusive) market sharing could also occur, but would be harder to sustain, as there is only one winner for each tranche. A competitor for the second tranche may not trust a rival whom it let win the first tranche four months earlier. Staggering also allows the NHS to monitor bidding strategies and spot collusion. In addition, incentives to collude are lower, since losing bidders will have another opportunity to bid in four months' time, and are therefore not necessarily left out of the market for a period as long as two years.

Moreover, the staggered approach allows the NHS to adjust for supply or demand changes every four months. For example, if total demand for a drug turns out higher than forecast, the NHS could increase the volume of the next tender for that drug (ie, that tender would be for more than one-sixth of the demand originally forecast). Likewise, the NHS can also adjust volume of the next tender if one of the tranche suppliers has production problems or pulls out of the contract (this would be a medium-term measure). If one of the tranche suppliers pulls out, the short-term measure of the NHS would be to rely on the other tranche suppliers (as further discussed below).

Finally, the staggered approach allows for the monitoring of market developments. Every four months, the NHS receives ample information through the tender bids, which allows it to track the development of prices, number of suppliers, etc. The NHS PASA also makes use of the information it receives this way. For example, the NHS could detect situations where, over time, a single supplier wins all the tenders for a certain drug as other suppliers pull out, and hence the price of that drug increases. Such situations are

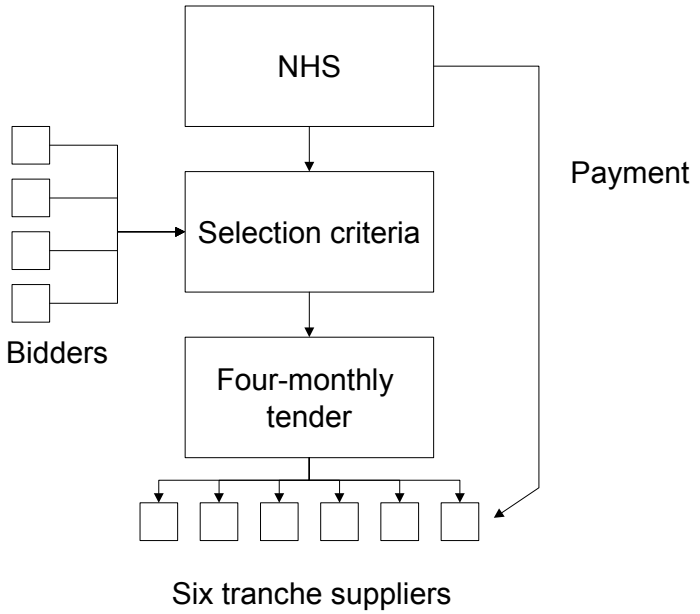
[25] See the examples of collusion in the spectrum auctions in the USA, discussed in appendix 8.

signalled as the main danger of centralised tendering. If the NHS were to observe such a pattern in time, it could take action to assist entry.

A1.2 Contracting with suppliers under full or partial tendering

This sub-section deals with issues concerning the tendering and contracting between the NHS and suppliers, as illustrated in Figure 12.2. The main issues are: which players are allowed to bid in the tender; how price and quantity are determined in the contract; and how suppliers are paid.

Figure 12.2: Contracting with suppliers under full or partial tendering



A1.2.1 Which players are allowed to bid in the tender?

Tenders should be open to all manufacturers, both UK-based and foreign, and generic and branded. The tenders could also be open to short-liners with an assured supply source, and to full-line wholesalers. It is important to set a rule that those manufacturers that agree to be the supply source for a participating wholesaler cannot participate themselves in the tender. Otherwise they would have two stakes in the tender, which could distort the outcome. This will reinforce the full-line wholesalers' reluctance to bid in the tender.

All bidders should be required to meet certain criteria to show that they can be a reliable source of supply and that they are 'within reach', should the NHS challenge them legally. They (or their agreed supplier) must of course also have the necessary product and manufacturing licences. In order to make this screening of bidders more efficient, a pre-selection process may be set up through which bidders can qualify for several tenders over a longer time period, rather than having to qualify for each individual tender.

Some suggestions for pre-selection are discussed in section 15.2.1. The NHS might also set up a database of qualified suppliers, following the example of the US Department of Defense, which implemented a Central Contractor Registration process. This is described in appendix 7.

Finally, some restrictions on participation by suppliers of other tranches of the same preparation should be imposed. One possibility is to limit each supplier to a maximum of five tranches. As such, one tranche is always reserved for a competitor, which prevents a monopoly. A similar approach was taken in the auction of spectrum for third-generation mobile telephony licences, where one of the five licences was reserved for a new entrant.

Overprotection of entrants to preserve competition may be counterproductive and may, in fact, reduce competitive pressures. A lower ceiling on the market share of one supplier (eg, three or four tranches) might induce collusion and market sharing. It would at any rate reduce competition for the remaining tranches, since all bidders know that the incumbent supplier cannot participate anymore. Hence, guaranteeing that one-sixth of the market is supplied by a competitor seems sufficient in order both to maintain competitive pressures in each bid, and to keep an alternative supplier in the market.

A1.2.2 Contracting and payment terms

For tendering contracts to function properly, enforceable penalty clauses for failure to deliver or other contract default are crucial. The simplest such clause would specify that a defaulting contractor should reimburse the NHS for the extra cost of obtaining supplies from elsewhere. For example, in the case of a generic manufacturer unable to supply contracted demand, the NHS would obtain the products from a second generic manufacturer (or possibly the branded manufacturer), and charge the defaulting manufacturer the difference between the price actually paid and the agreed contract price.

The contract between the supplier and the NHS should allow for some flexibility in the agreed volume. In this way, adjustments can be made if demand turns out to be lower than forecast, or one of the other tranche suppliers fails to supply. For a two-year contract for one-sixth of total demand for a certain preparation, it may be reasonable to require the supplier to deliver a volume within a range of, say, ±10% of the tendered volume at the same price. Any volume adjustments beyond +10% may then be priced at a premium (and, in some cases, the NHS could pass on this premium to the failing tranche supplier). The NHS would also be obliged to pay the supplier, even if demand fell below 90% of that contracted.

Some upward price flexibility in the contract may be desirable to protect suppliers from cost increases beyond their control, and thus reduce the likelihood of defaults. However, such protection should be only partial, as manufacturers might also be expected to pass on some of the risks of cost changes to their suppliers in turn. Contract suppliers would have to demonstrate clearly that the cost increases are in fact exogenous to them.

Downward price flexibility in favour of the NHS, to reflect exogenous cost decreases, does not seem desirable. It would increase uncertainty for the bidders and might raise concerns over discretion by the NHS. It would also be difficult for the NHS to demonstrate that a cost decrease is indeed exogenous, as the NHS has less information on supply conditions than the industry. At any rate, truly exogenous cost decreases would eventually be reflected in lower prices to the NHS in subsequent tenders, which is a further advantage of the staggered approach.

Finally, with regard to payment, the tendering scheme presented in this section follows the principle that each player (manufacturer/supplier, wholesaler/distributor and pharmacist) would be paid or reimbursed after fulfilling its task. As such, each tranche

supplier is paid the agreed tender price when the product is delivered into the distribution chain. In sections 12.6, three payment options are discussed: under the first, the tranche supplier would be paid by the NHS; under the second, by the wholesaler/distributor; and under the third, the NHS and the wholesaler/distributor would both pay the tranche supplier a part of the price.

A1.2.3 The possibility of different prices for different tranches

During any four-month period, each of the tranches may be supplied at different contract prices. In the hospital sector, prices for existing framework agreements may be adjusted downwards if the price of the latest tender is lower (and the NHS PSA is satisfied that this lower price is a 'true' market price). However, this mechanism increases the pre-tender uncertainty of bidders and, hence, may have a negative effect on the outcome of the tender. Therefore, in the tendering options presented in this section, each tranche supplier should be paid the price agreed through the tender.

If the same supplier wins different tranches at different prices, this supplier should be paid a weighted-average price, since the drugs it produces cannot be identified by tranche. This is equivalent to paying that supplier the actual price it bid for each tranche. Once the oldest tranche expires, the price of that tranche is no longer taken into account in the weighted average.

The problem with having different prices for different tranches is that this creates opportunities for arbitrage between the tranches, both by wholesalers and by pharmacists. Unlike the hospital sector, this model for the community sector has no regional separation between the tranches. Such arbitrage has benefits in the current commodity-type generic drugs market, but would no longer be desirable once tendering is introduced, for reasons explained below.

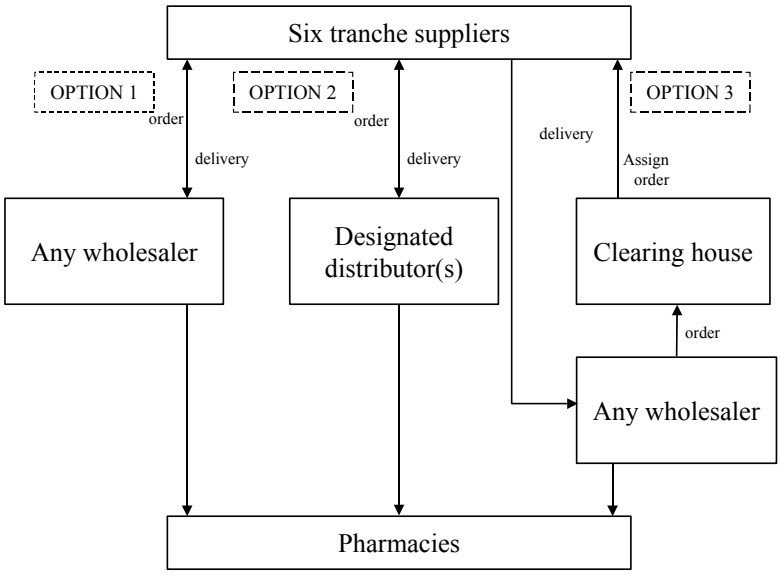
Tendering relies wholly on competition between manufacturers (and other suppliers) during the tendering process, not on competition further down the supply chain. To make this competition work, the NHS must commit to a certain demand volume for the winning bidder. Such commitment would be difficult if wholesalers and pharmacists had incentives to prefer one tranche supplier over another.

Means of preventing arbitrage are presented in sections 12.5 and 12.6. At any rate, it will be of crucial importance that pharmacists endorse properly, identifying the manufacturer of each drug dispensed.

A1.3 Options for distribution of tendered drugs

The distribution of the centrally tendered drugs could be arranged in three different ways, as illustrated in Figure 12.3.

Figure 12.3: Three options for distribution under full or partial tendering



A1.3.1 Distribution option 1

Distribution option 1 would basically preserve the existing distribution system, in that any wholesaler could order the tendered drug from any of the six tranche suppliers, and then deliver it to pharmacies on demand. The main difference with the existing system would of course be that the market price of the drug of each tranche supplier has been determined through the tender. Hence, the wholesalers would only function as distributors, not as intermediary traders, similar to their role in the existing agency schemes (as described in Phase I of this report). The wholesalers would receive a distribution fee for their services. How that fee might be determined is discussed in sub-section 12.5.4 below.

The disadvantage of distribution option 1 is that, even though the market price is fixed, wholesalers still have incentives to arbitrage if prices differ across the six tranches. For example, if the distribution fee were set as a percentage of the market price—a common practice in pharmaceutical wholesaling—then wholesalers would prefer the tranche supplier with the highest price, as this gives them a higher fee per delivery. This arbitrage is undesirable, as discussed above, because it makes it more difficult for the NHS to commit to a certain demand volume. A per-item or per-delivery distribution fee would not create such arbitrage incentives (see sub-section 12.5.4 below).

The other two options prevent arbitrage and allow volume commitment by the NHS to tranche suppliers.

A1.3.2 Distribution option 2

Under distribution option 2, a ‘designated distributor’ would take care of delivery of the drugs tendered for. A single distributor could be designated for the six tranches of the same preparation. In this case, the distributor is responsible for allocating demand across the six suppliers. Alternatively, each tranche supplier could have a different designated distributor.

The NHS could contract out, or put out for tender, the function of designated distributor for a certain preparation or group of preparations. Alternatively, tranche suppliers could negotiate the distribution arrangements themselves, and these could form part of the original bid in the tender. This is even more straightforward if tranche suppliers are wholesalers themselves (subject to minimum delivery requirements and non-discrimination between vertically integrated and independent pharmacies).

The main disadvantage of distribution option 2 is that distribution-chain efficiency may be lost. It has been suggested that many wholesalers, including even the national full-line wholesalers, do not have the capacity to distribute the entire national demand for certain preparations. In addition, pharmacists would have to order different drugs from many different designated distributors, so they might receive several deliveries a day. However, this is common practice in the book industry, where some bookstores may receive seven or eight deliveries without presenting any problems. A further difficulty is that vertically integrated wholesalers would have to deliver to pharmacists that are integrated with another wholesaler, while also delivering fewer products to their own pharmacists.

A1.3.3 Distribution option 3

The third distribution option prevents arbitrage and maintains existing efficiencies in the distribution chain. This option includes the creation of a clearing house. Any wholesaler can distribute any product. All orders must be placed at the clearing house, which then assigns the order to one of the six tranches, making sure that, on aggregate, sufficient demand is allocated to each of the tranches. The wholesalers can thus no longer choose a preferred tranche supplier (nor can the pharmacists).

This prevents arbitrage by wholesalers, and the clearing house can ensure that demand is evenly spread over the six tranches. It also allows the clearing house to monitor product flows from each tranche, which can be used for payment to the tranche suppliers. In other words, under the option where the NHS pays the suppliers after delivery into the distribution chain (see below), the clearing house can monitor when that delivery occurs. The clearing house does not receive any payments itself, nor is it involved in price setting.

Table 12.1 summarises the main advantages and disadvantages of the three distribution options.

Table 12.1: Advantages and disadvantages of the three distribution options

	Option 1: Any wholesaler	Option 2: Designated distributor	Option 3: Clearing house
Prevents arbitrage between tranche suppliers, allowing NHS to make demand commitments	No	Yes	Yes
Allows efficient monitoring of product flows from tranches	No	Yes	Yes
Maintains efficiencies of current distribution structure	Yes	No	Yes
Avoids vertically integrated wholesalers and pharmacists having to deal with competitors	Yes	No	Yes
Allows distribution to be part of bid in supply tender	No	Yes	No
Avoids creation of new government agency	Yes	Yes	No

A1.1.1 Setting the distribution fee

Wholesalers can be expected to have sufficient incentives to participate in this system as distributors, despite the fact that they can no longer make use of trading opportunities in the tendered generics as the market price is set between the NHS and the manufacturer/supplier. For example, wholesalers wish to offer pharmacies a broad product range, including generics as well as branded and PI drugs.

In addition, wholesalers still earn a distribution fee on generics, similar to the agency arrangements they currently have with some branded and generic manufacturers. Likewise, in the USA, where most drug prices are negotiated directly between the health maintenance organisations (HMOs) (and pharmacy benefit managers, PBMs) and the manufacturers, the role of the wholesalers is also mainly limited to distribution, rather than intermediary trading (see appendix 7).

Following the principle that each player should be paid or reimbursed after fulfilling its task (see section 12.4), the wholesalers should be paid the distribution fee by the pharmacists (see below) after delivery.

The way the distribution fee is determined could be a difficult issue. If the designated-distributor option is chosen (distribution option 2 above), the fee can be negotiated either with the NHS (possibly through a tender) or with the winning tranche suppliers. Under the other two options, where any wholesaler can distribute, the NHS should determine a single distribution fee for each tendered preparation.

During Phase I, the full-line wholesalers reported margins on generics of between 10% and 15% (net of discounts to pharmacies). In New Zealand, wholesalers receive a net fee of 10% of the manufacturer's price for distributing tendered generic drugs. This percentage is based on historical practice.

Alternatively, a per-item or per-delivery fee could be set instead of an ad-valorem fee. A major advantage of per-item fees is that arbitrage incentives are reduced. This would be appropriate under the option where the NHS pays the tranche suppliers directly (see below), so the wholesalers no longer 'own' the products they handle, and therefore do not incur financing risks. A hybrid of a per-item and an ad-valorem fee is also possible.

Finally, it should be noticed that, under distribution options 1 and 3, where any wholesaler can distribute the tendered drugs, there is still scope for some competition between wholesalers in selling to pharmacists. Wholesalers could offer discounts to pharmacists, although the upper bound of this discount would be the fixed distribution fee, since the tranche supplier's price is fixed.

The additional discount might be clawed back through the Discount Inquiry or left in the system. However, such discounts are likely to be low, and the NHS's commitment to the tendering system would be more credible if it focused on the creation of competition through the tender itself.

A1.2 Three options for reimbursement of tendered drugs

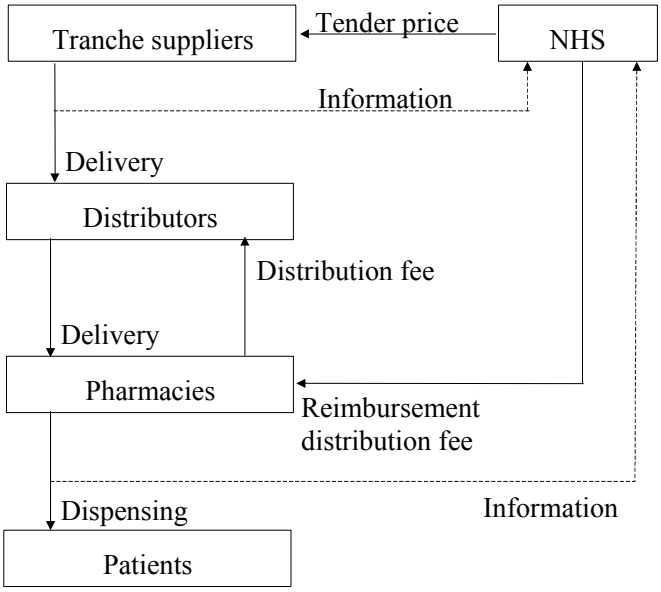
There are three options for pharmacy reimbursement of tendered drugs, with different implications for payment flows throughout the chain. In principle, each of the reimbursement options is compatible with all three distribution options assessed above.

However, it is indicated below that some combinations of distribution and reimbursement options might be preferable over others.

A1.2.1 Reimbursement option 1

Under reimbursement option 1, illustrated in Figure 12.4, the NHS pays the tranche supplier the tender price directly after delivery of the product into the distribution chain. This implies that neither the distributors nor the pharmacists 'own' the product as it is moved through the chain—ie, they no longer pay the product price to their direct supply source.

Figure 12.4: Reimbursement option 1 for full or partial tendering



The advantage of this option is that arbitrage by wholesalers and pharmacists between tranche suppliers is minimised. There are also no incentives to bypass the tranche suppliers and obtain products from suppliers that did not win the tender.

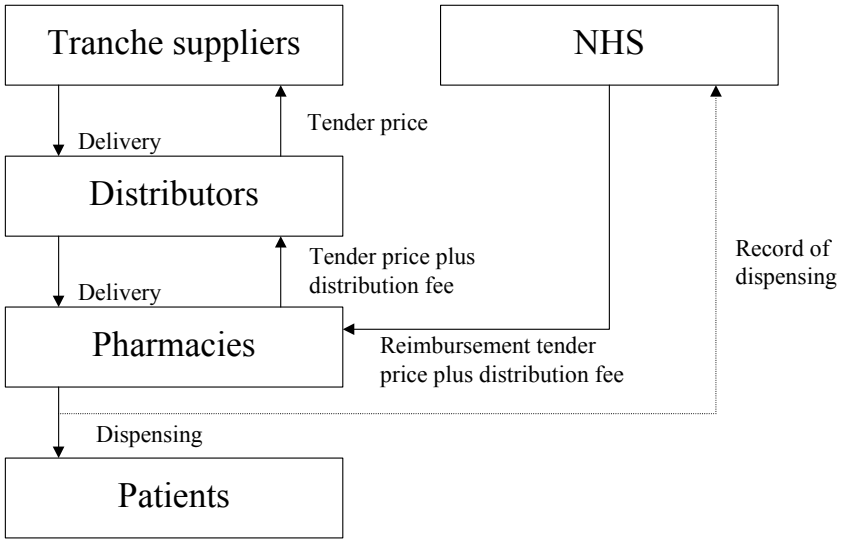
The main disadvantage is that wholesalers and pharmacists may have incentives to hold excessive stocks—although this would be mainly for their own convenience or precaution, and not for speculation, since the market price is fixed. This may, however, lead to products 'disappearing' abroad, although this would amount to theft, and might be prevented through policing and standardisation of 'NHS-branded' packs—perhaps with 'Only licensed for dispensing in the UK' on the foil. The ideal solution would be a system that allows the monitoring of tendered products throughout the chain, from manufacturing to dispensing.

Distributors can just order the product without paying for it. Once they deliver the product to pharmacies, they receive the agreed distribution fee for their service. Pharmacists have to pay the distribution fee, which will to some extent limit incentives to hold excessive stocks. The NHS reimburses the distribution fee to the pharmacist after a product has been dispensed. This would be through the current reimbursement mechanism, the difference being that the agreed distribution fee, rather than the Drug Tariff price, is reimbursed.

A1.2.2 Reimbursement option 2

Under reimbursement option 2, illustrated in Figure 12.5, wholesalers and pharmacists would pay for the products and therefore 'own' them as they move through the chain. This is similar to the existing system (although the market price and the distribution fee have been fixed). The wholesaler pays the tranche supplier the agreed tender price after delivery. Next, the pharmacist pays the wholesaler the tender price *plus* the agreed distribution fee. This differs from current business practice, where the distribution fee is usually implicit (and hence also less transparent) in the price paid by the pharmacist. Finally, after dispensing, the NHS reimburses the tender price plus distribution fee to the pharmacist.

Figure 12.5: Reimbursement option 2 for full or partial tendering



One advantage is that this option does not create incentives to hold excessive stocks or smuggle products abroad.

In addition, the NHS would pay for the products at the end of the chain (ie, after they are dispensed), as in the current system. Under reimbursement option 1 above, the NHS would already have to pay the tranche suppliers up front (ie, after delivery into the distribution chain). This can be several months earlier, depending on how fast products move through the chain. However, the difference may be less if tranche suppliers allow later payments. Standard terms can be as much as 120 days.

The main disadvantage of reimbursement option 2 is that wholesalers and pharmacists still have incentives to prefer some tranche suppliers over others, so this may lead to arbitrage. If option 2 is implemented, then arbitrage should be prevented at the distribution level of the chain, either through designated distributors (distribution option 2, described in section 12.2) or a central clearing house (distribution option 3). Arbitrage by wholesalers may also be prevented by setting per-item or per-delivery, rather than ad-valorem, distribution fees. In addition, managing a system with multiple reimbursement prices for the same preparation is costly, and requires significant information flows from pharmacy to the PPA.

This option could also create incentives to bypass the tranche suppliers completely and obtain the product from suppliers that did not win the tender. However, this is only worthwhile if outside prices are lower than the agreed tender prices. In these cases, such bypass could only be prevented by making it illegal.

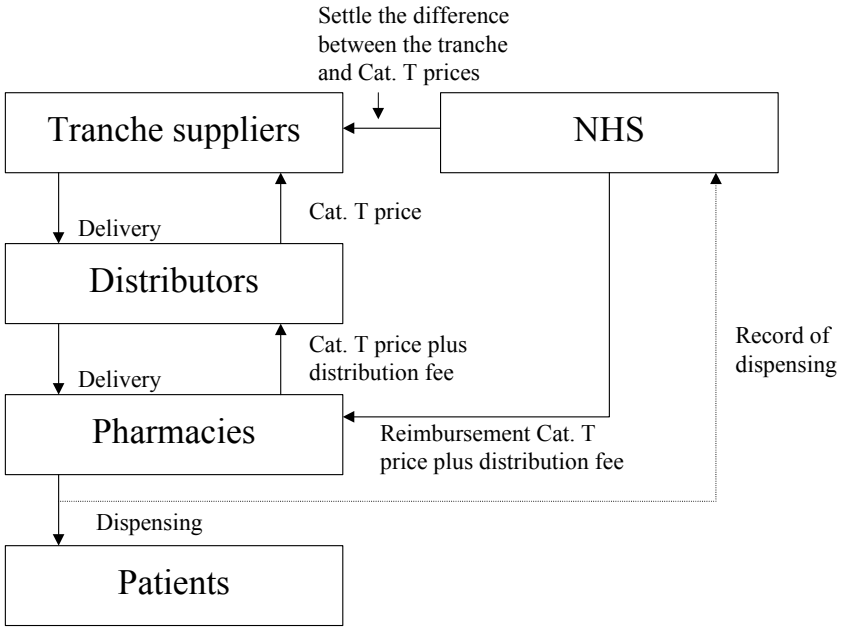
Another disadvantage under this option is that the actual tender prices of each of the suppliers would have to be publicly revealed. Not revealing these prices may be beneficial in terms of making the tendering process more competitive and reducing the probability of collusion. Reimbursement options 1 and 3 (below) do not require tender prices to be revealed. However, the NHS may still want to reveal the tendering outcomes for transparency purposes, and the success of competitive tendering does not crucially depend on whether prices are revealed.

A1.2.3 Reimbursement option 3

Under reimbursement option 3, the possibility of price differentials among the tranche suppliers of a certain preparation is maintained, but the NHS would set a single price to be paid by wholesalers and pharmacists for that preparation. The difference between this single price and the price of each tranche supplier agreed in the tender is settled directly between the NHS and each tranche supplier.

The single price for a tendered preparation would function as a Drug Tariff price, and could be presented as such. For example, a new 'Drug Tariff Category T' could be introduced, listing the prices set by the NHS for each of the tendered preparations. The difference with existing Drug Tariff prices is that the Category T price is the price paid by *wholesalers* to the tranche suppliers. Pharmacists, in turn, pay the wholesalers the Category T price, plus the predetermined distribution fee (see the previous sections). The NHS then reimburses pharmacists the Category T price plus the distribution fee. The process is illustrated in Figure 12.6.

Figure 12.6 Reimbursement option 3 for full or partial tendering



Thus, under reimbursement option 3, possible price differentials between the tranche suppliers of a certain preparation—which should be allowed in order for the staggered-tendering scheme to function, as explained in section 12.4—are not passed on downstream into the distribution chain. This has several advantages:

- as under reimbursement option 1, wholesalers and pharmacists are indifferent as to which tranche supplier to buy from because they pay the same (Category T) price to each. This prevents arbitrage, and gives the NHS the option not to reveal the prices resulting from the tenders;

- as under reimbursement option 2, wholesalers and pharmacists pay a near full price for the products they trade and dispense, thereby reducing incentives to hold excessive stocks or smuggle products abroad (under reimbursement option 1 pharmacists only pay the distribution fee).

Two questions remain to be answered:

- how should the Category T price be determined?
- how should settlement between the NHS and the tranche suppliers take place?

In principle, the precise level of the Category T price is irrelevant, since any differences with the agreed tender prices are settled with the tranche suppliers.

However, it is important to set the Category T price *below* the lowest agreed tender price. Otherwise, tranche suppliers, wholesalers and pharmacists would have an incentive to bypass the tendering contract. The supplier would sell the product at a higher price than agreed with the NHS (but below the Category T price), and the wholesalers and pharmacists would buy this product because they would be paid the Category T price. Thus, the Category T price should be set as a certain percentage of the lowest price of the six tranches—for example, 60%.

Another important factor is that, once the Category T price has been determined, it should not be changed too often. This is because every change brings with it transitional problems, For example, a reduction in the Category T price would affect pharmacists with remaining stocks of products which were acquired at the previous, higher, price. Section 15.3 discusses in more detail how such transitional problems could be dealt with.

Providing that the following rounds of the staggered-tendering scheme lead to prices above the Category T price, adjustments are not necessary, even if the initial lowest tranche price is no longer the lowest.

An additional benefit is that the resulting Category T price would be quite low, and bypass of the tranche suppliers would be less likely than under reimbursement option 2. Only in the rare case that an outside supplier can underbid the Category T price would there be incentives to bypass. In these cases, such bypass could only be prevented by making it illegal.

With regard to settlement, it is important to note that this would require extensive monitoring. Reimbursement option 3 could therefore best be implemented in combination

with distribution option 3 (see above), which involves a clearing house. The ideal solution would be a system that allows the monitoring of tendered products throughout the chain, from manufacturing to dispensing.

Since the Category T price will be designed to be lower than all the different tranche prices, settlement will involve the NHS paying the difference to the tranche suppliers (ie, settlement is one-way). This settlement could take place upon delivery of the product into the chain, consistent with the principle that every player is paid after fulfilling its task (reimbursement options 1 and 2 are also consistent with this principle).

Alternatively, settlement could take place after the product has been dispensed. For the NHS this has the advantage that it would fully pay for the products only at the end of the chain (ie, after they are dispensed). This is similar to the current system. The tranche suppliers would only receive the Category T price upon delivery into the chain, and receive the remainder after the product is dispensed. If the Category T price is set significantly below the agreed tender price, then this might make participation in the tender less attractive.

Table 12.2 summarises the main advantages and disadvantages of the three reimbursement options.

Table 12.2: Advantages and disadvantages of the three reimbursement options

	Option 1: Distribution fee only	Option 2: Full tender price	Option 3: Category T price
Prevents arbitrage between tranche suppliers, allowing the NHS to make demand commitments	Yes	No	Yes
Reduces the likelihood of bypass via non-winning suppliers and PI	Yes	No	Yes (partly)
Reduces likelihood of excessive stock holding and smuggling products abroad	No	Yes	Yes (partly)
Allows the NHS to pay for drugs after dispensing	No	Yes	Yes (if settlement is delayed)
Gives the NHS the option not to reveal winning tender prices	Yes	No	Yes
Reimbursement prices can be announced in the Drug Tariff, thereby providing clarity to pharmacists	Yes, but only distribution fee, so may look unfamiliar	Yes, but different prices for different tranches may cause confusion	Yes
Transitional problems are only one-off	Yes	Yes	No
Follows the principle that each player is paid after delivery	Yes	Yes	Yes (if settlement is immediate)

A1.1 Tendering option 1 (full) versus tendering option 2 (partial)

The tendering scheme described in this section, including the various options for distribution and reimbursement, can be used for both full tendering (option 1) and partial tendering (option 2). The scheme is designed for preparation-by-preparation tendering, so

it does not matter whether all, or only a part of, the generic preparations are tendered in this way.

Partial tendering does have some advantages over full tendering.

- Partial tendering of only a limited number of drugs would be easier to administer. There is a rump of generic drugs that are only infrequently prescribed, so the cost savings obtained through tendering these drugs are unlikely to offset the cost of setting up and administering tenders for them. The Department's short-term arrangements also apply to a limited number of drugs. Possible criteria to select those drugs that are tendered for are examined in section 15.

- Under partial tendering, the appropriate status of a given presentation could be monitored (ie, either tendered or open market). If market conditions change, new presentations could be absorbed into the tendering process.

With partial tendering, the NHS can still rely on the existing supply-chain competition for those drugs that are not tendered. However, there are some risks of having such a dual system.

First, if the partial tendering covered a substantial proportion of total generic prescriptions, only excluding a few infrequently prescribed drugs, the supply of these drugs might be affected (since, at present, these drugs are often subsidised by manufacturers offering a full range of products). On the other hand, supply of these infrequently prescribed drugs is unlikely to be competitive under the current system either. It is likely that the possible increase in price of the infrequently prescribed drugs would be more than offset by the price reductions for the tendered drugs.

Second, if partial tendering only covered a few frequently prescribed drugs, manufacturers might seek to cross-subsidise the tendered drugs with receipts from drugs sold in the open market, especially if the latter are not competitive. However, incentives to do so are probably limited. Cross-subsidies currently occur from the community sector to the tendered drugs in the hospital sector. However, cross-subsidies between the hospital and community sectors are mostly made by the branded companies, and for the same drug (ie, the same drug is sold at a lower price to hospitals than to the community). Intra-drug, intra-community cross-subsidy cannot occur under tendering since the entire community demand for a specific drug is tendered.

A2. Tendering Option 3: Tendering for Buffer Stocks

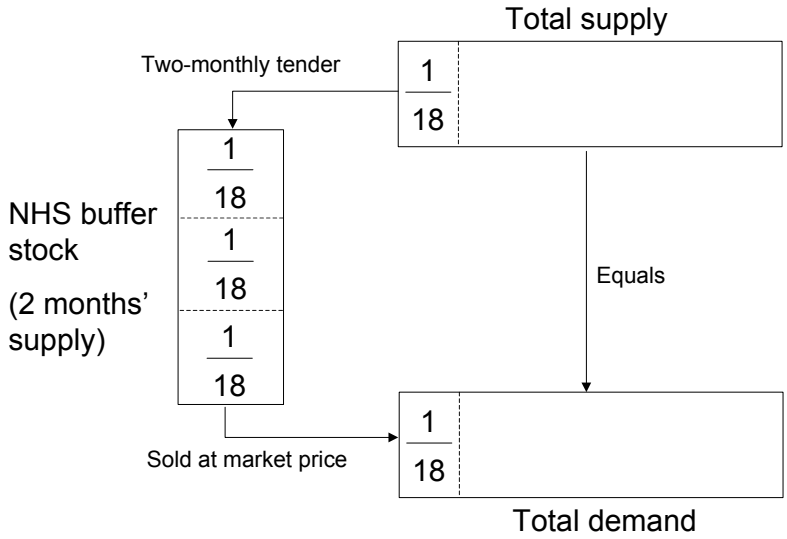
A2.1 How buffer-stock tendering would work

Tendering for a buffer stock is the third tendering option presented in this report. It aims specifically at the Department's objective of preventing shortages and maintaining price stability. Buffer-stock tendering can be implemented leaving the current supply system intact. However, in principle, it could also be implemented in combination with the full or partial tendering options presented in section 12.

Under this third option, the NHS would tender for the supply of, say, 15–20% of total annual demand for certain preparations, to be kept and managed by the NHS as a buffer stock. This buffer stock would on a first-in, first-out basis, to ensure that it was always within the appropriate shelf life.

Thus, the tenders would be required continually, but for relatively small volumes after the initial acquisition. For example, suppose the shelf life of a drug is two years, and that it is still acceptable for the NHS to place the drug in the supply chain with a remaining shelf life of 18 months. Now, the equivalent of one-sixth (16.6%) of total annual demand for the drug is tendered to form the initial buffer stock—sufficient to satisfy two months of demand. Every two months, the NHS sells one-third of this stock—or one-eighteenth (5.6%) of total demand—into the supply chain, at the prevailing market price. At the same time, the NHS organises another tender to replenish the buffer stock by the same amount. (It should be noted that the proportion and duration used in this example could be varied in practice.) This process is illustrated in Figure 13.1.

Figure 13.1: Buffer-stock tendering (tendering option 3)



Hence, once the process has been in operation for over six months, the buffer stock will always consist of three equally sized tranches, the first with a shelf life of 22–24 months, the second of 20–22 months, and the third of 18–20 months. The third tranche will be the first to be sold into the supply chain at the end of the current two-month cycle. Each of the three tranches could, in principle, be supplied by a different manufacturer or wholesaler, depending on who wins each tender.

Furthermore, in each period, total industry supply equals total market demand, with one-eighteenth of total supply being bought by the NHS and one-eighteenth of total demand being provided from the NHS buffer stock. The only exception is the first period, when total supply has to exceed total demand by one-sixth in order to form the initial buffer stock.

In case of a shortage—still signalled via the PSNC and the PPA—the NHS can supply its stocks into the market at the prevailing Drug Tariff price, or at the contract price it obtained in the tender. This gives a breathing space of two months for the supply chain to resolve any manufacturing problems. It may also be possible to have a call-off clause in the tender contract with the buffer-stock supplier(s) to provide back-up supply in case of a shortage. Moreover, the supply from the buffer stock could be combined with rationing, to ensure that the drug is evenly distributed across the country.

The buffer stock is similar to an exchange-rate intervention—although with more limited means than those of a central bank. Buffer stocks are also used in many other commodity markets, such as rubber and coffee, although in most of these cases, as well as in exchange-rate interventions, the prime objective of the buffer is to achieve price stability, not security of supply.

An additional advantage of buffer-stock tendering is that it could be used as a means to retain a number of suppliers (up to three) in the market, thereby helping to prevent excessive concentration. It could also be used to assist a new entrant. Should the market become highly concentrated and prices rise, these alternative suppliers may be able to expand production quickly. For this to be effective as a mechanism of maintaining competition, the buffer-stock tender should be closed to the one or two existing manufacturers with the largest market shares.

Choosing the drugs to hold as buffers is complicated. It may require modelling of both supply and demand, in order to hold only those with a critical risk of shortage. A proxy may be those drugs of critical importance in a health sense, plus those with a limited number of licence-holders.

A2.2 Potential disadvantages of buffer-stock tendering

Buffer-stock tendering also has some important disadvantages.

- The whole process would need to be actively managed by the NHS. Managing the shelf life and deciding which drugs to hold in the buffer requires significant market knowledge from the buffer-stock manager.

- Continually supplying into the open market could be problematic. First, the NHS bears a price risk if the spot market price falls below the contract price. Second, the suppliers may anticipate the buffer supply, knowing that the NHS needs to sell the product every two months. They may therefore attempt to drive the price down below the spot market level. This could be resolved by a contract with a 'designated' wholesaler to take the product at a 'reasonable' market price (or the Drug Tariff price), perhaps with the accompanying condition that the same wholesaler would be the conduit for the stock at times of shortage.

- As with exchange-rate intervention, the buffer stock only works for temporary shortages, not for serious shocks. The call on the buffer stocks would be extremely rapid in the case of a shock, and two months' worth of supply may be insufficient. Hence, during those two months, the NHS should actively encourage entry.

- Once the buffer stock is exhausted, the market price jumps up again. Thus players may have an incentive to delay (re-)entry until this happens. This means that shortage situations, once officially triggered, might not be resolved within the two months.

- Finally, holding buffer stocks is expensive. First, it requires an up-front investment equal to one-sixth of total annual sales of the drug, which can be substantial. Second, holding the stock bears an opportunity cost of working capital. Third, the NHS runs a price risk by buying on contract and selling into the spot market. In addition to financial costs, the NHS has to store the buffers in appropriate warehouse facilities (perhaps rented from manufacturers or wholesalers).

An alternative to buffer-stock holding is signing back-up supply contracts with manufacturers. For example, in New Zealand, PHARMAC, the authority that manages the generic drug tenders (see appendix 9), is considering back-up supply contracts for critical drugs. One option under consideration is to negotiate a contract with an Australian supplier for emergency supply with 24 hours' notice.

However, if the NHS followed this example, it would not be in control of the buffer stock, and monitoring the reliability and sufficiency of the emergency supply source could be problematic. In addition, it should be noted that New Zealand is a relatively small market, which allows it to rely on surpluses from the Australian market. The UK is not in this position.

A3. Tendering Option 4: Tendering for Framework Agreements

The fourth tendering option presented in this report is similar to the tendering system set up by the NHS PASA for the hospital sector (described in appendix 7). It involves tendering for framework arrangements with manufacturers, which wholesalers and pharmacists have the option to use for the purchase of their drugs.

In this system, manufacturers bid to become the framework arrangement supplier, whose role is to supply the drug in question to any pharmacist at the agreed framework price (although the wholesaler used to deliver the product should be paid a distribution fee, see below). The manufacturer that offers to provide this service at the lowest price wins the tender.

Effectively, the framework price will function as the maximum price that any wholesaler or manufacturer can charge to pharmacists for that drug. It is therefore also the maximum reimbursement price paid by the NHS.

In this sense, the system is similar to the short-term arrangements implemented by the Department, which also set maximum prices on the sale of drugs to community pharmacists (and dispensing doctors). Drugs can still be traded along the different levels of the chain at prices below the maximum price. The Drug Tariff price could also be lower if other Drug Tariff basket suppliers offer cheaper list prices than the framework supplier; however, prices will not be above the framework price since any pharmacy has access to this price.

The main problem of tendering for framework arrangements—which also exists in the hospital sector—is that the supplier receives no commitment from the NHS in terms of volume demanded under the arrangement. The framework supplier could be completely bypassed if the market price turns out to be lower than the framework price, whereas it could be required to supply 100% of demand for that drug if the market price rises above the framework price. This could make bidding in the tender unattractive, and, as a result, the framework price determined via the tender could turn out much higher than the prevailing market price, rendering it meaningless.

In fact, the framework agreement is similar to a financial instrument called an 'American call option'. Pharmacists—like hospitals under the NHS PASA framework agreements—have the option, but not the obligation, to buy the product at the specified price from the framework supplier at any point in time until the framework agreement expires.[26] The framework supplier has the obligation to supply the product at the specified price. Via the tender, the NHS buys this American option on behalf of the pharmacists. The manufacturer is the seller (or 'writer') of the option.

In financial markets, buyers of the option pay a premium to the seller of the option. In this example, the NHS would pay this premium to the framework supplier the moment the contract is signed. With extensive market information and sophisticated analysis, the value (or premium) of the framework arrangement could be calculated. According to

[26] *Call* options give the right, but not the obligation, to *buy* a certain good at a certain price. *Put* options give the right, but not the obligation, to *sell* a certain good at a certain price. *American* options can be exercised throughout the lifetime of the contract. *European* options can only be exercised at the date of expiry of the contract.

option pricing theory, in particular the Black–Scholes formula,[27] this premium depends on several factors:

- *the volatility of the returns of the underlying good*—here this would be the volatility of the market price of the drug in question. The higher the volatility, the higher the premium for the option;
- *the strike price*—here this would be the agreed framework price. The lower the price, the higher the premium for the option;
- *the market price*—this is the price of the underlying good (ie, the drug) in the market. The higher the price, the higher the premium for the option;
- *the risk-free rate*—this refers to the risk-free interest rate in the market;
- *the time to expiry*—this refers to the duration of the contract (ie, the framework arrangement). The longer the duration, the higher the option premium because the future price of the drug in question becomes more uncertain.

This premium could be determined by letting participants in the tender bid in two values as a package:

- the price at which the participant would supply the drug to pharmacists; and
- the option premium which it would ask from the NHS in return for making the framework arrangement.

The manufacturer that bids in the most attractive combination of these values (ie, the lowest weighted-average value of the package) would win the tender. Assessing the weighted-average value of the bid package is feasible, since the option premium depends in part on the framework (strike) price, as explained above. Owing to the complexities involved, such a complicated option valuation assessment of any bids received may not be feasible. This may make it difficult for the NHS to choose between different proposals.

A further question is how to determine the appropriate distribution fee. To some extent the issues here are the same as those discussed in section 12.5.2 above. In the Department's short-term arrangements, the maximum prices refer to sales to pharmacists. These prices are also maximum reimbursement prices to pharmacists, so the pharmacists will not be willing to pay a distribution fee in addition to those prices. Hence, the distribution fee to wholesalers must come out of the maximum price, and will have to be negotiated between manufacturers and wholesalers.

In this tendering option, paying the distribution fee out of the agreed framework price would make participation in the tender even more unattractive to manufacturers. Hence, it would be more appropriate (as in tendering options 1 and 2 discussed in section 12) to determine a distribution fee on top of the framework price for drugs purchased under the framework agreement. Pharmacists would have to pay this distribution fee to the wholesaler, and the NHS would have to reimburse this amount to the pharmacists.

[27] Black, F. and Scholes, M. (1973), 'The Pricing of Options and Corporate Liabilities', *Journal of Political Economy*, **81**, 637–59.

A4. Setting Up a Pilot for Tendering Option 2

If the Department wishes to pursue a centralised purchasing scheme, whether full or partial, it would seem sensible either to introduce the scheme gradually, or to conduct a pilot scheme.

It has been discussed elsewhere how making changes to only part of an imperfectly competitive market is unlikely to succeed—for example, driving down prices in the hospital sector may simply lead to higher prices in the primary-care sector, as companies are able to cross-subsidise between the two. For the same reason, it would be difficult to conduct centralised purchasing for only a proportion of the supply of any one drug. If, for example, centralised purchasing were introduced for one drug in one geographic region of England, pharmacists in that region could sell the product on to other regions, and undermine the pilot. It may be possible to tender for supply to one region of the country, and produce packs that state 'Only to be dispensed in the south-east region', although this may be insufficient to prevent product leakage. This would then require additional changeover costs if it were subsequently to be rolled out nationwide.

To pilot the centralised tendering scheme, it would appear sensible simply to choose a small number of drugs, and tender them first nationwide. If the scheme proved successful, it would then be possible to add more drugs to the tender list.

The pilot tendering scheme should be similar in scope and design to the desired full tendering scheme. The remainder of this section assumes that the tendering option chosen is that described in section 12 (ie, tendering option 2). In this option the NHS predicts demand and offers manufacturers financial guarantees (ie, it will compensate manufacturers if demand falls below the range agreed in the contract), but does not actually purchase the drugs directly. The drugs are purchased in the normal way, but reimbursement is fixed by the tender price plus a wholesale/distribution/dispensing margin, and orders are processed either through a central clearing house, or distribution is handled by one preferred company. This is the simplest option because it requires the least change from the current situation. However, the pilot tendering scheme could easily be adjusted to test the other tendering options.

In designing this initial scheme, it is necessary to define criteria for determining which drugs to include in the tendering process and how the success of the scheme will be judged. Additional measures that may be necessary to manage the transition process also need to be designed.

A4.1 Selection criteria

Criteria for selecting products (chemical entities or preparations) for the initial tendering round might include:

- *predictability*—on inspection of quarterly demand data, it is clear that drug demand is predictable, but it might be sensible to start with drugs where demand is more or less constant (ie, those for which demand is most easily predicted);
- *volume*—if the scheme is to be a useful test of the tendering system, it makes sense to choose high-volume drugs;

- *cost*—the potential for savings may be higher for high net cost drugs, although it might be easier to manage the transition period (eg, by building a safety stock) if the drug is cheap;
- *recent problems*—testing the system with a drug that has been in short supply recently might provide a high-profile demonstration that the new system has merit;
- *number of licence-holders*—the number of companies potentially able to tender is obviously limited by the number of primary licence-holders. As such, selecting several drugs with different numbers of licence-holders would be a good test of the new system (any drug with only one licence-holder would require the Department to enter into price negotiation); and
- *availability of therapeutic alternatives*—the precautionary approach might be to choose drugs that have a readily available close therapeutic alternative, in case of any supply problems. (This could be the branded equivalent, a different strength of the same generic, or possibly a near equivalent drug. The first two would not require a new prescription to be issued, so care would be needed to ensure that this did not lead to 'leakage' from the tendering system.)

The list of drugs chosen for the first round of tendering should all have therapeutic alternatives available. It would be sensible to include mostly drugs with at least three licence-holders. At least one of the drugs should be one that has experienced recent problems (either shortages or price spikes). If more expensive drugs were tendered, the scope for cost savings would be higher. However, the cost of maintaining back-up stocks or dealing with any supply problems would be greater.

A suggestion for the initial list of drugs that could be tendered is presented in Table 15.1 below. It includes drugs that are high-volume but which have a low unit cost, and some where the scope for savings is greater. OXERA has not, however, attempted to choose drugs with available therapeutic alternatives.

Table 15.1: Pilot scheme sample drug preparations

	Vol. (items, m)	Vol. (rank)	Cost (NIC/£m)	Cost (rank)	% of total cost	Licence-holders	Alternative preparations	Problem/ shortage
Warfarin Sod tablets (3mg) *mid-vol., mid-cost*	79	51	4.8	48	0.5	5	1mg, 5mg and two liquid specifications	only in 1mg preparation
Thyroxine Sodium tablets (25mcg) *mid-vol., mid-/low-cost*	122	35	4.1	57	0.4	3	yes, different strengths	yes
Aspirin Dispers tablets (75mg) *high-vol., low-cost*	607	1	3.6	61	0.4	8	yes, different strengths, branded alternatives	no
Amoxycillin oral suspension (125mg/5ml) *high-vol., low-cost*	225	25	2.7	81	0.3	17[1]	yes, different strengths, and tablets, capsules	no
Frusemide (40mg) *high-vol., high-cost*	286	7	16.5	7	1.8	[2]	different strengths	no
Co-Proxamol (32.5/325 mcg) *high-vol., high-cost*	955	3	13.5	9	1.5	12		no

Note: [1] Licence data for 250mg preparation. [2] Licensing information not currently available.
Source: OXERA calculations; drug data from Department of Health, Statistics Division; licence data from MCA.

The total annual cost of these six preparations is around £45m.

A1.1 Preparatory market information

This is the information that would need to be collected to draw up the list of products that are to be tendered. As discussed in the preceding sub-section, this is mostly licensing information. While this information is available from the MCA, it is not always apparent whether all of the licence-holders are in a position to manufacture the product. For example, several licences for the same product may belong to subsidiaries of the same manufacturer, perhaps following takeover activity. Before beginning the tendering process, it would be sensible to discover how many firms currently manufacture (as opposed to simply supply) each product, and how many could do so in a reasonably short timescale.

A1.1.1 Pre-qualification

A pre-qualification round could be used to collect and analyse information about potential bidders outside the timescale of the bidding process itself. For example, this process might address financial positions of potential tenderers—are finances sufficiently secure that contracting with them would not prejudice security of supply (ie, do bidders have the resources to pay penalty clauses)?

Care would be needed to ensure that any formal pre-qualification procedure was legal and not unfair to any potential bidders (especially new entrants). For example, while it might be reassuring only to contract with manufacturers that can demonstrate a history of good service levels, this would be a barrier to new entry.

A1.1.2 Invitations to tender

Prior to the formal announcement of the tender, the NHS should consult on its plans to tender. As the tender award being discussed in this report would exceed the threshold determined for public authorities purchasing supplies, any tendering design must take into account the European Commission procurement rules under the ruling of the EEC Treaty, European Economic Area Agreement.[28] The European Commission procurement rules require that contracts covered by the regulations must be the subject of a call for competition by publishing a contract notice in the *Official Journal of the European Communities* and its electronic equivalent, *Tenders Electronic Daily*. In most cases, time allowed for a tender must be no less than a specified period.[29]

A1.1.3 Information requirements in tenders

In addition to the price information, tenderers could also be asked to submit information that would contribute to the qualitative assessment of the tenders. This might include, where possible:

- company structure, financial resources, and demonstration of ability to fulfil the contract;
- record of historic ability to supply;
- all relevant licensing information, including the identity of plants and suppliers that will be used to fulfil the contract, and any back-up arrangements that are in place (this might include option contracts for supply of ingredients from alternative suppliers);
- distribution and stock-management arrangements; and
- any additional steps that will be taken to guarantee supply.

A1.2 Transition process

A number of problems might become apparent during the transition from the current system to the tendering scheme. Also, since a rolling staggered-tendering system is being proposed, it would be necessary to treat the first round of tendering differently from subsequent rounds. The first tendering round would call for bids for the six tranches of the market. The first tranche would be for four months, the second for eight months, and so on up to the full two years. All of the tranches would start on the same date. In subsequent rounds every four months, one of these tranches will always finish at the same time as a new one starts.

The transition from the current system to the tendering arrangement needs to be managed because of the stock in the supply chain. It is likely that some manufacturers that were not

[28] As implemented into UK law by Regulations made by the Treasury under Section 2(2) of European Communities Act 1972.

[29] Guidance on the European Commission rules and their application can be obtained from the Procurement Policy Division, HM Treasury.

awarded a contract would have unsold stock, and wholesalers and pharmacists will hold stock that will not be eligible for reimbursement under the new scheme.

The solution to this otherwise redundant stock could be simply to announce the results of the tender some weeks before the contracts start, and to allow a transition period where old stock is reimbursed at the old price, followed by a period at which old stock is reimbursed at the new price. After that only new stock would be reimbursed. This is the system that has been used in New Zealand (see appendix 9).

If the government decided to pursue a tendering system where the NHS owned drugs in the supply chain, rather than reimbursing pharmacists as at present, the transition process would expose it to the risk of paying twice for some stock in the chain during the transition. This risk would have to be appropriately shared between pharmacists, wholesalers, and the NHS, but would probably lead to at least some additional cost to the NHS. If the NHS tried to reduce this cost too far, pharmacists might run their stocks to dangerously low levels during the transition period in order to avoid the possibility of not being reimbursed for stock for which they had already paid.

In addition, at the point when the new system begins to operate, wholesalers will need to route their orders for the tendered drugs via a central clearing house. It may be necessary to negotiate with at least some wholesalers to ensure that the necessary adjustments to their ordering systems are made and tested before the new system starts.

A1.3 Institutional arrangements

In order for the tendering system to operate, the following functions must be performed:

- administration of the tendering process (publication in the *Official Journal*, writing contracts, receiving tenders);
- collecting information about the operation of the scheme;
- managing and overseeing transitional arrangements;
- collecting orders from wholesalers and assigning the appropriate volumes to all of the manufacturers that have been awarded contracts.

These functions could be performed by a new institution, although they could be fulfilled by existing institutions, at least at the pilot stage.

- The NHS PASA is experienced at conducting a tendering process for generic drugs in the hospital sector. It might be sensible for this organisation to be responsible for operating the tendering process in the primary-care sector also. While many products are only used in hospitals, many are prescribed in both hospitals and the community sector. It would be possible to combine the tendering arrangements for these products so that hospitals would purchase drugs from the same manufacturer as pharmacies in the primary sector, using the same system. NHS PASA could also collect information about the operation of the scheme and its impact on the market—for example, the evolution of tendered prices through time (all tenders, not just the winning ones), and the number of bidders at each round.

- The newly formed Office of Government Commerce (OGC) has been established as the central procurement organisation for the various departments of the UK government. The OGC will be responsible for formulating an integrated government procurement policy and strategy. It has been established with the purpose of undertaking procurement on behalf of departments and agencies where aggregation of purchasing could allow for significant value-for-money improvements. The OGC could prove to be a useful resource in the implementation of centralised purchasing of generic pharmaceuticals.

- The PPA already collects a significant amount of information. It would be in a good position to oversee the transition arrangements between the current system and a tendering system, discussed above. Information and audit on stock levels, prescribing rates, and reimbursement would be required. Since the PPA already collects prescribing information (ie, demand information), it may be sensible for this organisation also to act as the clearing house, assigning orders to appropriate manufacturers (under the system where the NHS purchases drugs directly, and then reimburses pharmacists only for dispensing and wholesaling). IT systems could facilitate this role (and other aspects of the PPA's work).

A1.4 Criteria of success

The first sign of success will be if realistic tenders are received, and if bids are received from most of the potential bidders (licence-holders). While some resistance from manufacturers to these proposals would be likely, if the drugs tendered are sufficiently valuable they will have a strong financial incentive to bid.

Volumes tendered and actual dispensed volumes should correspond to predicted demand, and the introduction of tendering should not alter demand for the products tendered. Supply problems should be dealt with without compromising patient care.

If the tendering system chosen is one where the NHS purchases the drugs and then reimburses pharmacists a wholesale/dispensing fee, there should be no significant fluctuations in volumes ordered by wholesalers that are not driven by demand from patients. Such fluctuations might indicate that wholesale/dispensing fees were set too low to effectively discourage hoarding. This fee should also be sufficiently high that, together with other measures (such as pack design and labelling), there is no theft of NHS drugs for sale abroad or under the counter in the UK. Such theft would show up as a discrepancy between volumes ordered by wholesalers and paid for by the NHS, and prescribing information.

There should be no significant market concentration (ie, the number of regular bidders should not fall in successive rounds).

Through time, in the absence of external shocks, tender prices should fall relative to the prices of non-tendered drugs (unless there are significant cross-subsidies which are revealed as the tendering process proceeds). If the scheme were to be judged successful, new drugs could be added to the tender list.

A2. Impact Analysis

The introduction of competitive tendering will result in a radical change to the generic drugs supply chain and may also have effects on other drug purchasing arrangements. This section critically analyses the full tendering option in particular, assessing how each element in the chain will be affected (sections 16.1 to 16.3) and estimating broadly the likely costs and benefits of the new policy for the Department/NHS (section 16.4). The impacts of the other tendering proposals—the buffer-stock arrangements and the framework agreement—are covered in the specific sections. Finally the possibility of achieving similar outcomes through more remedial changes, such as some of those proposed in Phase I, is then considered in section 16.5.

A2.1 The impact on manufacturing

The response of those manufacturers already active in the UK market to the suggestion of any form of centralised purchasing through competitive tendering has been uniformly negative. Some foreign manufacturers were more encouraging, perhaps seeing an opportunity therein. Section 11 broadly outlined the advantages and disadvantages of tendering, drawing on these comments. The key issues that have been raised by manufacturers are outlined, and each is addressed in the sub-sections that follow:

- monopolisation of supply is likely, as manufacturers claim that they will drop out of markets if they do not win the first (or early) tenders;
- very few players would have sufficient capacity to supply the whole of England and Wales;
- production risks would increase for manufacturers, since they would be vulnerable to losing large parts of their business if they lost a tender on renewal;
- quality and security of supply may be jeopardised because of focusing solely on price as the determinant of preferred supplier;
- there may be a difficulty in tendering in a line-by-line fashion for individual drugs, since manufacturers claim that production processes, and hence costs, are structured around bundles of products, not individual ones;
- if prices fall too low, existing players will either cease trading, or relocate to other markets.

A2.1.1 Monopolisation

The impact of tendering on manufacturers' entry and exit decisions is key to the dynamic success of centralised purchasing. The experience of purchasing of hospital-only products and vaccines is that there have been examples of monopolisation of supply of particular products, which has led to security-of-supply issues and concerns about future price levels. Increasingly, the NHS PASA is moving towards a system that does not rely solely on price as the determinant of success in a tender, but has regard to the dynamic effects of changes to market structure.

In a situation where there are only one or two suppliers, any system may be vulnerable to high prices and supply disruption. The question is whether, under tendering, the appropriate signals are in place to encourage further entry. In a competitive market, the signal for this entry is high prices. Manufacturers are clearly concerned that tendering may make entry more difficult.

The proposed structure establishes a number of potential protections to ensure that such monopolisation is unlikely, or, where it exists, that the NHS's exposure to price and security risks is minimised.

- The restriction that all tranches cannot be supplied by the same manufacturer ensures that there are at least two players in the market. However, if one manufacturer is supplying five tranches and experiences production problems, this still represents a security-of-supply risk. However, it may be possible for the other supplier to increase production while a new supplier is sought. The feasibility of such a significant increase in production from the smaller supplier would depend on the lead time, warning of any difficulty. This second player should at least give some breathing space, while other supplies are sought.

- Central monitoring of licensing activity can provide warnings of drugs where exit is occurring. In the USA, the FDA sees ensuring that there is more than one supplier of any generic drug as part of its public-health remit. Where it identifies a problem, it seeks potential entrants and notifies them of the gap in the market. It does not offer supply commitments.

- Manufacturers without full licences could be allowed to enter the tendering process. Once it is indicated that their bid has a high chance of being successful, the licensing process is completed. This could be combined with a fast-track MCA process. No denigration of quality standards should occur. This process has been used to good effect elsewhere. If the licence is not forthcoming, the supplier has to rectify the MCA's concerns and wait four months until the next tranche is tendered.

- The final tranche could be used as a means of encouraging entry. Manufacturers active in other markets (USA, Germany) said that gaining access to the UK market was a difficulty for them. Clearly, identifying a volume contract that is not available to the incumbent may encourage entry.

A2.1.2 Production volatility

With regard to the production risks, the proposed tender design should mitigate this problem as well. Splitting the market for any particular drug into a number of tranches and offering them in a staggered fashion should lessen the likelihood that a large proportion of total production of any one player will be up for tender in a given period. It also ensures that no one player is responsible for the entirety of production for England and Wales. The use of negotiation through the tendering process and the pre-qualification requirements ensures that price need not be the sole determinant of choice of supplier.

A2.1.3 Line-by-line tendering

Where tendering has been introduced elsewhere, line-by-line tendering predominates and manufacturers seem to have little difficulty responding in this fashion. Some examples are in the USA (supply to PBMs and HMOs, see appendix 7), New Zealand (sole subsidised supplier of selected generics, see appendix 9), and Boots in the UK (which tenders a large number of generic presentations every six months to a year). Boots' tendered portfolio represents around 10% of the UK generic demand. Also, the main UK

suppliers all report that the changing ownership structures and increasing internationalisation of their business have led to an increased understanding of individual drug profitability. Global parents scrutinise drug performance across a range of countries, identifying opportunities to improve margins. This may involve ceasing production of some drugs, or switching supply to an alternative market. The implication is that, regardless of whether tendering is introduced, the NHS may find the prices of older drugs rising if these drugs are currently below cost. While tendering may accelerate this process, it should also lower the prices of the drugs that are currently cross-subsidising the older, low-value drugs. Unwinding such cross-subsidies is not necessarily a negative outcome.

Some bundling of drugs has been pursued by various purchasers (see discussion in section 12.1). This can be justified since there may be economies of scope associated with production of two particular preparations together (for example, different presentations of the same chemical entity). The tendering process suggested is flexible enough to allow such bundling, if the price advantages warrant it.

A2.1.4 Impact on profitability

Many of the practical concerns of the manufacturers are therefore addressed through the proposed system. Although unvoiced, there may be a concern that margins and profitability will be reduced by tendering.

If the introduction of competitive tendering is successful, prices *paid* by the NHS for generics should certainly fall. The impact on manufacturers' prices is less clear. Manufacturers claim that their factory-gate prices are low and highly competitive, but that excessive margins are being taken elsewhere in the chain. If this is the case, then manufacturers may benefit from tendering, through cost benefits (eg, lower risk, an ability to negotiate better contracts with active-ingredient suppliers, and better production scheduling to exploit economies of scale). Moreover, if existing factory-gate prices are already very low owing to competitive pressures, they are unlikely to fall further in the tendering process. The real financial losers in this scenario are then wholesalers and pharmacists. Unfortunately, there is no public-domain data available to investigate the difference between 'market' prices and 'reimbursed' prices.

Regardless of existing profit levels, the main question is whether tendering will drive prices to unfeasibly low levels. Tendering is a tried-and-tested way of ensuring that suppliers reveal costs. If prices initially fall to a level that excludes many suppliers, but the low-cost player is unable to supply the whole market (and therefore only tenders for a limited number of tranches), other suppliers will enter and win higher-priced tenders. With the incentive always being to bid actual costs, then the tendering should be robust to predatory behaviour, given that manufacturers and foreign players have suggested that re-entry barriers are quite low. With low entry barriers, a player cannot successfully drive other suppliers out of the market by lowering prices since, when prices rise in the future, the other entrants return to compete away excess margins.

Thus, given the tender design, only if manufacturers are currently earning prices significantly higher than costs should they expect to see their returns significantly affected.

A2.1.5 Dynamic impact

There is a risk that the shape of UK manufacturing will change if current suppliers do switch to higher-margin markets (such as France), and other suppliers (presumably lower-cost) enter the UK. This should not necessarily be of concern to the NHS. Such an outcome is only feasible if there are entry barriers to these other suppliers into the higher-margin market (thus their only option is to supply the UK), or if they have greater capacity than UK suppliers so that they can supply both markets, but with different returns. Alternatively, the prices across Europe will converge, as suppliers into the UK will offer prices in the tender that are similar to those they can achieve elsewhere in Europe. Tendering will not accelerate this process, but will be robust to these external changes, which would affect the competitive price in a similar fashion.

With careful design of tenders and monitoring of market behaviour, most of the practical concerns raised by manufacturers should be resolved. It is possible that their returns could fall, but not if they are currently supplying at a competitive price. In this case, the tender will reveal this price to the NHS and reduce the returns elsewhere in the chain, but will not affect manufacturers' returns if they are successful in the tender. There is a (small) possibility that an existing UK supplier could win no tenders. This would imply that its costs were not competitive with those of most other suppliers. In that case, it could switch to a market where tendering does not exist, (although it is unclear why it would necessarily be more successful there). Alternatively, it could improve its efficiency for the next round of tenders.[30] In addition, if hit-and-run entrants are currently prevalent and these suppliers do not want to commit to two-year supply contracts, prices for particular drugs could rise. These suppliers would then disappear from the UK market. In this case, while manufacturers may be better off, with an increase in the factory-gate price, it is unlikely that the price paid by the NHS (the reimbursement price) would rise.

A2.2 The impact on wholesalers

The role of wholesalers, both full-line and specialist generic distributors, in the distribution of generic drugs would change significantly under a centralised purchasing arrangement. The two types of wholesalers are considered separately.

The impact analysis in this report focuses on the three distribution options outlined in section 13.5—any wholesaler (distribution option 1), wholesaler designated by drug (distribution option 2), any wholesaler, with centralised clearing house (distribution option 3). Clearly, service levels are also important to wholesalers, and these depend on secure supply. To the extent that tendering makes supply more (less) secure, it will be beneficial to (problematic for) wholesalers. The information systems required to underpin tendering may require changes to the internal systems of wholesalers.

A fixed fee for distribution is proposed, either a percentage or per-item rate, although under distribution option 2 the distribution service could be explicitly tendered for and a smaller margin may emerge.

[30] With sufficient warning of the introduction of competitive tendering, inefficient producers may respond by improving efficiency to enhance their competitiveness in open tenders.

A2.2.1 Full-line wholesalers

Wholesaling would be reduced to mainly a distribution function, given that the price is set through the tendering process. This is similar to existing agency arrangements with manufacturers and with the US wholesalers. Under all three options, the wholesalers lose any income that accrues currently from purchasing generic drugs at prices below published list prices that are used to set the reimbursement price. Given that generics are only a small part of the full-liners' business by volume (and even smaller by value), they profess to be not very concerned about this non-core segment.

Distribution option 2 is likely to have the greatest impact on distribution costs. Distributors would then have to deliver to all pharmacies in the country, which is likely to affect the number of vans, etc, required. It also means that tied pharmacies would receive deliveries from other wholesalers, something which already occurs to a small extent in times of shortage or other unusual circumstances.

The effect of using this distribution option may be that wholesalers enter the tender upstream, probably jointly with a given manufacturer, but also through the wholesaler contracting with the NHS and sub-contracting supply. If the wholesalers actively encourage new entrants, in order to strengthen their chances against existing suppliers, this may lead to an increased range of tender participants. Under this option, there might be lost efficiencies in distribution because of multiple deliveries to pharmacies. Wholesalers may also face increased competition from logistics companies, or pre-wholesalers, which team up with manufacturers to offer full manufacture and distribution service to the NHS.

Under distribution options 1 or 3, where the pharmacist chooses the wholesaler for a particular drug, there will be incentives for wholesalers to encourage pharmacists to concentrate orders through volume discounts. This would be a similar arrangement as currently occurs for the bulk of branded purchases. The greater the volume of generic drugs, the more of the margin the wholesaler would be prepared to pass through to the pharmacist. This would mean no loss of economies of scale, and may benefit the full-line wholesalers since, without the price incentive to look elsewhere, many pharmacists may be happy to concentrate all their drug purchases with a full-liner. Given the structure of wholesaling, this has beneficial economies of scale. Under these arrangements, the effects on full-line wholesalers would not be substantial.

A2.2.2 Specialist generic distributors

For these players, the implications are greater. At present they play a potentially useful role by bringing new sources of drug supply into the market. There are two types of short-line wholesalers: those that acquire product licences, and have a portfolio of products (often produced on contract); and those that purchase on the spot market. If tendering is introduced, the first group would have the option to participate in the tenders. They could bid for supply, or supply and distribution if their distribution network were sufficiently well developed. The second group is unlikely to have a strong role in a tender. This means that these players would be reliant on PIs for their core business, although they could still aim to distribute generics under distribution option 1 or 3, being paid the fixed wholesale margin.

It is conceivable that the structure of tendering is such that no existing specialist distributor is prepared to commit to the supply contract and the potential penalties—they

could consider the risk too great. In this case, this source of supply would disappear from the market. This could be detrimental to the success of the tendering if these suppliers hold product licences in significant numbers. The proposed tendering arrangement is designed to encourage these players to continue to have a role in the market, through the manageable tranches and the staggered contracts. Since some specialist distributors already contract with their suppliers for up to five years, with penalty clauses in the case of default, it seems feasible for them to play a role. In the New Zealand experience, it is this class of trader that has benefited significantly from the tendering arrangements.

The other role that short-liners play in the current market is in providing competition within the supply chain. Incentives for this would still exist under distribution options 1 and 3, but in a more limited fashion (competing over the wholesale margin). The importance of this is much reduced with competitive tendering as opposed to the market environment; however, it still plays a role in keeping wholesalers efficient.

A2.3 The impact on pharmacy

The structure and nature of pharmacy is changing. There is increasing vertical integration and growing concentration at the pharmacy level. For the larger independent pharmacy chains, there are opportunities to put resources into purchasing, which may lead to substantial financial gains under current arrangements. The Discount Inquiry is designed to claw these back. In the case of the vertically integrated pharmacies, the Discount Inquiry cannot accurately assess the actual transfer price of drugs between the two levels of the chain.

Pharmacy will be affected across a range of issues: financial, patient care, incentives for fraud and continuity of supply. These are discussed below.

For pharmacists, the financial impact will be different according to which strategy is being pursued in the existing market: independent pharmacist (or pharmacy group) who trades; independent pharmacist who does not trade; and tied pharmacist. The impact on each of these groups is discussed in turn below, as is the impact on Boots. Overall, the financial impact is likely to be negative if, under the current system, good purchasing practice makes a positive contribution to pharmacists' incomes. If, in general, reimbursement under the current system accurately matches actual purchasing costs, the impact of moving to tendering is likely to be small.

- *Trading pharmacist*—this player will see a significant drop in income if the margin between the market price and the reimbursement price is substantial on some drugs, as appears to be the case. It is not clear, however, to what extent these pharmacists benefit from this, and the PSNC could offer no estimates of the financial impact of removing this source of income.

- *Non-trading pharmacist*—this category of pharmacist (usually small pharmacies or older pharmacists) is likely to be making less profit than trading pharmacists. Evidence of this is seen in the trend towards concentration in pharmacy. Under the tendering system, there will be no structural bias against this type of pharmacist, as the contractor's role in purchasing is removed. This may be beneficial to these smaller players, alleviating the pressures towards consolidation. They may see a

financial impact, but it is unlikely to be of the same proportion as that for a trading pharmacist.

- *Tied pharmacist*—here, it is the parent wholesaler that is likely to see an impact on returns. Margins on generics will be constrained at the wholesale plus retail margin, say around 15%. Many wholesalers reported this as standard on their generic businesses in the current environment. If this is the case, they are unlikely to find the proposed system problematic in financial terms.

- *Boots*—as a self-supplying pharmacy retailer, the proposed system will have a negative effect on Boots. As described, they will lose their own-brand products, their ability to negotiate brand equalisation deals, and the profits they earn from their existing in-house tendering. All of this will be replaced with the NHS product arrangements.

Assessing the appropriate level of remuneration for pharmacists is outside the scope of this report. It is important, however, to recognise that the introduction of a tendering scheme will have an impact on the pharmacy sector through removing much of the trading income.

The three distribution options will have differential effects on pharmacies. Options 1 and 3 are likely to be preferred, as these retain some possibility for pharmacists to earn income through discounts that effectively share the wholesaler's fee in return for bulk business. Option 2 is likely to be costly for pharmacies, as it requires multi-ordering, depending on which wholesaler is the designated supplier of a given drug (although a centralised information system would facilitate this), and there could be multiple deliveries every day. In the interviews, there was variability across pharmacies about how many wholesalers they actively contract with. Traders had orders with a large number of suppliers; some pharmacists purchased all their drugs through their chosen full-line supplier. Frequency of delivery may fall because of the costs to each wholesaler of committing to twice-daily services to every pharmacy.

Pharmacy will benefit from the extra time saved from not having to search for low-priced generic drugs. This will enable them to spend more time on patient care, and play an increased role in the community as a healthcare resource between the doctor and patient.

The three reimbursement options suggested have different effects on pharmacies. With the option that pharmacists pay in full for the stock and seek full reimbursement, incentives for fraud may be introduced, the prevention of which would require significant monitoring. With six tranches of supply, all potentially with different prices, there may be an incentive for a pharmacist always to endorse the prescription as having dispensed the most expensive supplier's drug, regardless of which drug the pharmacist actually paid for and dispensed. Problems would be observed, as the PPA would have reimbursed more of supplier A's (say) stock than supplier A had actually supplied. Tracking back which pharmacists had incorrectly endorsed a prescription would be extremely time-consuming and would require significant assistance from all wholesalers. The introduction of a Category T price overcomes this latter problem.

If pharmacists are expected to pay up front for drugs, and are not reimbursed in full for some weeks, but no longer have any opportunity to earn money through purchasing well, they may seek compensation for the holding losses entailed in the existing system.

Continuity of supply was frequently mentioned by pharmacists as a negative effect of the shortages in 1998 and 1999. Patients with chronic conditions (often the elderly) do not like it when the look and dosage instructions of their drugs change from month to month. Pharmacists often seek to dispense the same manufacturer's product to such a patient for every repeat prescription. This is potentially difficult in a system where there are six suppliers, all of which may have drugs that look different.[31] There may be pressure for pharmacists to order one supplier's drugs over others, which could lead to supply difficulties. One solution may be that there is an NHS tablet shape and livery which all tender winners must produce. This may require a minor licence variation, but should take less than four weeks to be approved by the MCA. Then, regardless of which supplier produces the drug, the patient has something that is identical each time a repeat prescription is dispensed.

Overall, if the existing reimbursement scheme works properly in clawing back savings on reimbursement prices, then pharmacists should be fairly indifferent to the introduction of tendering. It may even be beneficial, given the expectation of price stability and lower risk of supply shortages. If, however, good purchasing practice makes a significant contribution to the viability of pharmacies, then tendering is likely to have serious financial implications for pharmacists.

A2.4 The impact on the branded sector

Tendering could be used to encourage the introduction of generic forms of off-patent branded drugs. If the NHS offers a contract for community supply, effectively consolidating demand, even in low-value branded markets, it may lower the size of the market required to elicit entry. If this is combined with a system whereby a supplier can tender before completing the licence requirements, then this will lower the risks of entry further. The potential savings on branded drug prices are substantially greater than in generic drugs. Any changes to the returns to the branded sector need to take into account the potentially negative impact on innovation and investment of reducing expected returns over the life of the branded drug.

While branded manufacturers could bid to be a tranche supplier for the given preparation, they will clearly only win if they bid below other suppliers. If they do not bid low, they will lose the tender and will have no option to supply the drug post-patent expiry. This further curtails the life-cycle earnings of their branded products, as it will hasten the collapse of post-patent expiry prices.

There is also a risk that prices may rise in some drugs for which there is no generic substitute. Branded companies will unwind implicit cross-subsidies when returns on more profitable drugs are cut. It is not clear that this should be of concern to the NHS. Overall the cost will not go up, unless drug companies have been earning very low returns. There are no distributional implications, since it is the NHS, not the individual patients, that pays the rebalanced prices. Unwinding cross-subsidies is a signal that markets are

[31] Counselling and patient support by pharmacists may overcome these issues.

becoming more competitive, since it is only in an uncompetitive environment that prices can be sustained above normal competitive rates.

A2.5 The impact on government

This sub-section looks at the benefits and disadvantages to the NHS itself of tendering. The introduction of such a scheme could have significant resource implications for the NHS. Disadvantages fall into two categories—direct costs and increased risks to the NHS. However, tendering would also deliver lower prices, enhanced transparency and increased information.

In what follows, the types of costs likely to be incurred are outlined, but no estimate of the costs of introducing the scheme is given. Some estimates of benefits are made. A full cost–benefit analysis should be done before implementing any tendering option.

A2.5.1 Costs

The two main areas of direct costs are implementation and running costs. These costs will differ depending on the particular tendering and distribution option chosen. The estimates below should be taken as broad guidelines, based on past experiences in very different markets. When expanding the scope of a system, say for hospital purchasing, to meet the needs of the whole community, it is not clear that it becomes cheaper (per unit), as there may be diseconomies of scale. A risk, and hence cost, of the proposed tendering system is that of a major supply disruption from a winner of a major tender. While the probability of a disruption may be smaller, its expected effect may still be significant.

Direct costs of the proposed tendering systems are considered first. There are two key categories of costs of implementing such a system:

- *IT costs*—at a minimum, a database for analysing tender submissions and a centralised clearing house for orders may be required if distribution option 3 is used. Demand-side analysis and forecasting needs to be reasonably sophisticated. A complete information-based system of tracking drugs through the chain would make monitoring of the tender very straightforward. An on-line exchange may be beneficial for administering the tender itself;
- *labour costs*—additional staff are likely to be needed, effectively to fulfil administrative functions of writing of specifications and contracts, evaluating tenders, negotiating final contracts, monitoring performance across the tender period.

Administration costs

A tendering authority is likely to be required and there is therefore a question about where its optimal location should be. The NHS PASA is an obvious option, but the function could also reside elsewhere. The OGC could play a valuable role in coordinating the tendering arrangements. To give some indication of potential administration and running costs, two sources are used: existing costs of NHS PASA and the costs of implementing tendering in New Zealand (see Table 16.2).

Table 16.2: Estimates of costs of establishing, and running a tendering framework

	NHS PASA	New Zealand PHARMAC total	New Zealand PHARMAC tendering division
Number of staff (full-time equivalents)	12.5	16	3
Staff costs (pa)	£500,000	£460,160	–
IT costs	£230,000	£508,600[1]	Negligible
Proportion of England community demand	~20%	–	<5%

Note: An exchange rate of 1 NZ$ = 0.299 GBP was used to convert currency. [1] Refers to office costs (including depreciation, rent, phones, library, purchase of data, ordinary legal costs).
Source: OXERA, based on relevant interviews.

The NHS PASA gives an estimate of its annual costs for general pharmacy contracting activity (ie, contracts administered/managed by the NHS PASA on behalf of hospital pharmacy groups in England) of around £500,000. This comprises 12.5 full-time equivalents (ranging from secretarial support, through buyers to executives). This estimate does not include corporate overheads or central services, such as postage and photocopying, but does include travel and IT support. It also does not give an estimate of the call on other NHS resources in the Department itself or hospital pharmacists. Also, while the NHS PASA sets the framework agreements, it is the hospitals that finalise the actual supply contracts.

The existing resources of the NHS PASA are well suited to many of the tasks involved in tendering; namely, experience in contract formulation and negotiation, and significant market knowledge. There may be a need to expand the skill base to include buyers with more experience of the community sector and those with skills in, and understanding of, market management. This could represent a significant increase on existing staff costs.

The costs of setting up the tendering system in New Zealand were relatively small because the existing framework was used. In particular, therapeutic group managers already employed by PHARMAC assist in designing the tenders. The tendering scheme itself takes three full-time equivalents to operate, with some services contracted out (eg, medical evaluation). This tendering team is embedded in the larger PHARMAC structure, which internalises many of the pharmacy and medical expertise costs that are not included in the NHS PASA estimates.

The New Zealand market is significantly smaller than the UK market, and tendering is not used for the full range of generic drugs, although it is used for the high-volume and high-value drugs.

The NHS's community drug needs are around five times those of the hospitals. How these costs would translate into a scheme for the whole of the UK depends on whether increases of that sort of scale yield cost efficiencies or require more extensive systems to be put in place.

IT costs

The costs of establishing the centralised clearing system required for distribution option 3 could be significant. Expert advice on these costs would need to be sought before

pursuing this option further. The system would need to be able to accept order enquiries from all wholesalers and pass these on to the suppliers for all drug presentations on the tender. This type of electronic system is feasible, and mirrors the systems within integrated pharmacies, where AAH and Unichem have electronic links between all their pharmacies (and other customers) and the distribution warehouses. Suppliers would need to keep the centralised system informed of stock levels and forward production plans, to enable orderly depletion of stocks across tranche suppliers. It may be sensible to have this embedded in the purchasing authority since it will give useful information on market supply conditions. If problems are flagged up, those responsible for the tendering are likely to be in the best position to elicit emergency supplies.

The NHS PASA uses a system called SupplyStream, which functions as a remote requisitioning IT system, passing orders from trusts to suppliers for procurement of non-drug items. Currently 18 trusts are making use of this service and another 20 are in the process of considering its introduction. A similar system could be used for the central clearing house.

It would be feasible for the NHS to contract out this clearing house function, although if it were run by an existing wholesaler or manufacturer, there would have to be strict ring-fencing to ensure they had no informational advantages from operating the system. Also, to the extent that the information would be key to ensuring the smooth functioning of the tendering, it may be preferable to keep all expertise in-house.

The PHATE database system of the NHS PASA used for registering and analysing tender information could be extended to include community tendering.

Contingency costs

The other major disadvantage from the introduction of tendering is the potential for a major supply disruption. The proposed tender design includes a number of features to protect the system from disruption, but even with all these protections, it is still possible for a major supplier to have production difficulties that seriously affect patient care in England.

There are two outcomes of such a disruption:

first, patients may see no service effect (except, perhaps, that the look of the pills change), but there is a significant cost impact on the NHS as it seeks to find replacement supply at short notice and a substantial premium to the tender price. In theory, such costs should be passed through to the defaulting supplier, but there may be some situations when the clauses could not be exercised;

second, shortages may occur, jeopardising quality of service to patients. The purchasing authority would be responsible for finding alternative supplies. While the central clearing house could play a role in rationing stocks of drugs in shortage, there could be a significant social cost if there are serious delays in finding replacement supplies. Alternative sources could be found through encouraging doctors to prescribe a therapeutic equivalent. The branded drug could also be supplied, if available.

There may be an additional concern, particularly in the early stages of the tendering scheme, as to whether the purchasing authority has sufficient experience to recognise the warning signs of supply problems. In a competitive market, there are strong incentives for

players to pick the drugs where problems are foreseen, in order to take advantage of the ensuing high prices. This activity generally leads to a broad availability of drugs. In a centralised purchasing system, this monitoring is done by the administrators, and their skills in market management will play a crucial role in the success of tendering.

A further contingency cost arises in the question of reimbursement. Three options are presented in section 12. If the NHS pays the manufacturer at the point of supply, this has a large impact on NHS financing. This is because there is a significant one-off cost as it moves from reimbursing as much as two months in arrears to reimbursing perhaps a month before dispensing. If the existing reimbursement system is retained, however, there is an increased risk of fraud, which may result in additional costs. The third option, with the Category T price, attempts to mitigate the incentives for fraud.

A1.1.1 Benefits

If the proposed tendering scheme is successful, it will achieve at least five of the six objectives of the Department. It will:

- reimburse pharmacists closely for what they pay for medicines dispensed under the NHS;
- ensure price transparency;
- maintain and improve the current quality of service to patients;
- support a competitive pharmaceutical market;
- secure value for money for the NHS.

It is unlikely to minimise the costs of distribution. Achieving these objectives is dependent on there being few supply disruptions. If tendering were to lead to significant supply problems, then the latter three objectives would be jeopardised. The costs associated with supply disruptions are discussed above.

These broad benefits are hard to quantify. The NHS will have control over its procurement process and will be able to monitor market developments for early warning of difficulties. It can use the tendering to elicit back-up supplies. Price transparency ensures that the NHS can benchmark its procurement performance more easily, allowing the objective of value for money to be assessed. Spending will be significantly less volatile, aiding budgeting.

In addition, an attempt can be made to estimate the direct financial savings that may accrue from tendering. Table 16.3 gives a range of savings that have resulted from tendering exercises across a wide range of industries.

Table 16.3: Estimates of cost savings on the introduction of tendering

Industry/study	Estimated cost savings (%)
London Bus Transport	20[1]
NHS Hospital Domestic Services	48[2], 34, 27 and 18[3], 24[4]
Refuse collection in England and Wales	20[5], 22[6]
UK Cabinet competing for quality study	18[7]
Australian Industry Commission study	10–30[8]
New Zealand PHARMAC tendering	15–20

*Source*s: OXERA, compiled from [1] Kennedy, D (1995), 'London Bus Tendering: The Impact on Costs'; [2] Milne, R. and McGee, M. (1992), 'Compulsory Competitive Tendering in the NHS: A New Look at Some Old Estimates', *Fiscal Studies*. [3] Domberger, S. and Jensen, P. (1997), 'Contracting Out by the Public Sector: Theory, Evidence, Prospects', *Oxford Review of Economic Policy*. [4] National Audit Office estimate given in Milne and McGee (1992). [5] Domberger, S., Meadowcraft, S. and Thompson, D. (1986), 'Competitive Tendering and Efficiency: The Case of Refuse Collection', *Fiscal* Studies, **7**:4, 69–87. [6] Szymanski and Wilkins (1993), given in Domberger, S. and Jensen, P. (1997). [7] UK Cabinet Office (1996), 'Competing for Quality Policy Review: An Efficiency Unit Scrutiny', London, HMSO. [8] Australian Industry Commission (1996), 'Competitive Tendering and Contracting by Public Sector Agencies', Report No. 48, January, Melbourne, Australian Government Publishing Service.

These estimates do not translate directly into savings expected from centralised purchasing of generic drugs. In all these cases, the underlying industry structures are different. However, what is interesting is that, despite substantial differences across all the reported industries, significant savings are consistently realised.

The question now is to derive a range of likely cost savings. As raised earlier in the discussion of the impact of tendering on manufacturers' profits, there are two scenarios. One is that the market price is already fully competitive and the tender is mostly delivering transparency and controlling the margins elsewhere in the chain. The other is that the current market price does deviate from average or marginal cost to some degree.

Obviously, in the second case, tendering is likely to deliver more substantial gains, and it is this type of case that results in the savings observed in Table 16.3. As tendering reveals the true cost conditions of suppliers, situations where prices initially deviate substantially from these costs are likely to result in the most significant savings.

Given that the average generic price in the UK is already well below the branded price, such startling reductions in *market* prices are unlikely to be achieved. However, there may well be scope for significant reductions in some *reimbursement* prices. Table 16.4 compares the prices achieved in New Zealand tendering exercises with those in the primary and secondary sectors of the NHS. It is important to bear in mind that New Zealand is significantly smaller than the UK and is well integrated with the larger Australian market. Its position as a small residual market is very different from the situation in the UK.

Table 16.4: Comparison of prices for selected drug preparations in New Zealand and the UK

Drug preparation	New Zealand current price per unit		UK PCA price per unit (NIC/QTY)	
	(in New Zealand cents)	(in UK pence)	(in UK pence)	(in UK pence less 11% claw-back)
Baclofen (10mg)	4.19	1.25	6	5.34
Isosorbide Mononitrate slow-release (60mg)	5.48	1.64	34	30.26
Metformin (500mg)	2.77	0.83	2	1.78
Tamoxifen (20mg)	10.0	2.99	14	12.46
Verapamil hydrochloride slow-release (240mg)	11.8	3.53	44	39.16
Amoxycillin capsules (250mg)	3.85	1.15	8	7.12
Amoxycillin capsules (500mg)	6.3	1.88	11	9.79
Ranitidine (150mg)	10.0	2.99	32	28.48

Notes: An exchange rate of NZ$1 = £0.299 was used. The UK hospital price per unit is an unweighted average of the different prices paid by different regions. New Zealand 'slow release' is assumed to be equivalent to modified release in the UK. The 11% claw-back refers to the average claw-back the government determined for generics in the most recent Discount Inquiry.
Sources: OXERA, New Zealand data from PHARMAC. UK community pharmacy data (NIC per unit) from the PCA, 1999.

This suggests that savings in the region of 10% on factory-gate prices may not be an unreasonable estimate for high-volume drugs.

The other estimate required is that of the potential savings on the supply-chain margins. Estimates arising from the negotiations around the short-term measures suggest that different drugs command different margins. For some drugs, the evidence suggests that very low margins are currently earned; for others, margins as high as 60% were suggested. A low and a high scenario are used in what follows.

- *Scenario 1*: it is assumed that 40% of the drugs have a 10% margin; 20% of the drugs have a 15% margin; and 40% of the drugs have a 30% margin, yielding an average margin of 19%.
- *Scenario 2*: it is assumed that 20% of the drugs have a 15% margin; 20% of the drugs have a 25% margin; and 60% of the drugs have a 50% margin, yielding an average margin of 38%.

Norton estimated that, in 1998, the supply-chain margin was around 39%, corresponding to the upper estimate above.[32] Using these two scenarios, the savings that could have been delivered by competitive tendering over the last two years can be estimated based on the different assumptions on manufacturing price reductions. It is assumed that tendering is introduced only in the top 80% by value of drugs (around 140 preparations), and that the remaining 20% are purchased at existing prices. If it is believed that there are currently cross-subsidies on some existing drugs, then the scenarios below correspond to the

[32] Information provided to OXERA by Norton.

situation where the 80% tendered for deliver greater reductions to offset any price rises in the remaining 20%. Table 16.5 provides a summary of these savings.

Table 16.5: Summary of direct benefits for total UK under tendering scenarios (£m)

	1999		1998	
	Scenario 1: lower supply margins	**Scenario 2: higher supply margins**	**Scenario 1: lower supply margins**	**Scenario 2: higher supply margins**
No savings on manufacturing	23	113	17	85
10% savings in manufacturing prices	89	170	67	128

Notes: Scenario 1 has an existing supply margin of 19% and Scenario 2 a supply margin of 38%. The savings on manufacturers' prices and lower supply margins are assumed to occur on only 80% of the value of NHS spend.
Source: OXERA.

These ranges give broad estimates of benefits and assume that a large number of drugs are successfully tendered and awarded in the first year. If supply-chain margins are not substantial and manufacturing is competitive then savings of around £30m are generated. Medium-range assumptions suggest savings in the region of £100m. If strong assumptions are made on the uncompetitiveness of both the supply chain and the manufacturers then high estimates of savings can be made—in the region of £150m.

Savings of this order are one-off if the tender works perfectly in revealing underlying costs the first time. Future tenders would deliver more modest savings from the, now lower, baseline, and would reflect underlying cost changes. Structural changes, such as a more international market, may lead to lower production costs; changes to the active ingredient could lead to increased costs.

These estimates are designed to be indicative of the orders of magnitude involved and are not set out as a detailed cost–benefit analysis of the introduction of tendering. Information on manufacturers' market prices and supply-chain margins is not available in the public domain. If supply-chain margins (received by wholesalers and pharmacists) are lower than 19% on average, then the benefits of reducing the margin to 15% will be even lower than suggested above. If there are substantial numbers of drugs with few licence-holders, there may be little competition in the initial tendering process and the estimates of savings of 10% may be overstated.

A1.1.1 Other effects

Tendering may also affect reimbursement, and the market behaviour of generic drugs not covered by the tender. The tendering system should be able to operate beside the existing market supply chain for branded drugs and for any generics not offered through the tender. For preparations that have been tendered, only the winning tender suppliers' products could be dispensed against a prescription. Thus brand equalisation or any other substitution would not be reimbursed. For non-tendered drugs, there would be no such constraints. The Drug Tariff would still operate, with the Drug Tariff price for tendered drugs being the agreed manufacturer price plus the agreed wholesaler margins. For all the full-line wholesalers, it is supply of branded drugs that is the core of their business, and this would not change.

The introduction of tendering on other drugs may jeopardise the supply of lower-volume and -value generic drugs by exposing their limited profitability. If this is the case, tendering could be introduced for vulnerable drugs, even if they are low-volume, to guard against supply risks. Alternatively, the price in the competitive market will rise, as cross-subsidies are unwound. The overall drugs bill should not increase.

A1.2 Alternative solutions

If the manufacturers' descriptions of market conditions are accurate—that the UK is one of the lowest-price markets for generics in the world—then tendering may not achieve lower underlying market prices, rather it may simply make these prices transparent to the purchaser—the NHS. Given there is no public-domain data on UK market prices, it is difficult to judge the underlying market price. If this is the case, it may be preferable to look at alternative means of ensuring transparency. The introduction of tendering may be an expensive and disruptive option if it is not actually achieving lower market prices than the competitive market.

Transparency is, however, a difficult goal to achieve. The existing system worked without requiring transparency by aligning the incentives of independent contractors with the NHS. The Discount Inquiry, held infrequently, was sufficient to recoup past gains, ensuring dynamic cost savings. This Inquiry focused on the price paid by pharmacies to wholesalers for generic (and other) drugs. As discussed in Phase I, changes in the underlying industry structure have occurred which have undermined the effectiveness of this system. Predominantly, the boundary between pharmacist and wholesaler has been blurred through integration so that the transfer price at this stage is unclear. Increasing integration means that there is less competition between wholesalers, and it is then unclear how the price paid for the drugs by the wholesaler relates to the price it charges its pharmacies.

In Phase I, a number of other options were raised, under the following three headings:

- reform reimbursement;
- request information;
- enforce vertical separation.

The issue is whether these can, at lower cost, deliver similar outcomes to that of tendering in terms of transparency. In the short run, the answer is likely to be 'yes', but there are two difficulties. First, these changes may not be robust to structural changes in the industry in the future. In three years' time, the Department may well be again revising its view of the value for money of its purchasing arrangements. Second, the Department may find itself having to judge appropriate cost levels in wholesaling and manufacturing.

Reforming the reimbursement system is a necessary and reasonably remedial option under any reform process. Removing Category D (already done) and producing a better market price representation through changing the basket supply rules is essential to making sure that the Drug Tariff begins to work properly. However, without addressing the underlying incentives to run dual price lists, etc, these reforms alone are unlikely to have a major effect on procurement performance.

Stringent information requirements could be imposed at all levels of the chain, similar to those under the short-term arrangements. Manufacturers seem eager to supply information on their underlying costs, and to negotiate with the NHS on appropriate levels of returns. The risk is that all players in the chain adjust their behaviour to obscure the underlying trading prices. Some examples of how this could occur in the future are as follows:

- manufacturers report list prices to the NHS and continue to offer discounts to wholesalers and pharmacists. These could take the form of free stock, rather than discoverable percentage discounts;
- international manufacturers produce drugs for their UK subsidiaries at reportedly high prices. They are actually supplied to wholesalers offshore, at lower prices;
- manufacturers integrate with wholesalers so that the whole chain is in one company. Meaningful transfer prices are then difficult to ascertain, although manufacture for non-integrated customers may still be observable. There is still the issue of whether to assume that prices offered to external customers can be used as signals of internal-transfer prices;
- wholesalers locate in Europe, purchase drugs offshore and then supply them into the UK through an internal transfer, possibly at a high price. The actual cost of acquisition is hidden.

One way of achieving greater transparency is through increased utilisation of IT. Options for automating certain operations in the current system include an automated PPA payment system, electronic prescriptions, on-line data delivery from manufacturers and wholesalers, and bar-code tracking of products for price and dispensing. This type of monitoring allows for greater transparency of prices and supply, while providing valuable data on dispensing and prescribing behaviour.

In the USA, every person covered for prescription benefits is issued an insurance number by their health plan or PBM (see appendix 7). Upon processing the prescription, the pharmacist dials into a network that contains formulary and reimbursement information for that particular patient, including what drugs are covered and at what copayment.[33] The data from this real-time network is processed by PBMs and used to track prescribing and dispensing patterns and other public-health information. It is also used to track the drugs bill that the PBM owes to the pharmacist for reimbursement, and the bill that the PBM will serve to the health plan for the balance of payment.

Such information systems are not impossible in the UK. In fact, some of the building blocks for such a central network are already in place here. For example, PCS Health Systems, a US PBM that manages prescription benefits for approximately 50m patients (roughly the same size as the UK) covered by roughly 1,200 different health plans, reported that its IT network handled approximately 1.2m transactions per day, with 94% of these managed in less than two seconds. Over 98% of all 56,000 US pharmacies have network access to the system, as do PBMs and health plans.

The UK essentially has one health plan—NHS coverage—and everyone covered already has a government insurance number. The universal nature of coverage and the existence

[33] Copayment is where patients pay part of the cost of their prescription, in return for lower insurance premiums.

of insurance numbers makes installing a streamlined IT system much easier. With Internet technology and an increasing number of small businesses with access to the Internet, such a system could be instituted. The costs of doing this would need to be carefully explored.

Enforced vertical separation at each level of the chain, combined with the reformed reimbursement and stringent information requirements, could lead to a system that is transparent for a long period of time. It should be emphasised that a careful assessment of the costs and benefits of such a major structural change should be investigated. If there are underlying efficiencies in integration, then commercial pressures may seek ways to circumvent the rules. Initially, the main impact would be felt by the integrated full-line wholesalers, which have invested significant amounts of money in building an integrated European network.

Such a change is a large intervention in the existing market structure. By contrast, tendering does not insist on any particular market structure, it just selects the best price from the range offered, however the companies choose to structure their proposals. Disintegration is likely to lead to consolidation at each level of the chain—international manufacturers, large wholesalers and large pharmacy purchasing groups. Prices should be transparent, but, again, there will be strong incentives for these large players to find ways to maximise their gains under the reimbursement rules.

Thus, reforming the reimbursement arrangements and requiring stringent information submissions, including licensing information, may lead in the short run to a market that is better value and functions more smoothly. These reforms are also likely to be significantly cheaper to put into practice than any of the tendering options. However, on their own, they do little to address the underlying problems in the supply-chain structure and, hence, similar problems may well occur in the future. Vertical separation is a way of changing the supply-chain structure; however, it is more interventionist than tendering, and the dynamic costs may well exceed the benefits.

A1.3 Summary

In terms of the direct comparison of likely costs and benefits of tendering, if successful, it is clear that, under some assumptions, centralised purchasing delivers major revenue gains. These could be, in the medium range, savings of perhaps £100m as a one-off, followed by smaller savings from the now lower price level. No estimate of direct costs to the government is made nor is there any estimate of the direct costs to the participants in the supply chain.

The difficulty in drawing a firm conclusion about these apparently significant benefits is the risks involved in *successfully* launching a tendering process.

- A serious supply disruption could be very costly to the Department to resolve (notwithstanding that the tender is designed to lower the probability of this occurring).
- Insurance, in the form of back-up contracts or buffer stocks, is expensive to set up and run. These costs should be set against the benefits from tendering.
- The other elements of the supply chain will incur costs in complying with the new system, and these could be large.

- Pharmacists may need to be remunerated differently, with an increase in the overall remuneration. This cost should be set against the benefits from tendering.
- Any increased likelihood of fraud will be costly.

The pilot scheme and the introduction of the tendering in a partial manner can help to reduce these uncertainties. If early indications are that the system is causing exit from the UK market, or that it is too complicated and vulnerable to theft and fraud, then the design can be adjusted, or in the extreme, abandoned, with limited costs. If the system works well, then its roll-out can be continued, or expanded. Of course, the full benefits of tendering are delayed in this process.

Before taking this any further, specialist advice should be sought on the necessary IT systems, and the costs and timing of setting these up, in order to gain a clear idea of the feasibility, timing and costs of initial set-up.

A2. Conclusions and Recommendations

Enhancing competitiveness in generic manufacturing and centralised purchasing through competitive tendering represents radical change to the existing NHS supply-chain arrangements. This report has outlined in detail the reasons why such radical options should be considered. It has proposed concrete processes for instituting these recommendations and has critically analysed each recommendation, including a detailed analysis of the impact of tendering on each element of the supply chain. In this concluding section, the various recommendations are summarised. For the tendering options, the critical analysis of each is shown as risks and opportunities for the NHS in introducing them, presented in a series of tables.

A2.1 Licensing

The recommendations are split into those considered ideal, but potentially problematic because of the need for European input, and those that could be introduced unilaterally.

The ideal changes to the licensing regime would be as follows.

- Investigate the extension of mutual recognition, both the MRP for product licences and MRA arrangements for manufacturing sites. MRP could be changed so that it applies retrospectively to all off-patent drugs, and it could be agreed with non-EU countries. MRA negotiations could be extended to countries such as India and Iceland.

- Highlight that a bibliographic application under Directive 65/65 can be made, even when the initial branded product has been removed from the market. Consider the nomination of a generic drug as the reference drug for this situation. The aim is to avoid the possibility that old drugs have falling numbers of suppliers.

- Modify the MCA's existing fast-track drug application procedures to apply them to drugs in shortage or those with few existing licences.

- Publicise more widely the possibility of 'piggyback' entry into all generic drugs.

The unilateral changes proposed are as follows.

- Establish a secondary market for licences, which may be as informal or as extensive as necessary, and could be run by the Department or the MCA.

- Introduce an active market-monitoring role for the MCA, which would involve monitoring the level of licences available for all generics, and attempting to identify potential shortages before they occur. This may be linked to a management of the market, whereby the Department or the MCA also take steps to rectify the identified problems.

- Reduce the time taken by the MCA in approving licence transfers.

- Introduce status-of-production reports for all UK generic licence-holders so that the level of production of drugs can be monitored, thereby aiding detection of potential shortages.

The aim of these changes is to facilitate entry into the UK market, both from established suppliers elsewhere in the world and from new suppliers for a particular drug, by lowering the barriers associated with new research into bioequivalence. Many of the suggested changes are not high-cost and could be implemented relatively easily. The effect of these reforms on supply conditions in the market could then be monitored.

A2.2 Centralised purchasing through competitive tendering

The key features of the proposed tendering system are as follows:

- contracts of two-year duration, but split into six parts, tendered every four months. A potential constraint could be introduced on the number of tranches any one supplier can win;
- every generic preparation is tendered separately;
- different prices for each tranche of the tender may exist, even if the supplier is the same. Reimbursement does not have to replicate this structure;
- a pre-qualification process should ensure that all bidders meet requirements;
- these requirements should include licence (complete or almost complete); manufacturing site (and back-up site possibly), and active-ingredient supply (and, possibly, back-up);
- penalty clauses should be put into contracts to ensure that defaulting manufacturers are required to compensate the NHS for costs involved in securing supply in times of shortage.

Three distribution options are considered:

- Distribution option 1 preserves the existing distribution system, in that any wholesaler could order the tendered drug from any of the six tranche suppliers, and then deliver it to pharmacies on demand.

- Under distribution option 2, a ‘designated distributor’ would take care of delivery of the drugs tendered for. A single distributor could be designated for the six tranches of the same preparation. Alternatively, each tranche supplier could have a different designated distributor.

- Distribution option 3 involves the creation of a clearing house. Any wholesaler can distribute any product. All orders must be placed at the clearing house, which then assigns the order to one of the six tranches, making sure that, in aggregate, volumes of all tranches are being filled.

Under options 1 and 3, the distribution margin needs to be set, as either a percentage or per-item fee. This could perhaps vary across different categories of deliveries. This fee can be determined through negotiation, benchmarking or detailed cost analysis.

Three reimbursement options are proposed.

- Under reimbursement option 1, the NHS pays the tranche supplier the tender price directly after delivery of the product into the distribution chain. This implies that neither the distributors nor the pharmacists 'own' the product as it is moved through the chain—that is, they no longer pay the product price to their direct supply source. Pharmacists do pay the wholesaler fee on delivery, and are reimbursed this.

- Under reimbursement option 2, wholesalers and pharmacists pay for the product and therefore 'own' it as it moves through the chain. This is similar to the existing system. The wholesaler pays the tranche supplier the agreed tender price after delivery. Next, the pharmacist pays the wholesaler the tender price *plus* the agreed distribution fee. Finally, after dispensing, the NHS reimburses the tender price plus distribution fee to the pharmacist.

- Under reimbursement option 3, the possibility of price differentials among the tranche suppliers of a certain preparation is maintained, but the NHS would set a single price to be paid by wholesalers and pharmacists for that preparation. The difference between this single price and the price of each tranche supplier agreed in the tender is settled directly between the NHS and each tranche supplier.

  The single price for a tendered preparation would function as a Drug Tariff price, for example, a new 'Drug Tariff Category T' could be introduced, listing the prices set by the NHS for each of the tendered preparations. The difference with existing Drug Tariff prices is that the Category T price is the price paid by *wholesalers* to the tranche suppliers. Pharmacists, in turn, pay the wholesalers the Category T price plus the predetermined distribution fee. The NHS then reimburses pharmacists the Category T price plus the distribution fee.

A partial tendering system is also proposed, with the above system being used for a sub-set of generic drugs. Table 17.1 presents the risks and opportunities under the proposed tendering scheme. Tables 17.2 and 17.3 repeat the tables summarising the trade-offs between the different distribution and reimbursement options on issues such as likely control of fraud, incentives for bypass and complexity.

Table 17.1: Risks and opportunities of full tendering

Option	Risks	Opportunities
Full tendering system	Supply disruptions	Lower, and less volatile, prices
	Centralised market management difficult	Entry assistance
	Complex system to administer for all drugs	Good understanding of supply conditions
	Some demand forecasting required	Transparency
	Arbitrage may occur between tranches if prices differ, or between countries	Scale economies in production
		Staggered contracts allow demand flexing over time
Partial tendering system	Similar to full tendering	Basic pilot approach starting with a few manageable drugs
	May need to establish most of the infrastructure for full tendering, even to run it partially	Allows adjustment if/when difficulties are found
		Gives an option to pull out without committing substantial resources
		Threat of moving from competitive market to tendering may be a powerful constraint on behaviour

Table 17.2: Advantages and disadvantages of the three distribution options

	Option 1: Any wholesaler	Option 2: Designated distributor	Option 3: Clearing house
Prevents arbitrage between tranche suppliers, allowing NHS to make demand commitments	No	Yes	Yes
Allows efficient monitoring of product flows from tranches	No	Yes	Yes
Maintains efficiencies of current distribution structure	Yes	No	Yes
Avoids vertically integrated wholesalers and pharmacists having to deal with competitors	Yes	No	Yes
Allows distribution to be part of bid in supply tender	No	Yes	No
Avoids creation of new government agency	Yes	Yes	No

Table 17.3:Advantages and disadvantages of the three reimbursement options

	Option 1: Distribution fee only	Option 2: Full tender price	Option 3: Category T price
Prevents arbitrage between tranche suppliers, allowing the NHS to make demand commitments	Yes	No	Yes
Reduces the likelihood of bypass via non-winning suppliers and PI	Yes	No	Yes (partly)
Reduces likelihood of excessive stock holding and smuggling products abroad	No	Yes	Yes (partly)
Allows the NHS to pay for drugs after dispensing	No	Yes	Yes (if settlement is delayed)
Gives the NHS the option not to reveal winning tender prices	Yes	No	Yes
Reimbursement prices can be announced in the Drug Tariff, thereby providing clarity to pharmacists	Yes, but only distribution fee, so may look unfamiliar	Yes, but different prices for different tranches may cause confusion	Yes
Transitional problems are only one-off	Yes	Yes	No
Follows the principle that each player is paid after delivery	Yes	Yes	Yes (if settlement is immediate)

From the tables above, it is clear that the clearing-house option (distribution option 3) has advantages over the other two, in terms of facilitating monitoring, preventing arbitrage and preserving distribution system efficiencies. It does, however, require the establishment of such a clearing house, which may be costly. Reimbursement option 3 also has advantages over the other two, since there should be limited theft and arbitrage incentives, and it should be relatively straightforward to put into operation. The main disadvantage is that when the Category T price changes, a transitional process is necessary; however this will only be required if subsequent rounds of tendering deliver significantly lower prices, which will, by necessity, also mean significant underlying cost savings to the NHS.

In theory any distribution option could work alongside any reimbursement option; however, there are two combinations that deserve comment. If reimbursement option 2 is chosen, then it is best not to use distribution option 1. The former has the highest risk of arbitrage, and the latter is the system under which it is most difficult to prevent arbitrage. Either of the other two distribution options make monitoring more straightforward (although the third option is probably preferred). If reimbursement option 3 is chosen, then distribution option 3 is preferable. This is because the settlement process implicit in reimbursement option 3 is facilitated by the clearing house centrally recording each month the volumes delivered by the different tranche suppliers. The same information could be sought under the other two distribution options, although it would be more cumbersome.

Two other tendering options are proposed in the report—tendering for buffer stocks and tendering framework agreements. Also, section 16 discusses alternative reforms proposed in Phase I that could achieve some of the government's objectives.

Tendering for a buffer stock is the third option presented. It is aimed specifically at preventing shortages and maintaining price stability. Under this option, the NHS would tender for the supply of, say, 15–20% of total annual demand for certain preparations, to be kept and managed by the NHS as a buffer stock. Tenders would be required continually, but for relatively small volumes after the initial acquisition.

The fourth option involves tendering for framework arrangements with manufacturers, which wholesalers and pharmacists have the option to use for the purchase of their drugs. It is similar to the tendering system set up by the NHS PASA for the hospital sector. In this system, manufacturers bid to become the framework arrangement supplier. The role of this supplier is to supply the drug in question to any pharmacist at the agreed framework price. The manufacturer that offers to provide this service at the lowest price wins the tender. Effectively, the framework price will function as the maximum price that any wholesaler or manufacturer can charge to pharmacists for that drug. It is therefore also the maximum reimbursement price paid by the NHS.

In Phase I of the study, a number of further options were raised, under the following three headings:

- reform reimbursement;
- request information;
- enforce vertical separation.

A summary of the assessment of these two further tendering options and the three options from Phase I is presented in Table 17.4.

Table 17.4: Risks and opportunities of alternative tendering options

Option	Risks	Opportunities
Buffer-stock tendering	Costly to hold stocks	Good insurance against supply disruptions
	Management of the stock difficult	Entry-assistance method
	Supply into the market may be costly if spot price lower than contract price	
	In the event of a disruption, there may be incentives for suppliers to wait until the buffer stocks have run out before resupplying	
Framework agreements	Without output contract, price that is bid can be meaningless	Option framework may be good solution for call-off requirements
	Complex to set up and complex for manufacturers to bid for. Conceivably there could be no bidders	Competitive market still exists alongside agreements
Information obligations	Short-term solution	Less costly to implement
	Supply chain manages to obscure true prices under new information obligations	Existing market arrangements continue
	No improvement in cost of drugs to the NHS	
Vertical separation	Serious resistance to such a substantial intervention in industry structure	Transparent prices
	Informal links are formed, although officially separated	Independent contractors will have incentives to negotiate good prices from suppliers
	Loss of the true efficiencies that provided the original incentive for the integration	
	Still strong incentives to hide true market information from NHS	

A successfully functioning competitive tendering scheme meets five of the six key objectives of the government. It removes financial risk from pharmacy, provides transparency, value for money, and good levels of service to patients, and can enhance competitiveness. It is not clear, however, that it will contribute to minimising the costs of distribution. These objectives are achieved through:

- increased security of supply and a less volatile market;
- price transparency;
- purchasing arrangements that are robust to market structure changes;
- cost-reflective prices.

Benefits arise from the introduction of centralised purchasing in the form of reductions in the prices of generic drugs supplied to the community. Depending on assumptions, these range from £30m to £100m–£200m. The highest numbers come from the scenario where significant margins are being earned in the supply chain and factory-gate prices fall by 20% on 80% of the value of community generic drugs.

Against these benefits, the risks of this radical change must be set. The risks are as follows:

- it could be expensive to introduce;
- complex organisation is required and significant market expertise is required of the tendering authority;
- substantial price reductions may not be forthcoming;
- supply failures may occur and could be difficult to resolve without a market mechanism in place.

Two key questions need to be answered before going forward with the introduction of centralised purchasing. Will tendering lead to:

- lower market prices and/or lower reimbursed prices?
- serious shortages?

This study has proposed a centralised purchasing structure designed to deliver cost-reflective prices and to ensure a secure supply of drugs. The likelihood that these objectives are achieved will depend on its performance.

The extent to which cost-reflective prices will be lower than current prices depends on how efficient the existing market is. There is strong evidence to conclude that reimbursed prices are well above costs, at least for some drugs, and some indication that market prices are also above costs. This suggests that real savings would be made through the introduction of tendering.

There is a further risk that the competitive tendering approach can have a negative dynamic effect on the NHS's objectives. Low initial prices lead to market exit, risks of supply interruptions and then higher prices in the future. The proposed design has been carefully constructed so as to minimise this risk. In general, the risks of supply disruptions should be low and there should be sufficient mechanisms in place (more than in the existing system) to elicit alternative supplies in the event of any production failures.

Of course, the test of such a system is in its practical implementation. The option of introducing partial tendering, starting from a small base and adding extra drugs over time, is a way of testing the design and controlling the risks identified above. Section 15 outlined how this could be done and how the performance should be assessed. Trialling the process and mechanisms will give useful feedback, and more complicated tenders, buffer-stock arrangements or back-up supply contracts could be included if the underlying basic tendering process proves successful.

APPENDICES

A1. Manufacturing

This appendix provides a detailed description of the manufacturing sector, based on the extensive interviews held with manufacturers, licensing information from the MCA, and information extracted from annual reports. The market structure in UK generic drug manufacture is described in section A1.1. Section A1.2 outlines the licensing process and the entry conditions in the industry. The third sub-section describes the manufacturing process, including production scheduling and pricing. The last part discusses the shortage situation in 1999, from the manufacturers' perspective. The examination of profitability of manufacturers is further explored separately in section 2.6 and in appendix 5.

A1.1 Market structure

There are few remaining true UK generic manufacturers, with the largest having moved their production facilities overseas. Table A1.1 shows the turnover of the main manufacturers supplying generic drugs to the UK market. Figures in the table are taken from the most recent available published accounts,[34] which relate to the 1998 calendar year unless otherwise indicated. Most of the companies supplying the UK market are owned by foreign companies and have production facilities outside the UK. CP Pharmaceuticals remains as a UK-owned, UK-based manufacturer. In order to supply into the UK market, any company must hold a UK product licence and the factory/manufacturer must have MCA authorisation. This is discussed in detail below.

Table A1.1: Generics manufacturers

Company	Turnover[1] (£m)	Market share[2] (%)
Norton[4]	167 (133)	39
Generics UK	70 (51)	15
Cox	55 (50)	15
APS	37 (36)	11
CP Pharmaceuticals[3]	25 (23)	6.7
Lagap	23 (23)	6.7
Rosemont	8	2.3
Ranbaxy	7.5	2.2
Regent[4]	11	3.2

Notes: [1] Figures in brackets indicate turnover relating to UK sales only. [2] Market share is expressed as a percentage of total turnover of the generic manufacturers, which excludes export but does not take account of possible double-counting or smaller players not listed in the table. [3] CP Pharmaceuticals figures relate to the 12 months up to the end of June 1999. [4] Figures for 1997—at the time of writing, figures for 1998 were not available.

The firms in Table A1.1 account for a total turnover of £342m. As shown in the table, some manufacturers export a small fraction of their turnover. It is common practice within the generics manufacturing industry for one firm to manufacture on behalf of another. Thus, it is likely that there is a degree of double-counting in adding up the turnovers figures in the table.

[34] At the time of writing.

It is difficult to estimate the turnover of any smaller firms not listed above, and the contribution of firms that are both manufacturers and wholesalers or importers (for example, Kent Pharmaceuticals). The BGMA has estimated the total turnover in the manufacturing sector to be around £350m.

The other main development that is likely to occur in generic manufacture in the next 10–15 years is increased globalisation. Large multi-national generics producers are already forming, and these will increase in number, size and geographic coverage in the years to come, as the licensing of generic drugs become increasingly uniform across Europe. Greater globalisation, with large firms achieving greater economies of scale, will place the UK domestic industry under price pressure.

A1.1 Entry conditions

A1.1.1 Licensing

There are three important licences relating to the manufacture and/or sale of generic drugs in, or for, the UK that must be obtained from the MCA. A product licence is needed to sell a medicine, a manufacturer's licence to manufacture it, and an importer's licence to import it from outside the European Community.

Site or 'manufacturer' licences from the MCA establish the quality and testing procedures that a manufacturer needs to implement. In particular:

> The licence-holder shall conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products conform with the standards of strength, quality and purity applicable to them under the relevant product licences and, in relation to medicinal products for human use, shall conduct all such operations in accordance with the principles and guidelines of good manufacturing practice[35]

Persons responsible for production, quality control and batch release must be approved and named on the licence. The latter person in particular must meet criteria of qualifications and experience laid down in European Community directives.

Manufacturers are allowed to wholesale products they manufacture themselves, without a wholesaling licence; however, most have wholesale licences as well, particularly for products they do not make themselves. These are inspected on a two-year cycle and Table A1.2 details the inspection fees for manufacturers.

[35] MCA (1997), 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors 1997', The Stationery Office, London, para 3, p. 4.

Table A1.2: Inspection fees for manufacturing plant by number of employees and type of manufacture (£)

	Sterile products[1]	Non-sterile products
Super site (>250 employees)	10,500	6,300
Major site (between 60 and 250)	5,775	3,675
Standard site (between 10 and 60)	3,675	3,045
Minor site (<10 employees)	1,785	1,640

Note: [1] A sterile product inspection fee includes any non-sterile products also made on that site.

Mutual recognition between the EU and third countries is under negotiation. It has been agreed with Australia and New Zealand, and is due to be agreed with Canada by April 2000 and with the USA by December 2001. Once agreed, drugs manufactured in those countries do not need to be re-tested when imported into the EU, and manufacturing sites do not need to be inspected by European Commission inspectors. Hence these agreements will directly benefit importers. Manufacturers making products exclusively for export still require a licence, but the products themselves do not need to be licensed in the UK. It also means that MCA inspectors do not need to inspect foreign sites, as mutual recognition implies that each country recognises the validity of inspection by the residing inspectors.

There are three types of site licences, all of which cost £1,730:

- standard manufacturer;
- manufacturer of specials;
- manufacturer AO.

Manufacturers with overseas plant that sell to the UK are not licensed by the MCA. They may be inspected (and approved) by the MCA where they are named on an importer's or a product licence. Their sales are subject to, and the importer must have, the specific product licence.

In addition to a site licence (or approved manufacturer for contract manufacture), firms require a product licence for each drug they wish to market in the UK. This licence specifies the exact characteristics of the product to be manufactured: its composition, including the supplier of the active ingredient (raw material); the site at which it will be manufactured; and the indications for the product (what conditions it will be recommended as treating).

Rather than engage in significant primary research, as do the R&D pharmaceutical companies, generic manufacturers copy a branded drug once it is off patent. They can gain a product licence from the MCA by establishing that their drug is 'essentially similar' to the originator product it is imitating. In order to do this, generic manufacturers

need reference not only to the chemical composition of the branded equivalent, but also to the clinical trials data which is held by the MCA.[36]

Having received the data, the generic manufacturer must carry out its own research in order to produce a drug for which bioequivalence to the original product can be demonstrated. This research takes a year to 18 months. The MCA then assesses the application for the drug licence. While manufacturers have suggested that the MCA can take up to a year before the product licence is agreed, the average net assessment time for these 'abridged' applications in 1998/99 was 90 days. However, the gross assessment time (ie, the total time taken, including time for the company to respond to questions on deficiencies in the application) is closer to 190 working days.[37] As the clinical trials data is only available while the originator product is on the market, for some drugs that have been in existence for a very long time it can be difficult to introduce new generic versions as the original brands no longer exist and the original clinical data is unavailable. This restricts entry to generic manufacture once the brand has been withdrawn, potentially providing market power to those suppliers that remain.

The product licence is very explicit. It states the exact raw materials used, even down to the specific supplier of the active ingredient. Variations can be made to the licence, but they must be validated by the MCA. For every generic drug that a manufacturer produces, it must therefore have a long-term relationship with the active-ingredient supplier. As a result of the cost of varying licences and to simplify contracting, most manufacturers try to certify two or three active-ingredient suppliers in the original licence application. The product licence also states the site at which it will be manufactured; this can also be varied to include another approved MCA site, but, as with other variations, takes on average three months to be accepted.[38] If the variation is for a site that has not previously been approved, then the site must obtain a manufacturing licence from the MCA separately.

There is increasing standardisation of licences for branded products through mutual recognition within the EU, which implies that new generics will be acceptable everywhere in Europe when current branded drugs go off patent. However, in the UK, there is a rump of old generic products that will never qualify for mutual recognition, and there will always be barriers to intra-Europe trade in these drugs.

Product licences have to be renewed every five years. Hence, they have a value on the open market. It is possible for firms to sell licences, with the only variation necessary being changes to the owner of the licence and the manufacturing site; even the site need not be altered, with the new licence-holder contracting the previous one to manufacture for them.

Manufacturers continually make decisions about which drugs they are going to produce from their licence portfolio (discussed in more detail below). Each product licence has a renewal date each year when service fees must be paid to the MCA to maintain the licence (this is separate from the five-year review). Manufacturers can therefore choose from three options: produce under the licence; do not produce but maintain the licence;

[36] This data is only available to generics companies for as long as the branded product is on the market.
[37] MCA information.
[38] The MCA has commented that Type 1 variations to a licence can in fact be completed more quickly than this.

or, if market conditions appear particularly poor, allow the licence to lapse. In this case, the only way to regain the licence is to go through the whole bioequivalence procedure again.

A1.1.1 New entry

Various entry decisions can be considered: a new start-up manufacturer; an existing manufacturer producing a new drug; or a new supplier into the UK market. Entry is possible at each of these levels, and becomes increasingly easy.

A new start-up manufacturer would need to invest in high-quality (and often high-technology) drug-production facilities and have to meet the stringent standards of the regulatory bodies. This may be a significant investment, and it is likely to take one to two years to create a new factory.

Although some change of ownership does occur, there is no obvious second-hand market in pharmaceutical plant, and, as discussed below, extensive contract manufacture can be seen as a form of leasing. Some elements, such as the packing lines, are more likely to command a resale value outside of drug production.

Once a firm has established a manufacturing plant or contracted out production, the barriers to entry to manufacturing a new product are not particularly high, provided the original clinical trials data from the originator product is still available. The principal barrier at this stage is the investment in drug development, which ranges from £70,000 to £1,000,000 and averages £150,000–£250,000. It is not even necessary for the prospective manufacturer to have a research facility, as the task can be contracted out. On average, there is a time lag of 18 months to two years between the entry decision and the arrival of the drug on the market.

The most likely source of new entry into the UK market is from overseas producers. There are growing global generic manufacturers, such as Teva in Israel and Ranbaxy in India, which own firms in, and produce for, many countries around the world (including the UK). These large firms can obtain licences relatively quickly as they often already manufacture the drugs for other markets. They also make use of more relaxed patent laws around the globe to bring new generic drugs to market faster than is possible in the UK.

Increasingly it is to be expected that the global generics firms will use central research facilities to develop generic products for many different markets. For instance Teva has developed and manufactured Fluoxetine in Israel but gained product licences for the USA, UK, Holland and Germany from the same research. Such procedures reduce the cost of obtaining product licences and may speed entry into new markets.

In addition, firms that are unable or unwilling to establish a manufacturing plant can use contract manufacture to supply the UK. It is not necessary for a firm to have either a product licence or a manufacturing site in order to sell a product under its own name. Contract manufacture occurs when one firm manufactures on another's behalf: if firm *A* holds a licence but does not have a manufacturing plant, it can contract with manufacturer *B* to produce the drug for it under *A*'s licence. *A* would need simply to vary the terms of its product licence to have *B* approved as a manufacturer (assuming *B* was an MCA or other EU regulatory authority-approved manufacturer). Alternatively, *A* could request *B* to manufacture a certain quantity of a drug under both *B*'s product and manufacturing

licences. *A* may hold an AO licence which enables it simply to repackage products manufactured elsewhere.

Any contract manufacture must, under MCA rules, state on each container (bulk or patient pack) who owns the product licence and who manufactured the product.

In summary, while entry as a traditional manufacturer into the UK market may appear relatively costly, and entry into the production of a new drug may appear to involve moderate investment, the possibility of contract manufacture significantly widens entry possibilities. There is an increasing number of global generics corporations that could swiftly begin production for the UK, as long as they have access to production from a UK-licensed plant. It would appear from this that entry and exit barriers are not substantial in this market. As mutual recognition makes international drug licensing more straightforward, these barriers will fall even further.

The profitability analysis[39] of appendix 5 suggests that entry, or the threat of it, has not had a significant effect on manufacturers' profits. They have remained high, even on an analysis which does not include the 1999 calendar year, with an average ROC of 29%, with gross profit margins averaging 36.7% and average operating profit margin of 9.9%. It would be consistent with this to consider that barriers to entry do exist, and incumbents do not feel the threat of entry keenly.

A1.2 The manufacturing process

The strict guidelines and requirements for manufacturing plant in the UK relating to hygiene and quality control set out by European Community directives and monitored by the MCA are designed to minimise the risk of imperfect or contaminated drugs being produced. Manufacturing facilities are high-quality plant with strict hygiene controls. The areas where products are physically made are 'clean' areas, with production 'suites' often protected by pressure gradients,[40] and, in places, airlocks.

There are about four or five stages in manufacturing solid-dose tablets, which are the main generic products. First, the active ingredient is mixed with the other components of the tablet, in the correct proportions—this powder is then run through a 'granulation suite' that creates a dry mixture of granules of relatively uniform size. These granules are pressed into tablets, and may be stamped with the manufacturer's logo (or, in some cases of contract supply, the logo of the distributor). The finished bulk tablets are then passed through to the packaging area. If the tablets need to be coated with colour and/or flavour, this is done immediately before transfer to packing.

[39] The following caveats about the profitability analysis should be noted. Some firms produce only abbreviated accounts, and, at the time of writing, information for the 1999 calendar year was not available for most firms in the sector. Some companies indicate the fraction of their turnover that derives from export; where no geographical breakdown is given, it has been assumed that all turnover relates to the UK market. It has been assumed that all information relates to generic business (some manufacturers produce branded products). Many of the firms in this study are subsidiaries—some firms record substantial short-term indebtedness to group undertakings, which significantly reduces the asset base of these firms.

[40] The pressure inside the rooms is slightly lower than that outside in order to create a flow of air into the room when the door is opened. This significantly reduces the possibility of powdered active ingredients (or other airborne substances) leaving the room and contaminating other production facilities.

The same production equipment is used to manufacture different products. When switching production from one drug to another, there must an extensive cleandown to remove all traces of the previous drug in order to avoid contamination. This cleandown may take 3–12 hours depending on the drug and the manufacturer, and is a significant aspect of production cost. Equipment also needs a changeover if other aspects of production (for example, tablet size or shape) change between runs. For this reason, manufacturers prefer longer runs of drugs as it spreads downtime over a greater production volume. Cleandown is the most significant switching cost between drugs for which licences are already held, and is also one of the main reasons why costs increase in periods of uncertainty.

There are some exceptions to interoperability for some types of drugs, for example penicillins and cytotoxics. These must be manufactured in a dedicated facility because cross-contamination of other drugs by these hazardous materials is particularly difficult to prevent by cleaning between batches.

There are normally a number of packing machines organised in ‘lines’. Each line performs the following operations: counting the tablets delivered in a large bin into the relevant pack sizes (bulk or patient pack); forming the pack (which, as described below, is far more complex for patient packs than bulk containers); adding labels and information; and packing into boxes for shipment. The area where the drugs are still exposed to the air, as they are placed into packs, is a closed hygienic environment, whereas there are no such requirements in the final stages of the line.

The process is significantly more complex for patient packs than for bulk. Bulk containers, generally plastic tubs, are filled, capped and then labelled and packed into boxes. Filling and labelling is done automatically, monitored by one or two operators at each stage, while packing into boxes may be done manually, and requires one or two staff alone, depending on the speed of the machines.

Patient packs, on the other hand, involve more complex machinery. The foil and PVC elements of the blister pack are fed flat off rolls onto the machines that impress the holes, fill them with tablets, and then heat-seal the pack with foil and PVC. At this point the pack passes out of the hygienic area where another machine opens up small flat-packed cartons, adds a label, patient information leaflet, and requisite number of blister packs, closes the carton, before wrapping a set number of packs for packing into boxes for shipment.

Staff are needed in the hygienic blister-pack filling area to monitor the stage where the blister packs are placed in cartons, and to pack the multiple-wrapped cartons into boxes. In general, the work rate of the blistering machine is controlled by the machine filling the cartons with blister packs; thus, blistering machine capacity may not be fully utilised.

Blistering machines are high-tech, complicated pieces of equipment with much less margin for error than those used in bulk production. For instance, every time a different product is run through it, the machine must be recalibrated to ensure that it cuts the blister roll at exactly the right point to deliver the correct number of tablets per blister and the

appropriate information on each blister strip.[41] Accordingly, there is considerably more waste arising in set-up and changeover of blister machines for patient packs than for bulk containers, and the process takes more time, reducing overall output.

During production, the tablets in preparation do not move seamlessly through the different stages, but are scheduled according to the availability of the equipment and production priorities. Various quality tests are also conducted during the process which may cause delay. On average, it takes about one month from the start of production for packed tablets to leave the factory. In addition, there is about a two-month lead time on ordering the active ingredient if none is available from stock. Hence, it takes a minimum of three months to produce and deliver a new product to the distribution system (ignoring, for now, the licence requirements).

Factories generally seem to operate on an eight-hour shift system, with most firms having two shifts per day, although some moved to three-shift (24-hour) working during 1999 to cover the shortages in the market.

In order to comply with the various demands of the product and site licences, tablets are monitored and tested throughout the production process. When a new product is first run through the production line, the manufacturer must engage in 'validation', which involves rigorous testing at each stage of the production process to ensure that the output is meeting its specification. Validation is a major exercise and is a significant cost for the manufacturer, as there is extensive downtime of the production equipment.

Having validated a product in the plant, a manufacturer must then keep accurate records of production of the drug. This includes regular sampling and testing at all production stages, and a log of any incidents that occur during production. The MCA may inspect a factory at any time and may ask to check these records, although this occurs generally about every two years. Thus, the machine operatives must be trained to a high degree to understand the functions they perform and how to check the products for acceptability.

A1.2.1 Production decisions

Manufacturers have different strategies regarding their production decisions. Some focus on being the first to bring newly off-patent drugs to the market, and continually revise their product range to reflect this, while others focus on particular parts of the market, such as high-volume, low-price drugs. Manufacturers also differ in the range of drugs they market. Some provide a 'full' range of generics and use contract manufacture for those they do not produce themselves, while others focus only on those drugs they produce.

The choice between full-range or self-production only is normally associated with the market that the manufacturer supplies. Those aiming to supply retail chains need to be able to offer a full range, while those supplying to wholesalers need sell only the drugs they produce. This is because pharmacists like the convenience of one supplier, whereas wholesalers are less concerned with the number of suppliers but purchase mainly on price.

[41] Details, such as the product licence-holder and the distributor, are printed on the continuous roll of blister backing film. This film must be fed onto the PVC tablet holder at exactly the right point to ensure that the information occurs in full on each blister.

UK manufacturers committed to providing off-patent drugs as quickly as possible for their customers, both wholesale and retail, will contract with foreign manufacturers to develop a product for them in advance of patent expiry. Usually a requirement of such a contract by the foreign manufacturer is that a certain volume of the licensed drug is purchased by the UK manufacturer from the developing firm. In this way, foreign suppliers gain revenue to subsidise research that they would otherwise have carried out at their own cost, and have guaranteed greater production runs in the initial stages of the drug release onto the market. The UK manufacturer will, however, have its own plant added to the product licence so that, once its commitment to the foreign manufacturer is complete, it can continue production in the UK.

Manufacturers monitor the market in terms of the number of producers of all generic drugs and the prices. Most manufacturers have a sales force at either the wholesale or retail level, or both, which feeds back information on the prevailing market price and the rival suppliers. Those firms without sales forces rely on wholesalers to provide them with feedback on their prices, and other routes for competitor information.

Having gathered price data, the sales and marketing team within the manufacturer determines which are the best products to market. This decision takes into account the potential margin on each drug, the number of suppliers (suggesting likely price movements), existing and future orders, and the corporate strategy. A number of manufacturers indicated that they would continue producing drugs even if they were retailing below cost if continuing to supply them was an important aspect of a customer relationship. In the long run, if the prices of certain products remain below cost, the manufacturers will cease production, and, as discussed above, may even let the licence lapse.

Most manufacturers use annual forecasting updated monthly. The annual forecast is generated from experience, and allows the production managers to draw up a schedule of production for each month. This schedule details which products are going to be produced when, and drives all aspects of the production process, such as ordering of raw materials, cleandowns and the level of shift working used. Each month the sales and marketing department provides a list of drugs and associated volumes required, and this is compared to the forecast schedule for the month ahead. Where necessary, the forecast schedule is altered to accommodate the changes in the market. In a normal year the forecasting accuracy is 45–55%.

Without exception, the manufacturers visited during this study stated that their forecast accuracy had fallen considerably in 1999. This was attributed to the extreme volatility in the market, and meant that most production schedules were rewritten monthly or even weekly, on the basis of which drug was in shortage and the most pressing back orders. The main result was reduced run lengths and considerably reduced efficiency. Almost all the manufacturers were practically rewriting their production schedules each month, and had experienced considerable back-order problems. For instance, one manufacturer normally ran a back-order book of around £0.5m–£1m in value, and, in 1999, it reached £3m.

Almost all the manufacturers visited expressed a desire for greater predictability of supply, as they were concerned about the impact of the market volatility on their production schedules. Over the previous year, demand had become considerably more

difficult to predict. This, in turn, reduced the length of production runs and increased changeover costs. Even in periods of more normal demand, manufacturers claim they would prefer long-term contracts with either the NHS or wholesalers.

When asked, both manufacturers and wholesalers said that the other was reluctant to sign such contracts. Apparently this was on the basis that it was too risky because market conditions, particularly price, might change. However, sophisticated contracts have been designed in other industries to cope with exactly these uncertainties. It appears that, despite concerns about lack of certainty, both manufacturers and wholesalers in fact prefer not to establish contractually based relationships.

A1.2.2 Pricing determinants

For manufacturers, the key driver of price of most drugs is the market price; in general, wholesalers buy from the cheapest supplier, and, even if they do not, they use other firms' prices as yardsticks for their preferred manufacturer to match or beat.

In general, generic manufacturers claim that market prices reflect the investment in the development costs of bringing new off-patent drugs to the market. However, supply does sometimes come in, usually contract manufacture, at a significant discount to the UK market price. Manufacturers allege that this supply is usually for limited product ranges and limited periods of supply. Such suppliers are described by the main UK manufacturers as 'non-serious players' or 'easy entry–easy exit' firms. These are essentially importers with no manufacturing facility, which may not even have wholesaling facilities. They therefore invest only in the working capital and the product licences required to enter the market.

Foreign manufacturers will be willing to supply into many markets, either through their own subsidiaries or via traders that bear the risk, as longer production runs improve their efficiency. Most of the large international production sites for such contract manufacture are based in Hungary, Israel, Canada and India. These are countries where Roche–Bolar-type patent provisions exist, allowing research into producing a bioequivalent generic version of the originator products to begin before the end of the patent life.

UK manufacturers claim that the main reason these foreign manufacturers and agents can supply at such a low cost is that they can spread the initial cost of researching and developing the drug over many different national markets, including the UK. Manufacturers go on to state that this undermines their incentive to invest in developing new generic drugs, and that, if these suppliers were allowed to continue, domestic production would be threatened.

Examples are wholly owned subsidiaries of foreign manufacturers, which sell only a limited portfolio of drugs but do have a warehouse licence. Other subsidiaries and independent traders (which can act simply as importing agents) may not have a licence at all. Such firms arrange for the importation of the drugs and sell them to UK manufacturers, which repackage them for sale under their own label. The importer may not ever physically handle the drugs, obviating the need for any wholesale or distribution licences. In this case, the manufacturer is listed in the licence as the wholesale depot for the importer's licence.

The impact of importers may be that they can reduce the market price. However, if the entrants generally sell only small volumes of drugs, maybe three or four months' supply, and then exit, the reduced prices over that period were alleged to be sufficient to cause some long-term manufacturers to exit the market for that drug. While the short-term players are supplying, there are no problems. However, once they exit, there may be either a shortage or a reduced number of suppliers, and prices can rise above the previous level.

OXERA has attempted to investigate this aspect of the market. There is some evidence of small firms importing from overseas, mainly short-line wholesalers. They generally have only a few product licences in which they have invested themselves to develop. From the number surveyed, they do not seem to be price leaders; rather, they accept the prevailing market price and supply what they can. By the end of the Phase I study, no players fitting the 'easy-entrant' description of manufacturers had been identified. However, in the absence of accurate supply volume data, it has been difficult to assess the extent of importers as suppliers to community pharmacy.

Economic theory suggests that the mere threat of this type of entry may be sufficient to maintain prices at a competitive level. On the other hand, short-term entry may increase the volatility of the market and inhibit investment. Greater instability of demand reduces the efficiency of manufacturers. In the long run, there may be two impacts of contestable entry:

- manufacturers seeking greater certainty of demand will look to integrate vertically with retail pharmacists or wholesalers; and
- the uncertainty of returns from new products may reduce investment and the flow of new generic equivalents of off-patent brands.

Contestable entry may also drive those predominantly supplying the UK market at present to mimic the more international players and expand their production scope. The issue for the NHS is whether short-term entry does have longer-term negative effects, or whether the commodity nature of the market ensures that the product will be available.

A1.2.3 Supply routes

Manufacturers (and other firms supplying generic drugs) have two main supply route options: sales to wholesalers, or direct supply to retail pharmacists. The former are easier and require considerably less effort as there is only a limited number of wholesalers. At most, a supplier would need a small sales team and contacts in the wholesalers. The drawback is that the wholesaler may appropriate a proportion of the available margin.

Direct supply to retailers is considerably more complicated and involves an extended sales force to market the product to pharmacists. The supplier would also have to arrange delivery to the pharmacist, either through its own operation or by contracting it out. As the manufacturer supplies the retailer directly, it receives the full price available but incurs greater costs.

There are differing attitudes between the main manufacturers as to preferred supply routes. Some, such as Norton and APS, use both wholesalers and a direct sales force, while others, such as CP Pharmaceuticals and Generics (UK), only market to wholesalers. There do not appear to be any manufacturers focusing on direct sales alone. There is also

a difference between product ranges for direct and wholesale supplies; in general those firms supplying directly are keen to maintain a full product range, while this is not as important for wholesalers.

A further alternative route of supply into the market is sales to other manufacturers. As already discussed, the manufacturers have many cross-contracting arrangements, but importers may also sell to established manufacturers.

A1.3 Manufacturers' views of shortages over the last year

The manufacturers contacted by OXERA were unanimous in highlighting three factors that caused the shortages in 1999:

- the closure of Regent;
- the relocations of Norton and APS; and
- the conversion to patient packs.

A1.3.1 Regent's closure

Although Regent did not have a significant turnover compared to other players in the market, it was nonetheless key in certain products. It specialised in producing high-volume, low-value, generic drugs, including antibiotics. In particular, it appears to have continued to produce certain drugs, even though other manufacturers had taken the decision to cease production as prices were too low. Its strategy of reducing costs to the minimum allowed it to compete with the imports from foreign manufacturers that were discussed above (also see below for a summary of manufacturers' views regarding these players).

As a result of its niche in the market, many other manufacturers had withdrawn from the products in which Regent specialised; some claim to have allowed their licences to lapse. Accordingly, there were initially few alternative suppliers to replace Regent's production, and, owing to its high volume of output, significant capacity constraints arose. Furthermore, the expectation in the industry was that Regent would rapidly recommence production.

Given the likelihood of only a short-term increase in demand while Regent was inoperative, no manufacturer was willing to commit to investing in expanding capacity. Rather, attempts were made to meet the shortfalls by increasing output at existing plant, mainly through additional shift(s).

A1.3.2 Plant relocations

Both APS and Norton relocated their manufacturing plant around the beginning of 1999, to Hungary and Ireland respectively. For Norton, it appears there was a small interruption in production, possibly up to a month, while this process was carried out, and the production facilities were approved. In particular, all drugs produced at the new plant had to be revalidated before full production runs could commence. APS moved to Hungary as a result of the availability of a high-quality plant that was not being fully utilised by its parent company, Teva. Ordinarily, it is unlikely that either of these relocations individually would have had a significant impact on supply in the market. However, not only did they occur simultaneously, but they also coincided with the closure of Regent.

A1.3.3 Patient packs

As the Department is aware, there has been considerable criticism within the industry of the changeover to patient packs. During interviews with OXERA, manufacturers took the opportunity of relaying their concerns on this matter.

The principal problem that has arisen is the omission of patient packs from the Drug Tariff. Without this, pharmacies cannot be reimbursed specifically for dispensing patient packs, and they have therefore continued to demand bulk from the manufacturers where possible. Thus, the manufacturers' patient-pack production was not being purchased, while the shortages of the bulk drugs (as most manufacturers had switched most of their production to patient packs) pushed the bulk packs into Category D.

This is clearly a short-term problem, but the manufacturers feel that it may be a significant explanation for the increase in the number of Category D listings in 1999 over previous years.

The manufacturers also claim that there are other, longer-term issues relating to patient packs. Patient packs cost more to produce as they require additional containers and patient information, and it is likely that this cost will be reflected in the price. Further, the conversion to blister lines requires additional investment in the packaging plant, and this will also cause prices to rise slightly, at least in the short term.

Patient packs also have a much slower throughput than bulk containers. Even with investment in additional blister and packing lines, it is unlikely that manufacturers will be able to produce patient packs as quickly as they could bulk. This reduces the overall output of the manufacturing plant and its efficiency.

A2. Wholesaling

In the pharmaceutical distribution chain, wholesalers perform the task of supplying pharmacies and hospitals with drugs (and other medical products) sold into the chain by manufacturers and importers. Another important service provided by the wholesalers to both suppliers and clients is information on demand, supply and stock levels. There are two types of wholesalers.

- *Full-line wholesalers* supply the whole range of pharmaceutical products—branded drugs, generic drugs and PIs (which are mostly branded drugs)—including both frequently prescribed and the less profitable, infrequently prescribed, drugs. Full-line wholesalers normally deliver drugs to every pharmacy or hospital two or three times a day. They buy the drugs and then sell them on with a margin. However, in particular for generic drugs, they also increasingly act as distributing agents for the manufacturers (ie, without buying the products themselves). In the UK there are three national full-line wholesalers: Gehe UK (AAH), Alliance UniChem, and Phoenix. Phoenix is a newly established national wholesaler, formed from five regional full-line wholesalers. There are ten independent regional full-line wholesalers.

- *Short-line wholesalers* supply only a limited range of, more profitable, frequently prescribed products. Short-liners usually concentrate on PIs and generics, although they may also sell a limited number of UK branded drugs. They have lower costs than full-line wholesalers, but usually do not offer the same frequency of delivery. Some short-liners deliver only once a week, but others deliver daily. Some 'short-liners' stock a wide range of generic drugs (1,200 different drugs), and can be considered 'full-liners' in generics.

While there is a small number of relatively large short-line wholesalers (including Waymade, Dudley Taylor, Munro and Dowelhurst), in practice, a large number of companies, including many (manager-owned) pharmacies and pharmacy chains, engage in short-line wholesaling activities. At present there are more than 1,000 companies with a relevant wholesale licence (see below). In addition, according to some sources, many pharmacies engage in wholesaling without a licence (such unlicensed wholesaling is permitted if these activities do not exceed an 'insubstantial' part of turnover).

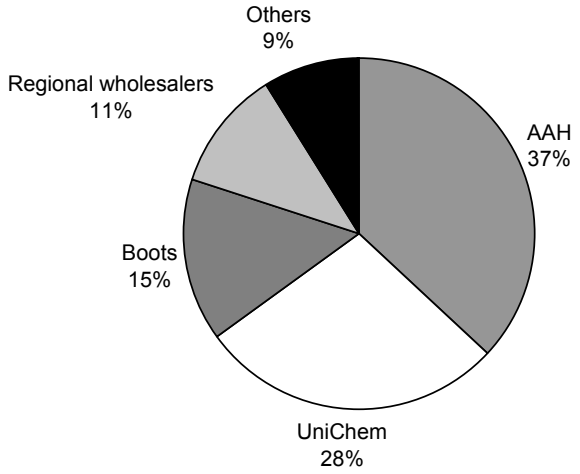
A detailed description is given below of the market structure, licensing arrangements, logistics, relationships with suppliers and customers, and integration patterns for wholesalers, focusing predominantly on full-line wholesalers.

A2.1 Market structure

A2.1.1 The UK market

Gehe's annual report of 1998 gives the following market shares of overall pharmaceutical wholesaling in Britain.

Figure A2.1: UK pharmaceutical wholesaling market shares, 1997



Source: Gehe (1998), 'Annual Report'.

In Tables A2.1 and A2.2 below, market shares are estimated on the basis of turnover of each wholesaler. This approach has several shortcomings for the following reasons, and the figures should therefore only be considered as indicative:

- not all wholesalers (particularly the short-liners) have provided their accounts;
- no distinction can be made between branded and generic drugs;
- the total wholesale market size (£5.4 billion) is based on a figure provided by the Department, and is at best only a rough estimate.

Table A2.1 gives the relevant figures for the full-line wholesalers, both national and regional. Table A2.2 gives the figures for (some of) the short-liners. The tables also give indicative information on the wholesalers' profitability. Profitability is further assessed in section 2.6 of the report and in appendix 5.

Table A2.1: Market share and profitability of full-line wholesalers, 1997/98

Company	Turnover (£m)	Market share[1] (%)	Return on sales[2]	Operating profit as % of turnover
AAH	1,800	33	10	4.4
UniChem	1,500	28	–	2.9
Phoenix[3]	484	9.0	12	2.3
Mawdsley-Brooks	82	1.5	7.3	1.7
East Anglian Pharmaceuticals	67	1.2	7.2	1.6
Graham Tatford	62	1.1	6.9	1.8
Sangers	37	0.7	6.8	1.9
Sants	31	0.6	7.7	1.3
F. Maltby and Sons	24	0.4	7.1	2.5
Norscott	19	0.4	11	3.4
Norchem	19	0.4	4.2	0.0
PIF Medical Supplies	16	0.3	6.1	2.2
Loveridge	8	0.1	23	1.1

Notes: [1] Market share based on an estimated total UK drugs market of £5,400m; total turnover listed in Tables A2.1 and A2.2 is £4,860m, which includes some double-counting and export business. [2] Return on sales is taken as gross profit as a % of turnover. [3] The figures for Phoenix are the sum of the figures for three of the four regional wholesalers it bought (Fosters, Philip Harris and Rowland; figures for the fourth, BCA, were not available).
Source: Company reports and accounts.

Table A2.2: Market share and profitability of short-line wholesalers, 1997/98

Company	Turnover (£m)	Market share[1] (%)	Return on sales[2]	Operating profit as % of turnover
Waymade Healthcare	136	2.5	11.8	6.6
Dudley Taylor	103	1.9	14.6	9.7
Munro Wholesale Medical Supplies	95	1.8	6.0	3.5
Dowelhurst	88	1.6	11	9.8
Necessity Supplies	60	1.1	13	12
Sigma Pharmaceuticals	60	1.1	11	2.3
Medihealth	56	1.0	15	3.9
Doncaster Pharmaceuticals	33	0.6	11	2.1
Kent Pharmaceuticals	29	0.5	21	4.8
Jumbogate	24	0.4	7.5	5.8
Freeman Pharmaceuticals	22.5	0.4	13	5.3
Chemilines	–	–	£1.3m[3]	£0.4m[3]

Notes: [1, 2] See notes to Table A2.1. [3] Only abbreviated accounts available.
Source: Company reports and accounts.

A1.1.1 European integration

Ownership patterns see increasing levels of European integration, with AAH and UniChem taken over by European wholesalers, and Phoenix creating a new national

wholesaler through the acquisition of a number of regional players. The advantages of such a strategy are the economies of scale and a wider breadth of service.

There is currently no single European market for generics, and price differences between countries prevail. However, the industry may be anticipating that there will ultimately be price harmonisation across Europe. Manufacturers are also integrating internationally, and they may centralise production in one place, requiring pre-wholesale services to national markets.

A1.2 Wholesale licensing

The obligation on governments of all the EU member states to ensure that pharmaceutical wholesalers are authorised is stated in Directive 92/25/EEC.[42] Pharmaceutical wholesalers must also comply with the 'Guidelines on Good Distribution Practice of Medicinal Products for Human Use' (94/C63/03). How these rules are incorporated into UK regulations is explained in the MCA's 'Orange Guide'.[43]

There are three classes of wholesale licence: a full licence; a licence restricted to general sales list products; and a licence allowing importation, for example from outside the European Community. In addition, every site of a licence-holder is licensed for certain product categories (eg, general sales list, pharmacy and prescription-only medicines), or activities (eg, wholesaling of PIs and 'specials').

Therefore, the most relevant types of wholesaler for the purposes of this report are those with a full wholesale licence and whose sites have a licence to handle prescription-only medicines. These wholesalers can buy drugs from any EU supplier. According to information from the MCA, there are 863 such wholesalers (although several may belong to the same parent company).[44] In addition, there are 150 wholesalers authorised to import (although some of these also have a wholesale licence and are therefore already included in the 863). These can sell imported drugs from outside the EU into the UK market, but cannot buy them from EU suppliers.

The licensing procedure is as follows. The wholesaler calls the MCA, which sends applications forms plus a guidance note. Once a licence has been applied for, the details are entered into the Business Licensing Information System, and the details are passed to the regional Medicines' Inspectorate which arranges inspection. Upon approval by the Inspectorate, the licence is issued centrally by the MCA. A wholesale importer is normally inspected every two years, and a full dealer every three to four years. All wholesalers, regardless of size, undergo the same basic procedure, although every site from which a wholesaler operates must be registered in the licence and inspected (and every site pays an inspection fee).

The fees charged are shown in Table A2.3.

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[42] European Council Directive 92/25/EEC of March 31st 1992 on the Wholesale Distribution of Medicinal Products for Human Use.

[43] Medicines Control Agency (1997), 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors 1997', London: The Stationery Office.

[44] Medicines Control Agency (1999), 'Register of Licensed Wholesaler Dealers Sites (Human Veterinary and Combined Sites) 1999', October 6th.

Table A2.3: Wholesale licence fees

	Application fee	Annual charge	Inspection fee
Full wholesale licence and wholesale (import) licence	£680	£130	£725
General sales list licence	£500	£78	£330

Source: MCA.

Inspection criteria are established in the guidelines on Good Distribution Practice, and cover, among other elements:

- adequate qualifications and training of personnel, including the designated 'Responsible Person';
- documentation of orders, procedures and records;
- adequate premises and equipment, including monitoring devices, for receipt and storage;
- delivery only to other authorised wholesalers or to persons authorised to supply drugs to the public in the UK;
- recall systems that record the source of supply and the (first) buyer of the drugs.

Pharmaceutical pre-wholesalers (which provide product storage and distribution services to manufacturers) and distributors also require a wholesale licence because, at some point, they must store products. Parallel traders normally require a manufacturing licence since they usually perform some basic assembly and repackaging. If this is not the case, traders would only require a wholesaling licence.

Pharmacies may engage in wholesaling activities without a licence if those activities are an 'insubstantial' part of their business. It is unclear whether this means that a pharmacy may occasionally sell a drug to another pharmacy that has a shortage, or that wholesaling representing 5–10% of turnover is acceptable. It has been alleged that many pharmacies act as short-liners under this exemption, and hoard products that are in shortage.

A1.1 The wholesale process

Full-line wholesalers have relatively higher market shares in branded drugs than in generic drugs. As a consequence, the share of generic drugs in their total sales is relatively minor. This may be less so for the regional full-line wholesalers.

Full-line wholesalers regard good service to their clients as their main objective. Full-line wholesaling requires a costly infrastructure for storage and distribution, as well as large investments in stocks of infrequently prescribed drugs in order to offer the full line. The delivery requirement of two or three times a day makes pharmaceutical wholesaling costlier than other wholesaling activities (although supermarkets may face similar challenges), leading to economies of scale in full-line pharmaceutical wholesaling. AAH, UniChem and Phoenix have all made large investments in the expansion and automation of warehouses.

Stock levels are nominally sufficient to cover average demand for a number of weeks. However, demand can fluctuate considerably, so stocks can be exhausted quickly. Automated stock-control systems can be used to generate an order as soon as stocks run low.

For the full-line wholesalers, the move to patient packs increases the costs of processing. These costs are a function of picking units, so an increase in units means an increase in costs. Patient packs may also increase pressure on warehouse space, but the main problem is with the vans, which are fuller because patient packs result in more plastic bins per van. Many vans have hit capacity constraints, requiring additional runs.

A1.2 Relationships with manufacturers and customers

A1.2.1 Manufacturers

The national full-liners deal with many manufacturers. AAH sells a wide range of generic drugs under its Hillcross brand. The only difference between Hillcross and other drugs from the same manufacturer is the labelling. Regional wholesalers seem to deal with a more limited number of suppliers.

The full-line wholesalers increasingly function as distribution agents for the manufacturers in the generics market. Under these schemes, the manufacturer sets the price to the pharmacy, and the wholesaler receives a predetermined distribution fee. The first such scheme was Norton Advantage, which has been in operation since 1996/97. Other manufacturers, including Cox, Sterwin and APS, followed. Typically, a pharmacy's first-line wholesaler will act as the manufacturer's agent, and passes on information regarding sales to the manufacturer.

These schemes usually account for a significant percentage of the generic drugs supplied by the national full-liners. Manufacturers are able to use these schemes to replace direct selling to pharmacies, retaining control of direct sales while contracting out physical distribution.

In times of shortages, the full-liners buy products from short-liners.

Boots uses tendering to contract out its manufacture. However, other wholesalers do not seem to have concluded long-term supply contracts with manufacturers.

A1.2.2 Pharmacies and hospitals

Because of the economies of scale in wholesaling, it is important for full-liners to function as a first-line wholesaler to pharmacies (ie, those pharmacies buy all their products from them). One way of securing sufficient volume is through vertical integration into pharmacies. Moss and Lloyds pharmacies (almost) always buy from their affiliates (ie, UniChem and AAH, respectively).

The full-line wholesalers' main mechanism to induce loyalty from *independent* pharmacies is volume discounts. These are normally structured such that it is more economic for a pharmacy to buy from only one wholesaler. Specifically, the discounts would only apply above a certain sales threshold, set at a level such that most pharmacies could not reach the threshold if they split their main purchasing between wholesalers. In practice, most independent pharmacies have one first-line, full-line wholesaler for their branded drug business, and this level of turnover is usually sufficient to meet the volume

discount threshold. This can either be a national or a regional wholesaler. Generics are sourced more widely.

The full-liners also offer services to pharmacies in return for which they ask the pharmacy, for example, to buy 70% of their turnover from that wholesaler. One such service is loan guarantees, whereby the wholesaler guarantees a loan from a bank to a (usually new) pharmacy. Another is the provision of computer equipment, including software, and modems (for which they make a nominal charge). The on-line software of AAH only works for purchases from AAH itself, but UniChem's system seems to be compatible with that of other suppliers.

As mentioned above, pharmacies now order most products on-line from the full-line wholesalers. IT systems do not always distinguish between integrated and independent pharmacies, or between pharmacies and hospitals. There is significant overlap between products for hospitals and those for the pharmacy sector. Thus, shortages in the primary-care sector can affect the secondary-care sector, and vice versa.

Most full-liners deliver to hospitals as well as to community pharmacies.

A1.2.3 Vertical integration with pharmacies

The national full-line wholesalers are vertically integrated. AAH owns the Lloyds chain of approximately 1,200 pharmacies, and UniChem the Moss chain of just under 600 pharmacies (plus around 70 located in superstores). Phoenix also owns a number of smaller chains through the regional wholesalers it acquired.

Wholesalers offer discounts to their customers. However, because of the way the Discount Inquiry works, wholesalers may have an incentive to offer reduced discounts to integrated pharmacies: in this way, a wholesaler can reduce the overall claw-back rate determined in the Discount Inquiry while keeping its profits upstream with the wholesale arm.

Vertically integration with pharmacies is pursued in other EU countries where permitted (currently it is restricted in many countries). It may be possible to achieve some of the benefits of integrating (eg, brand consistency) through 'virtual chains' or franchising. For example, pharmacies may unite in some alliance that provides advice to manufacturers. There are many types of such networks.

A1.3 Short-liners

The larger short-liners are most active in parallel importing, followed by generics. Short-liners are quicker and more flexible players in the market and may foresee shortages. Many pharmacists buy most of their generic drugs and some branded drugs from short-liners. The price paid by pharmacists is negotiated with the short-liner. This is in contrast to the full-line wholesalers, which do not normally negotiate with pharmacies, and sell at the list prices (offering standard volume discounts). Another competitive advantage of short-liners is that they can change prices on a daily basis.

UniChem set up its own subsidiary short-liner, OTC Direct, a few years ago as an 'inquiry unit' to find out why UniChem had started to lose first-line OTC clients. OTC Direct is now a company that seeks 'opportunities in the market' (with the market

including prescription drugs as well as OTC), although it is not permitted to sell to UniChem's clients.

A1.4 Wholesalers' views on the 1999 shortages

Many wholesalers, both full-liners and short-liners, blamed the shortages on the three supply shocks at the end of 1998 and beginning of 1999: the closure of Regent; the relocations of Norton and APS; and the conversion to patient packs. Wholesalers also stated that the shortages were exacerbated by speculative hoarding of products. Here, the different industry players hold each other responsible. The full-line wholesalers particularly blame the short-liners. The wholesalers also blame the manufacturers for selling, rather opportunistically, to these short-liners instead of to their regular clients.

A2. Pharmacy

The community pharmacist, as contractor, is the central focus of the government's purchasing strategy for NHS drugs. Below, pharmacist remuneration, standard processes for drug purchasing, and pharmacy experiences in the 1999 shortages are explored in detail.

The pharmacists interviewed for this study worked in shops that dispensed between 2,500 and 10,000 items per month. This included single-shop independents, small chains, and the large integrated chains. The value/volume split of generics/branded was consistent across this range. Of the total number of prescriptions, 60–70% are dispensed generically, but this represents only 20–25% by value.

There are significant links between pharmacy and wholesaling, apart from those pharmacies owned by wholesalers. Many pharmacists engage in wholesaling activities. There is apparently no active checking of pharmacists' unlicensed trading activity.

A2.1 Reimbursement

There are two key components to pharmacy payments: reimbursement and remuneration fees. The reimbursement system is not intended to reward pharmacists but rather to ensure that they are reimbursed overall as closely as possible for the net acquisition costs of the drugs they dispense. Remuneration includes a dispensing fee per item and an overall fee for the service to patients.

Payments to community pharmacy in the UK (including both reimbursement and remuneration) are among the lowest in the world, as demonstrated by the information in Table A3.1, provided by the PSNC.

Table A3.1: Comparison of pharmacy profitability

Country	Average gross profit per prescription in 1997 (US$)	Average contribution margin on prescription-only drugs in 1998/99 (%)
UK	2.08	15
Ireland	2.50	24
New Zealand	3.99	n/a
South Africa	4.13	n/a
Australia	4.68	n/a
Canada	5.75	n/a
USA	7.81	n/a
Poland	n/a	20
Luxembourg	n/a	24
France	n/a	25
Germany	n/a	26
Netherlands	n/a	26
Spain	n/a	28

Source: PSNC.

The design of the reimbursement system is such that, for individual pharmacists or pharmacy groups, there are opportunities to earn income from purchasing. Reimbursement is set at the weighted average of the list prices provided by certain basket providers. The Discount Inquiry highlights where actual prices paid are less than these list prices, and a claw-back is set. This claw-back varies according to the turnover of the pharmacy, reflecting wholesaling discount structures. The last Discount Inquiry found prices paid for drugs to be at an 11% discount from the price paid by the NHS. The key is that claw-back levels are determined on the average behaviour of the whole of community pharmacy. Those contractors that manage to 'beat the market' will benefit financially, and those that do not invest effort in purchasing may well lose out.

The interviews gave the impression that the yardstick nature of this design is effective at delivering value for money to the NHS (ie, pharmacies complained that they are under pressure to obtain good deals, and some wholesalers said the pharmacies are being 'squeezed out' by the government). A yardstick incentive mechanism is one where an agent is judged against the performance of all its peers, and its performance is an element of the target for other agents. Those that lower their purchasing costs benefit financially and contribute to higher levels of claw-back, thereby reducing the total NHS bill.

As the Discount Inquiry is an infrequent activity, if the prices reimbursed by the PPA are markedly out of line with the market, there will be substantial extra costs for the NHS through the period. The claw-back may seem significant, but may be an underestimate, given that most pharmacists do not necessarily purchase generic drugs from the basket suppliers in the Drug Tariff. Indeed, these seven suppliers probably supply only around 40% of the market. The manufacturers do supply the market indirectly, but their list prices may be different from the prices at which they supply the drugs to wholesalers. Therefore, it is difficult to determine the exact price paid to non-basket suppliers.

The yardstick element is only a feature of reimbursement for those generic drugs widely available. Once a drug is in short supply (ie, in Category D) then a pharmacist is reimbursed for the price paid for the product. A pharmacist endorses the prescription with the supplier and price paid, and the PPA reimburses that price. The aim is to ensure high levels of service to patients without a financial penalty for pharmacists. Here the incentives are very different. A pharmacist is unconcerned about the price level (assuming they are confident that they can endorse and be reimbursed correctly), and may prefer a higher list price. There is anecdotal evidence that some pharmacists look for the highest priced available source of a product, once it is in Category D.

Accurate endorsement of Category D purchases is clearly an essential part of the system. It is unclear whether the system is fully understood by all pharmacists. There seems to be very little available information about where these drugs are being supplied from, as even the endorsement information is flawed. Only by looking at pharmacy invoices would an accurate picture of actual suppliers be possible.

Many pharmacists describe endorsement as a hit-and-miss activity, and that it is not given proper attention. There is substantial anecdotal evidence of inappropriate endorsement. Pharmacies may automatically endorse the brand for a Category D product although the actual drug dispensed may be different.

Despite these difficulties, the Department's view is that the reimbursement system has been relatively successful at meeting the NHS's objectives for some time (ie, it has delivered declining prices for generic drugs over a significant number of years). Pharmacists, however, are dissatisfied with it.

A fairly consistent set of complaints was heard, including the following:

- the system is arcane and impenetrable;
- pharmacists claim that it is impossible to audit the payments by the PPA, to know how they have been reimbursed for particular purchases;
- Category D endorsement is difficult and time-consuming;
- the delay in payments[45] is considered unacceptable and leads to overdraft costs (that are not reimbursed).

A1.1 Purchasing strategies

The key relationship for a pharmacist is the first full-line wholesaler. A consistent pattern in purchasing strategies was found, with most pharmacies using AAH or UniChem for the bulk of their branded purchases. This level of expenditure is generally sufficient to meet the threshold for the wholesaler's volume discount. For generics and PIs, pharmacists use alternative suppliers, usually short-liners, and sometimes directly from manufacturers. Most pharmacists are interested in levels of service as well as price; they like on-line ordering, and deliveries of more than once a day.

[45] For example, for reimbursing December 1998 prescriptions, an 80% estimate of the reimbursement would have been paid in January 1999, and the remaining 20%, adjusted for the estimation, in February 1999.

Some pharmacists may be reluctant to purchase PIs, although recognising that this was the only way to 'beat the claw-back'. Some feel that is not professionally appropriate for them to spend significant amounts of time on purchasing strategy, preferring to spend it with patients. All see service levels, particularly availability and continuity in dispensing, as an important aspect of their relationship with patients. Pharmacists describe anecdotes where the shortages in 1999 led to significant patient confusion because the pharmacist changed supplier. Box colour, and shape and number of tablets are all considered to be important attributes that patients do not like to see changed.

In general, purchasing may not be seen as a priority by small chains (one or two shops), older pharmacists and busier shops—the latter simply because of time constraints. These types of contractors generally use a limited number of suppliers, and had extra set-up costs in the shortages when looking for new suppliers. Those who do not expend effort purchasing are likely to be being reimbursed less than they pay for drugs. In contrast, small independent chains usually have someone managing their purchasing. They are very aware of the market-place and will use a wide number of suppliers. They often have a wholesaling licence, and will sell on to other pharmacists and sometimes dispensing doctors in their regions.

The differential success of these types of contractor has a significant effect on the evolution of the pharmacy sector. On the one hand, the more successful the 'business-minded' pharmacists are, the more downward pressure there will be on generic prices, under normal circumstances. The increased prevalence of wholesale trading by these pharmacists may limit these benefits. On the other hand, it increases the pressures for concentration and does not reward pharmacists with an interest in high-quality patient care, either in time spent with them, or in ensuring continuity of dispensing.

Table A3.2 looks at the structural trends in community pharmacies. Concentration and integration patterns have increased over the last five to ten years. This seems a rational response to a system that rewards buyer power at the pharmacy level.

Table A3.2: Structural trends in community pharmacies

	1991[1]		1995[1]		1999[2]	
Size of chain	**Number**	**%**	**Number**	**%**	**Number**	**%**
Over 50 stores	2,388	20	3,448	28	n/a	n/a
21–50 stores	237	2	100	1	n/a	n/a
6–20 stores	485	4	428	3	n/a	n/a
1–5 stores	8,843	74	8,275	68	6,411	53
Total	**11,953**	**100**	**12,251**	**100**	**11,984**	**100**

Note: n/a, not available.

Source: [1] MMC (1996), 'UniChem PLC/Lloyds Chemists plc and GEHE AG/Lloyds Chemists plc: A Report on the Proposed Mergers', July, Table 4.20. [2] Figures provided by RPSGB. Taken from pharmacy 'Own Member' register plus companies registered as retail-related in RPSGB's Bodies Corporate register. Figures are as at January 28th 1999.

From the table, between 1990 and 1999, the number of independent pharmacies (chains of five pharmacies or fewer) in England and Wales fell by 27%. However, the source for the data in 1999 is different from the earlier years and may not be directly comparable.

One of the developments in recent years is the entry of supermarket-based pharmacies. All the major supermarkets have entered this field.[46] Tesco has 218 pharmacies, of which 178 can dispense NHS prescriptions. Sainsbury's has 58 pharmacies. No supermarket self-supplies its pharmacy prescription medicine demand.

A1.1 Shortages in 1999

Most pharmacists emphasised that their main concern during the shortages was to ensure that they could supply patients, not whether they were going to be reimbursed for the drugs at the price paid. Many said that they could not understand why particular drugs were so persistently difficult to acquire. However, there have been few, if any, reports of real shortage.

A wide range of strategies was used to obtain access to drugs.

- Significant amounts of extra time and effort can be spent on sourcing supplies (up to six times the usual level).
- Many pharmacies increased the number of owings, effectively rationing available stocks. There are extra processing costs associated with this.
- Pharmacies—particularly pharmacists working in chains that do not have purchasing or trading authority—often barter with other nearby pharmacies. Some reported that this had increased during shortages, and others that it had decreased because colleagues were protecting stocks. Barter obviously undermines the scope for speculative hoarding.
- To cope with the Bendrofluazide 2.5mg shortage, pharmacists had been splitting 5mg tablets in half, or directing patients to do this. Pharmacists considered such arrangements to be unsatisfactory.
- A number of pharmacists, particularly those working with nearby surgeries, had discussed shortages with GPs, with the result that prescribing patterns changed. Different presentations or alternative therapeutic drugs would be prescribed. Widespread uptake of such practices would again undermine hoarding incentives; however, for many of the drugs in shortage, such substitutions were limited.

It is clear that some pharmacies have been trading in drugs in shortage, and may have been profiting from this activity.

A1.2 Patient packs

Most pharmacists have been very critical of the process surrounding the introduction of patient packs, in line with the stated position of their representatives, the PSNC. Overall, most pharmacists were positive about the benefits of patient packs, in reducing dispensing time and providing better information for patients.

The particular problems that most pharmacists raised were as follows.

[46] Tesco and Sainsbury's were interviewed as part of this study.

- Substantial space constraints requiring costly refits, not only of storage areas, but also delivery areas. Space requirements had increased by between six and ten times, according to pharmacists' estimates.
- The lack of coordination between number of tablets prescribed and manufacturers' pack sizes means that pharmacists are frequently having to split and cut packs, removing most of the time-saving advantages of patient packs.
- The absence of any bulk packs is problematic for supplies for nursing homes and managed-dose systems. For such systems, pharmacists are taking pills out of blister packs and placing them inside new dispensing devices, which they claim is a costly and time-consuming activity. A bulk source would be significantly more cost-effective.

The fact that patient packs were not initially listed in the Drug Tariff was mentioned by many pharmacists as a source of confusion.

A2. Licence Alteration Data

Table A4.1: Number of licences and licence-holders for a sample of drug preparations

Drug name (preparation)	Total number of granted licences	M-type granted holders		
		Total number of licence-holders	BGMA members + GUK	Other
Acyclovir cream (5%)	14	6	1	5
Co-Amilofruse tablets (5mg/40mg)	22	10	4	6
Amoxycillin oral suspension (250mg/5ml)	35	17	6	9
Atenolol tablets (100mg)	37	20	6	14
Captopril tablets (12.5mg)	40	20	4	16
Cimetidine (800mg)	25	15	5	10
Co-Danthramer suspension (25mg/200mg/5ml)	7	5	0	5
Co-Danthramer capsules (25mg/200mg)	1	1	0	1
Codeine Phosphate linctus (3mg/5ml)	2	2	0	2
Diazepam tablets (5mg)	23	14	6	9
Domperidone tablets (10mg)	14	7	1	6
Aspirin tablets (75mg)	13	8	1	7
Fluoxetine capsules (20mg)	21	16	5	11
Glicazide tablets (80mg)	8	7	3	4
Hydrocortisone Cream (1% W/W)	49	29	3	26
Hyosine Hydrobromide injection (600cg/ml)	1	1	0	1
Ipratropium Bromide inhalation	9	6	1	5
Methotrexate tablets (2.5mg)	3	3	0	3
Mianserin Hydrochloride tablets (30mg)	6	3	2	1
Nitrazepam tablets (5mg)	19	14	6	9
Quinine Sulphate tablets (300mg)	42	15	4	11
Terbutaline syrup (1.5ml/5ml)	2	2	1	1
Thyroxine Sodium tablets (25 and 50mcg)	4	3	1	2
Tramadol capsules (50mg)	14	11	2	9
Warfarin tablets (3mg)	10	5	1	4
Zinc Sulphate eye drops (0.25%)	1	1	0	1
Total	**421**			

Source: OXERA analysis of MCA data.

Table A4.2: Location of manufacturing sites (finished product) for a sample of drug preparations

Drug name (preparation)	UK	Ireland	Europe	North America	Singapore	Australia	India	Israel	Denmark
Acyclovir cream (5%)	5	0	9	0	0	0	0	0	0
Co-Amilofruse tablets (5mg/40mg)	9	7	2	0	0	2	1	0	1
Amoxycillin oral suspension (250mg/5ml)	14	11	4	0	1	0	4	0	1
Atenolol tablets (100mg)	13	7	10	0	0	1	5	1	0
Captopril tablets (12.5mg)	7	3	23	5	0	0	5		0
Cimetidine (800mg)	6	8	5	0	0	0	4	1	1
Co-Danthramer suspension (25mg/200mg/5ml)	6	1	0	0	0	0	0	0	0
Co-Danthramer capsules (25mg/200mg)	1	0	0	0	0	0	0	0	0
Codeine Phosphate linctus (3mg/5ml)	1	0	0	0	0	0	0	0	1
Diazepam tablets (5mg)	9	4	3	0	0	2	1	0	4
Domperidone tablets (10mg)	4	1	9	0	0	0	0	0	0
Aspirin tablets (75mg)	10	2	1	0	0	0	0	0	1
Fluoxetine capsules (20mg)	3	1	13	0	0	1	2	1	0
Glicazide tablets (80mg)	2	1	4	0	0	1	0	0	0
Hydrocortisone Cream (1% W/W)	30	2	15	1	0	0	0	0	1
Hyosine Hydrobromide injection (600cg/ml)	1	0	0	0	0	0	0	0	0
Ipratropium Bromide inhalation	3	0	6	0	0	0	0	0	0
Methotrexate tablet (2.5mg)	0	0	2	1	0	0	0	0	0
Mianserin Hydrochloride tablet (30mg)	1	2	2	0	0	1	0	0	0
Nitrazepam tablet (5mg)	8	5	1	0	0	1	1	0	3
Quinine Sulphate tablet (300mg)	26	4	4	0	0	4	1	0	4
Terbutaline syrup (1.5ml/5ml)	1	0	1	0	0	0	0	0	0
Thyroxine Sodium tablets (25 and 50mcg)	4	0	0	0	0	0	0	0	0
Tramadol capsules (50mg)	3	0	11	0	0	0	0	0	0
Warfarin tablets (3mg)	7	1	1	0	0	0	0	0	1
Zinc Sulphate eye drops (0.25%)	1	0	0	0	0	0	0	0	0
Total	**174**	**60**	**126**	**7**	**1**	**13**	**24**	**3**	**18**

Source: OXERA analysis of MCA data.

Table A4.3: Cancelled licences

Drug name (preparation)	Total number of cancelled[1] licences	Total ceased production	Ceased production in UK	Ceased production elsewhere	Ceased production unknown	Transfer afterwards
Acyclovir cream (5%)	2	0	–	–	–	2
Co-Amilofruse tablets (5mg/40mg)	5	0	–	–	–	5
Amoxycillin oral suspension (250mg/5ml)	20	18	7	9	2	2
Atenolol tablets (100mg)	19	9	4	4	1	10
Captopril tablets (12.5mg)	4	0	–	–	–	4
Cimetidine (800mg)	10	10	6	3	1	0
Co-Danthramer suspension (25mg/200mg/5ml)	0	–	–	–	–	–
Co-Danthramer capsules (25mg/200mg)	0	–	–	–	–	–
Codeine Phosphate linctus (3mg/5ml)	6	6	3	0	3	0
Diazepam tablets (5mg)	21	17	10	4	3	4
Domperidone tablets (10mg)	8	4	3	1	0	4
Aspirin tablet (75mg)	14	11	7	2	2	3
Fluoxetine capsules (20mg)	5*	0*	–	–	–	0[2]
Glicazide tablets (80mg)	0	–	–	–	–	–
Hydrocortisone Cream (1% W/W)	43	30	23	1	6	12
Hyosine Hydrobromide injection (600cg/ml)	0	–	–	–	–	–
Ipratropium Bromide inhalation	2	1	0	0	1	1
Methotrexate tablets (2.5mg)	3	3	0	0	3	0
Mianserin Hydrochloride tablets (30mg)	7	5	3	1	1	2[3]
Nitrazepam tablets (5mg)	29	21	13	5	3	8
Quinine Sulphate tablets (300mg)	26	19	15	1	3	6
Terbutaline syrup (1.5ml/5ml)	4	2	1	1	0	3[4]
Thyroxine Sodium tablets (25 and 50mcg)	3	3	3	0	0	2[5]
Tramadol capsules (50mg)	0	–	–	–	–	–
Warfarin tablets (3mg)	7	4	3	0	1	2
Zinc Sulphate eye drops (0.25%)	5	4	1	0	3	1
Total	**233**	**163**	**101**	**32**	**30**	**63**

Note: [1] 'Cancelled' refers to cancelled or lapsed licences. [2] Refers to Eli Lilly activity. [3] Refers to Beecham internal activity. [4] Refers to Astra internal activity. [5] Refers to Medevale activity.
Source: OXERA analysis of MCA data.

Table A4.4: Transfers of licences

Drug name (preparation)	Total number of transfers	No. of times a granted licence changes hands			
		0	**1**	**2**	**3**
Acyclovir cream (5%)	2	12	2	–	–
Co-Amilofruse tablets (5mg/40mg)	6	16	6	–	–
Amoxycillin oral suspension (250mg/5ml)	2	33	2	–	–
Atenolol tablets (100mg)	16	28	9	3	–
Captopril tablets (12.5mg)	8	33	6	1	–
Cimetidine (800mg)	0	25	–	–	–
Co-Danthramer suspension (25mg/200mg/5ml)	0	7	–	–	–
Co-Danthramer capsules (25mg/200mg)	0	1	–	–	–
Codeine Phosphate linctus (3mg/5ml)	0	2	–	–	–
Diazepam tablets (5mg)	5	18	5	–	–
Domperidone tablets (10mg)	4	10	4	–	–
Aspirin tablets (75mg)	3	10	3	–	–
Fluoxetine capsules (20mg)	0	21	–	–	–
Glicazide tablets (80mg)	0	8	–	–	–
Hydrocortisone Cream (1% W/W)	8	38	10	–	1
Hyosine Hydrobromide injection (600cg/ml)	0	1	–	–	–
Ipratropium Bromide inhalation	1	8	1	–	–
Methotrexate tablets (2.5mg)	0	3	–	–	–
Mianserin Hydrochloride tablets (30mg)	0	6	–	–	–
Nitrazepam tablets (5mg)	6	13	6	–	–
Quinine Sulphate tablets (300mg)	8	34	8	–	–
Terbutaline syrup (1.5ml/5ml)	0	2	–	–	–
Thyroxine Sodium tablets (25 and 50mcg)	0	4	–	–	–
Tramadol capsules (50mg)	1	8	–	–	–
Warfarin tablets (3mg)	3	7	3	–	–
Zinc Sulphate eye drops (0.25%)	1	0	1	–	–
Total	**73**	**348**	**66**	**4**	**1**

Source: OXERA analysis of MCA data.

A1. Profitability Analysis

The profitability analysis described in this appendix was carried out in order to address the following questions.

- How does profitability within the sector compare to that in other sectors of the economy?
- Are returns in the sector consistent with a competitive market?

A1.1 Methodology

This analysis is based on published accounts for the companies involved in the manufacture, supply, wholesale and distribution of generic drugs. The names of the companies in the analysis are given in Table A5.8. As most of these are not listed on the London Stock Exchange, financial information has been obtained from copies of annual reports and accounts from Companies House.

For the most part, this analysis addresses conditions in the sector between 1990 and 1998, where data is available. At the time of writing, no published information was available for the calendar year 1999.

A1.1.1 Comparators

Comparisons between companies in the sector can illustrate whether some are much more successful than others in any single year, and comparison between years can illustrate the variability of returns through time. To judge whether returns are high, it is necessary to compare returns with some other measure of returns achievable elsewhere in the economy. For firms quoted on the stock market, it is possible to do this by measuring the WACC for those firms. This measure is an indication of the riskiness of investing in that firm, and, hence, the minimum rate of return that investors require in order to make that investment. Returns significantly above the cost of capital would normally be regarded as excessive if they have been sustained over a significantly long period of time.

Very few firms in the generics drugs sector are quoted. Accordingly, this analysis compares profitability of these firms with that of firms in other sectors of the economy. The companies in the generic drugs sector are compared below with four groups of companies:

- the three major R&D drugs companies listed on the London Stock Exchange (Glaxo Wellcome, SmithKline Beecham, and AstraZeneca);
- eight companies described in LBS Risk Measurement Service as distributors (every fourth company in an alphabetical list was selected, excluding vehicle distributors);
- nine companies from the same listing described as food and drug retailers; and
- nine companies described as food processors.

Annual returns, market data, and other information were obtained from Datastream.

The R&D companies were chosen since profitability in this sector is well known (it is regulated under the PPRS scheme). Distributors were chosen as performing a similar function to drugs wholesalers (storage and distribution of a very large number of different stock items), although perhaps with less service pressure. Food processors were chosen as operating in a similar environment to manufacturers of generic drugs (high standards, rather simple manufacturing process, and use of common machinery across many product lines). Food and drug retailers were chosen since they share a number of characteristics with larger, partially vertically integrated chains of community pharmacies.

A1.1.2 Measures of profitability

The measures used to characterise the sector are gross profit, operating profit, and return on capital (ROC). These measures are defined below. For companies in the generics drugs sector, all information comes from published accounts:

- **gross profit** is taken directly from annual accounts, and expressed as a percentage of turnover;
- **operating profit** is also taken from annual accounts, and expressed as a percentage of turnover; and
- **ROC** has been measured as operating profit, expressed as a percentage of total assets less current liabilities (for the few companies that do not report this measure in their accounts, net assets was used instead).

For comparator companies, all information comes from Datastream:

- **gross profits** is total sales less cost of sales, expressed as a percentage of total sales;
- **operating profit** is operating profit expressed as a percentage of total sales;
- **ROC** is operating profit expressed as a percentage of total assets employed less current liabilities;
- **market-to-book value** is market value plus net debt, divided by total assets employed; and
- the **WACC** has been calculated from share-price and gearing information.

A1.1.3 Assumptions and detailed methodology

Assumptions made in calculating the WACC are as follows:

- a real risk-free rate of 3.5% (this is approximately the average over the 1990s);
- an equity risk premium of 4.25% (this is the mid-point of the range 3.5–5% suggested by the MMC in its December 1998 report on Cellnet/Vodafone);[47]
- a debt premium of 1%, a tax adjustment of 1.19 pre-1999 and 1.429 during 1999. The beta values are taken from the LBS Risk Management Service.

The denominator used in calculating ROC is slightly different for the calculations based on annual accounts and on data from Datastream. The measure of capital employed taken

[47] MMC (1998), 'Cellnet and Vodafone: Reports on References under Section 13 of the Telecommunications Act 1984 on the Charges made by Cellnet and Vodafone for Terminating Calls from Fixed-line Networks', December.

from annual accounts is total assets less current liabilities (fixed assets, stock and debtors, less creditors and current liabilities).

The following points describe the treatment of data extracted from accounts supplied by Companies House, and general observations on the nature of the information conveyed by this data.

- Data has been aggregated by calendar year. Thus, data from a company with a year-end in March 1997 has been assigned to calendar year 1996.
- Some companies do not report gross profits. The turnover of these firms has been included in the total turnover figures, but sector-average gross profit has been calculated correctly by ignoring the turnover of firms that do not report gross profits. Thus, total gross profits cannot be obtained by multiplying total turnover by average gross profits.
- Some companies produce only abbreviated accounts, which typically do not disclose turnover.
- Many of the companies in the analysis were first incorporated or have grown considerably during the decade. Some are slower than others to file their accounts. For these reasons, total turnover appears highest slightly before the end of the period examined, as, early in the period, the market was smaller and some firms produced only abbreviated accounts, and up-to-date information was not available for all the firms in the sector. In particular, the analysis does not include the financial data for the 1998 accounting year of Norton, a significant player in the generics manufacturing sector.
- The survey includes the major manufacturers and full-line short-liners of generic drugs in the UK. However, the small number of short-line wholesalers considered in this analysis was selected from the more than 1,000 licence-holders on the basis of API membership and the fact that these companies were most often mentioned by industry participants as short-liner suppliers during the course of this study.
- In addition to these firms, accounts were obtained for other firms listed by the MCA as possessing AO manufacturing licences. These firms generally trade in both generics and PIs.
- Some companies indicate the fraction of their turnover that derives from export; where no geographical breakdown is given, it has been assumed that all turnover relates to the UK market.
- Many firms in this study are subsidiaries. Some record substantial short-term indebtedness to group undertakings, which significantly reduces their asset base.

Firms within each sector trade with each other. For example, most of the manufacturers contract out some production of their own-label products to other manufacturers. Thus, the same physical output appears as turnover for both companies. In the wholesale sector, companies trade with each other as well as with manufacturers and retailers. Thus, total turnover incorporates some double-counting and consequently overestimates total volume.

A1.1.4 Returns on intangibles

Firms can pay returns above the cost of capital by exploiting either a brand, or market power arising from a failure of competition. One difference between the two is that it is expensive to build and maintain a brand. Thus, the brand itself is an investment, and the

extra return above the cost of capital achievable through exploiting a brand represents a return on this investment.

Some attempt is usually made to value brands in order for the firm's balance sheet to provide an accurate reflection of the distribution of the firm's assets. However, such valuations are inevitably imprecise.

Returns on capital employed are calculated (see above) as a percentage of *book values* of investments. If intangible assets (such as brands, reputation, know-how) are undervalued in the firm's books, the asset base on which returns are measured is too small, and the returns will appear correspondingly too high.

In order to test the relative importance of intangible assets, a comparison is drawn between the book value of a firm and its market value. This is done for comparator sectors. The market value reflects the actual value that investors place on the firm's assets—this value derives from the ability of those assets (tangible and intangible) to earn returns. The market values brands; it also values market power or monopoly position since these allow excess returns to be extracted. Table A5.9 below shows that the market-to-book ratio for comparable sector companies varies between 1.5 and 2. This information is used to adjust the rates of ROC for the generic drug manufacturers.

A1.2 Results

The results of the profitability analysis are shown below. Data for individual firms has been aggregated. As OXERA's analysis is based solely on published annual accounts, a number of caveats should be raised.

- Many of these companies have only been in existence for a few years and, hence, there is a danger that they are not being observed over a full business cycle.
- The distinction between, for example, shortliners and assembly-only (AO) licence-holders may be arbitrary.
- Some generic manufacturers produce branded drugs as well as generics (this is particularly important for CP Pharmaceuticals and Norton). This analysis does not distinguish these two sales streams.
- UK 'manufacturers' may simply import finished or part-finished product from a second company within the same group structure. In this case, the UK company would have a very low capital base, and the real costs of production would only show up in the accounts if the transfer price within the group were similar to the relevant market price.
- UK and export business cannot always be separately identified.

A1.2.1 Data

Table A5.1: Manufacturers of generic drugs (nine firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	47	123	155	121	255	280	352	441	236	
UK turnover (£m)	39	107	135	109	227	250	305	381	201	
Gross profit (%)	30	33	37	32	37	46	40	37	38	**37**
Operating profit (%)	6	8	9	9	9	10	13	16	9	**10**
Return on capital (%)	25	36	25	41	24	24	28	38	22	**29**

Note: At the time of writing, Norton had not filed accounts for 1998 at Companies House, which explains the lower-than-average industry turnover in 1998.
Source: Companies House and OXERA calculations.

Table A5.2: Full-line wholesalers (13 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	938	1,146	1,379	1,479	2,969	3,255	3,449	3,943	7,595	
UK turnover (£m)	933	1,137	1,367	1,462	2,950	3,229	3,429	3,939	7,573	
Gross profit (%)	7	11	10	10	9	10	10	11	8	9
Operating profit (%)	2	2	2	2	3	3	3	3	3	2
Return on capital (%)	25	18	28	22	27	23	31	29	48	28

Source: Companies House and OXERA calculations.

Table A5.3: Short-line wholesalers (11 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
Turnover (£m)	18	86	146	179	293	384	456	618	477	36	
UK turnover (£m)	18	71	127	157	262	334	410	580	438	36	
Gross profit (%)	7	8	10	10	9	8	10	12	11	25	9
Operating profit (%)	4	3	4	4	4	4	5	7	4	10	4
Return on capital (%)	28	38	44	39	48	33	38	53	40	65	40

Source: Companies House and OXERA calculations.

Table A5.4: AO licensees (12 firms)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	av.
Turnover (£m)	7	31	38	65	69	93	112	229	245	
UK turnover (£m)	7	30	38	63	67	90	110	223	242	
Gross profit (%)	31	21	24	27	30	29	24	21	17	25
Operating profit (%)	11	9	9	4	8	5	5	5	5	7
Return on capital (%)	18	42	41	20	34	14	14	24	40	27

Source: Companies House and OXERA calculations.

A1.1 Comparators

Table A5.5: Pre-tax nominal WACC, various sectors (%)

	'92	'96	'98
R&D drug companies	10.1	10.1	10.8
Distributors	10.4	10.7	10.6
Food and drug retailers	8.5	9.9	10.2
Food processors	9.7	10.6	10.1

Source: Datastream and OXERA calculations.

Table A5.6: ROC (%)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
R&D drug companies	–	–	–	–	29	29	24	36	34	41	32
Distributors	–	–	–	6	17	19	23	25	25	22	20
Food and drug retailers	–	–	–	24	19	14	16	17	16	16	18
Food processors	–	–	–	11	15	14	14	12	13	11	13

Source: Datastream and OXERA calculations.

Table A5.7: Gross profit (%)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
R&D drug companies	60	64	65	66	63	60	68	70	72	72	66
Distributors	30	28	28	29	27	26	27	27	25	24	27
Food and drug retailers	12	12	12	13	13	12	12	11	11	11	12
Food processors	18	18	17	17	17	18	17	17	16	21	18

Source: Datastream and OXERA calculations.

Table A5.8: Operating profit (%)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
R&D drug companies	–	–	–	–	32	29	19	27	27	25	27
Distributors	–	–	–	2	7	7	9	9	8	6	7
Food and drug retailers	–	–	–	7	8	5	6	6	6	5	6
Food processors	–	–	–	7	5	5	5	5	5	6	5

Source: Datastream and OXERA calculations.

Table A5.9: Market to book value (%)

	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	av.
R&D drug companies	3	3	5	4	3	3	4	4	7	–12	4
Distributors	1	1	1	1	1	1	1	1	1	1	1
Food and drug retailers	2	2	2	2	2	2	2	2	2	2	2
Food processors	1	2	2	2	3	2	2	3	2	2	2

Note: Figure in brackets rejected as outlier.
Source: Datastream and OXERA calculations.

Table A5.10: Summary comparison of average profitability measures (%)

	WACC (%)	Gross profit (%)	Operating profit (%)	ROC (%)	Ratio of market to book value
R&D drug companies	8	66	27	32	4
Distributors	8	27	7	20	1
Food and drug retailers	7	12	6	18	2
Food processors	8	18	5	13	2

Source: Datastream and OXERA calculations.

Table A5.11: Companies included in profitability analysis

Manufacturers	Full-liners	Short-liners	AO licensees
Regent GM	AAH	Doncaster Pharmaceuticals Group*	Alcon Laboratories
Rosemont	Unichem	Dowelhurst*	Ashbourne Pharmaceuticals
Ranbaxy	Graham Tatford	Dudley Taylor Holdings	Discpharm Distributions
APS	JM Loveridge	Freeman Pharmaceuticals	Europharm of Worthing
Cox	F Maltby and Sons	Jumbogate	Eurochem
CP Pharmaceuticals	Mawdsley Brooks	Kent Pharmaceuticals	G Pharmaceuticals
Generics UK	Norchem	Medihealth	Glenwood Laboratories
Lagap	Norscott	Munro Wholesale Medical Supplies*	Grifols UK
Norton	Phoenix (Philip Harris)	Necessity Supplies	Interport
	L Rowland	Waymade Healthcare*	Stiefel Laboratories
	PIF Medical Supplies		Swingward
	Sangers (Maidstone)		Unipack

Notes: The four starred short-line companies also have AO licences. Only two of the designated AO licensees do not also have wholesale licences.

A1. The UK Hospital Framework

This appendix gives a brief description of the mechanism by which generic drugs are purchased by hospital trusts in England. Drugs that are used in hospitals are purchased at the hospital-trust level. Hospitals spend about 20% of the NHS drugs budget.

A1.1 Formularies

In contrast to the primary-care sector, prescribing in hospitals is governed by agreed formularies (lists of drugs that the hospital prescribes). Within a therapeutic category, this allows for a restricted (possibly a single) presentation of a drug to be selected as the preferred treatment. This permits hospitals to concentrate their purchasing within therapeutic categories, with the aim of achieving bulk discounts. Typically, as soon as generic versions of an existing drug become available, hospital formularies switch to dispensing the generic version. Much of the hospital drugs budget is spent on a small volume of very expensive drugs, and some drugs (or, at least, presentations) are not used outside hospitals. For example, some drugs that would be given as oral doses in the primary sector are often given as injections in hospitals.

A1.2 Price discrimination

With respect to purchasing of drugs within hospitals, the same management system deals with budgets, contracting, and design of formularies. Thus, in general, price analysis is an important component of prescribing decisions within hospitals—certainly far more important than in the primary sector.

Some drugs are sold to hospitals at prices far below those for the same drugs in the primary sector. Anecdotal evidence suggests that patients who begin a course of treatment in hospital are unwilling to switch (for example, from a branded product to a generic equivalent) on leaving hospital. It has been said that each prescription in a hospital generates around 15 repeat prescriptions in the primary sector. Thus, manufacturers may be eager to sell their products to hospitals at a substantial discount (perhaps even below cost) in order to capture a portion of the primary market, where prices are higher. Some generic manufacturers have said that this practice is becoming less common as there was little evidence of extra returns in the primary sector.

Discriminatory pricing may be more significant for branded drugs if brand loyalty among patients (or doctors) is higher (brand and company names being more recognisable than in the generics sector), and because there is a much higher brand premium from which discounts can come. Furthermore, under the PPRS, revenues, rather than prices, are controlled. Thus, companies are to a certain extent free to cross-subsidise between the hospital and primary-care sectors.

A1.3 Purchasing mechanism

Actual purchasing of drugs for use in hospitals is carried out at the level of individual hospital trusts, with pharmacies ordering drugs from wholesalers as and when stocks run low. However, there is a long history of hospitals and trusts grouping together to negotiate price reductions with suppliers. This has not been on the basis of actual aggregated purchasing; rather, purchasing groups have typically opened negotiations with suppliers over prices for particular products, and then selected a preferred supplier.

Subsequently, purchases are made at this agreed price by orders being processed under the agreed framework. However, the negotiating process has not in the past led to a commitment, on the part of the trusts, to purchase.

To avoid confusion in the following sections, the outcome of these negotiations is referred to as a 'framework agreement'. This does not have contractual force, in the sense that it is not a contract for the supply of goods. Orders subsequently made within (or outside) these agreements are formal contracts for the supply of goods.

A1.4 Framework agreements

Framework agreements are concluded at a regional level. For the most part, such agreements in England are now divided into six regional groups. The purpose of the framework agreement is to share the burden of identifying the cheapest supplier, from the point of view of the hospitals, and to insulate customers from some price risk. From the point of view of the supplier, the attraction of making such an agreement is that it may be possible to retain market share without having to follow every price dip in the spot market. Thus, low prices (but not necessarily the lowest) and high market share are traded for stability of demand.

In recent years, steps have been taken to rationalise and standardise the procedure for negotiating framework agreements. In particular, it was felt necessary to ensure that tendering events were staggered in order to avoid different regions coincidentally tendering for the same products at the same time. Accordingly, the tendering process is now coordinated by the NHS PASA. Following a transition period to allow the six English regions to adjust their contract timings, the intention is that each region will put its requirements out to tender on a rolling two-year cycle. The tenders will be staggered by four months from region to region so that the cycle repeats itself over the two-year period. The NHS PASA will provide support to all of these four-monthly tenders.

Under a standard agreement, a supplier is selected on the basis of competitive tender (price being an important criterion, but not the only one). Having been selected, the supplier signs an agreement with the NHS PASA. The supplier agrees to supply the specified product at a specified price whenever it receives an order from a customer (a customer being one of the hospital trusts taking part in the tendering process in that region). The supplier formally receives little in return beyond an indicative forecast of demand and an indication that it is likely to be the supplier of first choice.

The framework agreement contracts are for two years, with the possibility of renewing twice, for a further two years each time. However, prices can be reviewed every four months. Under current proposals, if the NHS PASA considers that prices being paid under the framework agreements do not reflect the market price for similar goods being paid outside the agreements, it may change the price. It must give the supplier one month's notice of a change in price, but the supplier is obliged to accept the new price (although it can then terminate the agreement). For example, if the north-west region were to obtain a price for a particular drug that was significantly below the price then in force in the south-east region, the NHS PASA might consider whether the price in the south-east ought to be reviewed. However, this review would not be automatic—the NHS PASA also wishes to avoid undue concentration in the market, and would not want to

drive prices down at the expense of security of supply. These proposals for mandatory price changes have not yet been agreed with the industry.

The decision on whether to extend or re-tender at the end of the first two two-year periods would be taken on a product-by-product basis.

A1.5 Tendering timescale

The NHS PASA contracting process operates on a timescale of about six months between announcement of the tender in the *Official Journal of the European Communities* to the start of the contract. Counting from the announcement in the *Official Journal*, tenders must be returned by week 11, the contract is awarded in week 20, and the contract starts in week 24. The NHS PASA operates two tendering cycles at a time so that tenders are announced and awarded every four months.

A1.6 Failure to supply

Under the framework agreement, suppliers undertake to fulfil orders at the agreed price. Suppliers may terminate the contract if they give three month's notice; however, otherwise they must supply. If, for whatever reason, a supplier is unable to supply, customers may purchase equivalent supplies elsewhere, and seek reimbursement of the difference between the price paid and the agreed price.

For the most part, hospitals contract directly with manufacturers. Drugs are typically distributed by the full-line wholesalers, which are paid separately by the manufacturers. This can lead to problems, in that IT systems at the wholesalers may not be able to account separately for supplies destined for the primary and secondary sectors. Thus, if a particular product is in short supply in the primary sector, the wholesaler may sell all its stock to community pharmacists (possibly at margins far above the typical 12% distribution fee for handling hospital stock). Since the wholesaler is unable to deliver to hospitals, the hospitals are forced to seek their supplies elsewhere (perhaps even buying back the same stock from short-line wholesalers). The cost of doing this is then passed back to the manufacturers. It appears as though manufacturers and wholesalers do not have any systems in place to prevent this happening, nor (apparently) do manufacturers routinely pass any penalties on to the wholesalers.

A1.7 Market management

Although group negotiations over price have not led to actual purchasing at the aggregated level, the general impression (obtained from NHS PASA, manufacturers and wholesalers) is that the purchasing arrangements in the hospital sector have, in some cases, been effective at driving down prices paid by hospitals. However, there is also an impression that the process has been 'too effective', in that prices may have been driven so low that security of supply has been compromised, and that prices have not been conducive to maintaining competition.

There are anecdotal examples of situations where suppliers that have been successful in obtaining a supply agreement have not subsequently been willing or able to supply at the agreed price. Other potential suppliers may have left the market because of low tender prices, and hence the potential for serious security-of-supply problems could arise. Vaccines have typified this type of problem.

It has also been suggested that the continuous downward pressure on prices may lead to suppliers leaving the market if they are not awarded contracts, which could result in a lack of competition, and, in turn, price rises in the longer term. It is further suggested that, *if* there are barriers to entry (or re-entry), prices could rise without prompting firms to re-enter. The conclusion of these arguments is that short-term savings may lead to longer-term price rises, and that the optimum strategy might be to engage in some form of active market management, rather than simply to buy from the cheapest supplier.

These concerns have been taken into account by the NHS PASA in designing the current framework arrangements, which have evolved from the regional purchasing arrangements previously in place. The concerns have led the NHS PASA to place some emphasis on 'market management' as it operates the tendering process.

In the context of the framework arrangements described above, this means that purchasers are discouraged from purchasing outside a purchasing agreement simply because a different supplier is offering lower prices in the short term. Thus, although it is not an enforceable part of any contract, suppliers are given an indication that hospitals may pay above the 'current market rate' in return for longer-term price stability. Furthermore, the NHS PASA would not necessarily expect to review the prices of other regional framework agreements if a new tendering round in one region were to result in a much lower price.

All purchases made by hospital pharmacies are registered on the PHATE database system. This information can be analysed centrally and forms part of the market information that is used in awarding tenders.

A1.8 Problems with hospital purchasing

Three potential problems have been identified by the designers of this system:

- prices are ratcheted so low that security of supply is compromised;
- prices are driven down in the hospital sector, but there are compensating price rises in the primary sector (price discrimination); and
- operating the system may involve a heavy administrative burden.

The first point is addressed by staggering the tendering process so that the market for any one drug is split (roughly) into six, and firms are given the chance to re-enter the market for each drug every four months. Furthermore, trusts are discouraged from purchasing outside the framework agreement.

The second point might be addressed by categorising products according to whether the potential for price discrimination was significant. Representatives from the primary sector could then be invited to participate in the tendering process. Representatives from primary healthcare groups may in any case be consulted by their hospital-sector colleagues about the design of formularies and other aspects of prescribing in hospitals.

The third point is addressed by providing central support to all six regions (the NHS PASA), and through operating an electronic contract-management system (PHATE). The two-year preferred contract length is a trade-off between administrative burden, the

ability to take advantage of short-term falls in price, providing manufacturers with some stability, and avoiding market concentration.

A1.9 Barriers to (re)entry

Barriers to entry into the UK generic market (licensing and so on) are discussed above. If a firm leaves the market for a particular product because prices have fallen too low, or because it has not won a contract to supply a NHS region, product licences might expire after sufficient time had elapsed. The firm would then face licensing and other barriers to entry if it subsequently wished to re-enter, just as any new entrant would. In the shorter term, however, it seems likely that barriers to re-entry would be lower those to new entry. For the broader market, indications from manufacturers are that they would re-enter with older products if the price justified re-entry, and that it would be unusual to terminate licences.

In addition to licensing barriers, there may in some cases be other barriers,. For example, in the cases of volatile anaesthetics or compressed oxygen, providing the containers for the consumable materials may be a significant one-off cost. If an incumbent supplier is able to retain ownership of the containers, this might constitute a barrier to entry.

A1.10 Conclusions

- The fact that the NHS PASA cannot guarantee demand or prevent trusts from purchasing outside the framework agreement is a significant constraint.

- The arrangements for purchasing in the hospital sector have delivered lower prices than for the same products in the community (although it is not clear to what extent this is owing to price discrimination, on the one hand, or buyer power, on the other). Manufacturers claim that these low prices would not necessarily be extended to the whole market if it were to be centrally tendered.

- The system is still in the early stages. Close monitoring and data collection is essential if the success of the system is to be measured.

A2. The US Drugs System

This appendix describes the healthcare market in the USA. The US experience contains useful lessons for other countries regarding market-driven provision of healthcare and the relationship between the public and the private sector. Germane to this report are:

- the US experience with tendering for bulk purchasing of pharmaceuticals between large healthcare plans and manufacturers;
- the effects of the use of legislation and other policy instruments to make generic entry easier and less costly;
- the increasingly important use of IT to track products and purchasing decisions through the chain, which allows for sophisticated monitoring and data for economic analysis.

Section A7.1 gives a brief history of the USA's health market. Section A7.2 covers US healthcare expenditures. Section A7.3 describes the role of some of the major players in the provision of healthcare. Section A7.4 gives an overview of the contractual relationships between these players and the pharmaceutical industry. Section A7.5 examines the US pharmaceutical industry as a whole, and section A7.6 deals with the US generic drug market.

A2.1 Background

Health spending in the USA has increased significantly over the past few decades. From $27 billion in 1960, it grew to $898 billion in 1993, increasing at an average annual rate of over 11%. In 1998 average healthcare expenditure per person was $4,094, up from $141 in 1960. This growth has given the healthcare sector a large share of the overall economy. Health expenditures were 5.1% of GDP in 1960 and rose to 13.7% of GDP in 1993. The US is comparable with other industrialised countries in terms of its percent of GDP spent on pharmaceuticals. For example, although the UK spends considerably less per capita on pharmaceuticals ($251 in the UK versus $408 in the USA), it spends a similar percent of GDP on pharmaceuticals (1.3% in the UK and 1.4% in the US).[48] Total prescription sales for the US pharmaceutical market in 1998 were approximately $94 billion, accounting for around 2.6 billion prescriptions.[49]

The annual percentage increases in prescription expenditures have surpassed most other components of health spending. Increased expenditures are influenced by increases in price and utilisation, and changes in the type of prescriptions used. Price rises have contributed less (18%) to increased expenditure than increased utilisation (43%) and changes in the type of drugs used (39%), with newer, more expensive, drugs typically replacing older drugs with the same therapeutic benefits. Between 1995 and 1998 prescription expenditures grew nearly 50%, while expenditures for physician services rose by 14% and for hospital care by 10%.[50]

[48] Prescription Data Trends, the Kaiser Family Foundation, 2000.
[49] www.gpia.org/edu_facts
[50] Prescription Drug Trends, the Kaiser Family Foundation, 2000.

The increased expenditure on pharmaceuticals can also be illustrated in the growth in pharmaceutical sales and in the number of pharmaceutical prescriptions dispensed.

Table A7.1: Total US pharmaceutical sales ($ billion)

	1993	1994	1995	1996	1997	1998
Total sales	54.3	58.6	64.4	72.1	81.2	94.0
Branded	48.5	51.6	56.5	64.6	73.4	86.0
Generic	5.8	7.0	7.9	7.5	7.8	8.0

Source: IMS Health for GPIA/www.gpia.org

Table A7.1 shows that the total prescription drug sales increased from $54.3 billion in 1993 to $94 billion in 1998.

These growth trends are expected to continue, especially with the increasing use of managed care, which favours intensive use of prescription drugs. National health expenditures are projected to total $2.2 trillion in 2008, growing at an average annual rate of 6.5% from their level in 1997. Healthcare is expected to increase to 16.2% of GDP by 2008. This trend is likely to place renewed pressure on public- and private-sector payers to search for additional ways to constrain costs.[51] National health expenditures for pharmaceuticals are projected to reach $243 billion in 2008.[52]

Overall, the US pharmaceutical market is not overly concentrated. The top branded drugs manufacturers according to total pharmaceutical sales each account for no more than 7% of the entire market for prescription drugs. However, this changes when it is divided into narrowly defined therapeutic classes. Within 35 of the 66 therapeutic classes of drugs studied by the US Congressional Budget Office in 1998, the top-three innovator drugs together constituted at least 80% of retail pharmacy sales in their class.[53]

A1.1 US Generic Drug Market

A1.1.1 Size and structure

In the USA, estimates predict that generics will grow to account for 15% (by value) of the US pharmaceutical market by 2005.

In 1997/98 the US generics market was valued at $8.6 billion. Although a large share of the total pharmaceutical market, the US generics sector relative to all pharmaceutical expenditures ranks fairly low among OECD countries (eight European countries have a higher generics share.)[54] In fact, many of the major generics firms in the USA are subsidiaries of larger R&D-based companies with European principals. For example, Eli Lilly, Hoechst Marion Roussel, Rhone-Poulenc Rorer, Pharmacia & Upjohn, SmithKline Beecham, and AstraZeneca all have generics operations in the USA.[55]

[51] HCFA government web site: http://www.hcfa.gov

[52] Smith, S. *et al*. (2000), 'The Next Decade of Health Spending', Health Affairs 1999, as quoted in Prescription Drug Trends, the Kaiser Family Foundation, 2000.

[53] Congressional Budget Office (1998), 'How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry'.

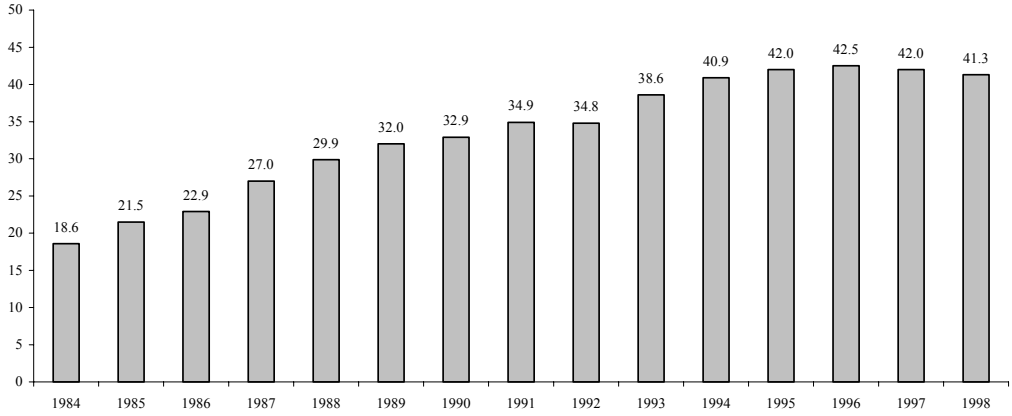
[54] *Global Generic Markets*, Financial Times Business Ltd, 1999.

[55] ibid.

The five largest generics companies in the USA, including the independents and those with research-based affiliates, command a share of about 30% of the generics market. This suggests concentration but not dominance in supply. The role of the research-based affiliates appears to be larger in the USA than in most of Europe. Of the leading research-based multi-nationals, 12 have a generic subsidiary in the USA.[56]

The US generics market has seen steady growth over the last decade, and this trend is forecast to continue in the immediate future.[57] Figure A7.1 shows the sustained growth of the generic market share of all US prescription drugs. Since 1984, the generics share of all US pharmaceuticals has grown substantially, from an 18.6% market share of all US prescription drugs in 1984, to 40–43% in the late 1990s.

Figure A7.1: Growth in generics market share (by volume) of all US prescription drugs



Source: IMS Health, www.gpia.org.

Three factors have been identified as contributing to the growth of the generics sector:

- the Hatch–Waxman Act 1984 facilitated entry into the generics market;
- the drug substitution laws passed by most states in the 1980s allow pharmacists to dispense a generic drug, even when a prescription calls for a brand name;
- the rise of managed care and the effects of government, as well as private health-insurance plans actively promoting generic substitution for branded drugs, have contributed to the growth in generic drug use.

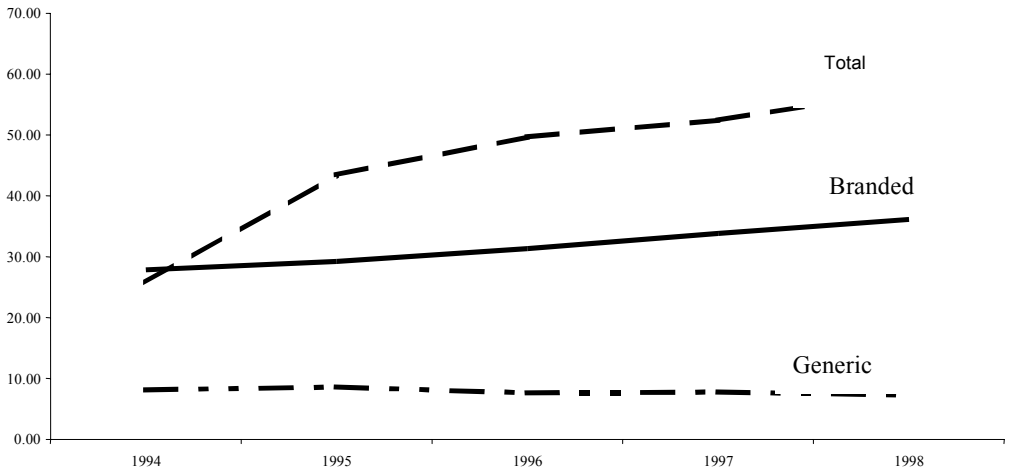
The proportion of prescriptions dispensed as generic drugs increased from 33% to almost 45% during the 1990s. However, the percentage of total pharmaceutical sales owing to generics has declined since 1996. Sales of generic drugs do not keep pace with those of branded drugs, even as they increase their market share owing to the changing mix of branded drugs with increasingly higher prices. That is, older drugs are being replaced with newer and more expensive branded drugs.

[56] NERA (1998), 'Policy Relating to Generic Medicines in the OECD: Final Report for the European Commission'.
[57] *Global Generic Markets*, Financial Times Business Ltd, 1999.

A1.1.2 New competition and effects on innovation

Branded medicines compete with other branded medicines in terms of quality and advertising. Generics, on the other hand, compete with branded medicines and other generics by lowering prices. Figure A7.2 shows that the price of branded drugs has risen steadily from 1994 to 1998, whereas the average price per script of generic drugs has fallen from 1994 to 1998.

Figure A7.2: Average price per script, branded versus generic



Source: IMS Health, www.gpia.org.

The Hatch–Waxman Act 1984 eliminated the need for duplicative testing of generic substitutes for branded drugs in order to obtain FDA approval. After 1984, generic drugs only had to establish bioequivalence with the innovator drug. Prior to that, they also had to demonstrate therapeutic and clinical efficacy. In addition, the new policy allowed production and testing of generic products to begin prior to expiration of the innovator's patent. This change made generic entry much less costly than previously, and reduced the average delay between patent expiration and generic entry from three or more years to less than three months.[58]

Perhaps even more importantly, the Hatch–Waxman Act increased the proportion of branded drugs facing generic competition when their patents expire. In 1983, only 35% of top-selling drugs with expired patents were facing generic competitors, now nearly all must face generic competitors.[59]

When launched at the time that a patent lapses, a generic drug is usually priced at around 30% less than the original branded drug. By the time there are five or six generic entrants, the prices fall to 60–70% less than the original branded drug.[60] From this it can be seen that facilitating generic entry, as the Hatch-Waxman Act accomplished in 1984, has placed significant downward pressure on pharmaceutical prices, generics and overall.

[58] ibid.
[59] ibid.
[60] ibid.

The lower average price of generic medicines has led to an increase in their use. Figure A7.2 above showed that, although the use of generics in terms of total prescriptions dispensed is on the rise, the proportion of generics in the total sales figures of pharmaceuticals is no longer increasing. This is explained by the fact that the increased use of generics is forcing average prices of generics down. Therefore, greater generic prescribing will not result in a significant rise in total sales figures if generic prices overall are still falling. Here, the increased competition from the Hatch–Waxman Act is proving to exert downward pressure on prices of generics. In theory, this increased competition ought to exert downward pressure on the price of branded medicines as well.

A Congressional Budget Office study of 21 branded drugs that first saw generic competition between 1991 and 1993 showed that, within 12 months of patent expiration, the branded drugs lost an average of 44% of market share to generics.[61] On average, the generics in this study cost 25% less than the branded equivalent at retail prices. It appears therefore that the generic drugs are threatening the branded drugs by taking market share. Thus far, this does not seem to have had much of a dampening effect on retail prices. However, it has had a significant effect on the deals negotiated by discount buyers such as PBMs and HMOs. As mentioned above, best-price discounts for bulk buyers of branded drugs are much lower when generic substitutes are available.

One effect of this loss of market share to generics is a decline in the returns on innovation. The Congressional Budget Office estimates that expected returns to marketing a new drug fell about 12% between 1984 and 1997, mainly owing to the increased competition from generic equivalents. Nevertheless, even with decreasing returns, expenditure on R&D continues to rise steadily. In 1975, $1.1 billion was spent on R&D, but this has increased up to $4.1 billion in 1985, $8.4 billion in 1990, $15.2 billion in 1995 and $21.1 billion in 1998.[62]

A1.2 Overview of US healthcare structure

In the USA individuals either have private medical insurance through their employer, receive government health insurance in the form of Medicare or Medicaid, or are not covered by health insurance.

The details of the operation and organisation of HMOs are detailed below, but one of the key features, and which has proved contentious, is the use of Diagnostic Related Group (DRG) guidelines and formularies. These restrict the procedures that doctors can use and the drugs that are supplied to patients. Both have been unpopular with doctors and patients alike; doctors prefer to prescribe medicines and diagnose procedures solely according to professional judgement, and patients have expressed concern that HMOs hold profits as a higher priority than patients' needs and quality of care. To address these concerns, the Patients Bill of Rights attempts to preserve patients rights while allowing health-insurance companies to act in a cost-effective manner.

Within the US healthcare market since the early 1990s there has been an overall trend towards consolidation. In particular, there has been an attempted merger of the top-four

[61] Congressional Budget Office (1998), 'How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry'.
[62] PhRMA Annual Survey, 2000 published on PhRMA web site www.phrma.org, May 1st 2000.

national wholesalers into two groups, and the increasing size of HMOs with wide geographical coverage has led to the establishment of large retail pharmacy networks. Similarly, a significant proportion of US hospitals have become members of large health system networks, called integrated delivery networks (IDNs). These large networks include member hospitals, doctors' surgeries, nursing homes, and other healthcare facilities that are connected through ownership or some other affiliation. As many as 90% of hospitals are now involved in some sort of IDN, and they contract their services as a healthcare package to HMOs or other providers.[63]

Employers offer a menu of insurance contracts that embody different health benefits, but also involve increasing levels of employee contribution. The employer arranges and purchases the appropriate healthcare coverage from a private-sector insurance provider, usually a managed-care health plan or HMO. In this way, employers are the purchasers of healthcare, but managed-care firms organise the actual provision of the care. In the case of government provision, individuals covered by Medicare or Medicaid sign up through the state or local government agency.

Managed-care organisations or HMOs contract with healthcare providers, such as pharmacy networks, doctors, hospitals and hospital networks. These arrangements involve reimbursement schemes that depend on the care providers adhering to guidelines determined by the managed-care organisation. The guidelines usually include DRG guidelines for procedures and a formulary of reimbursable drug preparations and brands for pharmaceuticals.

Health-plan members, and those with Medicare entitlement, usually make a contribution towards the cost of prescription or hospital treatment. For prescriptions this copayment is small, around $5–10, but this figure can rise to several hundred for hospital operations. Those without health-insurance coverage, or private or government aid, are forced to pay retail prices.

In this way, the use of the formulary allows health plans and PBMs to manage the prescription use of patients as well as the prescribing patterns of specific doctors and the dispensing behaviour of the pharmacists. The PBM or health plan is also able to negotiate low prices from manufacturers in return for a place on the formulary.

A1.3 Description of some of the major players

A1.3.1 Contractors

Health maintenance organisations

As mentioned above, large managed-care organisations have become the main providers of private health insurance in the USA. HMOs are characterised by an approach to healthcare that aims to provide at constraining cost, and, as such, they manage to offer lower premiums than are available from private indemnity-insurance plans.

Most HMOs arrange the supply of their healthcare through PBMs, which are selected on the basis of cost and the extent of their pharmacy network. PBMs also negotiate hospital care on behalf of the HMO, although some HMOs are vertically integrated, owning their

[63] *Pharma*, US Comment 'Pharmaceutical Procurement' 106.

hospitals. In essence, therefore, many HMOs are little more than financial organisations with healthcare expertise. The main exception to the arm's-length relationship between the managed-care organisation and the healthcare provision is Kaiser Permanente. Kaiser is completely vertically integrated, owning the hospitals, pharmacies and distribution facilities. Through its subsidiary, Permanente Medical Group, it also has an arrangement with its doctors.

The principal benefit to Kaiser of the vertical integration is the alignment of objectives throughout the network. All elements within the healthcare provision chain are involved in, and benefit from, the various measures taken to reduce costs and improve clinical performance. Through this communal approach, Kaiser achieves very high compliance rates to its group initiatives, such as 99% generic prescribing.

Many HMOs have instituted DRG guidelines for physicians and hospital providers, limiting the type and number of procedures that will be reimbursed for a patient with a given diagnosis. The administration of managed care involves physicians keeping coded records for HMOs which report the procedures used and demonstrate compliance with the DRG guidelines. Without compliance, no reimbursement is made. In this way, HMOs try to induce physicians to consider cost efficiency within the scope of their professional judgements. Those HMOs that use PBMs inform the PBM of the formulary and DRG restrictions that are to be used for the various health plans offered by that HMO.

Preferred provider organisations

Preferred provider organisations (PPOs) are managed-care organisations. They are administered in a similar way to HMOs, except that a PPO allows patients more choice of doctor or healthcare provider. Where HMOs only reimburse patients' visits to certain physicians or healthcare facilities, PPOs will reimburse fully for those specified preferred providers with whom they contract, but will reimburse partially (perhaps 60–80%) for alternative sources of treatment that the patient may decide to use.

Pharmacy benefit managers

PBMs are the operational element of the managed-care system. In effect, HMOs sub-contract the operation of pharmaceutical benefits for their healthcare plans to PBMs, which organise the provision of pharmacy services. Some PBMs contract with large employers, while some HMOs internalise the PBM function. PBMs manage information and payments between pharmacies and HMOs, and they operate a sophisticated database that informs pharmacists of every patient's health-plan entitlements.

Through the aggregation of demand from many pharmacies and several HMOs, PBMs are able to negotiate lower prices for pharmaceuticals by offering manufacturers a place on the HMO/PBM formulary—ie, the list of reimbursable drug brands and preparations available for HMO members. This delivery of a market share of customers induces manufacturers to offer substantial price discounts to the managed health plans (largely in the form of rebates from manufacturers in return for delivery of some level of demand).

PBMs have developed in reaction to the needs of the managed-care sector, and now manage significant proportions of the market—in 1998, PBMs were processing about 40% of all prescriptions dispensed. The PBM market in that year was dominated by three

firms which represented 64.2% of prescriptions processed by PBMs and 27.1% of all US prescriptions dispensed.[64]

In addition PBMs collect information about drug prescribing, make predictions about the cost–benefit ratio of the use of specific products, and buy drugs in bulk for their clients. One important innovation from tracking pharmaceuticals through PBMs and formularies is the increased information made available by the electronic information networks. Health plans, PBMs and pharmacies all have access to a database of drug products prescribed and dispensed, which allows for the monitoring of specific information and data collection for economic and clinical performance analysis. Doctors' adherence to guidelines other than the formulary or DRG can also be monitored, and initiatives implemented to improve areas such as the level of generic prescribing.

Medicare funds (federal control)

Since 1966, Medicare has covered most of the elderly, aged 65 or over. In 1973, disabled people and individuals with end-stage renal disease also became eligible, as well as certain otherwise non-covered elderly persons who elect to pay a premium for Medicare coverage.

Medicare consists of two parts: Hospital Insurance, or Part A, and Supplementary Medical Insurance, or Part B. Hospital Insurance covers in-patient hospital care, skilled nursing care and hospice care, and is generally provided automatically for all US citizens aged 65 or older. The latter covers out-patient services including physical therapy, radiation therapy and practitioners who are not doctors, such as registered nurses, clinical psychologists and social workers. It is offered on a voluntary enrolment basis to everyone covered by Hospital Insurance.

The Hospital Insurance programme is financed primarily through a mandatory payroll tax (approximately 1.45% of earnings) and the Supplementary Medical Insurance is financed through premium payments ($45.50 per beneficiary per month in 2000). Medicare is a federal health-insurance programme, although administration is often performed at the state level.

Medicare funds most of its benefit on a fee-for-service basis. It establishes fee schedules with doctors, hospitals and other providers on which it reimburses. These are fixed and set the maximum that doctors can receive if they accept a Medicare patient. If doctors do not accept the Medicare fee schedule, but treat the patient, the maximum they can charge is 15% above the Medicare price. These prices are set on a unit basis, for example, per day or per diagnosis, and there is a 20% patient copayment. For example, Medicare may state that a particular operation will be reimbursed at $1,500. If the physician accepts this rate, he or she will receive $1,200 from Medicare and the remaining $300 from the patient. If the doctor does not accept the Medicare rate, then the maximum he or she can charge is $1,500 + 15%, an increase of $225 which is borne entirely by the patient, whose copayment now rises to $525. Physicians can refuse an operation, but in doing so they remove themselves completely from the Medicare system and can never again accept a Medicare patient.

[64] Prescription Drug Trends, the Kaiser Family Foundation, 2000.

There has been considerable debate in Congress about extending Medicare to include out-patient prescriptions which are currently not included. This will cause considerable funding issues, as Medicare would then account for about 35% of total drug expenditure in the USA.

Medicare currently covers 95% of the nation's elderly population, as well as many on disability benefits. In 1999, there were 39m Hospital Insurance claimants with benefit payments of $128.8 billion, and Supplementary Medical Insurance covered 37m enrolees with benefit payments of $80.7 billion.[65]

Medicaid funds (federal and state control)

Medicaid was created by the Social Security Act 1965 and is designed to provide medical assistance for individuals and families with low incomes and resources. The programme is jointly funded by the federal and state government, but is run by the individual states. Each state establishes its own eligibility standards, determines the type, amount, duration and scope of services, and administers its own programme.

Entitlement to Medicaid support is awarded if a family or individual is determined to be categorically or medically needy. However, Medicaid does not come close to covering all impoverished Americans, and over 44m Americans are completely without insurance. These are not necessarily the very poorest; rather, it is generally the 'near poor'. There is effectively a healthcare poverty trap for those who earn too little to have healthcare benefits through their employer, but do not qualify for government health insurance on the basis of the means testing of Medicare and other welfare benefits.

Medicaid provides both in- and out-patient services on a fully funded basis, with a schedule of rates for treatments and drugs, and a nominal copayment. Each state Medicaid programme publishes its payment rates for different therapeutic treatments, and doctors or other healthcare providers choose whether to treat the patient on the basis of these rates. The doctor will either accept the Medicaid rate or tell the patient to go elsewhere.

Medicaid data reported by the states indicates that more than 41m people received healthcare services through the Medicaid programme in 1999. Total outlays for the Medicaid programme in 1999 include direct payment to providers of $133.8 billion, payments for various premiums of $31.2 billion, and payments to the disproportionate-share hospitals of $15.5 billion. Excluding administrative costs, the total expenditure for the nation's Medicaid programme in 1999 was $180.9 billion ($102.5 billion in federal and $78.4 billion in state funds).[66]

A1.3.2 Providers

Individual hospitals

Most US hospitals are private, non-profit or profit-making institutions. There are some state and local hospitals, and a small number of federal government hospitals, most of which exist primarily for armed services veterans and are funded through the Department of Veterans Affairs. Individual hospitals may be affiliated with some university teaching

[65] HCFA government web site: http://www.hcfa.gov
[66] HCFA government web site: http://www.hcfa.gov

and research centres. Hospitals are the main providers of specialist care in the USA, and often feature out-patient clinics along with their in-patient services. Generally, hospitals have their own internal pharmacy through which purchasing and distribution throughout the hospital are organised. The pharmacy can purchase directly from pharmaceuticals manufacturers and hospital suppliers, but often they join a larger buying group, such as an IDN. Some hospitals are affiliated to HMOs or other healthcare organisations that arrange purchasing for them.

Most hospitals are part of large groups that compete to supply healthcare services for HMOs and other contractors. A small number are vertically integrated into an HMO, such as the hospitals in the Kaiser organisation.

Group purchasing organisations

Group purchasing organisations (GPOs) are companies that purchase pharmaceuticals and other medical supplies on behalf of their clients (member hospitals and health systems). By aggregating many hospitals' demand, these organisations are able to negotiate lower prices and more consistent supply than are usually available to individual hospitals. However, despite managing a significant share of hospital pharmaceutical purchases, GPOs have no control over the clinical drug utilisation within hospitals. This means that they are often unable to deliver the volumes guaranteed to manufacturers in order to achieve very low prices.

As a result of the high administrative fees charged by GPOs, many hospitals have begun forming IDNs (see below). Suppliers have also complained about GPOs, arguing that they force suppliers' profit margins down to unreasonable levels and prevent negotiations with individual members.

Integrated delivery networks

Since the early 1990s, a large portion of US hospitals have become members of larger healthcare systems called IDNs. As many of 90% of all US hospitals are now involved in such a system. Many IDNs negotiate purchasing agreements directly with manufacturers or suppliers on behalf of their member hospitals. In this way they, like some HMOs and PBMs, are using their buying power to purchase directly from pharmaceutical manufacturers and distributors.[67]

A1.4 The prescription drug industry

A1.4.1 Manufacturers

Manufacturers of pharmaceuticals in the USA can be divided into two categories: those that focus on research and branded drugs, and those that produce generics. After purchasing active ingredients and production supplies, manufacturers sell pharmaceutical products to wholesalers at the average manufacturer price. However, manufacturers often make deals with health plans and PBMs, offering discount prices to these bulk purchasers in return for a place on the formulary.

[67] *Pharma*, US Comment 'Pharmaceutical Procurement'.

Major pharmaceutical manufacturing in the USA appears to be a relatively competitive industry, more so than generic manufacturing in the USA. However, within many therapeutic categories, the market is highly concentrated.

In terms of profitability, manufacturers of pharmaceuticals in the USA have been the top-ranking industry for profits as a percent of revenue. In 1999, pharmaceutical manufacturers had a profit margin of 18.9% compared to a median of 5% for all Fortune 500 firms.[68]

Increasingly manufacturers are outsourcing certain R&D activities such as pre-clinical and clinical trials. 'Study mills' and contract research organisations specialise in performing drug trials more quickly and cost-effectively than well-known university testing groups and pharmaceutical companies could do themselves.[69]

A1.4.2 Wholesalers

In the USA, the wholesaler industry is a concentrated market dominated by five firms. Wholesalers act as distributors, buying pharmaceuticals from manufacturers at the average manufacturer price, which is equal to the wholesale acquisition cost, and then selling them on to pharmacies using a 'cost-plus' approach (plus a mark-up percentage) or a 'list-less' approach (average wholesale price less a discount percentage). During the last decade, wholesalers experienced declining gross margins—the difference between the wholesale acquisition cost they pay the manufacturer and the price they sell to pharmacies—declining net profits and declining operating expenses.

A1.4.3 Pharmacies

US pharmacies include independent pharmacies, traditional chain drug stores, and mass-merchandiser pharmacies. Pharmacies purchase drugs from wholesalers at the actual acquisition cost, or sometimes directly from manufacturers at the average manufacturer price.

From 1990 to 1998, there was a decline in the number of retail pharmacies (from 59,000 to 52,000), and a shift away from independently owned pharmacies (40% in 1998 compared to 54% in 1990). Mail-order and Internet pharmacies in the USA also make up a small part of the market. The retail pharmacy industry appears to be moderately competitive, although sales from the top five pharmacy chains account for nearly 80% of prescription sales for the top ten firms.[70]

The US pharmacy represents the virtual interface of patient, physician and health plan. Upon arrival to the pharmacy, patients with insurance present a card or number to the pharmacist who is able to access a network listing the drug formulary for the patient. In this way, the physician's prescription can be managed by the health plan with the cooperation of pharmacists. Pharmacists have taken an increasingly active role in drug therapy in the USA. In recent years, this has led to alliances between large retail pharmacy chains and managed health plans.

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[68] Prescription Drug Trends, the Kaiser Family Foundation, 2000.
[69] *Global Generic Markets*, Financial Times Business Ltd, 1999.
[70] Prescription Drug Trends, the Kaiser Family Foundation, 2000.

A1.5 Contractual relationships and pricing

There is a complex web of contracts and arrangements that underpin healthcare provision in the USA. In outline, all purchasers of healthcare obtain the actual patient treatment from the private healthcare market, which covers everything from doctors' surgeries to major hospitals and specialist clinics. The purchasers must therefore arrange contracts and/or prices with these providers, either directly or by delegating the operation to a third party. The level of contractual complexity has escalated significantly since the managed-care system has been in operation.

The operation of fee-for-service indemnity plans is relatively straightforward, with the insurer determining the healthcare facilities that the patient can attend, the treatments available under the plan, and the drugs that will be reimbursed. The care provider charges the insurer once the patient has been treated, and the insurer charges the patient for their copayment portion of the total bill. In this way there are only limited contractual arrangements between the insurer and the providers.

The price base for drugs in the USA is the AWP, which is an average of the list prices from manufacturers and wholesalers. This price is very similar to the NHS Drug Tariff and suffers from the same problem—it is largely discredited as an accurate measure of the cost of drugs. However, it is widely used as a reference point for setting prices.

The small number of Medicare drugs are purchased at AWP – x, where x is determined legislatively. In the process of setting this discount, manufacturers complained that the returns would be too small, and x has remained small. The actual setting of AWP is recognised to be somewhat arbitrary, and attempts are under way to move the level closer to the actual acquisition cost. As x cannot be altered, this is to be done through a reappraisal of AWP itself, possibly through a judicial investigation of the actual prices charged. AWP is set by a few agencies appointed by the government, which receive the price data from manufacturers and wholesalers.

The extension of Medicare to include out-patient prescriptions would present a significant purchasing problem for the Health Care Funding Administration (HCFA) (ignoring the funding issue already discussed). The primary option would be for HCFA to go into the market to negotiate. However, many firms already fear that the government would not negotiate, but, owing to its buying power, would instead set prices.

One option is to allow PBMs to become the government's agents. They would compete for regional contracts to supply prescription drugs for Medicare contracts on a two- or three-year basis. This issue is not yet fully worked out, and one of the key points is how any tender mechanism would operate over time, and whether it would have the anticipated effect (eg, which firms would actually win the contracts).

There are 56 state Medicaid programmes, and they have introduced a mechanism to work around the lack of price transparency in the drug pricing system. Pharmacists are reimbursed at close to their acquisition price of the drug, and are also given a flat dispensing fee. The main problem has been determining the appropriate acquisition price that could be applied to all pharmacists.

In order to overcome the problem of rebates and other methods of distorting AWP, the Medicaid Rebate Law forces manufacturers and wholesalers to reveal to the HCFA the

prices paid for different drugs. The data gained in this way is kept very confidential—even other departments are not allowed access to the information. However, it is used to determine whether Medicaid obtains the best price from manufacturers.

The Rebate Law does not guarantee Medicaid the best prices as there are exceptions to its coverage—particularly the Veterans Association, which is known for obtaining very keen pricing from manufacturers. There are also various methods of evading full-disclosure cheap prices, but the HCFA is satisfied that the law is largely effective.

From an economic standpoint, the Rebate Law is not necessarily a pro-competitive tool. It could be considered as a most-favoured-nation clause, which is prohibited under competition law owing to its anti-competitive effects. In particular the Rebate Law would be expected to reduce the level of discounts available to all players, as any discount could, in theory, be made available on a mandatory basis to Medicaid. However, an investigation by the Congressional Budget Office concluded that the overall level of discounts had not changed from before the Rebate Law, and only the very lowest discounts had disappeared.

A1.5.1 Private sector

The structure of the industry for HMOs and other managed-care organisations is as follows. The responsibility for organising delivery of pharmacy services is delegated to PBMs, or coordinated by an internal PBM function.[71] Hospital and other in-patient services are organised by the HMO itself, contracting with healthcare groups. For instance, Promina Health Services in Atlanta is in partnership with two of the largest HMOs (Cigna and Blue Cross/Blue Shield) to provide hospital service in support of their mass retail health plans.

Before contracting with a PBM, HMOs generally determine the drug prices that they are willing to pay. Drugs are one of the major cost drivers within the health system, and so accurate forecasting and low prices are critical to the profitability of the whole organisation. HMOs often use a maximum allowable cost basic for determining the price they pay through PBMs to pharmacy chains for drugs, if they do not negotiate directly with manufacturers to establish individual drug prices. Maximum allowable cost varies between HMOs, and is based on AWP when there are sufficient manufacturers for prices to fall. The end-price paid by HMOs is determined by the manufacturer price net of any rebates negotiated by either the HMO itself or its PBM.

The definition of a reasonable price is often subject to negotiation between the HMO and PBM, but maximum allowable cost is normally in the region of AWP – 40% to AWP – 55%. This represents pharmacists' acquisition costs plus 30–50%, and is between 50% and 70% of the branded price. Overall there is a fairly good margin for the pharmacist. There is an additional dispensing fee of $1.50–2.

The PBM will usually be chosen by the HMO on the basis of its ability to negotiate rebates from manufacturers, its administration costs, and the extent of its affiliations with pharmacies. The PBM may be affiliated with large independent chains, such as Rite-Aid

[71] The following discussion focuses on independent PBMs, but the same processes as described occur when the PBM function is internalised within the HMO, and so PBM should be read interchangeably as an external PBM firm, or internal PBM function.

or Walgreens. Such independent retail chains contract directly with manufacturers or large wholesalers, and arrange a schedule of retail prices which then forms the basis of the reimbursement price and copayment determined by the HMO, or by the HMO in conjunction with the PBM. Similarly, PBMs will negotiate with manufacturers for rebates on specific drugs, based upon the total expected sales volumes guaranteed by the PBM.

The volume delivered by a PBM may include the business of several HMOs as well as indemnity plan and welfare prescription businesses. PBMs are able to guarantee a certain volume by adding a particular drug to the formulary list of the HMOs with which it contracts. In addition PBMs have a significant role in educating doctors and other health professionals so that they follow best practice recommended by the HMO.

HMOs, or PBMs on behalf of HMOs and other clients, negotiate price contracts (rebates) with manufacturers: for branded products, this is a straight volume-based negotiation, whereas, for generics, there is a competitive bid. The PBM chooses the manufacturer offering the lowest price (or most generous rebate), given security-of-supply guarantees. However, the market is not as fluid as it might appear because most pharmacy chains and the largest wholesalers employ 'meet-the-competition' clauses for off-patent products. The contracts are structured such that the incumbent supplier has the opportunity to match any price offered by a rival, which, in theory, enables the purchaser to benefit from price competition while maintaining continuity of supply of the same generic product, which is important to patients.

The result of these contract forms is that there is a rush for market share once a product comes off patent, and incumbents are very difficult to dislodge, especially if all firms have similar cost bases. Being late into the market after patent expiration by as little as three weeks can result in gaining only a very small market share. Customers are also very concerned with continuity of supply, and are therefore unwilling to accept supply from manufacturers or distributors that can only guarantee a short period of product supply or on a short-term basis (ie, no 'fly-by-night' activity). As would be expected, it appears that the market quickly settles into an equilibrium at prices that appear higher than they might be under 'true' competition, and market shares remain fairly static once the initial period of entry has passed.

The price charged by manufacturers is heavily dependent on the degree of competition. When the first manufacture produces the generic drug, the price normally falls to about 70% of the branded. However, once there is more than one firm (often there are many, once the exclusive six months is up), the price falls to 20–30% of the branded level. For Captopril the price has fallen to 10% of the branded equivalent. This low price led to some manufacturers ceasing production.

Most HMOs organise provision of drugs to their patients through independent pharmacy chains, either negotiating contracts themselves or delegating this to a PBM. However, some HMOs, most notably Kaiser Permanente, are vertically integrated and own the pharmacy chain. For these operators, having negotiated a price with a manufacturer, they also contract for delivery from a wholesaler that is selected on the basis of price, service attributes and reliability. Selection is often carried out through a tender process.

The HMO passes the details of the contract it has negotiated with the manufacturer to its selected wholesaler. The wholesaler purchases the supply volume from the manufacturer

at the manufacturer's list price (not the HMO contract price), and supplies to the HMO pharmacists at the HMO contract price plus a mark-up. Wholesalers frequently carry out a reconciliation with the manufacturer in order to take account of the purchase price of products supplied to the particular HMO, which is significantly below the manufacturer's list price.

An important feature is that the wholesalers' margins are often very slim, sometimes in fact negative, which implies that the wholesaler effectively pays the HMO to handle its volume. A major source of income for the wholesalers, about 25% of profit, comes from exploiting cash flows. They take advantage of differential payment dates between the manufacturers and customers (HMOs, PBMs or pharmacists). That is, they are generally reimbursed by the contractor within seven days of submitting an invoice, but the manufacturers have 60–90-day credit terms. Therefore wholesalers have the (significant) funds for the intervening period. In addition wholesalers make around half their profit from rebates from the manufacturers (over and above the price negotiated by the buying organisation where appropriate), and the remaining 25% was percentage mark-up on products that the wholesaler supplied on behalf of a buying organisation at a fixed price.

For health plans, PBMs and independent retail chains that do not contract directly with manufacturers, wholesalers buy from manufacturers at the best price possible and then supply in competition with other wholesalers. Pharmacists charge health plans or PBMs for the prescriptions they have filled, and receive the reimbursement designated by the plan. In addition, any patients who do not have prescription healthcare coverage pay the full retail cost of the drugs they have been prescribed.

The alternative to using a PBM is for an HMO to negotiate rebates with manufacturers, and then contract directly with large retail chains, such as Rite-Aid and Walgreens, which cut out the wholesalers. These chains agree supply with the manufacturer, warehouse the products themselves, and then claim the HMO-agreed price (with rebate) against volumes dispensed for that particular health insurer. Their ability to do this depends on whether they are the appointed preferred retail outlet for the patients of that health plan.

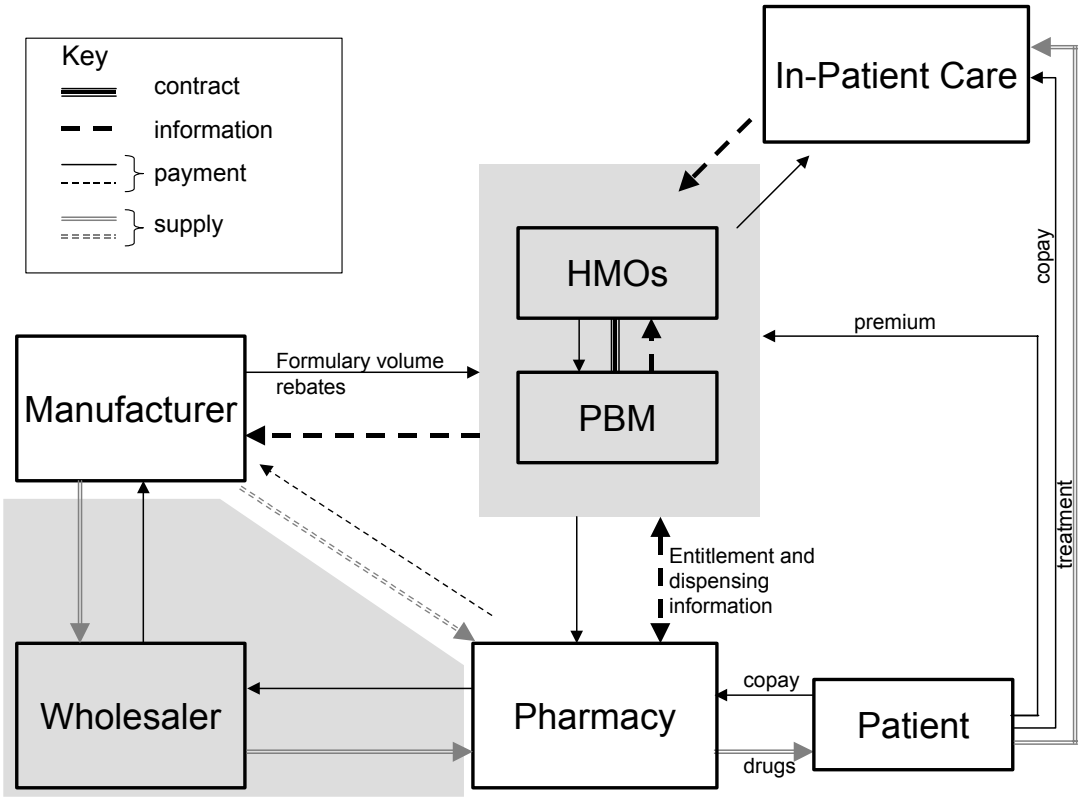
Underlying the whole system is an extensive use of IT systems. In the first instance these are necessary for individual pharmacies to check patients' entitlements under their health plan, and determine their level of copayment for any particular prescription. This is achieved by a link from the pharmacy to a data clearing house which takes the patient's details, interrogates the database of the appropriate HMO (or PBM if this function has also been delegated by the HMO), and provides a response to the pharmacist. This can all take only a few seconds and is done while the patient is waiting.

However, the level of data collection goes much further, with every aspect of the healthcare system being linked into the database operated by the HMO. Hospitals, clinics and doctors record all aspects of patient care, especially their prescribing behaviour. The volumes of drugs supplied under the contract with the HMO where applicable are detailed, providing a cross-check against dispensing data.

Figure A7.3 below shows the contract and payment network in the US system. At the centre is the HMO, which may or may not sub-contract the operation of its health plan to a PBM. If it does not, the PBM function is internalised—hence the dotted line surrounding the HMO–PBM linkage. In addition, large retail chains, such as Rite-Aid and

Walgreens, arrange their own pricing, supply and distribution from the manufacturer, whereas smaller chains and independent pharmacists buy from wholesalers. This is illustrated by the dotted line around the wholesaler function, indicating that this element of the chain is omitted for some retailers.

Figure A7.3: Contractual and payment network in the US health system



Source: OXERA.

A1.5.2 The effects of managed care on generics

Facing steadily rising costs, healthcare purchasers and payers in the USA are expected to be increasingly vigilant about containing costs. In the managed-care environment, in particular, cost-control measures are expected to have effects on the pharmaceutical market. Managed-care companies use a computer network linked to pharmacies that lists the drugs included on the formulary that are available to an enrolee. These formularies typically encourage generics rather than branded drugs, and managed-care health plans and PBMs use formulary placings as a means of obtaining greater discounts and rebates from manufacturers. According to a 1998 report by the Congressional Budget Office, hospitals and clinics pay 9% less than retail prices; managed-care health plans or HMOs pay 18% less than retail prices; and the federal facilities pay 40% less than retail prices. These figures do not account for any manufacturers' rebates or other benefits.

These discount buyers exert downward pressure on generic prices. Although this does not seem to affect the retail prices of branded drugs directly, the presence of generic substitutes for a given branded drug leads to better discounts for managed-care companies, hospitals and other bulk buyers when they purchase branded drugs. For

example, the best price discount for a branded drug was found to be 10–14 percentage points higher when a generic version was available for four or more manufacturers.[72]

[72] Congressional Budget Office (1998), 'How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry'.

A2. The Drugs System in the Netherlands

This appendix describes the supply and distribution of drugs in the Netherlands, and the Dutch government's medicine policy. Section A8.1 briefly describes the structure of the generics industry in the Netherlands, at the manufacturing, wholesale and pharmacy levels. Section A8.2 sets out the general objectives of drugs policy in the Netherlands. Section A8.3 explains the price control and reimbursement system in more detail. Section A8.4 gives some indicators of the performance of the Dutch system, while section A8.5 deals with recent policy proposals which basically rely on increasing the role of the health insurers, particularly in using their buyer power in the purchasing of drugs. Finally, section A8.6 shows the perception that some Dutch industry players have of the UK market, and their views on licensing and tendering.

A2.1 Overview of the Dutch pharmaceutical industry

The total drugs market size in the Netherlands is approximately $2 billion, of which generics constitute 12.5%.[73] In volume terms, the share of generics is between 30% and 35%. This indicates that the price differential between generics and branded drugs is lower than in other countries, including the UK.

Of drugs dispensed in the Netherlands, approximately 85% in value terms are manufactured abroad; for generic drugs, this is around 60%. In 1995, PIs constituted 11% of the total market, although this may have since fallen as a result of the Medicines Pricing Act 1996. The other imports are drugs manufactured for the Dutch market. The generic drugs are mainly imported from within Europe, and via short-liners. The generic manufacturers located in the Netherlands do not have much capacity to export.

PCH is the largest generic manufacturer, with 30% of the generic market and annual sales of $80m. Another large manufacturer is Magnafarma, with 18% of the generics market. PCH sells 90% of production through the full-liners, and 10% through direct delivery to pharmacies.

Until recently, PCH was owned by OPG, the major full-liner, just as Magnafarma is owned by Brocacef, the other major full-line wholesaler. However, in 1998 OPG sold PCH to Teva, as part of the company's strategy to divest its manufacturing activities.

At the wholesale level, there are four major full-liners: OPG, Brocacef, Interpharm and Euromedica. OPG is the largest full-liner, with estimates of its market share ranging between 30% and 50%. OPG's share in generics is also around 30%. Brocacef and Interpharm have between 15% and 20% of the total drugs market. Brocacef is partly owned by Phoenix.

In addition, there are about 20 short-liners, known as distributors, and a range of smaller wholesalers, which are mostly trading pharmacists. Short-liners usually deliver drugs once or twice a week.

[73] Evers, P. (1999), 'Global Generics Markets', *Financial Times Pharmaceuticals and Healthcare Management Reports*, p. 43. According to PCH, generics currently constitute 14% of the market.

OPG delivers once a day, but also offers a special three-hour delivery service. It carries the full line of about 4,500 branded drugs and 11,000 drugs in total. OPG's revenues are 90% from drugs, 5% from OTC, and 5% from GSL. In value terms, 15% of OPG's sales are generics (in volume 30%) and 10% are PIs.

OPG buys from all branded manufacturers and most of the generic manufacturers (the latter also deliver direct). OPG has long-term relationships with manufacturers (ie, there is no day-to-day trading), although these are not formal agreements.

The position of wholesalers in the Netherlands is reputed to be strong compared to other countries. They not only focus on the logistics side of the business, but also seek commercial intermediary-trading opportunities, not fearing the confrontation with the manufacturers. At the European level, OPG is part of the International Pharmaceutical Service Organisation, as is UniChem in the UK. However, this mainly involves pre-wholesaling activities.

Wholesalers' margins vary among different products. On average, the margin may be around 9%, and somewhat higher on generics. Some popular, fast-moving products give a margin of 30%. Wholesale margins have been falling, which may be one of the reasons behind increased vertical integration with pharmacies.

OPG also supplies to hospitals but through a separate subsidiary, Distrimed. The logistics are separate (contrary to how UniChem and AAH operate in the UK). As in the UK, the hospital sector is a different market. 80% of supply to hospitals is through wholesalers, but, in 60% of all cases, the wholesalers function as distributing agents which receive a fixed fee.

In the Netherlands there are around 1,600 community pharmacies, 100 hospital pharmacies, and 650 dispensing doctors. In addition there are 4,200 pharmacies which sell OTC drugs. As in the UK, there is increasing horizontal integration among pharmacies, which, in turn is mainly driven by growing vertical integration between wholesalers and pharmacy chains. OPG owns the largest pharmacy chain in the Netherlands, Mediveen, with 70–80 stores.

Horizontal integration among pharmacies had until recently been prohibited by the professional body of pharmacists, Koninklijke Nederlandse Maatschappij ter bevordering van de Pharmacie (KNMP), which may explain why even the largest chains are small compared to those in the UK. In the past, the KNMP had established a range of restrictions on conduct and entry by pharmacists, which had the effect of reducing competition. Some years ago, many of these rules were declared unlawful by the Ministry of Economic Affairs. However, the government competition report considers that, in practice, the old rules still have some impact, as some health insurers have adopted them in their contracts with pharmacists.

A2.2 Medicine policy in the Netherlands

The medicine policy of the Dutch government is implemented by the Ministry of Health, Welfare and Sport, and has three main objectives, to ensure:

- the quality of medicines supply;
- access to essential healthcare for everyone; and
- efficient and affordable medicines supply.

The quality objective is addressed through the requirement that each drug be registered at the Medicines Evaluation Board, which issues trading licences to the supplier (these can be either national or EU licences). The Medicines Evaluation Board also determines the status of each drug (ie, whether it is prescription-only or OTC).

The access objective is addressed through two principles that are embedded in the policy: the principle of solidarity as to who is entitled to receive healthcare; and the principle of solidarity in financing healthcare.

The efficiency and affordability objective is addressed through the price control and reimbursement system, as discussed below.

A2.3 Price control and reimbursement system

The Dutch reimbursement system is broadly similar to that in the UK, although there are some important differences (the Dutch system is also slightly more complicated than the UK system). There is the same distinction between primary and secondary care. Drugs dispensed within hospitals form part of the entitlement to hospital care and are covered by the hospital budget.

In the primary-care sector, drugs are prescribed by GPs, dispensed by pharmacists (who also purchase the drugs from manufacturers and wholesalers) and, eventually, reimbursed by the government. However, some of the mechanisms within this system differ from the UK system. For example, reimbursement does not take place centrally through the government (or a single government institution), but rather through the health insurers. These are private, not-for-profit (or 'for-limited-profit'), mutual trust organisations which compete against each other at the national level (before 1992, each health insurer was confined to one region). There are approximately 65 health insurers, some of which form part of one of the six or seven major clusters of health insurers.

Roughly two-thirds of the Dutch population are insured through one of these health insurers under the Health Fund Act. Such insurance is compulsory for employees up to a certain wage limit. This insurance is paid for by an employer–employee shared contribution, related to the employee's income and a flat-rate fee paid by the employee based on the number of adults and children covered. The health insurers also receive government contributions through the central health funds, based on a total amount that is determined for community drugs expenditure. The rest of the population has health insurance through private health-insurance companies.[74]

Individual health insurers, on the one hand, and pharmacists and GPs, on the other, must agree on a service contract (pharmacy and general practice are considered to be 'free professions' and are therefore not automatically entitled to a contract with a health

[74] Senior citizens and 'bad-risk' individuals who are entitled to health insurance, but fall outside the scope of the health insurers, are also insured through the private health-insurance companies. The government partly compensates the companies for accepting these individuals.

insurer). The terms of these contracts are governed by the outcome of centralised negotiations between the relevant representative bodies—ie, that of the health insurers, of the pharmacists (KNMP, which could be considered the equivalent of the PSNC in the UK), of the GPs and of the medical specialists.

The health insurers pay the pharmacists under contract a remuneration fee consisting of two elements:

- a service fee for dispensing the drug (fixed at Hfl. 11.85—about £3.35), as approved by the College of Healthcare Tariffs, an independent public institution, under the Healthcare Tariffs Act. This service fee must cover the pharmacist's total costs of service delivery, including acquisition, preparation, care and dispensing; and
- reimbursement of the cost of the drug. The range of drugs that qualify for reimbursement *to patients*, and the reimbursement price, are determined centrally by the Minister. The range of drugs is determined under the 1996 Health Insurance Fund (Provision of Pharmaceuticals) Regulation. There is an exclusive list of medicines that form part of the public healthcare package and therefore qualify for reimbursement.[75] Generally, the same list applies to those who are privately insured.

In the Dutch system there are in fact three separate mechanisms to control prices of medicines, which are used at different levels of the supply chain.

- The first is the Medicine Pricing Act 1996, which stipulates that a *maximum* price can be set for each medicine, based on the average of the prices in four reference countries (Belgium, France, the UK and Germany). This is the maximum price at which pharmacists are allowed to purchase a given drug. Hence, the Act sets maximum prices for manufacturers (and importers). It is left to the market how the wholesale margins for distribution from manufacturers to pharmacies are determined.

- The second mechanism is the Healthcare Tariffs Act, which sets limits on the amount that can be reimbursed for a drug by the health insurer *to the pharmacist*. It should be noted that, in the Dutch system, reimbursement not only means reimbursement to the pharmacist but also to the patient. This difference is explained below.

  Under the Act, for each individual drug in the public healthcare package—and for each form of presentation of each drug—a maximum reimbursement price to pharmacists is determined. These prices are published in the 'Taxe', which is equivalent to the Drug Tariff in the UK, except that it also includes branded drugs. For branded and generic drugs that are produced for the national market, the maximum reimbursement price is equal to the list price of the cheapest supplier that can supply the whole market. For PIs (both of branded and generic drugs),

[75] Drugs on the list are usually prescription-only medicines. Only a few OTC drugs for treatment of chronic diseases qualify for reimbursement, and then only after the first 15 days of treatment.

there is a maximum reimbursement price for each country of origin, equal to the list price of the cheapest supplier of that country.

Pharmacists are entitled to this maximum reimbursement price for each drug dispensed, minus a claw-back of 6.82% on each drug dispensed (with a maximum claw-back of Hfl. 15 per drug dispensed).[76] This claw-back was introduced after a one-off, large-scale investigation in 1997 into discounting to pharmacists—ie, there is no regular Discount Inquiry as there is in the UK. The claw-back percentage was gradually increased from around 3.3% to the current level of 6.82%.

If pharmacists cannot obtain a drug at the cheapest price as determined by the Healthcare Tariffs Act, they will usually purchase the branded equivalent instead (either nationally or through PI), and will be fully reimbursed for the cost of the branded drug. The patient pays the difference (if any) between the price of the branded drug and the maximum *patient* reimbursement price (as determined according to the mechanism outlined below).

Under the Act, there is a further incentive mechanism aimed at pharmacists. If they dispense a drug that is cheaper than the reimbursement limit, they are entitled to a third of that price differential. This should in particular create an incentive for pharmacists to substitute generics for brands.

- Finally, the third mechanism is the drugs reimbursement system, which determines the maximum price that can be reimbursed to *patients*. For this purpose, drugs are grouped in clusters according to therapeutic category (ie, a formulary approach is taken). A cluster may include both branded and generic drugs, and several branded drugs of the same therapeutic category.

  The reimbursement limit for each cluster is based on the average price of the medicines included in that cluster. This average price is based on the list prices of manufacturers. Hence, if the price of a dispensed drug is higher than this limit, the patient must pay the additional cost (or has to return to the GP to ask for a cheaper drug in the same cluster). According to the Ministry, there are usually in practice enough alternatives available to allow for the selection of a fully reimbursable drug.[77]

A2.4 Performance of the system

Overall, it appears that the Dutch system has thus far functioned reasonably well in terms of controlling the public expenditure on drugs. One study in 1999 showed that, according to some indicators,[78] the Netherlands performs best compared to other European countries:

- the share of expenditure on drugs is 1% of GDP—the lowest in Europe;

[76] The claw-back percentage is calculated on each individual invoice sent by the pharmacist to the health insurer.
[77] Under the drugs reimbursement system, patients also make own contributions, although these amount to less than 1% of the total drugs bill.
[78] Commissie de Vries (1999), 'Een Helder Recept'.

- the share of expenditure on drugs in total healthcare expenditure is 11.1%—the lowest in Europe;
- expenditure on drugs per head of the population is Hfl358—the lowest in Europe; and
- gross profit margin of pharmacists is around 25%—the lowest in Europe.

According to industry sources, the price of medicines has fallen significantly as a result of the Medicine Pricing Act 1996, which sets maximum prices for drugs benchmarked against other countries. Before the Act, in 1995, prices were 26.8% higher than the EU average.[79] The price effect has been strongest for branded drugs. Before 1996, the main check on the price of branded drugs was through PIs (which form a significant part of supply in the Netherlands, as discussed in the next section). Now, the main check is through benchmarking. According to some market parties, a side effect of the Act is that many generic drugs have been pushed out of the market by the price reductions in branded drugs.

The Dutch system also seems to have performed well in terms of shortages, which occur infrequently, and then only for a certain drug at a certain time (for example, owing to a batch failure with a manufacturer). In these cases there is usually a move to the branded equivalent, and a higher price is paid (although, as mentioned above, the branded price may still be relatively low owing to the international benchmarking).

One market party said that branded PI drugs are sometimes in shortage because of the branded manufacturers' practice of restricting supply to wholesalers per country. However, in most cases, PI drugs are available, and, in any event, this type of shortage does not normally lead to an overall shortage of the drug.

The absence of shortages may partly be explained by the formulary approach in the community sector. In practice there are usually enough alternatives available in a cluster to allow for the selection of a fully reimbursable drug.

However, despite these positive indicators of performance, the government has signalled a number of practices and developments that imply the need for change of the system.

- As in many other countries, total drugs expenditure is likely to increase significantly in the future. While there are several 'positive' reasons for this—diseases can increasingly be treated with medicines, also allowing more patients to be treated outside the hospital sector—the Dutch government believes there is still further scope for price reductions.

- The quality and efficiency of prescribing may still be enhanced by reducing the variety of drugs that are in the public healthcare package (through formularies) and stimulating generic prescribing.

[79] Evers, P. (1997), 'The European Generics Market', *Financial Times Pharmaceuticals and Healthcare Management Reports*, p. 55.

- As in the UK, under the current reimbursement system in the Netherlands, suppliers have incentives to keep the list prices high, while competing on discounts to pharmacists. The benefits of this discount competition accrue to the pharmacists and not the health insurers (except for the claw-back).

- The full-line wholesalers seem to be in a strong position in the supply chain, and they are increasingly integrating vertically by buying up pharmacy chains. The government report on the fundamental review describes instances in 1994 and 1996 where the wholesalers (and pharmacists) prevented the introduction of mail-order pharmacies by collectively boycotting the initiatives.

- There is limited competition among pharmacies owing to all kinds of professional services rules (although many of these have now been declared unlawful). According to the government competition report, there are still, for example, excessive quality, equipment and dispensing requirements on pharmacists, which function as barriers to entry.

These concerns led the government to announce in April 2000 a range of policy reforms, as described in the next section (with the exception of those related to increasing competition among pharmacists).

A2.5 Policy reforms

The main thrust of the policy reforms is to enhance the role of the health insurers, which compete against each other for patients (ie, the insured). Under the proposals they will have greater freedom to offer differentiated insurance fees and conditions. The health insurers will also have more responsibility over their total budget, of which drugs form a part. Hence, the assumption is that the health insurers have the appropriate incentives to stimulate efficient prescribing and to reduce their cost of drugs. Their enhanced role will be reflected in two basic tasks.

First, the health insurers will have a guiding role in relation to pharmacists and GPs with regard to prescribing and dispensing. The health insurers are expected to become the driving force behind the enhanced coordination at the regional level with community pharmacists, hospital pharmacists, GPs and medical specialists (called the pharmaco-therapeutic transmural consultation, or FTTO). The aim of the FTTOs is to promote efficient prescribing and dispensing (eg, by establishing regional formularies). Also, the health insurers, through their contracts with GPs, are expected to stimulate efficient (and generic) prescribing.

Second, the health insurers will take over from the pharmacists the responsibility for purchasing drugs. As a result, the pharmacist's role will increasingly focus on dispensing and healthcare advisory functions. The assumption is that health insurers have far greater buyer power than the pharmacists. In the words of the Minister:

> Some insurers purchase drugs for one or two insured and therefore are a powerful party in the price negotiations. Such an insurer can easily tell a manufacturer that his cholesterol reducer is far too expensive.[80]

Purchasing by the health insurers has the advantage of making the prices of drugs more transparent by eliminating the discount competition in supply to pharmacists, as well as the advantage of reducing overall prices through increased buyer power.

The health insurers will have flexibility as to how they fulfil their role as purchasers. The government competition report identifies several options, ranging from minimal to maximum control by health insurers. The health insurer:

- only specifies which drugs will be reimbursed and selects the sources of supply, but leaves the actual price negotiations and ordering to the pharmacies;
- lets the pharmacist do the purchasing, but on a completely transparent basis (ie, no hidden discounts). The two parties then agree on how to divide the benefits of the price reductions obtained;
- delegates the purchasing and dispensing functions to newly established pharmacies (community, hospital, supermarkets, etc), with which the health insurer agrees service and reimbursement terms, thereby completely bypassing the existing pharmacies;
- negotiates price and delivery of drugs with suppliers (in addition to specification of drugs and selection of suppliers). The health insurer could do this through contracting with a third party to undertake the purchasing (eg, a full-line wholesaler or a hospital pharmacy). In the first case, the full-line wholesaler agrees to undertake the purchasing for the group of pharmacies under contract with the insurer in a certain region. Alternatively, the health insurer can negotiate and order (provided that it acquires the necessary knowledge to perform this function). Under both models, the health insurer could negotiate the price and leave the responsibility of ordering with the pharmacists (ie, a type of framework arrangement), or it could also do the ordering;
- integrates vertically into pharmacy.

The insurers may have insufficient knowledge of the market to negotiate with the 40 or so manufacturers. It is also doubtful whether the insurers will set up their own logistics operations. Thus insurers may have three options:

- to ask the larger pharmacy chains to negotiate deals for them with the manufacturers, which would mean that the wholesalers would no longer play any major role;
- to ask individual pharmacies to negotiate with manufacturers and use the wholesalers as agents; or
- to ask the wholesalers to negotiate with manufacturers, in which case the pharmacies would play no role in buying drugs.

[80] Ministry of Health, Welfare and Sport (2000), 'Zuiniger en Zinniger voorschrijven; Minister Borst Kiest voor Meer Marktwerking', *VWS Bulletin*, **4**, April.

The quality and efficiency of prescribing are expected to improve as a result of the new role of health insurers. However, there are doubts over whether prices will actually be reduced because the health insurers may in fact have only limited incentives to reduce the cost of drugs. Furthermore, even if they do reduce the cost, they might not pass the saving on to patients. This is because the cost of drugs is a relatively minor part of their overall budget. One commentator has argued that the most that can be saved by using more buyer power is around Hfl.600m, on a total healthcare budget of Hfl.65 billion.[81] Hence, insurance fees could, at the most, be reduced by 1%, which would give a health insurer little competitive advantage over the others.

A2.6 Perceptions of the UK market

Major players in the Netherlands view the UK market as a true commodity market, where competition is strong and few profits can be made. The closure of Regent is mentioned as an outcome of this fierce competition.

Patients and GPs in the Netherlands apparently do not want the 'commodity' generics as sold in the UK. Apparently, in the Netherlands, reputation of the brand of a drug is important to patients and GPs, a quality concern that has been promoted by the branded manufacturers. Hence, generics are also sold in a pack with a known brand name on it.

It is difficult for Dutch generic manufacturers to enter other markets (eg, the UK) because of the licensing regime. To obtain a product licence takes around two years, and requires large investments in R&D. Even if generic manufacturers have the research already, it may still take up to a year to obtain mutual recognition.

Trading in licences is another option, but this may also take weeks or months. The main problem is to change the manufacturing site on the licence, which can take up to a year. Entering a new market through contracting out the manufacturing also takes a long time. All this is illustrated by the fact that Dutch manufacturers could have entered the UK market after the Regent closure, but they could not do so quickly enough because of the licensing problems.

[81] Van Praag, B.M.S. (1999), 'Medicijnplannen Zijn Geen Panacee', *Economisch Statistische Berichten*, December 17th.

A3. Tendering for Medicines in New Zealand

The Pharmaceutical Management Agency Ltd of New Zealand (PHARMAC) is a not-for-profit company owned by the Health Funding Authority of New Zealand. Its role is to manage the national pharmaceutical schedule on behalf of the Authority.

The schedule is a list, updated monthly, of over 3,000 subsidised prescription drugs and other medical products available in New Zealand. The schedule records the price of each drug, the subsidy it receives from public funds, and the conditions under which it is funded. Upon dispensing a drug, a pharmacist is reimbursed the amount of the government subsidy and the patient pays the difference, if any, between the subsidy and the price.

The PHARMAC board makes decisions about what drugs to include on the schedule. In so doing, it seeks to balance the needs of patients for equitable access to medicine with responsible management of costs. Reimbursement to pharmacists is based on a reference pricing system by which the drugs are subsidised at the level of the cheapest therapeutic equivalent.

In 1996 and 1997, PHARMAC first implemented competitive tendering as a means of purchasing pharmaceuticals. Two suppliers dominated the generics market: Douglas, a local New Zealand company, and Pacific, a subsidiary of E-Merck. Generic prices were quite high, close to the prices of branded equivalents.

The New Zealand generics market has shifted within five years from one that could be characterised as high-price, low-volume to one that can now be characterised as low-price, high-volume. As a result of tendering, there is new competition for the generics market in New Zealand, which makes up 20–25% by volume of the total pharmaceutical market.

Tendering was first discussed in New Zealand in 1996. The first drug to be tendered was paracetamol, launched for a one-year experimental tender in 1996. In 1997, PHARMAC invited tenders for sole-subsidised-supply status for specific preparations of 23 chemical entities.

In response to the invitation to tender, suppliers offered to reduce prices if PHARMAC would defer the tender on specific chemicals. These reductions ranged between 20% and 60% less than the existing price of many products. By accepting these price-reduction proposals, PHARMAC was able to save NZ$18m (approximately £5.4m) in the first year. Through tendering the remainder of the chemicals, it was also able to save NZ$7m (approximately £2.1m) in the first year. In the second year of the initial tender, only one chemical was deferred for price reduction and NZ$25m (approximately £7.5m) was saved directly by tendering.

Price reductions resulting from tendering for sole subsidised supply in the first tender averaged around 39–40%,[82] with results exceeding PHARMAC's expectations.

[82] PHARMAC Annual Review for the year ending June 30th 1999.

Owing to the success of the first multi-product tender, in 1998 PHARMAC consulted on another, larger tender in markets worth approximately NZ$70m. Some proposed revisions to implementation from the previous tender were:

- allowing suppliers to bid for preferred-brand status in addition to sole-supply status;
- allowing suppliers to make bids involving more than one chemical;
- increasing the length of the trade-in and trade-out periods to allow suppliers and pharmacists to manage stock more easily.

After evaluating consultation responses, PHARMAC entered into three contracts with suppliers which involved price reductions from March 1st 1999 for some products. In return, PHARMAC agreed to provide protection from tendering for a particular period. Price reductions from these contracts are estimated to save approximately NZ$4.7m per year.

PHARMAC tendered a subset of the products on the original consultation list in December 1998. Savings from this tender are expected to be approximately NZ$15m per annum, with subsidy reductions to occur in 1999/2000.

In 1998/99, PHARMAC managed a reduction in pharmaceutical expenditure by NZ$55m owing to major price reductions (up to 60 and 70%) for eight different medicines. According to the Annual Review, without PHARMAC interventions, the drug subsidy bill in 1999 would have been NZ$257m higher, and NZ$322m higher next year.[83]

A3.1 The tendering process

The tendering process is open to manufacturers and traders. In the first phase of tendering, PHARMAC identifies suitable candidate drugs. With the help of a medical evaluation board, drugs which are not suitable, such as those with a narrow therapeutic index, are eliminated from the tender. Also eliminated are drugs for which it is difficult to achieve sufficient generic competition (eg, hormone products), some of the larger asthma products, and niche products.

After the consultation period, during which a suitable group of drugs is chosen, PHARMAC issues the invitation to tender, which includes the terms of the contract. To encourage entry, it allows bids from unlicensed suppliers as well as those already licensed in New Zealand.

If the best bid is from an unlicensed supplier, the board will delay awarding a tender until an independent assessment of the licensing requirements has been made. The board will consult with the potential winner and instruct certain changes that need to be made to the dossier. If the potential winner is close to market approval, the board will sometimes announce the award of the tender before approval. In cases of uncertainty about approval, the importance of continuity of supply always takes precedence over lowest price.

[83] ibid.

After the invitation is released, suppliers are given two to three months to submit closed bids. Bids for sole-subsidised-supplier status must contain the ex-manufacturer price being offered, as well as supporting information to show that the supplier can provide security of supply (eg, previous supply record, location of the primary and alternative plant, source of active ingredients, etc). The winner of the bid is granted sole-subsidised-supplier status for community pharmacy prescription sales only. Hospital and OTC medicines are not included in the bid. Information about licensing must also be provided in the bid.

Evaluation of bids is based largely on price and continuity of supply, and evaluation is staggered, with the most important drugs in terms of cost savings processed first. In the first tender, it took approximately one month after receiving bids to decide the tender for 5–6 products, with 25 products being decided one month later, and the following 15 being decided a month after that.

The winner of the tender is announced to the market. A transition period is allowed so that suppliers and pharmacists can use up old stock and the winner of the tender can gear up for increased supply. Through the first two months after the announcement of the winner, the market continues as it did pre-tender. At the end of the two months, the tender price or subsidy comes into play. After four months, other suppliers are delisted from the schedule.

The design of the tender is such that potential suppliers are bidding for status of sole-subsidised supplier. There is no volume guarantee; rather, in the invitation to tender, PHARMAC gives the indicated total market size for a given drug preparation. Winning sole-subsidised-supplier status binds the supplier to three years of meeting total market demand, with no minimum or maximum volume determined. The supplier indemnifies the government in the case that an unexpected shock disrupts production or supply. In the case of such a shock, the government looks to other suppliers and the sole-subsidised-supply winner pays the difference.

The auction is sealed-bid, and results from the first tender show that suppliers have poor information about each other's costs. For example, in some cases, the best bid was an 85% price reduction versus the next closest bid of a 35% price reduction. The sealed bid is an attempt to keep as much information about bidders' costs secret so that there is less chance for collusion.

PHARMAC does not contract for distribution directly. Subsidies are based on the ex-manufacturer price and are paid by the government to the pharmacies after dispensing. There is a historically based notional wholesale mark-up of 10% and a retail mark-up of 3%, plus a dispensing fee. In the past, these mark-ups had been set at 10% and 11% respectively. This has been rebalanced, with more of the retail reimbursement now in the form of the dispensing fee.

A3.2 Effects on the chain

Overall, tendering made the market attractive for new players. According to PHARMAC and based on post-tender interviews with suppliers, winning a tender lowered the costs of the winner. Post-tender, they had a new, or larger, market share, were able to buy chemicals in bulk and exploit economies of scale in production, and, importantly, did not

have to pay bonuses to pharmacists, which had previously dealt only with two, or possibly three, suppliers. New entrants were primarily local New Zealand traders and emerging suppliers from India and other parts of the world.

Before tendering, the two generics suppliers shared the market with multi-nationals which controlled approximately 60% of the market with branded drugs. After tendering began, the generics firms were willing to undercut the branded prices (ie, choosing high-volume, low-cost). As a result, the branded multi-nationals lost significant market share owing to the more competitive generic sector.

Pharmacists have not reacted smoothly to the announcement of tender awards. The demand for the sole-subsidised supplier's brand is very high from the first day of the announcement of the award. Owing to risk aversion, pharmacists do not want to have any other brand on their shelves as soon as the tender is announced. One resulting problem for the winning manufacturer is that demand shifts from perhaps 20–30% to 100% of market share from the first day of the tender award. To respond to this, a delayed announcement can be made in order to give the bid winner time to gear up stocks.

A3.3 Key design features

Two important features of the New Zealand tendering design are the allowance of bidding from unlicensed suppliers and the long length of time for the tenders. Regarding the length of the contracts, suppliers have reported in interviews that it allows them to offer lower prices as they can negotiate bulk purchasing of active ingredients and have the certainty of a long supply contract. However, most contracts have not yet been re-tendered. It remains to be seen whether a sufficient number of bidders will remain in subsequent rounds.

Allowing unlicensed bidders reduces barriers to entry. With relatively low entry barriers, incumbents with low costs cannot be sure that they will not be underbid by a new entrant. There is always a risk of delay, however, in the event that the new entrant's application will be problematic.

The contract design is made explicit in the invitation to tender. Thus far, tenders have been organised for individual preparations and for bundles across preparations of the same chemical entity. PHARMAC is currently considering bundling across different chemicals. In addition, it is exploring the idea of making tenders exchange-rate adjustable and allowing different prices for each year of the tender.

PHARMAC has experienced one major supply disruption. The successful bidder experienced manufacturing problems in product and a supply problem arose a year into the tender period. PHARMAC was able to obtain the supply that it needed from some of the other suppliers which had lost the tender, but had stock available.

A3.4 Costs and benefits

The costs of setting up the tendering system in New Zealand were relatively low because an existing framework was used. Therapeutic group managers already employed by PHARMAC participated in designing the tenders. The tendering scheme itself takes three full-time equivalents to run, with some services (eg, medical evaluation) contracted out. With regard to IT, nothing new was designed for the tender.

The benefits of the tendering process have thus far been promising, exceeding PHARMAC's expectations in terms of lowering prices. In terms of overall savings results, Table A9.1 below summarises savings from price competition in the off-patent markets in New Zealand since consultation on tendering began. The types of savings fall into three categories: sole-supply contracts, preferred-brand contracts, and tender-deferral contracts.

Table A9.1: Overall savings from price competition since the introduction of tendering in New Zealand

Year	Contract type	Number of chemical entities	Annualised savings (NZ$m)
1997/98	Tender deferral	20	18
	Preferred brand	7	2
	Sole supply	15	7
1998/99	Tender deferral	8	7
	Preferred brand	7	15
	Sole supply	47	19
1999/2000	Tender deferral	4	1
	Preferred brand	0	
	Sole supply[1]	33	21
Total			**90**

*Note*s: Some chemical entities occur more than once (eg, some presentations of a chemical may be part of a tender-deferral contract, while other presentations of that chemical are part of sole-supply contracts, etc).
[1] The savings for sole-supply contracts in 1999/2000 are savings as at mid-2000. Many of the same chemicals as in the 1997/98 tender-deferral contracts.
Source: PHARMAC.

Sole-supply contracts are awarded by tender and the winner receives the status of sole-subsidised supplier for a given drug preparation (or bundle of preparations of the same chemical) for a given period (generally three years).

Preferred-brand contracts were an experimental form of contracting, whereby pharmacists were required to dispense the preferred brand if they could legally substitute for the branded product (ie, if the prescription was written generically). Generic suppliers took a risk for this kind of contract and offered major price reductions, but market share has been small (ranging from about 20% to 50%), as branded suppliers responded by persuading doctors to prescribe by brand and use no substitution prescription pads.[84] None of these contracts was awarded in 1999/2000.

Tender-deferral contracts resulted from consultations with suppliers after the invitation to tender for certain drug preparations. These contracts took the form of significant price reductions in return for PHARMAC agreeing not to tender particular drug preparations for a set period, usually two years.

For the 1997/98 tenders, weighted price reductions were around 40%. For the tender in 1999/2000, they were on average over 60%. Table A9.2 summarises some of the price

[84] This form of contracting is not generally recommended by PHARMAC. Although it has the advantage that stock shortages are less likely, prices ultimately tend to be higher.

reductions resulting from tendering certain preparations and shows how the New Zealand prices compare to those paid in the UK.

Table A9.2: Price savings for selected drug preparations as a result of tendering for pharmaceuticals in New Zealand

	New Zealand price per unit		UK PCA price per unit (NIC/quantity)	
	(in New Zealand cents)	(in UK pence)	(in UK pence)	(in UK pence less 11% claw-back)
Baclofen (10mg)	4.19	1.25	6	5.34
Isosorbide Mononitrate slow-release (60mg)	5.48	1.64	34	30.26
Metformin (500mg)	2.77	0.83	2	1.78
Tamoxifen (20mg)	10.0	2.99	14	12.46
Verapamil hydrochloride slow-release (240mg)	11.8	3.53	44	39.16
Amoxycillin capsules (250mg)	3.85	1.15	8	7.12
Amoxycillin capsules (500mg)	6.3	1.88	11	9.79
Ranitidine (150mg)	10.0	2.99	32	28.48

*Note*s: An exchange rate of $NZ1 = £0.299 was used. UK hospital price per unit is an unweighted average of the different prices paid by different regions. New Zealand 'slow release' is assumed to be equivalent to MR in the UK. 'Less 11% claw-back' refers to the average claw-back the government determined for community pharmacy in the most recent Discount Inquiry.
Source: OXERA. New Zealand data from PHARMAC. UK community pharmacy data (NIC per unit) from the PCA, 1999.

It should be noted that Table A9.2 gives results for some of New Zealand's most successful drugs. For example Baclofen (10mg), Isosorbide mononitrate slow release (240mg) and Metformin (500mg) posted best price reductions of 96%, 91% and 84% respectively compared to prices paid five years ago.

Prices paid by PHARMAC after tendering are significantly different from those paid in the UK, both in the hospital and the community pharmacy sectors. Table A9.3 shows the percentage difference between New Zealand prices and those paid in the UK community pharmacy and hospital sectors for the sample of drug preparations in Table A9.2.

Table A9.3: Difference (%) in prices paid in New Zealand and the UK for a sample of drug preparations

Drug preparation	% increase from New Zealand price to:	
	UK PCA price	UK hospital price
Baclofen (10mg)	310	18
Isosorbide Mononitrate slow-release (60mg)	1728	252
Metformin (500mg)	97	83
Tamoxifen (20mg)	300	67
Verapamil hydrochloride slow-release (240mg)	992	349
Amoxycillin capsules (250mg)	502	138
Amoxycillin capsules (500mg)	404	165
Ranitidine (150mg)	835	22

Note: PCA price used is less 11% claw-back. All prices converted to UK pence per unit (eg, tablet) and compared.
Source: OXERA analysis of data from the PCA, 1999, and PHARMAC.

Overall, the New Zealand move to centralised purchasing of pharmaceuticals has gone quite smoothly. In continuing to refine the system, PHARMAC is considering back-up supply contracts for important products. One possibility is to enter into a contract with Australian supplier, Hexalon, for 24-hour-notice emergency supply in times of crisis. Pacific provides back-up of its own through the E-Merck network.

The introduction of centralised tendering has led to a shift toward generics and a significant decrease in pharmaceutical prices in New Zealand. PHARMAC is pleased with its cost-savings success of 15–20% of ex-manufacturer expenditure thus far. However, the system is relatively new, and it will be interesting to see how tendering progresses in repeated rounds of bidding.

The manufacturing industry claims that there has been an exodus of direct investment in pharmaceuticals in New Zealand; however, aggregate data suggests there was no substantial pharmaceutical industry presence in the country in the early 1990s.

Beyond price reductions and the introduction of tendering, PHARMAC is also making demand-side initiatives to cut expenditure, such as promoting through workshops and publications the message of responsible (ie, cost-effective) prescribing to physicians, and confronting the increasing trend of direct-to-consumer advertising by manufacturers with its own educational campaigns.[85] It is estimated that total cumulative savings for decisions made between 1993 and 1998 regarding the introduction of tendering, demand-side initiatives and changes in the board structure have led to net savings of NZ$80m in 1997, NZ$123m in 1998, and estimated net savings of NZ$257m and NZ$322m in 1999 and 2000, respectively.[86]

[85] PHARMAC Annual Review for the year ending June 30th 1999.
[86] ibid.

A1. List of Interviewees and Information Sources

Country	Organisation
Government	
UK	MCA
	PPA
	NHS Supplies
USA	FDA—Office of Generic Drugs
	Office of the Assistant Secretary for Planning and Evaluations
	FTC
The Netherlands	Ministry Health, Welfare and Sport
New Zealand	Health Funding Authority
	PHARMAC
Manufacturing	
UK	APS Berk Pharmaceutical
	CP Pharmaceuticals
	Generics UK
	Lagap
	Norton
	Ranbaxy (UK)
	Sanofi Winthrop Ltd
USA	Watson Pharmaceuticals
	Taro Pharmaceuticals Industries Ltd
The Netherlands	OPG
	PCH Pharmachemie (Dutch Generics Manufacturers' Association)
Wholesale	
UK	Alliance Unichem
	Boots The Chemists
	Dominion Pharmaceuticals
	Freeman Pharmaceuticals
	GEHE(UK) AAH
	L Rowlands & Co
	Medihealth
	OTC Direct, subsidiary of Alliance Unichem
	Norchem
USA	Bergen Brunswig Drug Company

Country	Company/Organisation
Retail	
UK	Moss Pharmacy (Alliance Unichem)
	Community Pharmacies
	PSNC
	Other Retailers
	Tesco
	Sainsbury's
	Waterstone's
Health insurer	
USA	New York Health Plan (HMO)
	Kaiser Permanente
	PROMINA (Hospitals)
	Physicians' Health Services (HMO)
	CIGNA Healthcare (HMO)
	PCS Health Systems (PBM)

Wholesalers and manufacturers surveyed

Manufacturers	Wholesalers
Aspar Pharmaceuticals Ltd	Mawdsley-Brooks and Co. Ltd
M&A Pharmachem Ltd	Cross-Pharma Ltd
Sterwin Medicines	Kent Pharmaceuticals Ltd
Thornton & Ross Ltd	Numark Ltd
CP Pharmaceuticals	Co-Pharma Ltd
Lagap Pharmaceuticals Ltd	Tillomed Laboratories Ltd
Ranbaxy (UK) Ltd	Freeman Pharmaceuticals Ltd
Norton Healthcare	Sangers (Maidstone) Ltd
Generics (UK) Ltd	The Boots Company plc
APS Berk Pharmaceutical	AAH Pharmaceuticals
Cox Pharmaceuticals	L Rowlands & Co Ltd
	Alliance UniChem plc