

Medicines distribution

An OFT market study



© Crown copyright 2007

This publication (excluding the OFT logo) may be reproduced free of charge in any format or medium provided that it is reproduced accurately and not used in a misleading context.
The material must be acknowledged as crown copyright and the title of the publication specified.

CONTENTS

Chapter	Page
Executive summary	1
1 Introduction	15
2 The distribution of medicines in the UK	20
3 Costs to the NHS	39
4 Services to patients	56
5 Competition implications	73
6 Recommendations	84

EXECUTIVE SUMMARY

Key facts, findings and recommendations

This study considers recent changes to the distribution of branded medicines in the UK, and builds on the OFT's recent market study relating to the PPRS.

Key facts:

- Government uses the PPRS to constrain list prices for branded medicines.
- The traditional wholesale model for the distribution of branded medicines involves manufacturers supplying to wholesalers, typically at the industry's conventional discount of 12.5 per cent to list price. In effect, therefore, the PPRS also indirectly controls discounts to wholesalers.
- Wholesalers then compete to supply pharmacies and offer discounts from list prices to attract business. The average discount from list price is around 10.5 per cent.
- Pharmacies are reimbursed at list prices and the NHS claws back some of the profits they make.
- The pharmacy contract guarantees pharmacy income so any fall in pharmacy discounts means the NHS has less to clawback.
- The net effect of clawback is that the NHS pays less than list price for medicines. On average it pays list price minus clawback.
- Many manufacturers have recently implemented, or have expressed interest in implementing, changes to their arrangements for distributing medicines. These involve the introduction of 'Direct to Pharmacy' (DTP) schemes and/or using fewer wholesalers.
- Under DTP schemes, manufacturers set the prices paid by pharmacies and pay wholesalers a fee for delivering their medicines according to their required service standards. There is no convention covering the level of discounts to pharmacies in these circumstances.

Findings and recommendations:

We recognise that there may be efficiency benefits to DTP and take the view that manufacturers should be free to choose the distribution method they consider to be most efficient. However, we consider that:

- There is a significant risk that DTP schemes will result in cost increases for the NHS which could amount to hundreds of millions of pounds a year. Pharmacies receive discounts of around 10.5 per cent under the traditional wholesale model. Competition cannot be relied upon to prevent manufacturers from reducing the discounts received by pharmacies under DTP schemes because pharmacists have no choice over which medicine to dispense for over 75 per cent of dispensed medicines. In the context of PPRS re-negotiations, we recommend that Government make changes to the PPRS which would ensure that discounts currently obtained by pharmacies are safeguarded.
- It is very likely that DTP schemes will lead to changed service levels to pharmacies and, potentially, patients. Under the traditional wholesale model, service levels to pharmacies are determined by competition between wholesalers. In contrast, under DTP a manufacturer sets, and pays for, the service levels its distributors will provide when delivering its medicines to pharmacies. Although the OFT has not attempted to determine whether the traditional wholesale model is the most efficient way of providing patients with satisfactory service standards or whether the service standards that result from this model are in any sense optimal, we consider that manufacturers have an incentive to reduce service standards under DTP schemes. Reducing service levels could enable manufacturers to cut their distribution costs given that this will not result in lost sales. If a pharmacy receives a lower level of service

from its wholesaler, this could impact on the level of service the pharmacy can offer patients, for example by increasing waiting times for out of stock medicines.

- There would be benefits from having greater clarity about the service level the NHS is paying for when agreeing prices under the PPRS. If the NHS is concerned that service levels might fall below satisfactory levels, we recommend that Government seek manufacturers' agreement on minimum service standards and, if lower service standards are introduced, cost savings should be shared with the NHS.
- Where a manufacturer appoints an exclusive distributor, that distributor has little incentive to excel in service provision as pharmacies have no alternative source of supply. In addition, the administrative burden on pharmacies is likely to increase if they have to deal with multiple suppliers. Finally, in the longer term, the appointment of exclusive distributors may lead to the creation of a wholesaler with significant market power. We anticipate that manufacturers will share our some of our concerns and note, in particular, that it is not in their long term interests for there to be insufficient competition between distributors. If more manufacturers do opt for exclusivity in distribution in such a way that competition in the sector is reduced significantly, future intervention by the OFT may be necessary.

We believe that our recommendations will safeguard against increased costs to the NHS and will ensure that satisfactory service standards to pharmacists and patients are obtained, while allowing manufacturers the commercial freedom to choose the distribution arrangements they consider to be most efficient and best suited to their portfolio of medicines. If DTP schemes cannot be used to circumvent pricing arrangements agreed under the PPRS, we can be more confident that, when they are adopted, they will lead to efficiency gains.

Background

Each year the NHS issues around 800 million prescriptions and spends approximately £11 billion on prescription medicines. £6 billion of these medicines are provided to patients in primary care¹ through approximately 12,600 pharmacies and 1,800 dispensing doctors in the UK.² The nature of the distribution arrangements for delivering medicines to pharmacies is important because it affects patients' timely access to medicines and the cost of medicines to the NHS.³

Several manufacturers⁴ – GlaxoSmithKline, Pfizer, AstraZeneca, Sanofi Aventis and Napp – have implemented, or may soon implement, substantial changes to the way they distribute their medicines, some of which involve DTP.⁵ In addition, there appears to be an emerging trend across many manufacturers to reduce the number of wholesalers used in the distribution of their branded medicines. These changes to the distribution of medicines in the UK are among the most significant changes to the UK pharmaceutical wholesaling sector for many years and have given rise to significant concerns, particularly among wholesalers and pharmacies.

1 Primary care refers to the community sector (GPs) as opposed to secondary care which refers to the hospital segment.

2 Unless otherwise stated, subsequent references to "pharmacies" should be taken to include retail pharmacies and dispensing doctors but to exclude hospital pharmacies.

3 References to Government include the Department of Health (DH), the Scottish Government and the Department of Health, Social Services and Public Safety Northern Ireland.

4 We are also aware that as of 26 November 2007, Astellas Pharma Ltd has appointed UniChem as its only LSP for two transplant medicines.

5 Prior to Pfizer's change in March 2007, GSK was the only major manufacturer to adopt a significantly different system. GSK adopted a DTP type scheme in 1991, although it continued to supply all full-line wholesalers.

We have chosen not to open an investigation under the CA98 at this point.⁶ While we have identified some concerns with DTP schemes and reductions in the number of wholesalers, these arise largely because current pricing arrangements under the PPRS are set up in the context of, and reflect, the traditional wholesale model. Our view is that the most appropriate way to deal with this is to enhance the PPRS so that it can accommodate different distribution methods. We do not believe that the additional concerns identified, which relate to the exclusive agreements⁷ assessed to date, are sufficient to warrant action under CA98 at this point in time. However, this conclusion does not preclude the possibility that the OFT might take action under CA98 in the future, in particular if there are agreements which give rise to significant competition concerns which are not covered and/or addressed by our recommendations.

We have also decided not to refer the market to the Competition Commission. This is because we consider that the concerns identified are best dealt with by recommendations to Government, so that a reference is not necessary at this time.

In this study, which was launched in April 2007, the OFT considers the likely impact of these changes on competition, on the cost of medicines to the NHS and on the level and quality of service that pharmacies are able to provide to patients.

The issues and recommendations in this study need to be set in the wider context of the other significant changes that are taking place in parallel in the UK pharmaceutical industry. In particular, the PPRS is in the process of being renegotiated by DH and the ABPI. We consider that this provides a timely and appropriate opportunity for steps to be taken to address the issues we have identified in this report.

Key changes in the distribution of medicines

We launched this study following indications by various manufacturers of medicines that they were to alter the way in which they distribute their medicines in the UK.

The following table illustrates the different distribution models that manufacturers have adopted.

	Manufacturer sells to wholesalers	Manufacturer sell to pharmacies
All full-line wholesalers appointed	Traditional Wholesale Model [Majority]	DTP with many LSPs [GSK]
Limited number of full-line wholesalers appointed	Limited wholesaler model [Napp, Sanofi Aventis]	DTP with exclusive/limited LSPs [Pfizer, AstraZeneca]

⁶ The reason for this is set out fully in Annexe H.

⁷ Or, similarly, from those agreements that limit the number of appointed wholesalers.

In the UK, under the traditional wholesale model, manufacturers have typically sold all of their medicines to all 'full line'⁸ wholesalers, who then compete on price and service levels to become a pharmacy's main supplier of medicines. The following two key features distinguish the new distribution schemes from this traditional wholesale model:

- Under DTP schemes, manufacturers sell direct to pharmacies and appoint one or more LSPs who are paid a fee to deliver the medicines on their behalf. Instead of competing to supply pharmacies, wholesalers compete primarily to become a manufacturer's appointed LSP.
- Some manufacturers are choosing to limit the number of wholesalers or LSPs who can distribute their medicines.

The following diagram provides a summarised comparison of a DTP scheme and the traditional wholesale model.

DTP and the traditional wholesale model

Traditional Wholesale Model

Manufacturers sell to all wholesalers at a discount of 12.5 per cent to the list price.

Wholesalers purchase branded medicines at a discount of 12.5 per cent. Wholesalers compete to become principal wholesaler to pharmacies. Competition is on the basis of discount and service standard.

Pharmacies choose a preferred principal wholesaler on basis of discounts offered and suitability of delivery and cut-off times. Payment made to wholesaler.

Service to patients a function of delivery service to pharmacies.

DH reimburses pharmacies at list price. Higher discounts to pharmacies mean DH can clawback a greater percentage of the list price.

Direct to Pharmacy Model

Manufacturers specify the service level required from LSPs. Appointed LSPs are paid agreed sums for delivery. Manufacturers set the discount level offered to pharmacies.

Wholesalers compete to be appointed as a manufacturer's LSP. LSPs are paid delivery fees by the manufacturer. Service standard set by manufacturer. Where there is more than one LSP, they compete on service quality for pharmacies' business.

Where more than one LSP is appointed, pharmacies choose between a manufacturer's appointed LSPs. Choice will be on basis of service standards. Discount set unilaterally by manufacturer. Payment made to manufacturer.

Service to patients a function of manufacturer requirement and LSP service to pharmacies.

- -> Financial flow -> Product movement

⁸ Full-line wholesalers account for the vast majority of medicines sales to pharmacies, and as their name suggests they are able to supply the entire range of prescription medicines (around 12,000 lines). See chapter 2 for further information.

It is important to note that a DTP scheme does not necessitate a reduction in the number of wholesalers supplying a manufacturer's medicines and a manufacturer can elect to use a smaller number of wholesalers to supply medicines without the introduction of a DTP scheme. For example, whereas Pfizer appointed only UniChem as a LSP under its DTP scheme, GSK's DTP scheme involves supply of GSK medicines to all full-line wholesalers. Similarly, while Napp and Sanofi Aventis continue to sell to wholesalers, and have not introduced a DTP scheme, they each now use only three wholesalers to distribute their medicines.

In this study, therefore, we have tried to distinguish the competition concerns that relate to the DTP model from those that relate to reductions in the number of wholesalers or LSPs appointed by manufacturers.

We have identified two main ways in which the adoption of a DTP model by manufacturers and/or reductions in the number of wholesalers or LSPs appointed by manufacturers could affect the NHS, as purchaser, and patients:

Changes relevant to price setting: The DTP model involves manufacturers supplying their medicines directly to pharmacies and setting the discount which they receive from the manufacturer's list prices. Manufacturers pay LSPs a delivery fee and ownership of the medicines passes directly from the manufacturer to pharmacies.

Under the traditional wholesale model, although manufacturers are not legally obliged to offer wholesalers a discount of 12.5 per cent from the list price, there is general adherence to it as a 'custom and practice' so that in effect the PPRS constrains prices to wholesalers (see box below).⁹ Under the traditional wholesale model, the price pharmacies pay for medicines is the outcome of competition between wholesalers and this competition results in significant discounts from list prices.

The PPRS and pharmacy reimbursement

The list prices of UK medicines prices are constrained by the profit and price controls included within the PPRS and monitored by DH. The NHS reimburses pharmacies for the medicines they dispense at the relevant list price. However, pharmacies generally secure a significant discount to the list price when purchasing branded medicines from wholesalers. In order to maintain pharmacy reimbursement at an agreed level, the NHS takes back some of the excess margin earned from high discount levels by using a 'clawback' mechanism. This is calculated as a percentage of the reimbursement price to pharmacies. Because pharmacies receive an agreed level of margin from the NHS, any decreases in the discounts received by pharmacies would be expected to increase the costs to the NHS as it would be able to 'clawback' less. The actual price paid by the NHS for medicines (on average) is a combination of the list price minus clawback. Any reduction in pharmacy discounts would therefore feed through directly into higher medicines costs to the NHS.

⁹ We have established that the vast majority of branded medicines are sold at a 12.5 per cent discount to wholesalers with the exceptions to this accounting for less than 3 per cent of sales value.

Changes relevant to service levels to patients: Under the traditional wholesale model, the service levels provided by wholesalers to pharmacies are, like prices, the outcome of competition between wholesalers and negotiation with pharmacies. In determining which wholesaler to appoint as a principal wholesaler, pharmacies consider many factors including the level of discounts offered and all aspects of the service standards being offered by the wholesalers.

Under a DTP scheme, manufacturers specify the service standards they require from their appointed LSPs when delivering their branded medicines to pharmacies. When a manufacturer invites LSPs to submit tenders to distribute its medicines, it can select the service level it considers appropriate. Where a manufacturer does not choose a DTP scheme but reduces the number of wholesalers through which it supplies, service levels are still the outcome of competition but this competition to supply pharmacies may be less intense than in the traditional wholesale model.

Main findings

The costs of branded medicines to the NHS

One of our key findings is that there is a high risk that the current and planned distribution changes will increase the price paid for medicines by pharmacies, leading to an increase in the effective price paid by the NHS for medicines and therefore increased costs.

Manufacturers of branded medicines enjoy an extremely strong negotiating position with respect to pharmacies for many medicines. When a pharmacy receives a prescription for a specific branded medicine or a generic prescription for a medicine where there is no generic alternative, it is obliged to provide that medicine and cannot dispense an alternative.¹⁰ Pharmacies' demand for branded medicines is therefore unlikely to be sensitive to changes in the discount from list price offered by a manufacturer where: (i) there is no generic alternative; or (ii) it is typically prescribed as a brand. Around 75 per cent of medicines expenditure in primary care falls into these categories.¹¹

Given this, for many branded medicines a manufacturer would not expect a significant fall in demand if the price of the medicine to the pharmacy increased. Under DTP manufacturers have the ability to reduce discounts from list price as they set these unilaterally when supplying directly to pharmacies and therefore have an incentive to decrease the discount offered to pharmacies.

Wholesalers do not have the same ability to decrease discounts under the traditional wholesale model as the discounts they offer are the result of, and constrained by, competition with other wholesalers.

There is little consensus amongst manufacturers as to whether the PPRS constrains the discounts that manufacturers can offer to pharmacies. Some have suggested that the 12.5 per cent discount is a cost they incur and that they are free to reduce that cost and increase their profitability where possible. Indeed, several manufacturers have expressed a desire to do so. Others argue that the 12.5 per cent discount convention has been used to cap the price that

¹⁰ Under their terms of service – see under 'Dispensing' in Annexe E.

¹¹ See Chapter 2 for details.

manufacturers can realise on their sales, and that PPRS price cuts apply to list prices and to the prices realised by manufacturers.

Pfizer has offered assurances to DH that its DTP scheme will not result in the NHS incurring higher costs for Pfizer medicines as it will maintain the aggregate level of pharmacy discounts. However, we are concerned that DH does not have sufficient information to monitor adherence to any such assurances and make any necessary adjustments to list prices in a timely manner. A change in the pattern of discounts to pharmacies could lead to higher costs for the NHS as the pharmacy contract guarantees pharmacy income. If discounts for some pharmacies fall, clawback is also likely to fall as it is assessed on the basis of discounts to independent pharmacies, which are most likely to receive reduced discounts.

The potential impact of this cost for the NHS is significant. Around 9 per cent¹² of the amount reimbursed to pharmacies in the UK is currently clawed back by the NHS. Each percentage point reduction in discounts received by pharmacies on medicines which they are obliged to dispense would cost the NHS over £50m a year.¹³

We generally presume that changes to distribution systems by manufacturers are driven by efficiency considerations, and are unlikely to raise competition concerns. In the context of considering distribution costs and discounts in the supply chain, we recognise that there may be many commercial motivations and efficiency benefits leading manufacturers to adopt DTP schemes. Under the traditional wholesale model, the distribution margin is typically a fixed percentage of a medicine's list price. This means that distribution costs do not reflect the size, weight and volume of medicines being distributed and instead relate to the list price of the medicine. Thus the higher the list price of the medicine, the higher the distribution cost. For this reason, manufacturers of high value/volume medicines consider that the traditional wholesale model results in them subsidising the distribution costs of manufacturers of low value/volume medicines.

Under a DTP scheme, a manufacturer can negotiate individual distribution costs with LSPs – its distribution costs should therefore be more transparent and more reflective of the manufacturer's actual costs of distribution. At the margins, such benefits might be expected to provide for enhanced incentives to develop high value medicines. Such medicines will attract lower distribution charges than under the traditional wholesale model and a higher proportion of their value can therefore be realised by manufacturers.

DTP may therefore be a more efficient method of distribution for some manufacturers. We have not, however, compared the relative efficiency of DTP versus the traditional wholesale model in any detail and reach no conclusion on this point in this study.

However, because DTP schemes may enable manufacturers to obtain higher effective prices, we cannot rule out the possibility that this, rather than increased efficiency, may be one of the motivations for introducing such schemes. We discuss below our recommendations to address this concern which involve the NHS in effect agreeing the price to be paid by pharmacies. This would ameliorate concerns about DTP leading to cost increases, and would give confidence that changes to distribution are driven by efficiency.

¹² The amount varies between the different countries in the UK. See Chapter 2 for more details.

¹³ See Annexe C for details of this calculation.

Conclusion on costs

In our view, manufacturers adopting DTP schemes have the ability to decrease the levels of discount currently received by pharmacies under the traditional wholesale model. It is not clear that, under the existing PPRS, DH is able to require, monitor or enforce assurances that the adoption by manufacturers of DTP schemes will not result in increased costs to the NHS.

Service standards to patients

We consider that DTP schemes, whether exclusive or not, have the potential to impact upon the service levels provided to pharmacies and, potentially, the services that they can in turn offer to patients. We have not, however, as part of this study assessed whether the traditional wholesale model is the most efficient way of providing satisfactory service standards or whether current service standards are optimal.

In the same way that manufacturers set prices to pharmacies under DTP schemes, they also determine the delivery service standards that their LSPs should adopt in supplying their medicines. As pharmacies often have little choice but to dispense a branded medicine, pharmacy demand for such medicines will not be particularly sensitive to reductions in service levels. Manufacturers therefore have an incentive to reduce levels of service.

We also note that LSPs have less incentive to maintain high service standards where they are appointed on an exclusive basis. Although LSPs are under contract to meet the service standards set by the relevant manufacturer, risks remain because the LSP, at least in the short-term, is guaranteed all, or a proportion, of a pharmacy's business. The same would be true if manufacturers chose to use an exclusive wholesaler under the traditional wholesale model, although so far no manufacturers have chosen to do so.

Where there is an exclusive LSP, pharmacies have no choice but to accept the cut-off and delivery times offered. Since the introduction of the exclusive DTP scheme by Pfizer, we have received complaints¹⁴ from many pharmacies who are dissatisfied with the delivery and cut-off times offered to them by UniChem for Pfizer medicines and yet are unable to switch to an alternative provider as they would have done under the traditional wholesale model.

Reduced service standards could, for example, result in a combination of the following costs to pharmacies, patients and the NHS:

- Higher pharmacy costs as more stock must be held to ensure that an equivalent number of patient prescriptions can still be satisfied on a timely basis.
- Patients waiting for longer to obtain medicines, where pharmacies are unable to increase their stock holding and can only dispense out-of-stock medicines when their less frequent deliveries are received.
- Patients facing increased search costs to find alternative sources of supply.
- Increased costs to the NHS, which may have to increase pharmacy payments in response to increased pharmacy stockholding costs.

¹⁴ These complaints have been taken into consideration during the market study and have, in addition to other information, informed us of stakeholder concerns.

We recognise, however, that DTP schemes may result in some efficiency and other benefits in relation service standards and potentially to patients. For example, Pfizer argued that one of its main motivations for adopting a DTP scheme was to help ensure that counterfeits of its medicines would not reach UK pharmacies. Whilst it is beyond the scope of this study to assess this in detail, we recognise that there are elements of the DTP model which may assist in preventing counterfeit medicines from entering the UK supply chain.

We also consider that, where there are stock shortages, a DTP model may help to ensure that medicines are distributed most efficiently to the benefit of pharmacies and patients. Under DTP schemes, manufacturers appear better able to observe where in the supply chain their medicines are, any instances of bulk purchasing and where stock needs to be diverted, to help ensure that pharmacy and patient requirements can most appropriately be met.

Conclusion on service standards

We reach no view on whether the traditional wholesale model is the most efficient way of providing satisfactory service standards or whether current service standards are in any sense optimal. However, we consider that DTP schemes have the potential to impact upon the service levels provided to pharmacies and the services that they can in turn offer to patients. We recognise, however, that DTP schemes may give rise to certain efficiency and other benefits in relation to pharmacy service levels.

Long-term implications of the distribution changes

The adoption of DTP schemes and the use of fewer wholesalers have prompted concern as to the future viability of full-line wholesalers not currently party to these new arrangements. Following the implementation of the changes described above (see the table above), such wholesalers will be unable to offer approximately 22 per cent of UK branded medicines.

It appears that, to the extent that more manufacturers choose to rationalise the number of wholesalers they use to supply their medicines across the UK, the viability of regional wholesalers' existing business models is likely to be threatened. However, as manufacturers' approach to distribution evolves, it is possible that many such wholesalers will also develop business models that help to ensure their continued presence in this sector. Indeed, a number of regional wholesalers have already formed a trading alliance in response to the changes that are taking place in the sector.

Even if some wholesalers do exit, concentration at the wholesale level would increase significantly only if the majority of manufacturers appointed the same exclusive wholesalers. This does not appear to be an inevitable consequence of DTP schemes particularly since, at this stage, most manufacturers have not appointed exclusive LSPs or wholesalers. However, given the limited number of wholesalers in a position to act as an exclusive LSP, there is certainly a risk that widespread adoption of exclusive agreements could lead to the creation of one wholesaler with a significant share of the market.

On the other hand, we note that barriers to entry in the sector do not appear to be insurmountable and that there are a number of potential entrants who may be actively considering whether the introduction and evolution of DTP schemes make market entry

easier and viable.¹⁵ However, although new entry does appear to represent a credible threat in the wholesale sector, it is by no means certain that those barriers to entry identified are sufficiently low to prevent further concentration in the market giving rise to a wholesaler with significant market power.

Conclusion on long-term implications

If exclusive DTP schemes become widespread, this could lead to increased concentration in the wholesale sector and less competition for DTP contracts. However, if most manufacturers do not follow an exclusive DTP model (and so far only Pfizer has chosen to limit distribution to one wholesaler), we anticipate that there is less risk that the distribution changes described in this study will give rise to significant longer term competition concerns.

Our recommendations

DTP schemes and the use of fewer wholesalers constitute a significant change to the arrangements for distributing branded medicines in the UK. We recognise that such schemes may give rise to efficiency and other benefits in the sector but are concerned that they have the potential to be driven by and result in cost increases for the NHS and to lead to a reduction in the levels and quality of services provided to pharmacies and, potentially, patients without compensating price reductions. We also note that, if exclusive DTP schemes become widespread, this could lead to increased concentration in the wholesale sector and give rise to longer term competition concerns.

We are making recommendations to Government that we believe would address these concerns, whilst allowing manufacturers the flexibility to adopt the distribution method they consider most efficient and commercially attractive. We are motivated to ensure that any potential benefits of DTP schemes and/or wholesaler rationalisation are realised for the benefit of the NHS, pharmacies and patients and also that any potential related negative effects resulting from these changes are minimised.

Recommendation one – safeguarding the cost of medicines to Government

We have outlined how the adoption of DTP schemes is likely to result in a decrease to pharmacy discounts and that the higher cost to pharmacies could be passed on to the NHS. We present two options below which we believe would safeguard the NHS from such cost increases.

¹⁵ See Chapter 5 for details.

Option one – Reduce list prices in the PPRS framework by an amount equivalent to the average discounts received by pharmacies

As outlined above, DTP schemes may enable manufacturers to appropriate the discounts currently received by pharmacies, and ultimately by the NHS via the clawback mechanism. Option one would see list prices reduced to reflect the removal of these discounts from the list price.¹⁶ The price set under the PPRS would be that paid to medicine suppliers (wholesalers or manufacturers) by pharmacies.¹⁷

Our proposal would effectively alter the level in the supply chain at which the transaction price of medicines is constrained.

One of the particular benefits of this approach is that it could accommodate both DTP schemes and the traditional wholesale model. Manufacturers continuing to use the traditional wholesale model could sell to wholesalers at a negotiated discount to the lower PPRS list price. The 12.5 per cent discount convention which currently exists would no longer apply. Alternatively, manufacturers supplying medicines using a DTP scheme could pay a distributor a fee per pack and charge pharmacies up to the revised PPRS list price.

The diagram below summarises how this option might work:

Recommendation one, option one

How the recommendation would apply to DTP



How the recommendation would apply to the traditional wholesale model



- -> Financial flow —> Product movement

¹⁶ The extent of the price cut would be formulated by reference to the discounts earned by pharmacies under the traditional wholesale model (which are estimated to be on average around 10 to 10.5 per cent).

¹⁷ We understand that to apply this scheme to wholesalers/LSPs would require a change to the remit of the PPRS.

This proposal would necessitate some changes to pharmacy reimbursement as the price reimbursed to pharmacies by the NHS would no longer be expected to provide any contribution to retained profit.¹⁸

We have considered two ways in which this issue may be resolved: through a direct payment from Primary Care Organisations to pharmacies based on the number of prescriptions dispensed or adjustments to other established payment mechanisms.¹⁹

Option two – pharmaceutical suppliers offer a minimum list price discount to pharmacies

Although there has been general adherence to the 12.5 per cent discount to wholesalers under the traditional wholesale model for some time, there is no equivalent benchmark or required discount in the context of DTP schemes (see Chapter 2 for details, particularly paragraph 2.70).

A second option to prevent increased costs to the NHS would therefore be to seek each manufacturer's agreement to offering a minimum discount on sales to pharmacies, within the PPRS framework. The minimum discount would be formulated by reference to the discounts earned by pharmacies under the traditional wholesale model.²⁰ This does not require any adjustment of the list price. The effect of this is similar to seeking an assurance on cost neutrality from a manufacturer but is more specific and easier to monitor.

As with option one, this system could accommodate both the traditional wholesale and the DTP models. Manufacturers using the traditional wholesale model could continue to apply the 12.5 per cent discount convention, the level of which might need to be explicitly built into the PPRS. A manufacturer using a DTP scheme would pay its LSP(s) a distribution fee and sell to pharmacies at list price minus at least the agreed minimum discount. If the minimum pharmacy discount could also be applied to wholesalers, a wholesaler would sell to pharmacies at list price minus at least the agreed minimum discount. The terms on which wholesalers purchased from manufacturers would then be determined by negotiation.

Option two represents a simpler way of safeguarding the costs to the NHS, as it would not require the same level of changes to the PPRS framework and pharmacy reimbursement arrangements as option one.

Option one is our preferred option, however, as this option would result in greater transparency of the actual prices paid by the NHS. Moreover, we recognise that the PPRS is in the process of being renegotiated, presenting an ideal opportunity to incorporate our recommended changes. However, we note that DH has considerable experience of negotiating the terms of the PPRS and may therefore recognise other options within the PPRS framework which would equally safeguard NHS costs but which may be even simpler to implement than our preferred option.²¹

¹⁸ Pharmacy would only earn purchase profits where they were able to negotiate a discount to the new list price.

¹⁹ For example, through Category M pricing. See Annexe D for more information.

²⁰ We would anticipate a minimum discount of around 10 to 10.5 per cent. See above.

²¹ We note that a temporary increase in the resources available to the PPRS team within DH may be required if our recommendations are to be adopted.

Although, both options identified involve some complexity, we consider this is inevitable given the PPRS framework and unavoidable if the risks we have identified are to be satisfactorily guarded against.

Recommendation two – manufacturers appoint LSPs on the basis of a required minimum service level

We have identified a risk that service standards to pharmacies and, potentially patients, will fall under DTP schemes. We do not express a view on whether the traditional wholesale model is the most efficient way of providing patients with satisfactory service standards or whether current service standards are optimal but note that a reduction of service level may be of concern. We recommend that Government should seek manufacturers' agreement to specifying minimum service levels for their appointed LSPs when adopting a DTP scheme. We consider that DH, The Scottish Government and The Department of Health, Social Services and Public Safety Northern Ireland are best placed to consider the value of different service level standards and to decide on the appropriate minimum level. In particular, they are able to consider the relative value of such services versus other the needs of patients. If a reduction in service levels is acceptable, Government should ensure that it receives some benefit in terms of reduced costs.

Concerns relating to exclusivity

We believe that the risks we have identified with exclusivity will also be of concern to manufacturers. If manufacturers appoint an exclusive LSP they may find it more difficult to ensure that appropriate service standards are maintained. Giving pharmacies a choice of supplier gives real incentives to LSPs/wholesalers to offer good levels of service since they will lose business if such standards are not satisfactory. Similarly, it is not in manufacturers' interests to appoint LSPs/wholesalers with the effect that the intensity of competition among potential wholesalers and LSPs is reduced significantly. If this occurred, manufacturers could find themselves unable to obtain competitive bids from LSPs to distribute their medicines. This study highlights these findings to industry. If competition is significantly reduced in the sector in future, it may well require further investigation by the OFT.

As the purchaser of medicines, DH also has incentives to ensure that it achieves value for money and that its service level expectations are realised by pharmacies to the benefit of patients. To that end, if DH has concerns that the exclusive appointment of a wholesaler/ LSP might serve to undermine its service requirements, it may wish to impose additional requirements upon manufacturers to ensure that pharmacies receive services of the required standard.²²

²² Various options may be available to DH, but possibilities may, as relevant, include making lower payments for lower service standards and/or a requirement for additional, more effective monitoring measures on the part of manufacturers using a single wholesaler.

Conclusion

We consider the potential impact of the distribution changes to be significant in terms of both costs to pharmacies, and ultimately to the NHS and service standards to pharmacies and, potentially, patients.

We have suggested solutions which we consider to be effective means of protecting NHS costs. Given the extent of the potential increases to the cost of medicines to the NHS – each percentage point reduction in discounts would cost over £50m a year – it is important that robust safeguards are put in place. Reducing list prices in the PPRS framework by an amount equivalent to the average discounts currently received by pharmacies under the traditional wholesale model is our preferred option for addressing this issue. We recognise though that alternative approaches may exist.

On service standards, we have recommended that, if Government is concerned about reductions in service, it should seek voluntary agreement from manufacturers to adhere to appropriate service levels. In any event, any deterioration in service levels should be reflected in the prices paid for medicines by the NHS.

We have also highlighted potential longer term competition concerns which might arise from exclusive DTP schemes.

We believe our recommendations safeguard against increased costs to the NHS and ensure service standards to pharmacies and patients will be maintained, while allowing manufacturers the commercial freedom to choose the distribution arrangements they consider to be most efficient and best suited to their portfolio of medicines. This means that any efficiency benefits arising from DTP schemes and/or reductions in the number of distributors can be realised without harming the NHS, pharmacies or patients.

1 INTRODUCTION

The launch of the market study

- 1.1 We launched this study following decisions by a number of manufacturers of medicines to alter the way in which they distribute their medicines in the UK. The study was launched on 4 April 2007. The aim was to provide us with a better understanding of the implications of the recent and proposed changes to medicine distribution arrangements in the UK.
- 1.2 On launching the study we committed to analysing how the changes in the distribution of branded medicines would impact upon competition in the UK medicines wholesaling sector, upon the NHS²³ and upon patients. In particular, this study considered how changes in distribution may affect:
- the cost of medicines to the NHS
 - the level and quality of service patients receive from pharmacies²⁴ and
 - competition in wholesaling in the longer term.
- 1.3 At the outset, we considered four possible outcomes of the study. These were:
- investigation(s) under the Competition Act 1998 (CA98)
 - a market investigation reference to the Competition Commission
 - making recommendations to Government or
 - no action, having identified no significant concerns.

The impetus for the market study

- 1.4 On 28 September 2006, Pfizer Limited (Pfizer) announced that it intended from 5 March 2007 to sell its prescription medicines direct to pharmacies and dispensing doctors, with UniChem Limited (UniChem) acting as a logistics service provider (LSP) on an initially exclusive basis. This distribution system was referred to as a 'Direct to Pharmacy' (DTP) scheme. Following this announcement the OFT became aware that other manufacturers were considering changing to similar, although not necessarily exclusive, distribution systems.

The market's response to Pfizer's announcement

- 1.5 Pfizer's announcement prompted widespread concern among pharmacies, dispensing doctors, competing wholesalers and smaller manufacturers who wrote to the Office of Fair Trading (OFT) urging it to launch an investigation under the CA98 into the proposed arrangements.
- 1.6 We received the first complaint in October 2006 and 482 similar such complaints, mainly from pharmacies and dispensing doctors, were subsequently made prior to the launch of the market study in April 2007. We also received 48 letters of complaint from Members of Parliament (MPs) on behalf of their constituents. In addition, we received detailed submissions from AAH Pharmaceuticals Limited (AAH), Lloyds Pharmacy Limited (Lloyds) and from the majority of the members of the British Association of Pharmaceutical Wholesalers (BAPW), as well as UniChem and Pfizer. We held meetings with a number of interested parties, including AAH, Lloyds, Pfizer, UniChem and the Department of Health (DH).

²³ All references to 'NHS' refer to the public healthcare provision in England, Scotland, Wales and Northern Ireland.

²⁴ Unless specifically stated otherwise, references to 'pharmacies' should be interpreted in this report as including also dispensing doctors.

The applications for interim measures and subsequent injunction application

- 1.7 The submissions that we received from AAH, Lloyds and the majority of BAPW members constituted, in part, a request for the OFT to take a decision adopting interim measures pursuant to Section 35(2) of CA98 requiring Pfizer not to implement DTP until the OFT had completed an investigation under the Chapter I and Chapter II prohibitions of CA98.
- 1.8 Following discussions with a number of key players in the market, the OFT rejected the requests for interim measures on the grounds of insufficient evidence of significant and irreparable harm. The OFT notified the relevant parties of this in a letter dated 27 February 2007.
- 1.9 On 2 March 2007 the majority of BAPW's members applied for an injunction against Pfizer and UniChem. In a Judgment dated 5 March 2007, Mr Justice David Richards refused to grant the injunction.²⁵

Further changes announced by other suppliers

- 1.10 Since the launch of the OFT's market study, a number of other medicines manufacturers have announced their intention to implement substantial changes to their distribution models.
- 1.11 On 20 April 2007 AstraZeneca announced that it intended to appoint AAH and UniChem as LSPs under a DTP model²⁶ from 1 October 2007. AstraZeneca has since postponed the implementation of its new distribution arrangements until February 2008. Sanofi Aventis Limited (Sanofi Aventis) and Napp Pharmaceuticals Limited (Napp) continue to use the traditional wholesale model, but now only supply their medicines for re-sale by AAH, UniChem and Phoenix.

The decision to launch a market study

The legislative options

- 1.12 Following receipt of the complaints outlined above, three options were available to the OFT. These were to: (i) launch a CA98 investigation into Pfizer and/or UniChem; (ii) launch a market study under EA02; or (iii) take no action. A market study was not seen as mutually exclusive to a CA98 investigation, since the latter could be undertaken subsequently if information collected via a market study indicated that it was appropriate.

The need for investigation

- 1.13 In the course of our initial inquiries, industry stakeholders raised a variety of concerns with respect to the agreement to be implemented by Pfizer and UniChem, as well as with similar agreements that were then understood to be under consideration. Having taken account of the OFT's prioritisation criteria, we were satisfied that the concerns raised were sufficiently

²⁵ [2007] EWHC 565 (Ch), see Annexe E for details.

²⁶ AstraZeneca does not consider that its arrangements comprise a DTP scheme. Its proposed arrangements do however fall within our definition of DTP (see paragraph 2.67). Any reference to DTP will therefore include the anticipated AstraZeneca model unless stated otherwise.

credible and significant to warrant further investigation.²⁷ In this regard, it was also relevant that the issue concerned healthcare, which was identified by the OFT as a priority area in its Annual Plan 2007/08.²⁸

Why a market study was the appropriate legislative tool

- 1.14 We therefore considered which of our legislative tools would prove the most effective and proportionate way to investigate the issues raised. The complaints received largely objected to the exclusivity of the appointment of UniChem as Pfizer's only LSP.²⁹ We were concerned however that any effects identified may also arise from DTP schemes generally, whether one or more LSPs were in fact appointed.³⁰ Consequently, we were concerned that any enforcement action under CA98 in respect of Pfizer's exclusive distribution agreement may not fully address the effects stakeholders had identified.
- 1.15 It was also relevant that we understood other manufacturers to be considering adopting similar DTP schemes. We considered a market-wide analysis of the competitive implications of DTP schemes to be more appropriate than a CA98 investigation, particularly as the potential competition effects from a large number of non-exclusive DTP schemes are likely to be different from the effects arising from the DTP schemes already operating in the market. It was important to take into account the interactions between different manufacturers' evolving distribution models, given their potential for wider and different effects on the distribution of medicines.
- 1.16 It was also apparent that the sector is characterised by a variety of regulations. A market study would enable us to consider whether such regulation might be amended to address any competition problems identified or whether it might itself be contributing to competition issues.
- 1.17 The Pharmaceutical Price Regulation Scheme (PPRS) is relevant to this study, and was itself the subject of an OFT study published on 20 February 2007. A summary of the PPRS study, and how it relates to this study, can be found in Annexe B.

²⁷ See <http://www.offt.gov.uk/news/press/2006/146-06>.

²⁸ See http://www.offt.gov.uk/shared_offt/about_offt/349517/ap08.pdf.

²⁹ The complainants requested that the OFT open an investigation into the agreement under Chapter I of CA98 and / or a Chapter II investigation into Pfizer's refusal to supply wholesalers with its medicines.

³⁰ We considered that concerns arising from changes to the margins earned across the supply chains may not arise purely as a result of the exclusive nature of the Pfizer/UniChem agreement, but could also arise because of DTP. We had similar concerns regarding services levels to pharmacies. For example, a manufacturer wishing to switch to a single or multi-party DTP scheme could invite tenders from logistics service providers having specified a particular service level for pharmacies.

Focus and scope of the study

- 1.18 Following the launch of the market study we invited submissions and comments from interested parties and set a deadline of 1 June 2007. We received a further 131 submissions. In light of the short timetable committed to by the OFT for the study, we could not engage with all potentially interested parties but targeted a number of specific organisations and companies, holding a series of meetings with the purpose of discussing in greater depth the issues raised. A full list of the stakeholders who contributed to our study is provided at Annexe A. We conducted extensive surveys of pharmacies and full-line wholesalers, details of which can be found at Annexe F. We also commissioned a study of distribution arrangements in other countries, for which see Annexe G.
- 1.19 Chapter 2 of this report sets out the market background to the market study. The representations made by industry stakeholders related to a number of key concerns. Those key concerns, and how they have been considered in the study, are outlined below.

The cost of medicines procurement to the NHS

- 1.20 Chapter 3 considers whether NHS costs could be increased by DTP as a result of a variety of potential factors. These include:
- the prospect of manufacturers using DTP as a means of departing from the standard level of discount traditionally offered to customers (previously to wholesalers but, under DTP, to pharmacies)
 - concerns among pharmacies that they would incur extra costs as a result of the distribution changes and
 - whether manufacturers of low volume/value medicines would incur higher costs as a result of some manufacturers using DTP, and whether the NHS would bear this cost.
- 1.21 The report considers the mechanisms by which such factors may increase NHS costs and the options that may be available to DH in preventing, mitigating or neutralising those potential costs.

The impact of the distribution changes on services to patients

- 1.22 Chapter 4 examines how the changes in distribution are likely to affect the levels and quality of services to patients:
- the potential for DTP to result in a decrease in the level and quality of service standards to the detriment, ultimately, of patients. In addition, the impact exclusive arrangements are likely to have on service levels
 - the argument put forward by Pfizer that DTP would improve patient service by helping to eliminate the potential for counterfeit medicines to enter the supply chain and
 - the impact of the distribution changes on the administrative burden for pharmacists. In particular, we consider the impact on pharmacies of the requirement to open additional wholesaler accounts and the possible impact of this additional burden on pharmacies' ability to provide high quality service to patients.

- 1.23 The report examines the potential impact on service levels to patients as a result of the changes in distribution taking place.

Long term competition implications

- 1.24 In addition to focusing specifically on the anticipated effects of DTP on the cost of medicines to the NHS and on service to patients, Chapter 5 of this report considers the potential longer term implications for competition in the distribution of medicines. In particular, we assess:
- the possibility and potential impact of a reduction in the number of wholesalers operating in the market
 - the scale of barriers to new entry to the distribution market and
 - the risk of price discrimination between vertically integrated pharmacy chains and independents in terms of discounts offered by manufacturers.
- 1.25 In relation to the three aspects above, we consider both the potential effects of decreased competition on the service levels and on the value for money provided by the remaining wholesalers.

Conclusion and Recommendations

- 1.26 In Chapter 6 we present our conclusions and propose recommendations to address the concerns we have identified.

2 THE DISTRIBUTION OF MEDICINES IN THE UK

Introduction

- 2.1 The distribution of medicines, from manufacturer to patient, generally involves three levels of the supply chain: manufacturers, wholesalers and pharmacies.³¹ This chapter sets out the markets in which these companies operate, identifies the key players, describes how prices are set and explains the various distribution models available to manufacturers.
- 2.2 The focus of this report is on the recent changes manufacturers have made to their arrangements for distributing medicines to pharmacies. Under the traditional wholesale model manufacturers sell their medicines to all full-line wholesalers who then compete to supply pharmacies. Direct to Pharmacy (DTP) schemes represent a departure from the traditional wholesale model in that they involve manufacturers selling directly to pharmacies, rather than through a wholesaler, and using a wholesaler as a logistics service provider (LSP) to deliver medicines on their behalf in return for a fee.
- 2.3 Some manufacturers are also departing from the traditional wholesale model by limiting the number of wholesalers they will supply. This restricts the choice available to pharmacies and may require them to open an account with an additional wholesaler.
- 2.4 The distribution models available to manufacturers and how these differ from the traditional wholesale model are shown in the following table:

Table 2.1: Distribution models

	Manufacturer sells to wholesalers	Manufacturer sell to pharmacies
All full-line wholesalers appointed	Traditional wholesale model [Majority]	DTP with many LSPs [GSK]
Limited number of full-line wholesalers appointed	Limited wholesaler model [Napp, Sanofi Aventis]	DTP with exclusive/limited LSPs [Pfizer, AstraZeneca]

- 2.5 This chapter considers the following areas:
- The primary care market
 - Competition between manufacturers
 - Competition between wholesalers in the traditional wholesale model
 - Pharmacies and patients
 - DTP and limited wholesaler models

³¹ Unless specifically stated otherwise, references to 'pharmacies' should be interpreted as also including dispensing doctors.

The Primary Care Market³²

- 2.6 In primary care, a patient generally takes a prescription written by a GP to a pharmacy. The pharmacy dispenses the medicine in question, with the patient either paying the prescription charge³³ or, more commonly, nothing. Dispensing doctors, who practise in more remote areas, dispense the medicines they prescribe. Pharmacies are reimbursed by the NHS at list prices constrained by the PPRS (for branded medicines) or the Drug Tariff (for generics).³⁴
- 2.7 About 90 per cent of medicines are delivered to pharmacies and dispensing doctors by wholesalers. Approximately six per cent of this is by short-line wholesalers. The remaining ten per cent are either self-supplied by the pharmacy or are supplied direct by the manufacturer.

Table 2.2: Expenditure on prescription medicines in primary care in the UK, 2005

£ millions	England	Wales	Scotland	N Ireland	Total
Generics	1,979	132	330	51	2,492
Brands	5,522	402	554	286	6,764
Total	7,501	534	884	337	9,256
Total (minus clawback) ⁽¹⁾	6,800	500	800	300	8,300

Source: prescriptions statistics;³⁵ and OFT calculations. The figures may differ slightly from those quoted elsewhere. Totals may not equal sum of constituents due to rounding.

Note (1) Estimates quoted to nearest £100 million.

- 2.8 Table 2.2 gives total expenditure on prescription medicines in primary care for the countries in the UK in 2005. NHS expenditure on prescription medicines in the UK was approximately £9.3 billion in 2005 (£8.3 billion after clawback).³⁶ Of this £9.3 billion, £6.8 billion was spent on branded medicines and £2.5 billion on generics.

Box 2.1: Secondary care

Arrangements for distribution to secondary care differ significantly from the traditional wholesaling model used to distribute to primary care. NHS trusts place orders for much of their business direct with suppliers and receive many medicines direct from the manufacturer.

³² Primary care refers to the Community sector including pharmacy and dispensing doctors, whereas secondary care refers to the hospital sector.

³³ Currently £6.85 in England, Scotland and Northern Ireland. The charge was phased out in Wales from April 2007.

³⁴ See Annexe D for a more detailed description of pharmacy reimbursement.

³⁵ Prescription cost analysis (PCA) data provided by the Prescription Pricing Authority (England), Health Solutions Wales, the Information Services Division Scotland and the Central Services Agency (Northern Ireland).

³⁶ The clawback is a deduction applied to pharmacies' reimbursement by the Department of Health. It is discussed in more detail in Annexe D.

Manufacturers

2.9 The pharmaceutical industry is global in nature: multinational pharmaceutical companies with turnover of tens of billions of pounds operate across national boundaries. While the UK pharmaceutical market is only a small part of a global industry, the relative sizes and importance of manufacturers in the UK in general reflects their global positions. The UK market shares of the leading manufacturers' sales to primary care are shown in Table 2.3 below.

Table 2.3: UK pharmaceutical manufacturers' sales at list prices to primary care and market share, year to June 2007

Manufacturer	Sales to primary care (£m)	Market share %
Pfizer	957	10.0
GlaxoSmithKline	913	9.6
Sanofi Aventis	597	6.3
Astrazeneca	573	6.0
Novartis	341	3.6
Merck	320	3.4
Johnson & Johnson	307	3.2
Wyeth	286	3.0
Eli Lilly	253	2.7
Roche	219	2.3
Boehringer Ingelheim	210	2.2
Novo Nordisk	194	2.0
Bayer	144	1.5
Servier	124	1.3
Mundi Int	100	1.0

Source: ABPI, figures includes OTC sales which are reimbursable under NHS

2.10 Table 2.3³⁷ shows the 15 manufacturers with market shares (based on sales to primary care) of more than one per cent. These make up just under 60 per cent of the market in total.

³⁷ Although these figures also include sales of over the counter ('OTC') medicines to primary care, the market shares are dominated by sales of prescription medicines and do not change substantially if sales of OTC medicines are removed.

Competition between manufacturers

- 2.11 In the longer term manufacturers compete through research and development to bring new medicines to market. In the shorter-term, they compete by seeking to have more of their medicines prescribed and/or dispensed.
- 2.12 Entry barriers into the research and development of medicines are significant, reflecting the high fixed costs required to develop a medicine. Manufacturers are often granted patents to protect their investments.
- 2.13 Patent protection means that direct competition is limited in the short term, although some competition may arise from substitute medicines which address the same therapeutic need. Manufacturers of therapeutically substitutable medicines will therefore compete with each other to influence GPs prescribing behaviour. Over time medicines may also face competition from new medicines which enter the market. When a medicine's patent expires, generic entry is possible which provides greater direct competition.
- 2.14 **The PPRS:** By a combination of profit and price controls, the PPRS constrains the list price of branded medicines. Currently, the PPRS has two main components which are applied to branded and branded generic medicines:
- Profit controls, which set both a maximum and minimum level of profit for manufacturers of medicines supplied to the NHS. Below the minimum point, prices of medicines supplied to the NHS may be raised. Above the maximum level of profit, prices should be lowered.
 - Price controls, which allow manufacturers to set the initial list price of a new medicine sold to the NHS, but which then constrain subsequent price increases. The price controls also comprise price cuts which are agreed during the periodic renegotiation of the PPRS scheme.³⁸
- 2.15 The terms of the PPRS apply directly to list prices rather than to transaction prices. However, when selling to wholesalers, manufacturers typically follow the custom and practice of giving a 12.5 per cent discount from list price. This discount is vigorously defended by wholesalers. There is no convention governing the discounts to be offered under a DTP scheme where a manufacturer sets prices to pharmacies directly.

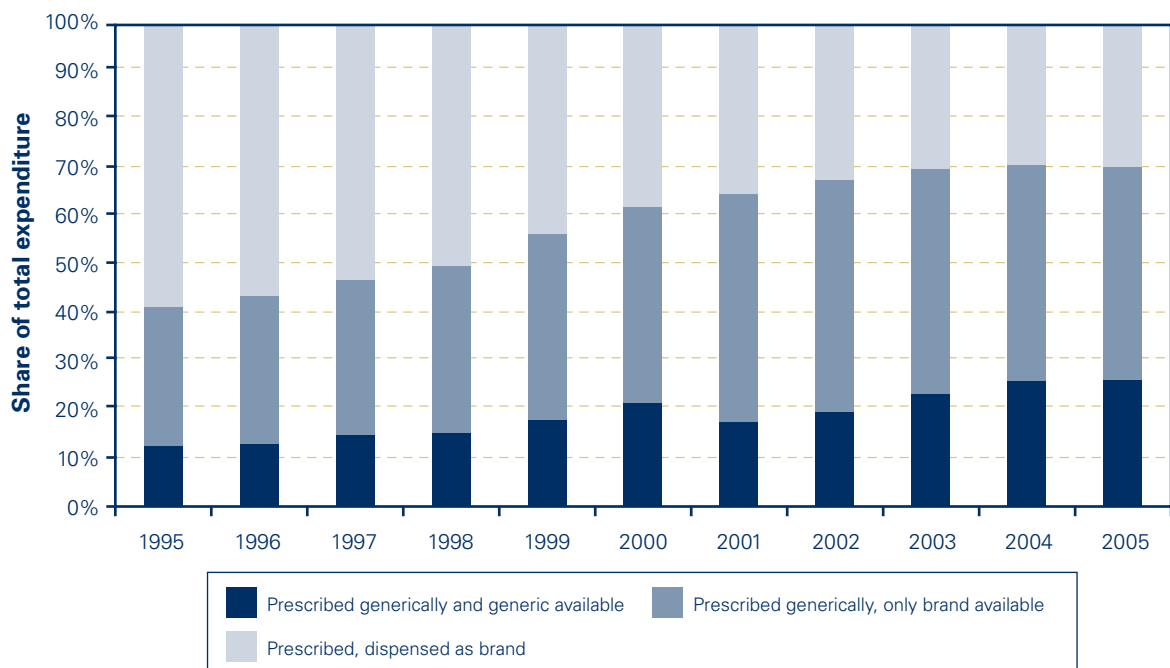
Competition between manufacturers at pharmacy level

- 2.16 On receiving a patient's prescription a pharmacist may have a choice of medicines to dispense, depending on whether (i) the medicine is prescribed generically (i.e. using its chemical name) or as a branded medicine and (ii) there is a generic equivalent to a given branded medicine. The extent of competition to supply a pharmacy can therefore be considered under two main scenarios:
- when a pharmacy has no choice as to which medicine to dispense because (a) a GP writes a prescription for a brand, or (b) the GP prescribes by generic name but only a branded medicine is available, and
 - when a pharmacy has a choice of medicines to dispense because a GP writes a prescription using the generic name and generic, alternative medicines are available.

³⁸ For example, the negotiation for the 2005 PPRS agreed a seven per cent price cut across all medicines supplied to the NHS. Manufacturers were given freedom over how to achieve this reduction across their portfolios of medicines; this flexibility is often referred to as modulation.

- 2.17 When the prescription uses the generic name, and there are generics available, the pharmacy can choose to dispense either a generic version or a branded version of the medicine. In this situation, the pharmacist has a range of sources available including the originator brand, any bioequivalent generics (including branded generics) and parallel imports. In such a case, reimbursement will be at the level set in the Drug Tariff, reflecting the cost of a generic medicine. In these circumstances, manufacturers of such medicines face competition for pharmacy custom. A lower discount to pharmacies would typically see pharmacies switch purchases to an alternative.
- 2.18 Where the prescription uses the branded name, or where there is no bioequivalent to the originator brand, the pharmacy is effectively obliged³⁹ to dispense the relevant brand and the only choice is between the UK sourced medicine and parallel imported versions of the medicine where these are available.
- 2.19 The following graph shows the extent to which prescriptions for medicines are written by brand name, by generic name where only a brand was available and where the prescription was by generic name and a choice of medicines was available.

Figure 2.1: Generic prescribing in the community, England, 1994 – 2004



- 2.20 The figure demonstrates that, by value, 25 per cent of prescriptions allow pharmacies some choice between which medicine to dispense. For the remaining 75 per cent of expenditure, pharmacies are unable to choose between alternative medicines on receiving a prescription.

³⁹ See Annexe E for more information.

- 2.21 Where a pharmacy is unable to choose between alternative medicines, manufacturers face a limited constraint on the prices they offer to pharmacies. When faced with a decreased discount on such medicines, pharmacies are unable to source alternative medicines except where they can secure a cheaper, imported version of the same medicine.
- 2.22 Manufacturers of such brands therefore have an incentive to decrease discounts to pharmacies where possible. As outlined in the box below, we estimate that over £5 billion of primary care medicines expenditure therefore corresponds to medicines where either there are no alternative medicines available (other than parallel imports) or where pharmacies are unable to choose between substitutable medicines due to restrictions in prescribing behaviour.

Box 2.2: Expenditure relating to prescriptions against which pharmacies can dispense a single medicine

Annual primary care expenditure on prescription medicines is around £9.3 billion annually (before the deduction of clawback).

As established above, around 75 per cent of expenditure relates to prescriptions against which pharmacies are unable to choose between alternative medicines. Around £7 billion of expenditure therefore relates to such prescriptions. Around £1.25 billion of this is estimated to relate to expenditure on parallel imports. Over £5 billion of expenditure therefore relates to medicines sourced domestically and where pharmacies are unable to choose between alternative medicines.

Although a very basic estimate, this figure helps to establish the proportion of medicines expenditure where prices to pharmacies are not generally constrained by competition, and where manufacturers could potentially decrease pharmacy discounts without inducing significant switching to alternative medicines.

A one percentage point reduction in the discount to pharmacies on all such medicines would raise NHS purchase costs by over £50 million, and a 10 per cent reduction would raise costs by over £500 million annually.

Wholesalers

- 2.23 There are eleven full-line pharmaceutical wholesalers operating in the UK.⁴⁰ Of these, only the largest three – UniChem, AAH and Phoenix – operate at a national level. The remaining wholesalers are much smaller and operate on a regional basis.
- 2.24 Table 2.4 below gives the approximate market shares of the top 10 full-line wholesalers in the UK by volume, (i.e. number of medicines distributed). This is based on the OFT's survey of full-line wholesalers and therefore does not indicate their market shares within the wider wholesale market as no account has been taken of short-line wholesalers or parallel importers. The May 2006 and May 2007 figures represent the shares of full-line wholesalers before and after the Pfizer agreement was implemented. Further details of the wholesaler survey may be found in Annexe F.

⁴⁰ We note that since Pfizer implemented its DTP scheme, in reality only UniChem provides the full range of medicines.

Table 2.4: Volume based shares of full-line wholesalers for prescription medicines

Wholesaler	May 2006 (%)	May 2007 (%)
UniChem	35 ⁽¹⁾	38 ⁽¹⁾
AAH	39	38
Phoenix	15	14
Mawdsley Brooks	3	3
Sants	2.7	2.6
Sangers NI	2.5	2.2
F Maltby	0.9	0.9
Sangers Maidstone	0.7	10.7
Norchem	0.5	0.6
Munro	0.2	0.3

Source: OFT Calculations based on responses to the OFT wholesaler survey. Figures are for the months of May 2006 and May 2007. Figures do not sum to 100 due to rounding. Figures do not include PIF Medical as it provided no response to the OFT survey. See Annexe F for further details.

Notes:

- (1) UniChem has informed the OFT that, based on market data it receives from data provider IMS Health, it considers this estimate to materially overstate its share.
- (2) These figures include branded and generic prescription medicines in the UK, and therefore exclude surgical products, OTC medicines and any other products supplied by full-line wholesalers to pharmacies.
- (3) These figures include self-supply among vertically integrated wholesalers and pharmacies.
- (4) These figures include volumes of GSK and Pfizer medicines.
- (5) Figures for May 2006 are before Pfizer's DTP scheme came into operation, while figures for May 2007 are after Pfizer's DTP scheme came into operation.

2.25 As well as the full-line wholesalers, there are a number of short-line wholesalers that supply a limited range of prescription medicines, particularly generics and parallel imports.

Competition between wholesalers – the traditional wholesale model

2.26 This section considers how medicines have been distributed under the traditional wholesale model and how wholesalers compete.

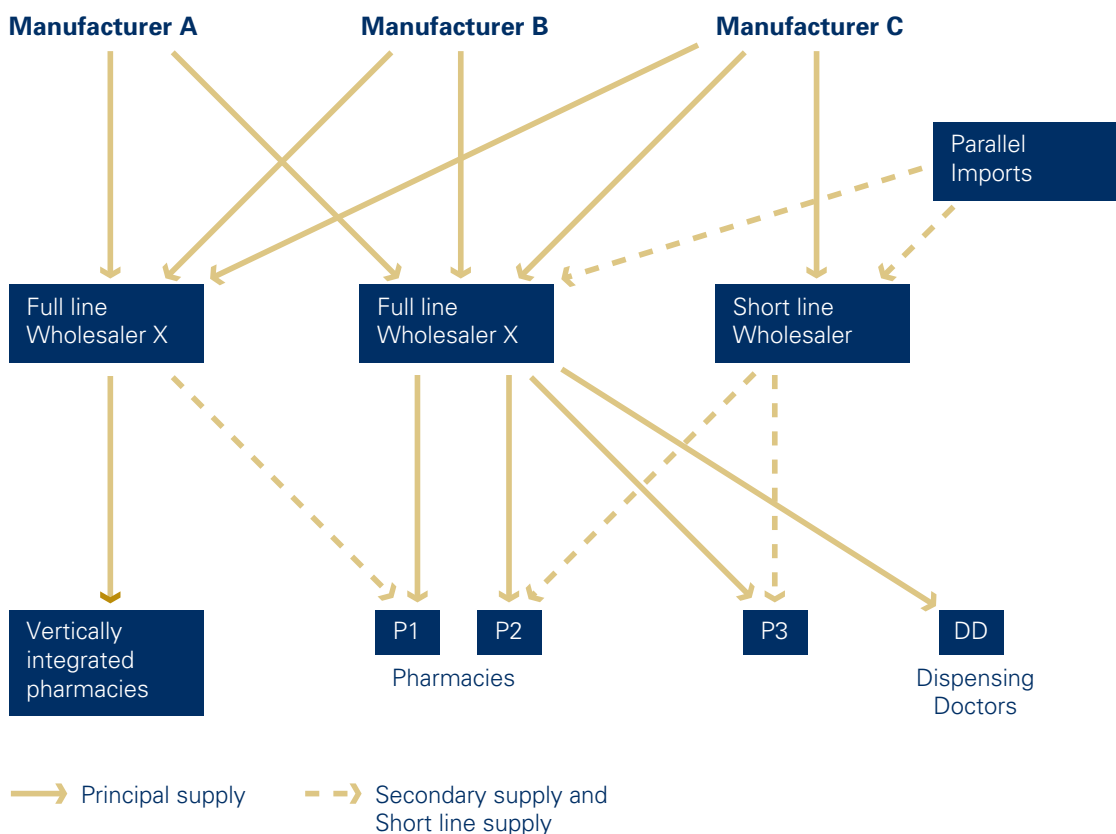
2.27 Under the traditional wholesale model, pharmacies obtain prescription medicines through a number of different channels. They buy medicines from full-line wholesalers, short-line wholesalers and parallel traders. Alternatively, they receive direct supply from manufacturers.

2.28 Full-line wholesalers account for the vast majority of sales to pharmacies, and as their name suggests they are able to supply the entire range of prescription medicines (around 12,000 lines). At present there are 11 full-line wholesalers operating in the UK⁴¹ and all but UniChem are members of the BAPW.

⁴¹ The OFT uses the term full-line wholesaler to include those wholesalers who since 5 March 2007 are unable to supply Pfizer products, but prior to that, supplied the full range of medicines.

- 2.29 Short-line wholesalers stock a narrower range of medicines (around 2,000 lines), and concentrate on generics, parallel imports and popular branded medicines. These are generally faster moving medicines that can be sold in large quantities. It is estimated that there are about 1,400 short-line wholesalers in the UK, varying significantly in size and in terms of the number of product lines stocked. Short-line wholesalers are distinguished from full-line wholesalers by virtue of lower delivery frequency, smaller product range and lower prices which are made possible by lower costs.
- 2.30 Prior to the introduction of Pfizer's DTP scheme, manufacturers have generally supplied all full-line wholesalers, and some also supply short-line wholesalers. Manufacturers may also have bi-lateral supply agreements directly with pharmacies or buying groups.
- 2.31 Independent pharmacies and dispensing doctors typically use a principal full-line wholesaler and a secondary full-line wholesaler for cases when the principal wholesaler is out of stock of a particular medicine. They typically use short-line wholesalers for obtaining greater volume discounts on medicines, such as generics and parallel imports.
- 2.32 Parallel imports into the UK come mainly from within the European Union. The incentive for wholesalers to participate in parallel trade arises because of price differences between national markets, and depends on factors such as the availability of sufficient supplies in the source country, market size in the destination country and the size of the price difference. Parallel trade in medicines has existed in the UK since the beginning of the 1970s, and now accounts for around 18 per cent of branded medicines sold in the UK.
- 2.33 Vertically integrated pharmacy chains are generally supplied by their group's wholesaler (for example Lloyds is supplied by AAH). They can, however, also order from other sources if necessary.
- 2.34 Buying groups are groups of independent pharmacists who contractually belong to a group and use the group's collective buyer power to negotiate discounts from wholesalers and manufacturers. These discounts are larger than those obtainable by the independent pharmacists negotiating alone.

Figure 2.2: Distribution of medicines under the traditional wholesale model in the primary care segment



Discounts offered by manufacturers to wholesalers

- 2.35 By traditional custom and practice, manufacturers typically sell branded medicines to wholesalers at a 12.5 per cent discount off list price. It is believed that this practice has been adhered to for around 25 years. While the origin of this practice is uncertain, it has become a widespread convention that is vigorously defended by wholesalers.
- 2.36 Wholesalers sell to pharmacies at discounts depending on volume purchased, with wholesalers' discounts averaging around 10.5 per cent.⁴²
- 2.37 Manufacturers and wholesalers have confirmed to the OFT that manufacturers generally give the 12.5 per cent discount. One exception is GSK, which has operated a form of DTP for many years.

⁴² See Annexe F for details.

Features of full-line service

- 2.38 Out of the 12,000 prescription medicines held by full-line wholesalers only about 20 per cent (i.e. 2,400 lines) are prescribed frequently. The remaining 80 percent (9,600 lines) are required only infrequently. It is not economical for a pharmacy to stock less frequently ordered medicines as this requires tying up money in stock and there is the risk that medicines may pass their shelf life. Storage capacity is also an issue for some pharmacies. As a result of these factors, pharmacies favour frequent deliveries from their wholesalers to minimise their stock holding risks and space needs.
- 2.39 A pharmacy will generally place an order for out-of-stock items after receiving prescriptions from a GP's morning surgery (around noon) and receive the order during the afternoon (14.30 onwards). At the end of the day (generally around closing time) the pharmacist will place a second order for delivery the following morning (generally around opening time). Exact delivery times vary across the country depending mainly on the distance of the pharmacy from the wholesaler's distribution centre.
- 2.40 Pharmacies make note of the medicines they need over the course of the morning or afternoon, and then place a single order. Most medicines ordered are for stock replacement, not in order to fill a prescription received that morning or afternoon.
- 2.41 Delivery times from principal wholesalers are generally quite predictable as the van does the same route every day and delivers to all pharmacies on the route, although the exact timing depends on factors such as weather and traffic conditions.
- 2.42 To some extent the pharmacy is able to predict the level of demand for different medicines as it is generally fairly stable with, for example, many repeat prescriptions (although we found this varied widely from pharmacy to pharmacy). Where demand cannot be fully predicted, the ability to order at short notice and obtain the required medicine within the same day enables pharmacies to satisfy most patients' needs within a short timeframe and without the patient having to go elsewhere.
- 2.43 Short-line wholesalers generally operate a next day delivery service but a typical pharmacy may not receive deliveries each day from the shortliners it uses. We found that some pharmacies could have a number of different deliveries on any day depending on how active it is in purchasing medicines from wholesalers other than the principal wholesaler.

The nature of competition between wholesalers in the traditional wholesale model

- 2.44 Full-line wholesalers compete with each other in a number of ways to be a pharmacy's preferred wholesaler. As noted above, it has been common for a pharmacy to have an arrangement with two full-line wholesalers to ensure that its requirements will always be met. In such instances, one full-line wholesaler is used as a principal wholesaler and will be relied upon for the main part of a pharmacy's supplies. The other full-line wholesaler (the secondary wholesaler) tends to be used mainly for items not immediately available from the principal wholesaler and hence generally represents only a small proportion of the pharmacy's supplies. Practice varies, however. Some pharmacies deal with only one full-line wholesaler, though they may also draw on short-line wholesalers and manufacturers for a proportion of their requirements.

Medicines distribution

- 2.45 A pharmacy chooses its principal wholesaler based on the discounts which are offered, the number of deliveries per day, the timing of these deliveries, cut-off times and ancillary services offered.
- 2.46 Price competition between full-line wholesalers takes the form of discounts offered from list prices. As described above, the manufacturer's selling price to wholesalers for branded medicines is typically set at 12.5 per cent below the list price. A significant proportion of this is passed on to pharmacies.
- 2.47 It is common practice for full-line wholesalers to publish standard discount terms, laying out the basis of discounts offered and the medicines which are eligible for discounting. Full-line wholesalers' standard terms tend to follow a common structure. They are based on the total monthly value of purchases of medicines eligible for discount. A minimum threshold is set for this figure below which no discounts are offered. Above the threshold a small number of discount rates (usually three or four) apply to set bands of the value of monthly purchases. Wholesalers may differ in their standard terms by virtue of the discount rates used, the monthly sales bands, and the range of medicines eligible for discount. In addition to these standard terms some wholesalers remove discounts (apply surcharges) to customers whose purchases are below a certain level.
- 2.48 Not all pharmacies are covered by standard discount terms and full-line wholesalers may negotiate discounts on an individual basis with different pharmacies. Our wholesaler survey found that on average the discount offered was around 10.5 per cent in 2007/08.⁴³

Pharmacies and patients

- 2.49 There are around 12,600 pharmacies in the UK and approximately 43 per cent⁴⁴ of these are independent. The remainder are multiples and include the major supermarkets as well as high street chains such as Boots. Table 2.5 gives the market shares for the larger multiples for 2006. Where a multiple is part of a group that also includes a wholesaler, the relevant wholesaler is shown in brackets.

⁴³ See Annexe F for details of how figures in relation to the discounts offered to pharmacists should be interpreted, and the caution that should be used in drawing conclusions from these discount figures.

⁴⁴ IPF submission (source: The Prescription Pricing Division of the NHS Business Services Authority).

Table 2.5: Retail pharmacies in the UK: market share of NHS revenue, 2006

Pharmacy	Market share %
Alliance Boots (UniChem)	20.8
Lloyds (Celesio (AAH))	13.3
Rowlands (Phoenix)	4.2
Co-operative Pharmacy (Sants)	2.8
Superdrug	2.2
Sainsbury	1.5
Tesco	1.4
Asda	0.9
Morrison	0.8
Others	52.1

Source: Verdict: The Retail Pharmacy Market 2006

- 2.50 As well as pharmacies, there are approximately 1,800 dispensing doctor practices⁴⁵ who are able to provide NHS dispensing services in remote rural areas and to patients who live more than a mile away from their nearest pharmacy.
- 2.51 Patients are the consumers of medicines, but in the main they do not pay for them. The majority of community prescriptions (at least 95 per cent by value) do not attract the prescription charge as patients benefit from an exemption.
- 2.52 The NHS is the main purchaser of medicines and buys nearly all medicines sold in the UK. By a combination of profit and price controls, the PPRS constrains the list price of branded medicines. Manufacturers sell at a discount from list price to wholesalers who then sell on to pharmacies, as set out in paragraph 2.15.

Payment for dispensing NHS prescription medicines

- 2.53 As described above, the prices pharmacies pay for medicines from full-line wholesalers are determined by competition between wholesalers for their business. Traditionally, wholesalers purchase medicines at a 12.5 per cent discount from list price and pass on a significant amount of this to pharmacies.
- 2.54 The revenue pharmacies receive from the prescription charge is remitted to central government. Pharmacies receive reimbursement for the prescription medicines they dispense, as well as receiving remuneration for NHS pharmacy services they provide, including dispensing fees and a professional allowance.

⁴⁵ Source: Pfizer's customer database.

- 2.55 Reimbursement prices for prescription medicines are set under two different schemes based on the following conditions:
- When pharmacies are obliged to dispense a particular branded medicine (either because a GP prescribed that particular brand by name or has prescribed a generic or chemical name but no generic is available) they are reimbursed at the manufacturer's list price for that medicine. This list price is set by manufacturers within the constraints of the PPRS.⁴⁶
 - When pharmacies are permitted to dispense a generic medicine (because a GP has prescribed a medicine using its generic or chemical name) and where such generic alternatives to the original branded medicine are available, they are reimbursed at prices set by the Drug Tariff. This market study does not cover the distribution of generic medicines and the Drug Tariff is not discussed further here (for more information see Annex D).
- 2.56 Reimbursements to pharmacies where they dispense a branded drug (and where no generics are available) are made at the PPRS list price. Since pharmacists have usually received a discount on list price when purchasing medicines from a wholesaler, they make a profit when reimbursed at list price.

Clawback of pharmacy profit

- 2.57 The clawback mechanism was designed to allow the NHS to share the profits pharmacies can make by purchasing medicines at below the price at which they are reimbursed. Clawback means that the NHS effectively pays less than list price for branded medicines. Table 2.6 shows how the clawback operates around the UK:

Table 2.6: Clawback rates in the UK

Country	Clawback on branded drugs ¹	Clawback on generic drugs ²
England and Wales	Between 5.63 and 11.5 per cent of a pharmacy's total monthly reimbursement depending on size of claim less exempt items. According to the PSNC, nationally the deduction is about 10 per cent of value at list prices. Average clawback (including zero discount products) is 9.2 per cent.	
Scotland	9.12 per cent	13.25 per cent
Northern Ireland	0 – 8.5 per cent	13.25 per cent

(1) Dispensed to prescriptions for the brand or an on-patent chemical.

(2) Or branded medicines dispensed to prescriptions when generics are available.

Note: slightly different clawback applies to dispensing doctors.

⁴⁶ Despite its name, the PPRS is closer to a demand-side control than a more traditional form of regulation. In practice, the PPRS list price is that paid by the NHS to pharmacies for medicines dispensed under the NHS. The prices of off-patent brands set through this process also impose a ceiling on the prices at which generic drugs prescribed in the NHS will be reimbursed. Total spend on generics in the NHS is about £3.25 billion.

- 2.58 **Applicability of clawback:** Clawback is applied to a wide range of medicines, including brands, branded generics, generics and parallel imports. There are however some medicines which do not tend to be sold by manufacturers at less than list price, including medicines for rare conditions, medicines with complex or controlled administration and some highly perishable preparations including temperature sensitive or cold-chain medicines.
- 2.59 Before September 2006, many such medicines would have been included on a zero-discount list of medicines to which clawback did not apply. Since 2006, the only medicines to which clawback does not apply are those that meet the following three conditions: the manufacturer and the two main wholesalers (AAH and UniChem) do not offer pharmacies a discount from the list price; the item is dispensed fewer than 500,000 times in a year; and the average net ingredient cost per item is more than £50.
- 2.60 **How clawback is determined – the margin or discount inquiry:** For England, the DH, in consultation with the PSNC, measures the discounts obtained by a small sample of pharmacies on a monthly rolling basis. This inquiry covers branded (including parallel imports) and generic medicines and is examined by auditing all the invoices of the sample pharmacies for the relevant period. The audited margin is then aggregated to cover the whole pharmacy market in England and Wales.
- 2.61 The DH typically uses samples of around 40 independent pharmacies and is now looking to extend the length of the margin inquiries to four months, and eventually to cover most months of the year. This will help DH to detect trends in the margins earned.
- 2.62 The discount inquiries focus on the margins earned by independent pharmacies since the prices of medicines purchased by vertically integrated pharmacies represent an internal transfer price within the integrated company and are not set by the market. Similar inquiries undertaken in Scotland have attempted to take into account the margins of vertically integrated chains of pharmacies. The Department of Health, Social Services and Public Safety of Northern Ireland does not undertake its own margin inquiries but relies on information from those inquiries undertaken in Scotland.
- 2.63 The margin inquiries are necessarily retrospective so it is not possible to predict changes in discounts before they happen. Instead there is a natural time-lag before changes in discounts are detected.
- 2.64 Under the pharmacy contract, pharmacies in England received total Government funding of £1.766 billion for 2005/06, a figure which has risen to £1.911 billion for 2006/07. Contractually, £500 million of the funding comes through retained margin (that is, margin between the price at which pharmacies buy medicines and the price at which they are reimbursed),⁴⁷ and the remainder from professional fees and other payments which depend on the level of service provided. In Scotland the dispensing margin is £50 million.
- 2.65 The information from discount inquiries is used along with that gained from suppliers as part of the category M arrangements (see Annexe D for details) to ensure that pharmacies receive the dispensing margin agreed in the Pharmacy Contract. Adjustments can be made in the short run by changing the aggregate margin on category M medicines, or in the longer run by changing the level of clawback which is applied to pharmacies.

⁴⁷ As pharmacy purchase prices can not necessarily be forecast with perfect accuracy, the actual amount (measured from margin surveys) may differ from the contractual amount. In the event, the retained purchase margin for 2006/07 was £650 million, rather than £500 million.

Direct to Pharmacy (DTP) Schemes

2.66 This section describes the DTP schemes and how they differ from the traditional wholesale model. It includes:

- A description of DTP schemes
- The motivation for moving to DTP schemes
- Pfizer's DTP scheme

DTP schemes

2.67 Under DTP schemes the manufacturer has a direct supply relationship with the pharmacist rather than selling through a wholesaler. It appoints one or more LSPs to supply its medicines to pharmacies. LSPs are generally paid on a fee per pack basis. The LSP does not take ownership of the medicine but may operate as an agent for the manufacturer.

2.68 Under the traditional wholesale model, the manufacturer has limited knowledge of where its medicines are sold after they are delivered to wholesalers. With DTP the manufacturer has far greater visibility as it knows exactly how much each pharmacy is ordering. This aspect is discussed further in Chapter 5 and Annexe I.

2.69 With DTP schemes, a manufacturer chooses its LSPs, whereas under the traditional wholesale model the manufacturer would generally supply all full-line wholesalers. The focus of competition has therefore changed from wholesalers competing for the business of pharmacies to competition to become a manufacturer's LSP's/wholesalers. In the exclusive DTP model where only one LSP is appointed, all competition to supply pharmacies is removed for some branded medicines. Where more than one LSP is appointed there is still service level competition between LSPs to supply pharmacies.

2.70 Under DTP schemes, the manufacturer sets discounts to pharmacies unilaterally and there is no conventional discount for sales to pharmacies that is equivalent to the 12.5 per cent discount applied to sales to wholesalers. DTP manufacturers have visibility of how much is paid for the distribution of their medicines whereas under the traditional model the manufacturer does not know how much of the 12.5 per cent discount is passed on to pharmacies. This aspect of DTP is discussed further in Chapter 3.

The motivation for moving to DTP schemes

2.71 This section considers the reasons why manufacturers may wish to alter their distribution arrangements from the traditional wholesale model to a DTP scheme. Those manufacturers that have already announced such changes to their distribution arrangements have given a number of reasons for the changes. We discuss those reasons and present information on other possible benefits and costs of DTP schemes.

- 2.72 There are several reasons why manufacturers may wish to alter the method by which their medicines are distributed. These reasons can be categorised as follows:
- Greater visibility of the supply chain
 - Control of brand image
 - Reducing counterfeit medicines
 - Ability to control parallel trade
 - Efficiencies for manufacturers
 - Closer relationship with pharmacies
- 2.73 **Greater visibility of the supply chain:** Under DTP schemes manufacturers have greater visibility of the supply chain through having a direct relationship with the pharmacist. This allows manufacturers to see the volumes of medicines being ordered and to trace more easily which of its customers receive its medicines. Such visibility could be particularly important in securing the swift withdrawal and recall of medicines in any case of counterfeit medicines.
- 2.74 **Control of the brand image:** Under the traditional wholesale model wholesalers sell the manufacturer's medicines to pharmacies. This can be a concern to manufacturers in situations where stocks are limited due either to problems at the wholesale or manufacturing level. Manufacturers have argued that wholesalers are more likely to attribute supply shortages to manufacturers rather than to acknowledge stock mis-management on their own part, and that this can damage manufacturers' brands. If the manufacturer uses a DTP scheme, it is able to explain fully any problems in supply or distribution of its medicines. Such possibilities may help to improve the brand image of particular medicines and manufacturers. Supply problems are discussed in Annexe I.
- 2.75 **Reducing counterfeit medicines:** Counterfeit medicines are a growing concern of manufacturers across the world and the scale of the problem is discussed in Annexe C.
- 2.76 In the traditional wholesale model, manufacturers sell their medicines to wholesalers who then sell the medicines to pharmacies. With DTP schemes, manufacturers sell directly to pharmacies, thus reducing the number of transactions. This shorter supply chain allows manufacturers to control their medicines until they reach pharmacies, providing a greater degree of security from the possibility of counterfeit medicines entering the legitimate supply chain.
- 2.77 **Ability to control parallel trade:** A DTP scheme may make it easier for a manufacturer to limit the opportunities for parallel exports, by limiting the level of supply to individual customers through a quota scheme designed to prevent excessive orders. Similar schemes are possible under the traditional wholesale model, where manufacturers can constrain wholesalers' purchase volumes. However such schemes may be more effective under a DTP model, where the manufacturer has information on the levels of orders placed by individual pharmacies. With this information, the manufacturer can impose restrictions to limit the size of orders to those considered to be reasonable.
- 2.78 Further details on the issue of quotas at the pharmacy level and the effects of DTP models on parallel trade can be found in Chapter 5 and Annexe I.

- 2.79 **Efficiencies for manufacturers:** Under the traditional wholesale model, the discount paid to wholesalers is based on a percentage of the list price. This means that the cost of distribution from the manufacturer's perspective is greater for a high value medicine than for a cheap medicine, even where the true costs of distribution are similar. This means that manufacturers with a portfolio of high value medicines pay a larger amount to wholesalers for the distribution of their medicines than manufacturers who have a portfolio made up of lower value medicines, resulting in a cross-subsidisation of distribution costs between manufacturers.
- 2.80 Where a manufacturer uses a DTP scheme, it can negotiate with its LSP to determine the relevant fee for distribution of its medicines without having to cross subsidise the distribution of others. DTP schemes usually involve a fee per service or a fee per pack payment by the manufacturer to its chosen LSPs. Some manufacturers have noted that there are significant costs from supplying a large number of wholesalers, including national full-line wholesalers, regional full-line wholesalers and short-line wholesalers. A large proportion of medicines are sold through a small number of wholesalers, and the volumes being sold through the remaining wholesalers are comparatively small. Consequently, some manufacturers have sought to restrict the number of wholesalers or distribution agents they supply. This can be done by appointing a limited number of LSPs or simply seeking to reduce the number of wholesalers supplied under the traditional wholesale model.
- 2.81 **Closer relationship with pharmacies:** Pfizer, AstraZeneca and GSK have stated that one of their motivations for moving to a DTP scheme is that it facilitates a closer relationship with pharmacies that enables them to offer various types of product and service support.
- 2.82. Manufacturers consider that by establishing a direct relationship with pharmacies they will be better able to provide additional healthcare services. GSK provides such services and has, for example, provided pharmacies with kits to undertake medical respiratory reports and to help explain to customers how to use inhalers properly.

Box 2.3: The Pfizer exclusive DTP scheme

Pfizer's DTP scheme commenced on 5 March 2007, with UniChem operating as its exclusive distributor.

Key features

- UK pharmacies and dispensing doctors purchase directly from Pfizer, with Pfizer's products delivered by UniChem.
- Pfizer retains control over, and ownership of, its products at all stages up to the point of sale to pharmacies. All pricing and other negotiations are direct between the pharmacy and Pfizer.
- Pfizer has a public and non-negotiable discount structure, based on the value of the individual (i.e. single business) pharmacy's spend on Pfizer products.
- Pfizer sets UniChem's performance standards through a service level agreement, and data is collected to monitor UniChem's performance.
- UniChem acts as a provider of logistical services to Pfizer, and does not take ownership of the products.
- UniChem will remain the only logistics provider for the first 18 months following the launch of the DTP scheme. After this, national organisations with their own pharmacy chains may be engaged to provide these services to their own outlets (e.g. AAH/Lloyds, Phoenix/Rowlands). After the first 24 months, Pfizer may appoint further LSPs alongside UniChem.
- Pfizer will have the opportunity to retender for the services, at the end of the 3-year period.

Motivations

Pfizer believes that the DTP policy will enable it to manage the supply chain with greater efficiency and more secure product safety in the following ways:

- Pfizer will be more responsive to stock-shortage or product recall situations and thus be able to increase the availability and safety of Pfizer products.
- With regard to safety, the DTP scheme will also allow Pfizer to reduce the risk of counterfeit medicines entering the supply chain and promote the physical integrity of packaging.
- Pfizer will be better able to predict end-user demand accurately and to match the production and distribution processes with end user demand. In Pfizer's view, wholesalers are not the best equipped to forecast end user demand, as their views will be affected by their own stock levels.

- 2.83 Annexe C describes the exclusive DTP scheme implemented by Pfizer in greater detail. It covers the service level agreement between Pfizer and UniChem and how this has affected pharmacies. It considers how competition takes place under DTP schemes.

The limited wholesaler model

- 2.84 Recently two manufacturers, Sanofi Aventis and Napp, have chosen to reduce the number of wholesalers they use to supply their medicines. Both companies have chosen to supply UniChem, AAH and Phoenix. These manufacturers are still using the traditional wholesale model for paying for their medicines and the wholesalers take ownership of the medicines.
- 2.85 Pharmacies that had no previous supply arrangements with either of these three wholesalers will have to open an additional account to purchase the branded medicines of these manufacturers. Pharmacies however still have some choice of supplier.

Conclusion

- 2.86 The traditional wholesale model for the distribution of branded medicines involves manufacturers supplying to wholesalers, typically at the industry's conventional discount of 12.5 per cent to list price. In effect, therefore, the PPRS also indirectly controls discounts to wholesalers. Wholesalers then compete to supply pharmacies and offer discounts from the list prices to attract business. The average discount to the list prices is around 10.5 per cent. Pharmacies are reimbursed at the list prices and the NHS claws back some of the profits they make. List prices are constrained by the PPRS
- 2.87 Many manufacturers have recently implemented, or have expressed interest in implementing, changes to their arrangements for distributing medicines. These involve the introduction of DTP schemes and/or using fewer wholesalers. Under DTP schemes, manufacturers set the prices paid by pharmacies and pay wholesalers a fee for delivering their medicines according to their required service standards. There is no convention covering the level of discounts to pharmacies in these circumstances.
- 2.88 In the following chapters we will examine what implications the changes to the distribution system are likely to have on the costs to the NHS, on the level of service provided to patients, and on competition.

3 COSTS TO THE NHS

Introduction

- 3.1 In this Chapter we consider the implications of DTP for costs to the NHS. In doing so, we have considered a series of hypotheses:
- First, we assess what impact moving to DTP has on manufacturers' ability to decrease the discounts from list prices offered to pharmacies.
 - Second, we analyse how some manufacturers' moves to DTP may affect the distribution costs of other manufacturers, and how such changes would impact upon the costs incurred by the NHS.
 - Third, arguments that DTP increases pharmacy administration costs are assessed.
- 3.2 We find that:
- DTP gives manufacturers the ability to decrease discounts to pharmacies, and that this could lead to significant cost increases to the NHS.
 - DTP will reduce or remove the distribution cost cross-subsidy associated with the traditional wholesale model. Higher costs for manufacturers of low value and volume medicines may be passed on to the NHS.
 - Different DTP systems that require pharmacies to appoint different wholesalers are likely to result in some increase in pharmacy administration costs.

Discounts to pharmacies

- 3.3 This section considers the implications of DTP for the discounts from list price received by pharmacies on branded medicines and the resulting impact on the cost of these medicines to the NHS. In doing so we assess the following:
- who bears the cost of decreased pharmacy discounts
 - how discounts are determined under DTP and the traditional wholesale models and
 - the ability of DH to monitor and control the level of discounts received by pharmacies.
- 3.4. Reductions in pharmacy discounts have the potential to significantly increase NHS expenditure on branded medicines. As outlined in Box 2.2 in Chapter 2, we estimate that over £5 billion of annual primary care expenditure relates to medicines where pharmacies have no choice but to dispense a branded medicine. A one percentage point reduction in the level of the pharmacy discount on this expenditure corresponds to over £50 million a year. The complete removal of the existing pharmacy discounts on branded medicines (around 10 per cent on average) would be equivalent to an NHS cost increase of over £500 million a year. If we assumed that manufacturers accounting for half of these sales adopted DTP, and that on average they lowered discounts by 5 per cent, this would result in NHS cost increases of over £100 million.
- 3.5 The factual background to this section can be found in Annexes C, D and E. Annexe C describes the traditional and DTP distribution models, Annexe D describes the sector's financial flows, and Annexe E describes regulations relevant to the distribution of medicines.

Decreases in the pharmacy discount would be passed on to DH

- 3.6 Reductions in pharmacy discount levels would result in either an increase in the medicine costs incurred by DH, or in deterioration in pharmacy profitability and viability. In the short term, only the former effect is likely, as DH is committed to providing agreed funding to pharmacies.
- 3.7 Under the Pharmacy Contract (see Annexe D) DH has agreed to ensure that pharmacies in England secure annual purchase profits of £500 million. Stakeholders have stated that pharmacy funding arrangements would be adjusted to ensure that, across the board, any changes in the cost of purchasing Pfizer medicines would be reflected in a change to pharmacy reimbursement levels. To protect pharmacy purchase profits, DH would be expected to either decrease the clawback rate, or increase the reimbursement prices of generic medicines (see Chapter 2). Either way, costs to the NHS would increase as the NHS would effectively pay a higher price for branded medicines.
- 3.8 DH also has an obligation to ensure that changes to the distribution of medicines do not result in extra cost to the public purse. This is expressed in various public documents, including a letter addressed to members of the PPRS, dated 2 May 2007:
- 'Since the Department of Health and the ABPI negotiated the 2005 [PPRS], several companies have decided to change the arrangements for the distribution of their branded medicines to the NHS. The Department has an obligation to ensure that there is no extra cost to public expenditure arising from these changes'.⁴⁸*
- 3.9 **Conclusion:** Because of its obligation to protect pharmacy income levels and to ensure that the distribution changes do not result in increased medicines costs, DH is effectively required to ensure that the discount obtained by pharmacies under DTP is comparable to that received under the traditional wholesale model. The rest of this chapter considers how DH might do this in practice.

How discounts are set under the different distribution models

- 3.10 This section considers how discounts are set under the traditional wholesale model and under DTP. We assess how competitive and regulatory considerations have affected discount levels to date under the two models.
- 3.11 **The traditional wholesale model:** As outlined in Annexe D of this report, the list price of branded medicines is constrained by the PPRS. An industry convention has been adopted whereby manufacturers typically sell branded medicines to wholesalers at a discount from the list price of 12.5 per cent. The discount that pharmacies receive is then determined by competition between wholesalers for pharmacy custom. On average, pharmacies receive a discount of 10 – 10.5 per cent.
- 3.12 Views about the 12.5 per cent discount vary between stakeholders at the different levels of the supply chain. Some manufacturers regard the 12.5 per cent discount as a cost that is incurred by them in selling medicines to the NHS. Other stakeholders regard it as part of the regulatory mechanism such that under the traditional wholesale model, the list price less 12.5 per cent is effectively the regulated price available to manufacturers.

⁴⁸ Letter dated 2 May 2007 from the DH to members of the PPRS.
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_074338.

- 3.13 As a result, perceptions as to whether, and in what circumstances, manufacturers are required to adhere to the 12.5 per cent discount convention also differ. Some manufacturers believe that, since the PPRS is focused on list prices and because the 12.5 per cent discount is merely a convention, there is nothing within the PPRS itself to prevent them from lowering the discount if they wish to do so. As a corollary of this, the same manufacturers consider that adherence to PPRS list price cuts does not necessarily imply that the actual prices realised by them must also be reduced by the agreed rate. DH's view is that PPRS price cuts are intended to decrease the cost of medicines by the agreed rate and that that rate should be applied to realised prices and the list price such that NHS expenditure is reduced accordingly. Paragraph 21.1 of the PPRS states:
- 'The price of medicines covered by the PPRS will be reduced by 7% from 1 January 2005. In imposing this reduction, the aim is to effect a corresponding reduction in the NHS expenditure on branded medicines.'*
- 3.14 Manufacturers and wholesalers have told us that there has been general adherence to the 12.5 per cent discount under the traditional wholesale model. We have been informed that deviations from the standard 12.5 per cent discount have occurred only in exceptional circumstances.⁴⁹
- 3.15 It is possible that adherence to the 12.5 per cent convention may be less common in future. This is because the recent GlaxoSmithKline v Department of Health judgement⁵⁰ found that only written PPRS terms must be adhered to by member manufacturers. The 12.5 per cent convention is not part of the existing PPRS and manufacturers may therefore be less inclined to offer it in future (the GlaxoSmithKline v Department of Health judgement is discussed further in paragraph 3.34 below and in Annexe E).
- 3.16 Manufacturers have raised two main concerns with the 12.5 per cent discount convention. First, they consider the 12.5 per cent discount to be excessive for some medicines when compared with underlying distribution costs. Moreover, it is unclear to manufacturers how much of the profit from wholesale efficiencies is passed on to pharmacy and how much remains with the wholesaler. Second, manufacturers contend that the discount results in high volume⁵¹/value medicines cross subsidising the distribution costs of low volume/value medicines (see paragraphs 3.58 to 3.73).
- 3.17 **Discounts to pharmacy under DTP:** Under DTP schemes wholesalers do not purchase drugs from manufacturers. Instead, manufacturers keep ownership of the medicines until they reach pharmacies. Manufacturers stipulate their discount structure for sales to pharmacies and pay fees to their appointed LSPs/wholesalers for distribution (further background is provided at Annexe C).
- 3.18 Manufacturers of branded medicines enjoy an extremely strong negotiating position with respect to retail pharmacies. This is because when a pharmacy receives a prescription for a specific branded medicine or a generic prescription where there is no generic alternative, it is obliged⁵² to provide that medicine and cannot dispense an alternative medicine. This means that pharmacies' demand for branded medicines is unlikely to be very sensitive to changes in the discount they receive where (i) there is no generic alternative or (ii) it is typically prescribed

49 For example, one instance upon which the 12.5 per cent discount has not been applied was with respect to a 'Zero Discount' classified product. On that occasion, the manufacturer negotiated a lower discount with members of the BAPW on what was a particularly highly priced new product. See Annexe C for further information.

50 GlaxoSmithKline v Department of Health [2007] EWHC 1470 (Comm).

51 That is frequently purchased products

52 Under their terms of service – see under 'Dispensing' in Annexe E.

as a brand.⁵³ When faced with a lower discount for such medicines, pharmacies are unable to switch purchases to alternative medicines.⁵⁴ As outlined in Box 2.2 in Chapter 2, we estimate that over £5 billion of primary care medicines expenditure relates to such medicines. Under DTP, manufacturers of such branded medicines therefore have an incentive to offer lower discounts to pharmacies than they receive under the traditional wholesale model.

- 3.19 In the absence of an industry benchmark for the price of branded medicines supplied to pharmacies, many stakeholders (including some manufacturers, wholesalers, pharmacies, and purchasers (i.e. Government)) have argued that a move to DTP distribution will make it easier for manufacturers to decrease the discounts ultimately received by pharmacies.
- 3.20 The ABPI has suggested that, in the absence of an industry benchmark, manufacturers do not have access to information that enables them to set discounts to pharmacies that are cost neutral to the NHS. The ABPI has stressed that under the traditional wholesale model, the discounts offered by wholesalers to pharmacies are not transparent to manufacturers and it is unclear how much of pharmacies' discounts are recovered via clawback. To some extent, setting appropriate discounts to pharmacies therefore relies on the manufacturers' judgement.
- 3.21 DTP also makes it easier for manufacturers to adopt different pricing strategies including brand equalisation deals (see Box 3.1 below) as they can apply different discounts to different medicines. Further, manufacturers have access to detailed pharmacy level purchase data that can inform such strategies.

Box 3.1: Brand Equalisation

A feature of competition between branded and generic medicines is the existence of brand equalisation deals. Brand equalisation deals are agreements between manufacturers of branded medicines and pharmacies whereby the manufacturer offers the pharmacy a single blended price for the supply of an off-patent branded medicine, to be dispensed against both branded and generic prescriptions. The blended price would typically be higher than the price of the competing generic but lower than that of the branded product. To secure the blended price, pharmacies must purchase an assigned volume of the branded product.

We consider that DTP could increase the occurrence of brand equalisation deals for two related reasons. First, the more direct relationship with pharmacies would improve a manufacturer's ability to negotiate such a deal with individual pharmacies. Second, DTP enables manufacturers to view and analyse the sales data for each of its medicines for individual pharmacies. Both factors are lacking under the traditional wholesale model as it is the wholesalers who hold a direct relationship with pharmacies and therefore have medicine by medicine pharmacy purchasing data.

This view is supported by one manufacturer, who noted that the introduction of a direct relationship with the pharmacy would be one factor relevant to a decision to enter into brand equalisation deals.

A detailed analysis of the features and implications of brand equalisation deals is beyond the scope of this report. We also note that if the recommendations outlined in our PPRS report were to be implemented, manufacturers would then be unable to offer deals of this type. However, in the event that DTP schemes become more widespread, this is an aspect of the market which may otherwise increasingly influence both pharmacy reimbursement and competition between manufacturers of branded and generic medicines.

⁵³ As explained further in Chapter 2.

⁵⁴ Except in those instances that they are able to switch to an imported version of the same medicine.

- 3.22 **GSK's DTP discounts:** The first major manufacturer to adopt a DTP scheme in the UK was GSK. GSK made changes to its distribution system in November 1991 when it appointed all of the full-line wholesalers as agents in a DTP model.
- 3.23 In early 2005, GSK announced changes to its pharmacy discounts and removed all list price discounts on a proportion of its medicines. The relevant medicines were those that were considered to face the least competition from generic medicines or parallel imports.⁵⁵ Initially, the majority of the medicines in question were added to the Zero Discount List⁵⁶ such that clawback was not applied to them. However, the criteria for the Zero Discount List were subsequently tightened by the DH. The result is that pharmacies now dispense affected GSK medicines at a loss equivalent to the clawback rate applied to them. This is because pharmacies receive no discount on these medicines but are nevertheless ultimately reimbursed at their list price less the pharmacy clawback rate. GSK has suggested that DH made changes to the clawback rate to compensate pharmacies for this lost margin. We understand that in order to protect NHS costs, certain list price changes were negotiated with DH to account for the amended discount levels.
- 3.24 **Pfizer's DTP discounts:** Pfizer's DTP scheme incorporates a pharmacy discount structure in which discounts vary according to the volumes purchased. Pfizer's DTP pharmacy discounts range from 8.5 per cent to 11.5 per cent. The applicable discount is applied to all of its medicines.⁵⁷
- 3.25 Pfizer's discount scheme was set following discussions with DH and PSNC. Pfizer has also stated that its discount structure 'will not impact on the list price of Pfizer medicines nor cost the NHS any additional money'.⁵⁸
- 3.26 There is, nevertheless, concern among many pharmacies that the Pfizer DTP discounts they now receive are lower than the pre-DTP discounts they received from their wholesaler(s). This concern is supported by the results of our pharmacy survey (see Box 3.2). Some pharmacies claim that Pfizer has reduced discount levels to them to the extent that they are now dispensing Pfizer medicines at a loss after clawback is applied.⁵⁹

⁵⁵ The Pharmaceutical Journal, Vol. 274, No 7337, page 197.

⁵⁶ See Annexe D for further details.

⁵⁷ Aside from those on the Zero Discount List.

⁵⁸ Pfizer discount letter to pharmacies November 2006.

⁵⁹ Community Pharmacy Scotland considers this concern to have been of particular relevance to pharmacies in Scotland. Pfizer implemented its discount structure uniformly across the UK despite the fact that pharmacy funding in Scotland differs from that in England and Wales. Scotland also has a single rate of clawback for branded medicines (and another for generics) whereas in England and Wales clawback is applied on a scale in relation to the size of a pharmacy's reimbursement claim (see Annexe D for further details). The clawback rate in Scotland is higher than the average rate in England and Wales.

Box 3.2: Pharmacy survey results on discount changes⁶⁰

Our pharmacy survey revealed that 90 per cent of those respondents⁶¹ (including Pfizer-only, UniChem principal full-line and secondary full-line customers) who purchase Pfizer medicines at branch level⁶² reported a reduction in the discount received on Pfizer branded medicines compared with what they were receiving before the introduction of Pfizer's DTP scheme.

63 per cent reported a decrease in discount of more than two percentage points; 18 per cent reported a decrease of between one and two percentage points; and nine per cent reported a decrease of up to one percentage point. Only two per cent reported an increase of more than one percentage point, and the remaining eight per cent experienced no change.

The analysis of discount changes for multiple pharmacies, who purchase centrally, is complicated by the fact that for a number of such pharmacies, their previous discount represented an internal transfer price from its wholesaler business (see Annexe F for further details). Notwithstanding these issues⁶³, we note that 65 per cent of multiples purchasing centrally (weighted by number of outlets) reported a decrease in their discount for Pfizer medicines.

- 3.27 A related issue raised by pharmacies concerns Pfizer's refusal to allow pharmacy buying groups to benefit from consolidating their purchase volumes as they do when purchasing from a full-line wholesaler under the traditional wholesale model. Independent pharmacies' ability to obtain a more favourable volume discount through collective purchasing is therefore removed. This means that even if Pfizer's discount structure was equivalent to the discount terms typically realised under the traditional wholesale model, global pharmacy medicines costs would nevertheless increase as buying group members are unable to realise the same volume discounts. It is not clear what approach other DTP schemes will take towards buying groups.
- 3.28 **Conclusions:** The evidence demonstrates the discretion that DTP manufacturers have when determining their discounts to pharmacies. For example, GSK chose to remove its pharmacy discounts on some medicines which did not face competition from generics and to increase discounts elsewhere. Pfizer however has so far adopted discount bands that apply across all of its medicines. There is less discretion under the traditional wholesale model, where manufacturers have generally applied the 12.5 per discount convention to their sales to wholesalers.
- 3.29. There is uncertainty among stakeholders as to whether GSK's and Pfizer's discounting has or will result in increased costs to the NHS. Responses to our survey suggest that, notwithstanding Pfizer's assurances to DH around ensuring cost neutrality, the majority of pharmacies are now receiving lower discounts on Pfizer medicines than under their previous purchasing arrangements. This is not to say that Pfizer has broken its assurance, but that the pattern of discounts between pharmacies has changed. However, of itself this could lead to higher costs for the NHS since clawback is assessed on the basis of discounts to independent pharmacies, which are most likely to have incurred reduced discounts.

⁶⁰ For full details of the results of our survey see Annexe F.

⁶¹ Excluding 'no answer' responses and 'Don't Know' answers.

⁶² This includes pharmacies that would usually purchase branded medicines as part of a buying group (see paragraph 3.27).

⁶³ and the relevant sampling issues considered further at Annexe F.

DH's ability to monitor and control pharmacy discounts

- 3.30 We have established that manufacturers have incentives to decrease their discount to pharmacies and that they have greater discretion in setting their discounts under DTP. It is therefore necessary to consider how effective we can expect the existing PPRS scheme to be in constraining manufacturers' ability to decrease pharmacy discounts and hence to increase costs to the NHS.
- 3.31 DH's success in ensuring that changes to the distribution of medicines do not result in increased costs depends on its ability to constrain and monitor costs within the industry.
- 3.32 To date, there appears to have been a general expectation on the part of DH that manufacturers should ensure that the PPRS price cuts apply to the prices paid by pharmacies as well as the list price.
- 3.33 However, some stakeholders have questioned the ability of DH to ensure that discount changes do not undermine the intended effect of PPRS price cuts. Further, some stakeholders have suggested that, even where increased costs are identified, DH is unable to enforce the price reductions that would correct this.
- 3.34 Some manufacturers argue that the terms of the PPRS are such that price cuts must only be applied to list prices and need not be applied to the prices actually charged by manufacturers on selling their medicines to either wholesalers or pharmacies. The recent *GlaxoSmithKline v Department of Health*⁶⁴ case is relevant in this context, as it found that only those terms that are written within the PPRS (rather than terms that are thought to be understood between the parties) may be enforced by DH. The extent to which DH may be able to require and enforce cost neutrality assurances in the future is discussed below.
- 3.35 To determine the ability of DH to contain costs, this section considers three issues:
- Monitoring cost changes from distribution changes.
 - Enforcing cost neutrality currently.
 - Requiring cost neutrality in the future.
- 3.36 **Monitoring:** To discover whether a manufacturer has implemented discounts that result in NHS cost increases, DH now has two sources of information. The first of these is the discount inquiry into pharmacy profitability (see Annex D). The second relates to recent requests for manufacturers and wholesalers to provide DH with sales information.
- 3.37 **Discount inquiry:** As part of the administration of the PPRS, the PSNC and DH carry out a periodic pharmacy 'discount inquiry' into the purchase profits obtained by independent pharmacies. Similar exercises are carried out by The Scottish Government in reaction to market changes. The purpose of the discount inquiry is to enable DH to determine the clawback rate that would ensure pharmacies receive the reimbursement levels specified by the Pharmacy Contract. However, as a means of monitoring the source of any decrease in pharmacy discounts, the discount inquiry has limitations. For example, the inquiry is focused only on the pharmacy level of distribution and consequently it does not consider the causes of any changes in discounts or margins.

⁶⁴ *GlaxoSmithKline v Department of Health* [2007] EWHC 1470 (Comm).

- 3.38 If a general increase in medicines costs is observed in the discount inquiry, DH is unable to determine whether that increase relates to changes in the composition of medicines purchased or to changes in a particular manufacturer's discount structure.
- 3.39 Another problem relates to the coverage of the pharmacy survey used by DH as the basis for the discount inquiry. The survey covers only independent pharmacies. This is because an assessment of vertically integrated pharmacies would make the cost data susceptible to transfer pricing and cost allocation distortions and the potential for mis-informed conclusions as to changes in pharmacy level costs. This focus on independent pharmacies may lead to incorrect conclusions as to whether a manufacturer's DTP discounts are on average similar to those applied previously. For example, where a manufacturer offered lower discounts to independent pharmacies and higher discounts to the vertically integrated chains, the discount inquiry would observe only the former change. This may therefore lead to incorrect conclusions as to the overall changes in a manufacturer's discounts.
- 3.40 Moreover, there could be a significant time lag before a discount inquiry actually results in the implementation of any subsequent adjustment to clawback rates or Category M prices. There is a natural time lag before DH can identify reduced pharmacy discounts through the inquiry as it is considered necessary to observe data over time in order to detect trends.
- 3.41 Wholesaler and manufacturer sales data: It is evident that DH recognises the necessity of obtaining market information in order to monitor the cost implications of distribution changes and whether the PPRS price cuts are achieving their cost saving objectives (see Box 3.3).

Box 3.3: Data monitoring by DH

Chapter 21 of the PPRS⁶⁵ provides for various information gathering arrangements which DH can use to monitor the delivery of expenditure savings. These include requiring the relevant scheme members to submit total sales revenues at list price and total net sales revenues for the previous calendar year, in addition to data in relation to medicines which have been subject to 'price modulation'.

- 3.42 On 2 May 2007, DH wrote to PPRS members to inform them of a new supplementary voluntary scheme⁶⁶ which would require member manufacturers to supply further detailed data on sales of branded medicines to a range of specified distribution channels. The required information is to be audited by the manufacturer annually and submitted to DH quarterly.⁶⁷
- 3.43 Whilst DH can use this data to monitor possible cost changes, it may be of limited use in determining whether PPRS price cuts have been made. This is because there is not a perfect correlation between a change in a medicine's discount and the revenue it generates. Over time, the revenue generated by a particular medicine will be affected by demand changes associated with, for example, competition from a generic substitute, or changes in GPs' prescribing habits. The difficulties of attempting to equate list price reductions with the

⁶⁵ The Pharmaceutical Price Regulation Scheme 2005. (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4093228)

⁶⁶ Although it is a voluntary scheme it is backed up by regulations including financial penalties for non-compliance.

⁶⁷ Letter dated 2 May 2007 from the DH to members of the ABPI. http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_074338.

achievement of specific cost savings for the NHS were highlighted by the High Court in *GlaxoSmithKline v Department of Health*, where it was noted that:

*'...it is impossible to calculate the net savings achieved by the NHS in the event of a list price reduction, because of the knock on effect of this upon others involved in the market.... What other entities in the market would or would not have done and how this would have impacted upon doctors and pharmacists in their prescribing and dispensing decisions is extremely difficult to assess... A 4.5% price reduction does not therefore automatically lead to anything like an equivalent 4.5% saving on the part of the NHS.'*⁶⁸

- 3.44 The Court's observation highlights the challenge of using value data to monitor the effect of PPRS price cuts. An observed cost increase for the NHS could be attributed to factors such as demand fluctuations and is not necessarily the result of a reduction in pharmacy discount. The result is that analysis of value data may lead to incorrect conclusions about discount changes implemented by a manufacturer.
- 3.45 **Enforcing cost neutrality currently:** DH believes that a range of actions are open to it if it observes that it has incurred cost increases. In the case of a dispute with an individual manufacturer, DH would prefer to negotiate a solution. However, in the event that binding assurances were provided to DH and then apparently breached, DH is of the view that it would be open to it to enforce them in the Courts if a resolution through arbitration was not achieved.
- 3.46 The most direct method by which DH can recoup any extra costs arising from DTP schemes is through the PPRS, in particular by renegotiating PPRS price cuts. As outlined in Annexe D of this report, under normal circumstances PPRS price cuts are negotiated every five years with the ABPI, whose members are then bound to implement the agreed list price reductions.
- 3.47 A complication in applying the current PPRS scheme relates to the prospect of DTP manufacturers implementing varying discount structures. This may require DH to negotiate different price cuts with different manufacturers. Further, because PPRS price changes are negotiated relatively infrequently, additional price cuts may be necessary in instances where manufacturers have decreased their discounts to pharmacies and in so doing failed to provide the savings required by a prior PPRS price cut.⁶⁹ The negotiation of future pharmacy discounts and PPRS price list cuts can therefore be expected to be increasingly complex. In view of the potentially large number of stakeholders involved and the monitoring challenges described above, it is likely to be difficult for DH to negotiate different specific PPRS price cuts with individual manufacturers.
- 3.48 **Requiring cost neutrality in future:** Some manufacturers consider that if they were to adopt DTP, they would not be obliged to offer DH cost neutrality assurances. This view is perhaps given greater credence by the recent *GlaxoSmithKline v Department of Health* judgement, which found that participating manufacturers are obliged to adhere to the PPRS rules as written in the agreement, rather than as DH considers them to have been intended and understood.
- 3.49 Chapter 21 of the 2005 PPRS⁷⁰ states, at paragraphs 21.1 and 21.2:
*'The prices of medicines covered by the PPRS will be reduced by 7% from 1 January 2005. In imposing this reduction, the aim is to effect a corresponding reduction in the NHS expenditure on branded medicines. Price cut will apply to the NHS **list price**...'* [emphasis added].

⁶⁸ *GlaxoSmithKline v Department of Health* [2007] EWHC 1470 (Comm), paragraphs 51 – 52.

⁶⁹ For example, where it was ultimately observed that distribution changes had resulted in lower discounts to pharmacies, this may be corrected by requiring a subsequent, higher price cut than would ordinarily have been implemented.

⁷⁰ The Pharmaceutical Price Regulation Scheme 2005. (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4093228)

3.50 At paragraph 21.11 it goes on to state that:

'The Department accepts the right of member companies to change discounts allowed on sales. Paragraph 21.1 of the scheme sets out the basis of the expenditure savings on branded medicines covered by this agreement. The net effect of changes in discount allowed on the sales of these medicines should not affect the delivery of this aim.'

3.51 The written requirements state that PPRS price cuts apply to medicine list prices, and not necessarily to the prices actually charged by manufacturers. This means that, notwithstanding the view on DH's part that PPRS price cuts are intended to apply both to list prices and to the prices realised by manufacturers, manufacturers may not be obliged under the terms of the PPRS to offer cost neutrality assurances, when implementing DTP.

Conclusions

3.52 Manufacturers have incentives to decrease the discounts they offer to pharmacies. In the absence of an industry benchmark for branded medicines that helps to constrain prices to pharmacies, manufacturers using DTP appear to have a greater ability to reduce pharmacy discounts compared with current levels.

3.53 Even given the assumption that the terms of the PPRS require cost neutrality, there remain significant challenges in using the current monitoring tools to determine whether the costs of medicines to the NHS have risen because of DTP.

3.54 In particular, we are concerned that the discount inquiry may lead to erroneous conclusions as to a manufacturer's adherence to cost neutrality assurances. For example, whilst it is possible that Pfizer's discounts are on average consistent with those realised by pharmacies for its medicines under the traditional wholesale model, the discount inquiry would be expected to imply a discount decrease to pharmacies. Given its focus on independent pharmacies, the discount inquiry would observe the apparent decrease in discounts received by independent pharmacies (see paragraph 3.37 to 3.40 above) but would not detect any corresponding increases in the discounts offered to pharmacy chains.

3.55 Additionally, it is not certain that manufacturers are bound by the PPRS, as currently formulated, to ensure that changes in distribution are cost neutral to the NHS. Further, it is to be expected that the implementation of the current PPRS scheme would become increasingly complex if it was to be applied to manufacturers offering differing and variable percentage discounts to pharmacies.

3.56 Under the traditional wholesale model there is a lesser risk that discounts to pharmacies will decrease. The 12.5 per cent discount is generally adhered to and competition between wholesalers ensures that pharmacy discounts are realised. However, in light of *GlaxoSmithKline v Department of Health* it is possible that manufacturers may seek to challenge any requirement to adhere to the 12.5 per cent discount convention which is not a written requirement of the PPRS. On that basis, there is now some risk that even under the traditional wholesale model discounts to pharmacies may decrease.

3.57 Overall, the current PPRS arrangements (including the cost information used to monitor it) do not appear to offer sufficient protection against manufacturers decreasing pharmacy discounts and thereby increasing costs to the NHS as a result of DTP.

The impact of DTP schemes on the distribution costs of manufacturers of low volume/value medicines

- 3.58 This section considers the argument raised by some wholesalers and manufacturers that manufacturers of low value/volume medicines will face an increase in their branded medicines distribution charges as manufacturers of high value/volume medicines switch to DTP.
- 3.59 One of the motivations given by Pfizer and GSK for introducing DTP is that under the traditional wholesale model, manufacturers of high value/volume medicines are paying too much for distribution and that they are cross-subsidising the distribution of lower value/volume branded medicines and generics. This concern arises because under the traditional wholesale model the distribution discount of 12.5 per cent is applied as a standard amount across the vast majority of medicines. Wholesalers then offer a discount rate that applies to the vast majority⁷¹ of branded medicines sold. Manufacturers of high value/volume medicines argue that as a percentage of their list prices or prices to pharmacies, they are paying too much for the distribution of their medicines (see box 3.4 below).

Box 3.4: Distribution charges under the traditional wholesale model

A manufacturer with a medicine worth £100 would apply a distribution discount of £12.50 per item. For a medicine with a list price of £10 and that required the same distribution resource (i.e. of identical size and weight) a manufacturer would apply a distribution discount of only £1.25. Further, these margins would not be sensitive to the distribution scale economies that could be realised where a manufacturer supplies significant volumes of a medicine or medicines.

- 3.60 Some manufacturers argue that a DTP scheme, based for example on a fee per packet delivered, represents a more economically efficient system which would be more accurately related to the actual cost of distribution. Under DTP, an individual manufacturer can invite tenders for the distribution of its own medicines and the subsequent competition between LSPs should ensure that the terms achieved by individual manufacturers more closely reflect the costs actually incurred in distributing that manufacturer's branded medicines. One would therefore expect that manufacturers of medicines identical in volume, weight and size would attract similar distribution charges even if their list prices differ significantly.⁷²
- 3.61 The concern that the distribution costs faced by manufacturers of low value/volume medicines will increase because of DTP has been raised by a number of stakeholders at the pharmacy and wholesale levels of the supply chain and by the Ethical Medicines Industry Group (EMIG), who represent smaller manufacturers. EMIG states:
- 'we are concerned that wholesalers' profits could be reduced by the distribution arrangements made by Pfizer, as well as the planned change of others, and will therefore look to recover these lost profits by increasing the margins they charge the small and medium sized companies, such as EMIG members'.*

⁷¹ Different rates would typically apply to ZD products, for example.

⁷² Distributors of relatively high value medicines may ordinarily expect a higher price to reflect the associated risks and higher working capital costs. However, even these considerations are not relevant to DTP distribution fees, as the manufacturer retains ownership of the medicine until it is passed to a pharmacy.

- 3.62 The OFT agrees that because manufacturers can negotiate their own distribution arrangements under DTP scheme, distribution costs incurred by those manufacturers are likely to be more cost reflective than is the case under the traditional wholesale model. This would result in wholesalers making lower absolute profits on the distribution of high value/volume medicines. This may in turn result in wholesalers seeking to maintain their profitability by increasing their distribution charges to manufacturers of lower value/volume medicines.
- 3.63 Some stakeholders have expressed concern that smaller manufacturers of low value/volume medicines would be particularly vulnerable in a more consolidated wholesale market. This issue is considered in Chapter 5 which assesses the competition implications of manufacturers appointing fewer wholesalers/LSPs.
- 3.64 **NHS cost implications:** Having determined that DTP schemes are likely to result ultimately in distribution charges attributable to low value/volume medicines increasing, it is necessary to consider what the cost implications may be for the different industry stakeholders.
- 3.65 Because of the conventional 12.5 per cent discount to wholesalers, it may not be the case that manufacturers of low value/volume medicines would themselves incur increased distribution costs as a result of others moving to DTP schemes.
- 3.66 If we assume that a number of manufacturers continue to supply medicines under the traditional wholesale model, and that under these arrangements there is continued general adherence to the 12.5 per cent discount convention, the removal of the cross-subsidy described above would result in lower discounts to pharmacies and higher costs to the NHS. This is because continued adherence to the 12.5 per cent discount convention would mean that, having lost margin on high value medicines distributed via DTP, wholesalers can be expected to decrease the discounts they then offer to pharmacies on the sale of the remainder of the medicines they distribute (see paragraph 3.61 above).
- 3.67 Therefore, even given the assumption that DTP manufacturers adhere to cost neutrality assurances for their medicines, under this scenario discounts to pharmacies would on average decrease with the effect that NHS costs would increase.⁷³ Manufacturers using DTP schemes would be implementing discounts comparable with those previously observed under the traditional wholesale model. However, the discounts that wholesalers are then able to offer on remaining medicines would have decreased, raising the overall cost of medicines to the NHS.
- 3.68 However, if, instead of passing costs down the supply chain, wholesalers could protect their profitability by securing an increased discount from manufacturers that was over and above the usual 12.5 per cent, NHS costs may not increase. In this regard, EMIG has outlined how it expects DTP to result in increased costs for smaller manufacturers:
- '... increased costs are already being imposed on smaller companies. Several members have experienced aggressive negotiation techniques from wholesalers.*
- '...it serves as a prime example of how wholesalers are imposing extra charges on smaller companies to recoup losses elsewhere in their revenue stream.'*

⁷³ See paragraphs 3.6 to 3.9 above which explains why the costs resulting from lower discounts to pharmacies can be expected to be passed on to NHS.

- 3.69 The potential for wholesalers to increase the list price discount they receive from manufacturers of low value/volume medicines will depend on their buyer power. In the short term, it is not obvious that a shift to DTP by manufacturers of high value/volume medicines would in itself increase wholesaler buyer power such that they can secure more favourable discounts from other manufacturers. If wholesalers generally had the buyer power necessary to secure higher discounts from manufacturers of low value/volume medicines, we would have expected such discounts to have been realised already. (This issue is considered in more detail in Chapter 5).

Conclusion on distribution costs

- 3.70 We consider that DTP schemes are likely to result in an increase in the distribution charges that are attributed to manufacturers of low value/volume medicines.
- 3.71 We are not intrinsically concerned about the manufacturers of high volume/value medicines seeking to end any cross-subsidisation relating to the distribution of low volume/value branded medicines. If they consider that they have paid too much for distribution under the traditional wholesale model, it is to be expected that they may wish to switch to a distribution model that enables them to secure more cost reflective distribution charges.
- 3.72 As a general principal, a system that provides for more cost reflective distribution is to be welcomed. At the margins, such a system is likely to provide better incentives for manufacturers to seek to develop more innovative, high value medicines. More cost reflective distribution costs would enable manufacturers of high value medicines to secure proportionately lower distribution charges and, as a consequence, a higher (and more appropriate) share of a medicines' price.
- 3.73 The concern with this re-attribution of costs is that, under the current system, it appears likely to result in increased costs to the NHS. If cost savings are achieved by high value/volume manufacturers who have adopted a DTP scheme, these will not typically be passed on to pharmacies via lower discounts if they have provided assurances to DH that their schemes will be cost neutral. However, any increased costs faced by low value/volume manufacturers can be expected to result in lower discounts to pharmacies for these medicines with the effect that overall NHS medicine costs will increase.

The effect of the distribution changes on pharmacy administration costs

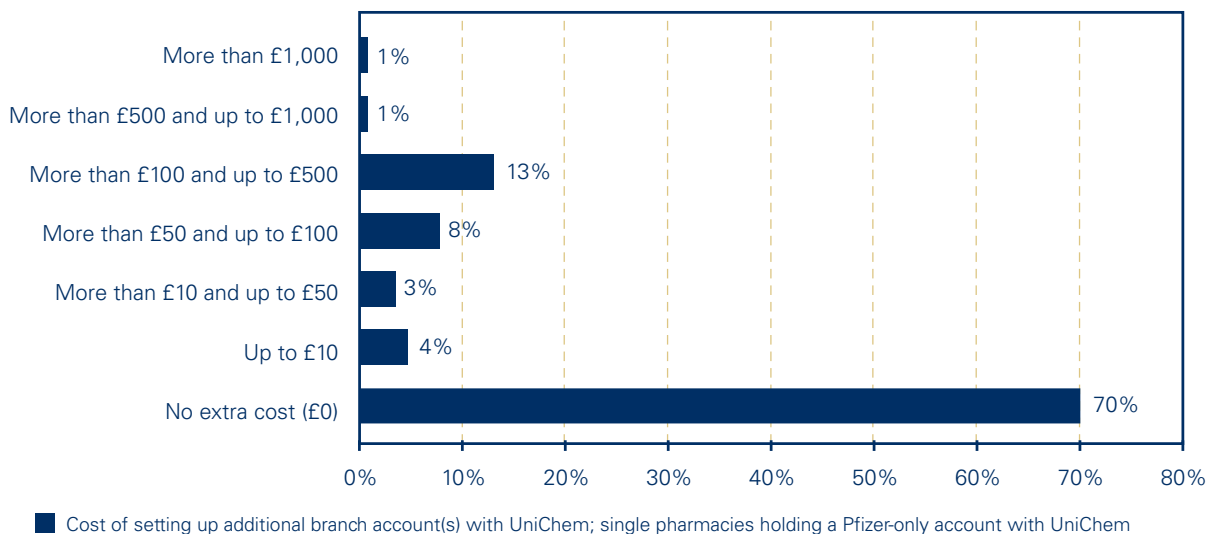
- 3.74 A large number of wholesalers and pharmacies have raised the concern that the current and proposed changes to distribution models for branded medicines will result in increased administration costs for retail pharmacies. Prior to Pfizer's DTP scheme, for example, a number of pharmacies who did not hold their principal account with UniChem expressed concern that they would incur increased administrative costs in having to deal with a separate wholesaler for Pfizer medicines.
- 3.75 This concern is relevant to a significant number of retail pharmacy businesses. Pursuant to the implementation of its agreement with Pfizer, UniChem has increased its customer base from 6,000 accounts to 15,000 accounts. Around 9,000 businesses therefore now operate additional accounts.

- 3.76 Broadly, two sources of potential increases to administration costs were identified:
- those relating to opening and operating a new account in the event that a pharmacy's existing supplier(s) has not been appointed as a particular manufacturer's LSP; and
 - those relating to a poorer standard of service from LSPs which are not subject to sufficient competition.
- 3.77 Pharmacies have noted that there are ongoing and set-up costs incurred in operating an additional account.
- 3.78 Set-up costs generally relate to the procurement and installation of any new IT software that is required to facilitate ordering through the new wholesaler.
- 3.79 Ongoing costs relate to extra staff time required to complete the ordering and administration associated with operating an extra account. The precise nature of such requirements, and their implications for staff time, are considered in detail in Chapter 4 where the potential impact on patient service is considered.
- 3.80 Poorer delivery arrangements may require pharmacies to increase their stock holdings of some medicines or to increase patient waiting times for out-of-stock medicines.

Cost of setting up a new account

- 3.81 The main set-up cost noted by pharmacies related to the purchase and implementation of the IT software necessary to facilitate ordering via an additional wholesaler / LSP.
- 3.82 Our pharmacy survey⁷⁴ sought to quantify the set-up costs associated with opening an additional, separate Pfizer account. The results for single outlet pharmacies that have opened an additional Pfizer-only account are summarised in the figure below:

Figure 3.1 Setup costs of a separate Pfizer account



⁷⁴ See Annexe F for more details of our pharmacy survey.

3.83 As outlined in Chapter 4, some pharmacies that have set up Pfizer-only accounts with UniChem have nevertheless continued to place Pfizer medicine orders with their existing wholesaler, who then forwards Pfizer orders to UniChem.⁷⁵ This may help to explain why a significant numbers of pharmacies report incurring no extra costs in setting up their additional account. Instead, their pre-existing wholesaler bore the administrative burden of then passing Pfizer orders to UniChem.

Ongoing costs of operating an additional account

3.84 As noted above, Chapter 4 includes a detailed outline of the additional tasks that many pharmacies consider to be necessary to operating an additional wholesaler account. This section therefore considers only the cost of the additional time that pharmacies have indicated is associated with operating an additional account.

3.85 The OFT's pharmacy survey requested that pharmacies and dispensing doctors estimate the extra staff time associated with operating a separate Pfizer account. The results were as follows for Pfizer-only single outlet pharmacies:

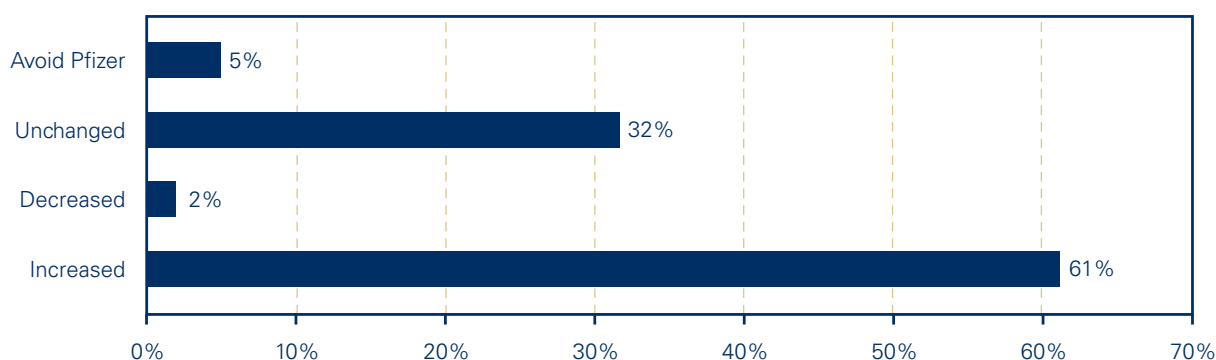
Figure 3.2 Time necessary to operate a Pfizer-only account



⁷⁵ On occasion, the pharmacies existing wholesaler supplies it with imported Pfizer medicines. Where this is not possible, the order will be passed to UniChem.

- 3.86 The hourly rates reported by pharmacies showed considerable variation (from £5.35 to £50). The high pay rates presumably reflect the fact that, in particular in smaller pharmacies, it is the pharmacist who is undertaking the additional tasks. Whilst it is difficult to quantify the costs of increased staff time meaningfully, increased staff costs may be something that would justify increased pharmacy reimbursement in future.
- 3.87 **Increased stock costs:** As outlined in Chapter 4, we consider that an outcome of DTP may be that manufacturers seek to lower the delivery service standards offered to pharmacies. We also believe that, where a single wholesaler is appointed by a manufacturer, that wholesaler may have less incentive to offer delivery and cut-off times that are convenient to pharmacies⁷⁶ and conducive to keeping low stocks whilst satisfying prescriptions quickly. If pharmacies wish to ensure that patient waiting times for out-of-stock medicines do not increase, they could achieve this by increasing their stock holdings.
- 3.88 Holding extra stock could result in different types of cost. In the short term, pharmacies would be required to finance the additional 'working capital' that is associated with holding stock. In the longer term, there may also be costs incurred where additional space is required to hold additional stock.
- 3.89 A number of pharmacies have told us that a significant increase in stockholding is physically and/or financially unfeasible in the short term. This is because these pharmacies do not have storage facilities that could accommodate such increases and/or they do not have the financial resources to increase their stock holding capacity.
- 3.90 Others have told us that they would anticipate increasing stock in response to less frequent deliveries. For this reason, our pharmacy survey sought to establish whether the Pfizer scheme had resulted in pharmacies holding more stock of its medicines. The results for all (i.e. single and multiple outlet) Pfizer-only customers are summarised below and outlined in more detail in Annexe F.

Figure 3.3 Changes in pharmacy stock holding



■ Impact on stock-holding; single and multiple pharmacies holding a Pfizer-only account with UniChem

- 3.91 We have not obtained data that enables us to determine what costs pharmacies have typically incurred in holding extra stocks of medicines. However, such costs are potentially significant given the very high value of some medicines and the infrequency with which others are dispensed.

⁷⁶ Such wholesalers/LSPs are unlikely to lose pharmacy accounts as a result.

Conclusion on administration costs

- 3.92 It appears that pharmacies incur costs in operating additional wholesaler accounts and potentially additional stock costs. The extent of those cost varies between pharmacies and depends on factors including the pre-existing capacity of staff already employed, the ability to place all orders via a pre-existing wholesaler, and the delivery service standards associated with the additional account.
- 3.93 Whilst the costs associated with additional accounts are variable and difficult to quantify reliably, there is evidence to suggest that they have not proved to be overly burdensome to the majority of pharmacies. This is demonstrated by the fact that so many retail pharmacies have decided to operate an additional Pfizer-only account rather than switch all of their purchases to UniChem (see Chapter 5 and Annexe F for further details). This suggests that such pharmacies have achieved some success in absorbing any extra costs associated with their additional account.

Chapter conclusion

- 3.94 This section discussed the potential impact of DTP on NHS costs. The information obtained suggests that DTP has the potential to lead to an increase in NHS costs through a number of factors.
- 3.95 The potential increase of most significance relates to manufacturer's ability to decrease their discounts to pharmacies. Manufacturers' appropriation of the discounts typically received by pharmacies could result in NHS cost increases running into hundreds of millions of pounds.
- 3.96 A further source of cost increase relates to prospect of the NHS ultimately bearing the increased distribution costs attributable to low value/volume manufacturers.
- 3.97 Where pharmacies are forced to open additional accounts to source a given manufacturer's medicines, this will increase their administration costs, and this may necessitate increased pharmacy reimbursement.
- 3.98 The OFT outlines its recommendations as to how these concerns should be addressed in Chapter 6.

4 SERVICES TO PATIENTS

Introduction

- 4.1 In this section we consider the effect that changes in the distribution of medicines may have on service levels to pharmacies and on pharmacy services to patients. In doing so, we have considered a series of hypotheses:
- First, we consider the impact of changes in distribution on manufacturers' and wholesalers' incentives to offer high delivery service standards to pharmacies. We discuss the likely impact of DTP schemes and of manufacturers appointing fewer or exclusive LSPs/wholesalers.
 - Second, we assess whether distribution arrangements that result in pharmacies having to use additional accounts raise the administrative burden on them, to the extent that the service level they can provide to patients is reduced.
 - Third, we analyse the potential for changes in distribution to limit the supply chain's exposure to counterfeit medicines.
- 4.2 We find that DTP has the potential to result in a reduction in the service levels provided to pharmacies, and the services that pharmacies are as a result able to provide to patients. Further the appointment of exclusive LSPs/wholesalers brings with it a greater risk that service standards may fall.
- 4.3 We also find that DTP schemes and the use of fewer wholesalers may increase pharmacies' administrative burden, where pharmacies have to use additional accounts. However it is difficult to predict what impact this may have on services to patients.
- 4.4 Finally, we find that DTP schemes and the use of fewer wholesalers can be expected to limit patient exposure to counterfeit medicines.

Effect of distribution changes on services to pharmacies and patients

- 4.5 This section considers how the recent and proposed changes to the arrangements for distributing medicines can be expected to affect the level of service that wholesalers and manufacturers provide to pharmacies and the resulting effect on services to patients. We consider separately the possible impact of DTP schemes and of manufacturers appointing an exclusive or a limited number of wholesalers/LSPs.
- 4.6 This section does not appraise Pfizer's DTP scheme but considers in broad terms how manufacturers' and wholesalers' incentives to provide current service levels are affected by DTP, and how this in turn might impact upon pharmacies' services to patients. Where information about the performance of Pfizer's arrangement is considered informative, it is drawn upon to support our analysis.
- 4.7 We do not take a view on whether the traditional wholesale model is the most efficient model for providing patients with satisfactory service standards, or whether the service standards that result from this model are in some sense optimal. We do, however, analyse the key distinctions in how service levels are determined under the traditional wholesale model compared with DTP schemes, and identify possible areas of concern. We also consider whether DTP schemes might result in benefits for service levels to patients.

- 4.8 Services to pharmacies include a variety of elements, the main ones being:
- Frequency and timing of deliveries. Pharmacies are reliant on regular and predictable delivery times to satisfy prescriptions that cannot be dispensed from stock. Frequency of delivery influences the speed at which out-of-stock prescriptions can be fulfilled. Predictable delivery times also enable pharmacies to provide an accurate indication to patients of when their medicines will be available.
 - Cut-off times. A cut-off time is the deadline for submitting orders for a pharmacy's next delivery from a wholesaler/LSP. For a given delivery time many pharmacies prefer the cut-off time to be as late as possible, as this provides the maximum chance that a prescription can be filled by the next delivery.
 - Wholesalers provide some pharmacies with ancillary services such as loan guarantees and IT support.
 - Manufacturer support. Pfizer and GSK have stated that DTP provides for a closer relationship with pharmacies and offers more effective product/service support.
- 4.9 Other factors which influence the service to patients include how stock is managed by manufacturers and wholesalers to ensure maximum availability to patients and how exposed the supply chain is to counterfeit medicines. The impact on the availability of medicines to patients is considered briefly in Chapter 5 and in more detail in Annexe I. The exposure to counterfeit medicines is considered later in this chapter.
- 4.10 The next section considers the following:
- how service standards are determined in the traditional wholesale model and the service levels that result
 - how service standards are determined in DTP schemes and the effect this might be expected to have on service levels and
 - the likely impact on service standards of the appointment of exclusive wholesalers or LSPs.

Service levels in the traditional wholesale model

- 4.11 In the traditional wholesale model most manufacturers typically supply all of their branded medicines to all full-line wholesalers (see Annexe C for further detail). Full-line wholesalers then compete on price and service levels to attract business to supply medicines to retail pharmacies. The service levels that emerge in this model are therefore an outcome of competition between full-line wholesalers for pharmacy and dispensing doctor accounts.
- 4.12 In choosing which wholesaler to use as its main full-line wholesaler, a pharmacy will consider many factors including the discount offered from list price, delivery times and frequencies and order cut-off times. A previous OFT merger decision found that delivery and cut-off times are important factors in a pharmacy's choice of wholesaler.⁷⁷

⁷⁷ Anticipated acquisition by Phoenix Healthcare Distribution Limited of East Anglian Pharmaceuticals Limited. Merger decision published 29 June 2005.

- 4.13 Competition between full-line wholesalers has resulted in a level of service which generally includes twice daily delivery and timely order cut-off times for most pharmacies. This enables the pharmacy to hold relatively low stocks in the knowledge that medicines are available on a near 'just in time' basis. Pharmacies can therefore dispense medicines within a relatively short timeframe, whether stocked or not. This is of benefit to pharmacies as they are constrained in their ability to hold more stocks because:
- some medicines are extremely expensive and/or infrequently demanded and pharmacies would incur high working capital costs in holding such medicines
 - some infrequently demanded medicines may go out-of-date before they are demanded resulting in wastage and financial loss and
 - there are space constraints which limit their ability to stock all medicines, or certain medicines, in high volumes.
- 4.14 A twice daily delivery service from a full-line wholesaler is standard for most independent pharmacies in the UK. However, twice daily delivery is by no means universal. For example, many dispensing doctors and some pharmacies typically receive once daily deliveries because of their remote location, and some vertically integrated pharmacies also operate on the basis of once daily deliveries. Integrated pharmacies may have less need for more frequent deliveries as they enjoy greater flexibility to transfer stock at short notice between branches or from their affiliated wholesaler.
- 4.15 As well as regular deliveries, pharmacies also require convenient cut-off and delivery times to enable them to offer a responsive service to patients while holding minimal levels of stock. For example, a late morning cut-off time, combined with an afternoon delivery, enables a pharmacist to obtain out-of-stock medicines on the same day for patients arriving from morning surgery.
- 4.16 Another feature of the traditional wholesale model is the provision of 'ancillary services' by wholesalers. Ancillary services include a range of value-added services which the wholesaler may provide to the pharmacy. These include guarantees for loan finance when a pharmacy is setting up or expanding its business, the supply of IT equipment and software, training (e.g. training pharmacy staff how to carry out a medicine usage review (MUR)), and merchandising and market support.⁷⁸

Box 4.1: Loan guarantees

These are guarantees for bank loans that wholesalers provide on behalf of a pharmacy business that typically requires the loan to purchase or upgrade a pharmacy outlet. Under the schemes wholesalers act as a guarantor for the loan and this enables a pharmacy to borrow money, often over a 10 year period. In return, the pharmacy agrees to purchase 70-80% of its requirements from the wholesaler in question. According to one source, some £24 million worth of loan guarantees were in place for the financial year ending 31 March 2006.

⁷⁸ Our survey of full-line wholesalers sought to measure the expenditure by wholesalers on the ancillary services provided to pharmacies. Further details can be seen in Annexe F.

Service levels under DTP

- 4.17 This section considers how DTP schemes affect the delivery service level incentives of manufacturers and LSPs.
- 4.18 Under DTP schemes, overall service levels for an individual manufacturer's medicines are determined unilaterally by the manufacturer. As already outlined at paragraph 2.16, when a pharmacy receives a prescription for a specific branded medicine or a generic prescription where there is no generic alternative, it is obliged⁷⁹ to provide that medicine and cannot dispense a substitute medicine. Pharmacies' demand for branded medicines will not therefore be very sensitive to changes in the service levels offered by a manufacturer where (i) there are generally no generic alternatives to its medicines or (ii) its medicines are typically prescribed by brand name. 75 per cent of branded medicines by value fall into this category.
- 4.19 Manufacturers using a DTP scheme are obliged, like wholesalers under the traditional wholesale model, to ensure the appropriate and continued supply of medicines. They will also be subject to reputational pressure to ensure reasonable service levels to pharmacies. However, beyond these constraints they have little incentive to offer high levels of service which cost more but will have little impact on demand for their medicines. Therefore, manufacturers can to a large extent set the service level to pharmacies, who are obliged to purchase their medicines.
- 4.20. The level of service supplied to pharmacies under DTP schemes has cost implications for a manufacturer, with higher service levels costing more to provide. Manufacturers therefore have an incentive to specify lower service level requirements (at a cost saving) provided that associated delays in availability do not result in a loss of sales or impact on reputation. Manufacturers' incentives on service levels are not aligned with those of pharmacies who have an incentive to provide a competitive and timely service to patients. Manufacturers, for example, may be less inclined to offer delivery services that facilitate shorter patient waiting times even though pharmacies place a high value on this aspect of service.
- 4.21 **Likely effects on delivery:** Consistent with the analysis of incentives outlined above, some manufacturers have expressed scepticism as to the need for twice daily deliveries to pharmacies, arguing that it is unnecessary for the following reasons:
- Some vertically integrated pharmacy chains already compete effectively using a once-a-day delivery service.
 - It is extremely rare that there is a medical need for obtaining prescription medicines urgently. Urgent cases are typically dealt with at the doctor's surgery or at a hospital.
 - Pharmacies could improve their ordering and stockholding arrangements such that twice daily delivery is less necessary to timely dispensing. Because there is a high proportion of repeat prescriptions, pharmacies could forecast demand better than they do.
 - Contingency delivery arrangements are in place where medicines are required urgently.
- 4.22 Despite these views, twice daily delivery has remained as a service requirement under the Pfizer, GSK and the planned AstraZeneca DTP schemes. Some of the requirements of their schemes are outlined in Box 4.2.

⁷⁹ Under their terms of service – see 'Dispensing' in Annexe E.

Box 4.2: Pfizer's service requirements:

Among other things, Pfizer's service level agreement requires UniChem to:

- make two deliveries a day where the pharmacy was (prior to the introduction of the DTP scheme) receiving two deliveries a day from its main supplier of Pfizer products
- ensure that no pharmacy that receives twice daily deliveries has a cut-off time earlier than 10 am for the afternoon delivery and earlier than 5 pm for the next morning delivery, and that no customer that receives one delivery per day has a cut-off time earlier than 10 am on the day prior to the delivery
- ensure that a minimum level of stock of Pfizer products is retained at any one time
- ensure that pharmacies are invoiced correctly for the Pfizer products received; and
- ensure that Pfizer products are delivered on time, in full and as notified to the pharmacy.

Pfizer has told us that it would not be economically feasible for it to move all pharmacies to an 11am cut-off time.

GSK Service requirements: GSK has informed us that it requires its distributors to deliver its medicines to pharmacies on a twice daily basis.

AstraZeneca service requirements: AstraZeneca and its agents are committed to maintaining its agents' existing service levels and current delivery frequencies, including twice-daily delivery to pharmacies in those parts of the UK where this is currently the norm.

- 4.23 One reason for the continued implementation of twice daily deliveries may be that wholesalers continue to offer a twice-daily delivery service for its full line customers under the traditional wholesale model. This means wholesalers are unable to offer significant cost savings to any DTP manufacturer seeking to appoint LSP's on the basis of once daily deliveries. While wholesaler competition for pharmacy business continues to be on a twice daily basis, the wholesaler's cost base would reflect this level of service and therefore it would be unlikely to offer manufacturers any savings derived from less frequent delivery. As a result, manufacturers wishing to move to a once daily delivery service may at present be unable to obtain significant cost savings from existing full-line wholesalers.
- 4.24 An exception to this could be if a manufacturer were to appoint an exclusive LSP to deliver only that manufacturer's medicines to pharmacies. An exclusive LSP might be able to offer a lower price in delivering to pharmacies once rather than twice daily, particularly to new⁸⁰ pharmacy customers who have no option but to accept delivery from the LSP.
- 4.25 New entrants to the medicines distribution sector may also be able to provide lower charges for once daily delivery. These are not constrained by the existing distribution costs to full-line customers and may therefore be more able to reduce delivery frequency. For example, where a logistics company with a once daily model wishes to distribute medicines, it would be able to offer a price to deliver to pharmacies that reflects the lower costs of such a system. The possibility of such entry is considered at Annexe C.
- 4.26 It is likely that if more manufacturers adopt DTP and seek, for example, once daily delivery, LSPs will be better able to deliver associated cost savings and adopt a distribution model that facilitates once daily delivery.

⁸⁰ That is the pharmacies to whom the LSP only supplies the relevant manufacturer's medicines.

- 4.27 The frequency of deliveries is clearly important to pharmacies but, as explained above, they are also concerned about favourable cut-off times for ordering since this affects the speed at which a prescription for an out-of-stock medicine can be dispensed. Pfizer requires UniChem to adopt cut-off times of no earlier than 10.00 and 17.00. These are generally worse cut-off times than were available from the pharmacy's primary wholesaler. Because the GP morning surgeries generally run until 12-12.30, the earlier cut-off times mean that if a patient arrives at the pharmacy with a prescription for an out-of-stock Pfizer medicine after the cut-off time, the patient would no longer be able to return in the afternoon to pick up the medicine. Instead the patient would have to wait until the next day. Similar issues arise with orders for Pfizer medicines prescribed at evening surgery (which generally run until 18.30 – 19.00).
- 4.28 Pfizer has little incentive to incur the costs associated with requiring later cut-off times, as it is unlikely to result in an increase in sales of its medicines. Pfizer has told us that it would not be economically feasible for it to move all pharmacies to an 11am cut-off time.
- 4.29 We find that manufacturers can to a large extent set the service level to pharmacies and have an incentive to cut costs. Moreover manufacturers have expressed scepticism over the need for twice daily deliveries. Despite this, manufacturers switching to DTP schemes so far have not required fundamentally different service standards from those currently provided to pharmacies. In particular, they still offer twice-daily deliveries. However, in relation to the Pfizer scheme many pharmacies have seen changes in cut-off times which they consider less convenient compared with those they have from their principal wholesaler.
- 4.30 **Likely effects on ancillary services:** Under DTP schemes, wholesalers primarily compete to be appointed as a manufacturer's LSP. Their contract will specify the level of service they should provide and the fee they will be paid. It seems unlikely that such contracts will include any allowance for ancillary services. Some stakeholders have argued that one consequence of this could be the loss of the ancillary services provided under the traditional wholesale model and that pharmacies will be unable to obtain these services elsewhere.
- 4.31 To the extent that such services are required and valued by pharmacies, we do not consider this to be likely. First, for as long as a number of manufacturers (of branded medicines or otherwise) use a traditional wholesale model and allow wholesalers the independence to set discounts to pharmacies, a wholesaler will have the discretion to offer such services in return for a commitment to purchase a given volume of medicines at given prices from that wholesaler. Second, even were DTP schemes to become the standard distribution model such that wholesalers had little ability to determine discounts, wholesalers could continue to offer ancillary services but charge for them separately. This would give pharmacies greater transparency about what they are paying for such services than they have under the traditional wholesale model, thus helping pharmacies to make an informed decision as to whether to purchase available ancillary services.
- 4.32 Our pharmacy survey found that 89 per cent of all pharmacies reported no change in the provision of ancillary services since the introduction of the Pfizer scheme.

- 4.33 **Manufacturer support:** Pfizer, AstraZeneca and GSK have stated that one of their motivations for moving to DTP is that it facilitates a closer relationship with pharmacies that enables them to offer various types of product and service support.
- 4.34 Pfizer explained that as greater emphasis is being placed upon pharmacies as healthcare providers, it sees benefits in securing a closer relationship with them. A direct relationship will help Pfizer to provide additional healthcare services.
- 4.35 AstraZeneca explained that more meaningful and insightful relationships with its end customers will enable AstraZeneca and its customers to provide patients with a more effective, relevant service and level of support.
- 4.36 GSK stated that DTP has enabled it to put more emphasis on manufacturer support for pharmacies in areas where GSK has expertise. For example, it has provided pharmacies with kits to undertake medical respiratory reports and to help explain to customers how to use inhalers properly. GSK informed us that it has invested several million pounds in such schemes. GSK noted that notwithstanding its investments, it had in fact anticipated a faster expansion of pharmacies' role in healthcare provision, and a greater need for pharmacy support, than has taken place.
- 4.37 A number of pharmacies have questioned the benefits of support from manufacturers and commented that they have received minimal support of this type. In particular they had not yet seen any difference in their contact with Pfizer since its implementation of DTP.
- 4.38 We would observe that the same support could be provided under the traditional wholesale model, as its provision does not appear to rely on holding a direct account for invoicing and purchase volume monitoring. However, given the access to pharmacy level product data that DTP affords, a DTP scheme does provide manufacturers with a means of better identifying where product support could be of most benefit.
- 4.39 The current value of such support cannot be quantified in any meaningful way. However, with the expected growth of pharmacy prescribing in the longer-term, manufacturers may see advantages in supporting pharmacies that dispense their medicines, similar to those currently gained by supporting GP's.⁸¹

Box 4.3: Pharmacy prescribing

The Royal Pharmaceutical Society of Great Britain (RPSGB) explained that, to become a prescribing pharmacist, pharmacists must have at least 2 years of experience and must attend a 3-6 month training course. RPSGB noted that there are currently relatively few prescribing pharmacists and expects that the increase in pharmacy prescribing will be slow. At present there are 268 independent prescribers and 1,347 supplementary prescribers.

RPSGB suggested that it could be 10 years before there are significant numbers of prescribing pharmacies. One of the main reasons for the small number of prescribing pharmacists is pharmacy access to patient records. An IT solution that facilitates shared patient records is required to resolve this.

⁸¹ The Code of Ethics for Pharmacists and Pharmacy Technicians may provide for some limit on the extent of manufacturer influence.

- 4.40 **Conclusion:** Manufacturers moving to DTP schemes have incentives to lower the standards (and cost) of distribution as long as the availability and sales of their medicines are not affected, and their reputation is not harmed. Some manufacturers question the need for twice daily deliveries although the manufacturers that have moved to DTP schemes so far have not required fundamentally different service standards from those currently provided to pharmacies. In particular, they still offer twice-daily deliveries. However, in relation to the Pfizer scheme many pharmacies have seen changes in cut-off times which they consider less convenient compared with those they have from their principal wholesaler.
- 4.41 We do not consider that DTP schemes are likely to threaten the provision of ancillary services where those services are of value to pharmacies. One would expect service offering and related pricing to evolve such that the provision of valuable ancillary services is maintained.
- 4.42 DTP schemes may facilitate more targeted product and service support from manufacturers. However, the use of this support is not widespread and it is difficult to analyse their potential benefits or how DTP schemes facilitate their provision.

Service levels with an exclusive LSP

- 4.43 As outlined above, pharmacies are obliged to dispense a branded medicine where: (i) there is no generic competitor and/or (ii) it has been prescribed by its branded name. Because of this, where a manufacturer appoints an exclusive LSP under DTP, a pharmacy has no choice but to open an account and receive deliveries from the manufacturer's chosen LSP. The same would be true if a manufacturer chose to supply its medicines through a single wholesaler but no manufacturer has chosen to do so to date under the traditional system. We therefore focus our discussion here on the appointment of exclusive LSPs.
- 4.44 Once it has won a contract with a manufacturer, an exclusive LSP faces no competitive pressure in obtaining pharmacy accounts for that manufacturer's medicines. In the case of Pfizer's medicines, for example, UniChem faces no competition in obtaining and retaining 'Pfizer-only' accounts. Indeed UniChem reports that only a handful of pharmacies have not signed up with it for Pfizer deliveries. In these circumstances, dissatisfied customers cannot take their business elsewhere and, in the absence of a short-term competitive constraint, we might anticipate less focus upon service standards.
- 4.45 The extent of reductions in service levels should ultimately be constrained by the minimum service level requirement specified and paid for by the relevant manufacturer. For example, Pfizer can monitor UniChem's adherence to its service requirements and ensure that UniChem takes corrective action if its performance appears to fall below the set standards. However, given that the effective monitoring of service standards may be costly and burdensome to manufacturers, it is possible that this constraint will be imperfect and some reduction in standards may occur without a significant risk of the LSP losing its contract with the manufacturer.
- 4.46 Astra Zeneca, Napp and Sanofi have all chosen to reduce the number of LSPs or wholesalers that they will supply but have each chosen to retain more than one. The remaining competition is likely to provide a degree of competitive pressure on service standards.

- 4.47 A number of wholesalers have suggested that, in competition for further DTP schemes, an LSP that is already the exclusive distributor of a manufacturer's medicines would be at a significant competitive advantage to win further manufacturer contracts. This is because first, it has a proven record of supplying to all pharmacies and second, it already has the required framework for doing so. Where an LSP wins an exclusive contract with a manufacturer, it must still compete to secure the remaining full-line demand from pharmacies. Again it has been argued that it has a competitive advantage because it is able to supply a fuller range of medicines than its' competitors given its exclusive access to one manufacturers' brands.
- 4.48 We anticipate that the potential concerns we have identified regarding service standards with DTP schemes involving exclusivity will also be shared by manufacturers, who may find it more difficult to ensure the service standards they require and pay for are maintained if they appoint an exclusive LSP. Giving pharmacies a choice of more than one supplier gives real incentives to LSPs to offer a good service to pharmacies, since they will risk losing business if their performance is unsatisfactory. By appointing more than one LSP, manufacturers can in effect transfer some of the effort of monitoring service standards on to pharmacies, who will base their decision of which LSP to use on the service standards each provides. Having more than one LSP could also ensure back-up if for some reason one supplier is unable to offer a medicine. These advantages need to be balanced against the possible increase in costs to manufacturers of appointing more than one LSP.
- 4.49 It may also not be in manufacturers' longer-term interests if exclusive distribution becomes widespread and where, ultimately, this results in a significant reduction in competition between LSPs. If this occurred, manufacturers could find themselves unable to secure competitive bids from LSPs to distribute their medicines in the future. This issue is discussed in Chapter 5.
- 4.50 **The service standards provided under Pfizer's DTP scheme:** Pfizer is the only major manufacturer that has appointed a single wholesaler/LSP to distribute its medicines. In this section we consider briefly the service standards maintained by UniChem in distributing Pfizer medicines. More detail on this is found in Annexe F.
- 4.51 As a result of its agreement with Pfizer, UniChem has increased its customer base from 6,000 accounts to 15,000 accounts. Around 9,000 pharmacies have therefore opened accounts with UniChem, the vast majority of which are on a 'Pfizer-only' basis, see paragraphs 5.22 to 5.27 for further details.

Box 4.4: UniChem cut-off and delivery times

Cut-off times: Responses to our pharmacy survey indicate that the majority (78 per cent) of UniChem's Pfizer-only customers have suffered some deterioration in their cut-off times since the introduction of the Pfizer DTP scheme. Only a very small proportion (2 per cent) reported an improvement in cut-off times while 20 per cent reported no change. Further details on this can be found in Annexe F.

When UniChem first became the exclusive distributor of Pfizer medicines, 45 - 60 per cent of Pfizer-only pharmacist customers had cut-off times of earlier than 11.00 (25 - 40 per cent with cut-off times between 10.00 and 10.30). UniChem has informed us that since the implementation of the Pfizer scheme, it has been able to make significant improvements to the cut-off times that are offered to its Pfizer-only customers. UniChem has stated that as of mid-July this year, the average difference in morning cut-off times between its full-line and Pfizer-only accounts was 21 minutes. However, our survey, carried out in August, found that a degree of dissatisfaction concerning cut-off times remained.

Delivery times: Pfizer-only pharmacies have complained that the timing of UniChem's deliveries are unpredictable. According to UniChem the variability in delivery times is largely due to the fact that on a Pfizer-only distribution route, not all pharmacies will require Pfizer medicines as regularly as they require medicines from their full-line wholesaler. Therefore the timing of a full-line route is more predictable as everyone on the route generally requires medicine, whereas the Pfizer-only routes are more variable. This unpredictability means that pharmacies cannot inform patients when Pfizer medicines will be available with the same confidence as is the case with other manufacturers' medicines.

The results of our survey show that 71 per cent of Pfizer-only pharmacies have experienced a deterioration in their delivery times since the introduction of the Pfizer scheme.

- 4.52 **Impact on patients:** Our pharmacy survey sought to establish the impact of any service level changes upon service to patients. We asked pharmacies to state what impact the Pfizer scheme had had upon services to patients in terms of the turnaround times for dispensing prescriptions.
- 4.53 Almost no Pfizer-only customers reported shorter turnaround times for dispensing prescriptions, and 73 per cent reported some degree of deterioration. This suggests that waiting times for patients for Pfizer medicines have increased. The results are outlined in detail at Annexe F.
- 4.54 However, where service levels deteriorated it did not result in increased patient waiting times in all circumstances. This is because some pharmacies have chosen to increase their stockholding of medicines to minimise the impact upon patients (see Chapter 3 which considers pharmacy costs).

- 4.55 **Conclusion:** Where a LSP is appointed on an exclusive basis, it faces no competition in the short-term to supply the manufacturer's medicines to pharmacies. Although the LSP is ultimately constrained by the manufacturer's service level requirements, this may be an imperfect mechanism particularly in the short-run. The LSP therefore has little incentive to excel in the provision of service. In the absence of competitive pressure from other LSPs there is a risk that service standards will fall and that this will result in increased patient waiting times and/or pharmacy stock holding costs.
- 4.56 The majority of pharmacies reported that the cut-off and delivery times offered by UniChem constituted a reduction in service as compared to their arrangements before the Pfizer scheme. We recognise that on its own this cannot be taken as evidence that this is due to UniChem not facing competition for their custom. We note that UniChem has made some service level improvements since implementation as its new systems have been refined.
- 4.57 The UniChem example provides some support for our analysis of the risks associated with the appointment of exclusive LSPs. When a pharmacy has to use an exclusive LSP it is unable to switch to an alternative provider even when it is unhappy with the service level provided. Exclusive LSPs cannot secure additional accounts by improving services to pharmacies and therefore benefit little from providing attractive cut-off and delivery times.

Conclusion on service levels

- 4.58 Our analysis suggests that DTP has the potential to result in a reduction in the service levels provided to pharmacies, and the services that pharmacies are as a result able to provide to patients. Some manufacturers have expressed scepticism as to the need for twice daily delivery, for example, and may require lower service levels if DTP becomes more common place. Lower service levels may result in certain efficiencies, but risk resulting in longer patient waiting times. Because the service that patients require is influenced by many factors including social and medical considerations, we have not reached a view on whether current service standards are in any sense optimal. We note, however, that with DTP schemes there is a risk of service levels to patients falling and that this may be a particular concern where the benefits of the associated lower costs are not shared with the NHS.
- 4.59 The appointment of exclusive LSPs or wholesalers brings with it a greater risk that service standards may fall. Where an exclusive LSP is appointed it is guaranteed the business of pharmacies, and it has little incentive to excel in providing high standards of service. When there is competition between LSPs and a threat of business being lost to a competitor, there is greater pressure to meet the service levels demanded by pharmacies. In the absence of competitive pressure from other LSPs there is a risk that service standards will fall and that this will result in poorer service standards to patients.

Administrative burden

- 4.60 This section discusses the extent to which distribution arrangements that involve pharmacies having to open additional accounts with LSPs or wholesalers may increase the administrative burden they face. We consider what impact this may have on pharmacies' ability to provide a good service to patients. The associated impact on administration costs is considered in Chapter 3.
- 4.61 A number of 'Pfizer-only' pharmacies have stated that their administrative requirements have increased through having to contend with:
- an additional ordering account
 - different cut-off times for different medicines
 - extra deliveries and unpacking and
 - separate invoices and other associated paperwork.
- 4.62 Some pharmacies have argued that as a consequence of the Pfizer DTP scheme, they have less time to spend advising patients and offering patient services. Some are concerned that the implementation of more front-line community health care work promoted by DH would be affected.
- 4.63 To help us assess changes in distribution that may ultimately affect patient services, our pharmacy survey sought pharmacies' views on the administrative impact of the Pfizer DTP scheme so far. These findings inform our analysis of how further changes in distribution schemes impact on patient service standards.

Management of accounts under the traditional wholesale model

- 4.64 The extent to which changes in distribution will increase pharmacy administration in part depends on how many accounts they currently operate. Pharmacies operating several accounts are more likely to have systems in place that will enable them to accommodate an additional account relatively easily. In addition, they are likely to have an existing account with a manufacturer's chosen LSP than those who rely primarily on one or two suppliers.
- 4.65 Several manufacturers, and UniChem, told us that pharmacies generally use numerous suppliers, including a number of short-line wholesalers. They argue that one additional account would constitute a relatively small additional operational change.
- 4.66 However, many pharmacies have informed us that they purchase the majority of medicines from their principal wholesaler and do not ordinarily receive deliveries from multiple wholesalers on any given day. Our survey results suggested that around two-thirds of pharmacies typically receive deliveries from only one or two wholesalers at least once per week.
- 4.67 Inevitably, different pharmacies take different approaches. Some pharmacies are prepared to incur the administrative costs associated with buying medicines from the cheapest possible source (for example imported or fast-moving medicines offered at lower prices by short-line wholesalers) whereas others prefer the simplicity of generally using one wholesaler. Requiring pharmacies using only one wholesaler to open an additional account can be considered a material change; the associated administrative burden is considered below.

Additional deliveries

- 4.68 Complaints to the OFT have included concerns about the additional burden of receiving and processing separate Pfizer deliveries from UniChem.
- 4.69 UniChem told us it does not consider that the time needed to deal with extra deliveries is high. It states that the delivery drops themselves typically take only 2-3 minutes. Our own observations from the pharmacy visits we undertook as part of this study suggested that unpacking and checking off the Pfizer deliveries can take between 5-15 minutes depending on the size of delivery. For more information see Annexe A.
- 4.70 The additional burden associated with extra deliveries does not necessarily occur twice a day. Many Pfizer-only pharmacies do not in fact require twice daily deliveries of Pfizer medicines, because they do not always have demand for Pfizer medicines at each possible delivery time.
- 4.71 Some pharmacies have informed us that in order to avoid the burden associated with receiving extra deliveries, they have requested fewer Pfizer deliveries and instead have opted to make less frequent but larger volume orders of Pfizer medicines. Such pharmacies find the additional deliveries sufficiently burdensome that they prefer to incur extra costs in holding extra stocks of Pfizer medicines and receive fewer deliveries. The impact of increased costs is considered in Chapter 3.

Ordering medicines

- 4.72 A number of pharmacies have expressed concerns that operating a separate Pfizer account requires them to devote significant resource to accommodating the separate ordering and invoicing that is required.
- 4.73 Some pharmacies have been able to minimise the additional ordering complexities by continuing to route orders for Pfizer medicines via their principal wholesaler⁸² who then passes on the order to UniChem. Where a customer chooses this option, the wholesaler is able to fulfil the order using parallel imports, if available, and forward any unfulfilled orders to UniChem. However, the additional paperwork in operating the UniChem account remains.
- 4.74 UniChem has informed us that prior to the implementation of the Pfizer scheme, it took steps to help minimise the ordering complications faced by pharmacies. It worked with all pharmacy Patient Medication Record system providers, clinical systems providers and hospital systems to ensure that Pfizer orders could be automatically routed to UniChem.

Impact on patients

- 4.75 Our pharmacy survey sought to establish what effect, if any, the increased administration referred to by pharmacies would have upon the service standards provided to patients. 57 per cent of Pfizer-only customers reported that the time available to provide advice to patients had decreased following the implementation of the Pfizer DTP scheme.

⁸² Pfizer has confirmed that it accepts orders placed from pharmacies through other wholesalers' systems. Pfizer noted that whilst this route does not always permit order confirmation to be received, involves more interfaces and might be less reliable, it is at the pharmacist's discretion to adopt this approach.

- 4.76 A number of pharmacies reported that they were able to absorb the increased administrative burden of the Pfizer scheme, ensuring that time spent with patients had not materially changed. They were concerned however that the combined effect of further expected changes in distribution could lead to a reduction in time spent with patients. The costs associated with increased staffing requirements are considered in Figure 3.2.
- 4.77 Pharmacies' ability to respond to the handling of an additional account is to some extent constrained by their size and staffing levels. For example, it was apparent from our pharmacy visits (see Box 4.5) and our discussions with pharmacies that smaller pharmacies may be particularly constrained in their ability to stock more medicines, use sophisticated IT ordering systems or to employ more staff. In such cases, it is most likely that further increases in administration arising from changes in distribution schemes will result in a decrease in the time that pharmacists can spend with patients.

Box 4.5: Pharmacy visits

In order to gain a better insight into the effects of using an additional wholesaler, we visited different types of pharmacy to observe how they manage ordering and taking deliveries of medicines, and to discuss their experience of Pfizer's DTP scheme. We visited an independent pharmacy in Bedfordshire, a Superdrug pharmacy in London, an independent pharmacy in Greater London, a Boots pharmacy in Berkshire and an Alliance pharmacy in Berkshire.

As outlined in Annexe A, the systems at each pharmacy, and the impact of the Pfizer arrangements, varied greatly. Whereas two of the five pharmacies typically received deliveries from a variety of wholesalers and were accustomed to dealing with multiple deliveries and orders, the others usually received deliveries from one or two companies. There were also differences in order systems. Whereas the Boots store benefited from a highly automated ordering system, the Bedfordshire pharmacy was placing Pfizer orders separately by phone or fax. Finally, the Bedfordshire store was generally operated only by the pharmacist, such that extra time for administration impacted directly on the time that was available to patients.

Conclusion on administrative burden

- 4.78 Our pharmacy survey found that Pfizer-only customers in particular reported an increased administrative burden since the introduction of the Pfizer DTP scheme. The survey also found indications that pharmacies considered that some patient services were being adversely affected as a result, although some respondents had found ways to mitigate the additional administration associated with operating a Pfizer account, such as ordering larger quantities but less frequently.
- 4.79 We are concerned that, if more manufacturers were to appoint an exclusive LSP and more pharmacies were required to open additional accounts, pharmacy administration could become more onerous and increasingly complex. We recognise however that the significance of any patient detriment (and/or costs to Government) that may result from this complexity is difficult to forecast with any confidence. We note that where more than one LSP is appointed, the impact of the administrative burden is greatly reduced because more pharmacies will be able to continue ordering from their principal wholesaler.

Potential impact of DTP and wholesaler rationalisation on patient exposure to counterfeit medicines

- 4.80 In this section we consider whether the risk to UK patients of counterfeit medicines entering the supply chain is likely to be reduced with DTP schemes. We also consider whether the likelihood of counterfeits medicines entering the supply chain will be affected.
- 4.81 Astra Zeneca and Pfizer have stated that one justification of their move to a DTP scheme is that it improves their ability to prevent counterfeits of their medicines entering the UK supply chain.
- 4.82 Some stakeholders have argued that such a justification is a 'smokescreen' designed to hide what they consider to be the real motivations behind manufacturers' decisions to move to DTP which they consider to be a desire to restrict the parallel trade of medicines. See Annexe I.
- 4.83 Despite a series of regulations designed to protect UK patients from counterfeit medicines (see Annexe C), it is nevertheless the case that counterfeit medicines can reach patients through the legitimate supply chain. Though relatively few counterfeit medicines have been identified as having done so, the patient safety and financial costs associated with counterfeit medicines are extremely significant.⁸³ There may therefore be considerable benefits from any actions which successfully reduce the risk of counterfeits medicines entering the supply chain.

Potential for DTP to reduce exposure to counterfeits

- 4.84 We have identified several ways in which DTP has the potential to reduce exposure to counterfeits. Because the occurrence of counterfeits entering the supply chain is relatively rare and DTP has only been implemented by Pfizer for a short period, it has not been possible to find any evidence to analyse to what extent these benefits will be realised in practice.
- 4.85 Under DTP, the supply chain is shorter than in the traditional wholesale model as the manufacturer retains ownership of the medicine until it reaches the pharmacy. Under the traditional wholesale model, however, there may be some trading in medicines between wholesalers (for example, where medicines near their expiry date, or where one wholesaler has excessive stock levels). Consequently medicines can change hands several times before reaching the pharmacy. In these circumstances, it seems reasonable to expect there to be less potential for counterfeit medicines to enter the supply chain under DTP.
- 4.86 Under DTP, manufacturers sell their medicines directly to pharmacies using nominated LSPs. This means that pharmacies can be confident that medicines sourced from the nominated LSPs are genuine. It also means that should counterfeit medicine be identified in a given retail pharmacy, manufacturers may not need to execute a full medicine recall given its knowledge that its domestically sold medicines are genuine.
- 4.87 Because DTP aids the effective distribution of medicines that are in short supply (see Annexe I), pharmacies may have less need to seek alternative sources of supply to their DTP wholesaler(s) when there are shortages. If pharmacies are under less pressure to source medicines from outside their established purchasing relationships, this may be expected to indirectly limit exposure to counterfeits.

⁸³ Limited numbers of counterfeit medicines have been identified in the UK. Over the last three years the MHRA has issued nine withdrawals of prescription medicines.

Box 4.6: Parallel Trade and Counterfeits

As explained at Annexe I, the ABPI argues that parallel imports, because of the number of times parallel trade product can be re-sold, represent a particularly long and exposed supply chain.

To the extent that DTP enables the use of quota systems that may discourage pharmacies from purchasing parallel imports, the risk of counterfeits reaching the pharmacy may be further reduced. Our analysis of quota systems indicates that they may potentially have the effect of discouraging pharmacies from purchasing parallel imports (see Annex I).

Any international implementation of DTP has the potential to constrain further parties' ability to parallel trade and therefore potentially source counterfeit product. Where distribution schemes in different countries include the imposition of supply quotas designed to constrain pharmacy bulk purchasing, it is to be expected that the outcome would be less availability of products in these countries for export and parallel trade. The implication would be that pharmacies have a limited ability to purchase products from any manufacturer other than the nominated LSP(s).

Potential for DTP to increase exposure to counterfeits

- 4.88 There do not appear to be any reasons why a DTP scheme should in itself increase the risk of counterfeits entering the supply chain. It has been put to us, however, that DTP will increase the likelihood of counterfeit medicines entering the supply chain because some independent pharmacists may be more inclined to seek the fast moving medicines outside the direct supply chain. We note that quota systems have the potential to dampen pharmacies' incentives to purchase medicines from sources where supply levels can be variable (such as imported medicines). See Chapter 5 and Annexe I which consider the use of quotas under DTP.

Conclusion on counterfeits

- 4.89 Given the ability to monitor where medicines are delivered to under DTP, and the tight supply chain associated with rationalising the number of LSPs appointed, it is likely that Pfizer's DTP scheme will have the effect of limiting UK patients' exposure to counterfeit Pfizer medicines. Pharmacies purchase directly from the manufacturer via a supply chain that can be monitored closely and they have less scope to source from elsewhere.
- 4.90 On the other hand, the success of DTP in helping to prevent counterfeit medicines from reaching UK customers rests to some extent on pharmacies' reaction to such schemes. Given pharmacy concerns, it is possible that pharmacies may be prepared to go to greater lengths to obtain medicines that are distributed via alternative sources where they are reluctant to purchase from the manufacturers' nominated suppliers. This may result in increased UK patient exposure to counterfeit medicines. It appears unlikely, however, that this effect would be significant.
- 4.91 While it is difficult to assess or quantify the impact that DTP schemes may have in reducing the risks of counterfeits entering the supply chain, they do, on balance, appear capable of limiting the UK supply chain's exposure to counterfeit medicines.

Chapter conclusion

- 4.92 DTP schemes can be expected to result in some reduction in the quality of services provided to pharmacies, which may in turn result in a reduction in the quality of the services pharmacies can provide to patients.⁸⁴
- 4.93 The appointment of exclusive LSPs can also generally be expected to contribute to the risk of poorer service standards, to the detriment of patient services.
- 4.94 Where pharmacies require additional accounts, the associated administrative burden may have some affect on pharmacies' ability to devote time to patient service. It is difficult to forecast the potential significance of this effect.
- 4.95 DTP and the use of fewer wholesalers under the traditional wholesale model can be expected to limit patient exposure to counterfeit medicines.

⁸⁴ Deterioration in services to pharmacies would otherwise result higher pharmacy costs and, ultimately, higher costs to Government.

5 COMPETITION IMPLICATIONS

Introduction

- 5.1 This chapter considers the dynamic process of competition for medicines distribution and how this process might be affected by manufacturers using schemes which restrict the number of wholesalers or LSPs, compared with the traditional wholesale model. Possible future implications of DTP are also assessed.
- 5.2 Pfizer and AstraZeneca have significantly restricted the number of LSPs they have appointed to distribute their medicines compared with the GSK DTP scheme in the UK, where all full-line wholesalers are supplied. In addition, Sanofi Aventis and Napp have both chosen to limit the number of wholesalers they supply to three.
- 5.3 Such reductions in the number of LSPs or wholesalers supplied by manufacturers could have a significant dampening impact on the long-run level of competition in the wholesale sector in the case where both of the following occur:
- a number of full-line wholesalers exit the market, or cease to be a competitive constraint, such that the remaining wholesalers and LSPs are not constrained by effective competition and are therefore able to charge higher distribution prices to manufacturers to distribute their medicines and/or offer lower discounts to pharmacies; and
 - the barriers to entry in the wholesale market are sufficiently high that even if distribution charges rose significantly,⁸⁵ such that margins enjoyed by remaining wholesalers and LSPs increased, entry would be unlikely.
- 5.4 This chapter discusses the likely impact of restricting the number of LSPs or wholesalers on the viability of those wholesalers that may be excluded from new arrangements.
- 5.5 We also consider briefly the prevalence of vertical integration in this sector. Such integration not only represents a barrier to entry in the wholesale sector (see Annexe C for details) but in the context of DTP it could, in theory at least, lead to manufacturers offering preferential terms to vertically integrated pharmacy chains.
- 5.6 We find that it is not inevitable that large numbers of wholesalers will exit the market in the short run, even if further manufacturers' limit the number of wholesalers they use. Even if some wholesalers do exit the market, we do not find that this will necessarily provide for insufficient competition. We consider that whilst there are barriers to entering this market, these are not insurmountable and we note that entry is being actively considered by some. Further, given the relative size of some of the smaller wholesalers, we find that they may only represent a relatively limited competitive constraint on the actions of the larger wholesalers.

Impact of reducing the number of wholesalers or LSPs supplied

- 5.7 This section considers whether the widespread use of arrangements which limit the number of wholesalers supplied will affect the viability of the regional full-line wholesalers, causing them ultimately to exit the market. It also considers whether this will act to the detriment of competition in the wholesale sector in the long run. Finally, the potential efficiencies that may result from the changes to distribution being instigated by manufacturers are discussed.

⁸⁵ Through higher distribution fees for manufacturers under DTP, or lower discounts to pharmacies under that traditional wholesale model.

- 5.8 Our study has found that, in addition to GSK's and Pfizer's DTP schemes, a number of manufacturers have plans to introduce DTP, and that others may contemplate it in due course. Also, some manufacturers have recently restricted the number of wholesalers they use while retaining the traditional wholesale model and not moving to DTP.⁸⁶ It is therefore likely that, if current trends continue, a significant proportion of medicines will not be available to some full-line wholesalers in the long-run.
- 5.9 The Pfizer and AstraZeneca DTP contracts have been awarded to UniChem, and UniChem and AAH, respectively. Sanofi Aventis and Napp have chosen to distribute through these two wholesalers plus Phoenix (the third largest national wholesaler). Those likely to lose business as a result of these changes are the regional full-line wholesalers who so far have not been appointed under any arrangements where the number of wholesalers has been reduced.
- 5.10 The potential impact of these changes will be discussed under the following headings:
- Revenues
 - Costs and service
 - Customer behaviour
 - Business model choice
 - Availability of small manufacturers' medicines
 - Potential entry
 - Market developments

Revenues

- 5.11 The significance of a wholesaler losing the business of manufacturers depends on the share of the market accounted for by the manufacturers in question. Annexe C shows that the manufacturer with the largest market share in the UK is Pfizer with approximately a 10 per cent share of the branded medicines supplied. The combined share of all the manufacturers that are known to be restricting the number of wholesalers they supply is just over 22 per cent. This suggests that regional wholesalers might expect to lose nearly a quarter of their branded medicines sales as a result of recent changes and around 20 per cent of their overall revenues from medicines.⁸⁷ The significance of this loss depends on the profitability and cost levels of a wholesaler, the scale of other distribution activities including OTC medicines, medical appliances and distribution of medicines to secondary care, as well as the extent to which costs can be reduced in response to the loss of revenue.
- 5.12 Some wholesalers have outlined scenarios that suggest that, given a relatively fixed cost base, an inability to supply the medicines of a number of major manufacturers' would inevitably result in their businesses becoming loss-making and unviable. We have a number of observations on this type of analysis.
- 5.13 First, the timescale for a significant number of major manufacturers restricting the number of wholesalers or LSPs they supply is less certain than this type of analysis might imply. If such distribution models are adopted, it could well be a number of years before a substantial number of manufacturers have implemented changes in the distribution of their medicines in this way.

⁸⁶ Further details of the current and planned changes to wholesale arrangements may be found in Chapters 1 and 2.

⁸⁷ This calculation was made using data on revenues supplied to the OFT as part of our survey of full-line wholesalers.

- 5.14 Second, manufacturers might introduce different DTP models to those of Pfizer or AstraZeneca, possibly through increasing the number of appointed LSPs in due course. It is by no means certain therefore that smaller or regional full-line wholesalers will necessarily be excluded from new distribution arrangements over the medium term.
- 5.15. Third, the revenue loss might to some extent be mitigated for some wholesalers by the fact that some manufacturers may choose to allow vertically integrated wholesalers to deliver to their own pharmacies outside of their DTP or limited wholesaler schemes. This is an option after 18 months of Pfizer's DTP scheme, as discussed in section E of Annexe C.
- 5.16 In summary, there is considerable uncertainty over the scale and timing of the moves to DTP and other changes by other manufacturers. Over time, however, if a critical mass of manufacturers choose to restrict supply of their medicines either through DTP or the traditional wholesale model, some wholesalers may experience a significant loss of revenue. It is unclear what effect this will have on the viability of the affected wholesalers' businesses as this will also depend on what happens to their costs over the same time period, and whether their business models can be adapted to their changed circumstances. These issues are discussed below.

Cost and service

- 5.17 The approach highlighted at paragraph 5.12 implies that costs do not vary with the volume of business undertaken. This assumes that even if no longer supplying one or several major manufacturers' medicines, the wholesaler would still have to make the same number of deliveries, and maintain the same levels of service and infrastructure.
- 5.18 However, we consider it unlikely that costs are entirely fixed in the way indicated in these calculations. At the very least, there must be some beneficial effect on cash flow and stock holdings if fewer medicines are supplied, and there may also be other options open to wholesalers to reduce costs. There are two pieces of evidence which support this view.
- 5.19 First, Phoenix's reaction to the decisions by both Pfizer and AstraZeneca to exclude Phoenix from their DTP schemes was to identify cost savings necessary to maintain profitability. Phoenix is in the process of implementing these savings.
- 5.20 Second, one regional full-line wholesaler mentioned the fact that if it were faced with reduced revenues, it would consider cutting individual delivery routes, offering some customers lower discounts, or providing a lower level of ancillary services. Again, this suggests that there is some possibility of reducing costs in response to potentially falling revenues. We note that some of these methods could have the unfortunate effect of causing certain customers affected to switch away to different wholesalers, but this could be mitigated by reducing discounts and service only on the least profitable routes in the business, thus seeking to maintain the core profitable routes and customers.
- 5.21 In summary, we consider that there are some options available to wholesalers to mitigate potentially falling revenues by achieving cost savings over time to help protect profitability in the long run.

Customer behaviour

- 5.22 There are two ways in which customer (that is pharmacy) behaviour can affect the viability of smaller or regional wholesalers. The first is through switching individual purchases of medicines between wholesalers, and the second is through switching accounts between wholesalers. Typically decisions to make such changes result from pharmacies seeking the most favourable combination of service level and discounts they can find.
- 5.23 The extent to which newly implemented distribution models that do not include a particular full-line wholesaler will undermine that wholesaler's viability depends in part on how pharmacies responds to the changes. Two extremes of outcome are possible:
- pharmacies use the appointed LSPs or wholesalers to source only those medicines that are not available elsewhere and remaining medicines are sourced primarily from their principal full-line wholesaler or
 - pharmacies use an appointed LSP or wholesaler as their principal full-line wholesaler and switch purchases of all medicines to them.
- 5.24 In the first scenario, the impact on wholesalers that are not part of the arrangements will be limited to certain medicines, and it would take a fairly large number of such revised distribution arrangements to be put in place before excluded full-line wholesalers found their full-line business model was no longer profitable.
- 5.25 Where moves to reduce the number of wholesalers supplied provide widespread incentives for pharmacy customers to switch their principal full-line wholesaler by opening a new account, the impact on excluded wholesalers will be much greater and the impact on the profitability of their full-line activities will be seen much more quickly.
- 5.26 The OFT's survey of wholesalers examined the number of customer accounts of wholesalers before and after the implementation of Pfizer's DTP scheme. This showed that, in aggregate, there was a slowly rising trend in the number of full-line wholesale accounts from June 2006 to May 2007.⁸⁸ At the time Pfizer's DTP scheme was introduced, some wholesalers experienced a drop in the number of accounts, while others experienced a rise in the number of accounts.
- 5.27 In summary, it does not seem to have been the case that Pfizer's DTP scheme has led to UniChem gaining a significant number of new full-line accounts, at least in the short run. This should allow excluded full-line wholesalers some time to consider how to adapt their business model to these changes and how to prepare for, and to the extent required mitigate against, similar changes in the future.

⁸⁸ This excludes new Pfizer-only accounts opened with UniChem under Pfizer's DTP scheme. See Annexe F for details.

Business model choice

- 5.28 Regional or national full-line wholesalers may be able to respond to the changes by exploring different business models. This may be possible as a number of products other than branded medicines are delivered regularly to pharmacies. The possibility of adapting their business model is in fact acknowledged by some wholesalers:
- '[Regional full-line wholesalers] will either have to become short-line players, concentrating on generics, over the counter products ("OTC") and perhaps non-pharmaceutical products (since the availability of parallel imports is likely to reduce as a result of DTP arrangements in other Member States), merge with one of the three national players, or close altogether.'*
- 5.29 Others in the industry believe that there may be opportunities for mergers and acquisitions with other logistics businesses, or to try to change the focus of the business towards ancillary services or other medical products. We are also aware that Deloitte Touche Tohmatsu recently held a seminar for the industry in which it outlined possible commercial options for the smaller full-line wholesalers.
- 5.30 One option available to regional wholesalers to enhance their ability to tender for national supply contracts and other agreements, is to work as a consortium to achieve wider coverage. This may allow them to exert a greater competitive constraint on the larger and national full-line wholesalers. We are aware that such collective bidding has already been used in one tender for logistics services. Further, we are aware that Mawdsley Brooks Ltd, Norchem Ltd and F. Maltby and Sons Ltd have recently formed a trading alliance:
- 'Wholesalers Mawdsleys, Norchem and Maltbys have formed a trading alliance in response to "aggressive" changes to the pharmaceutical supply chain... Mawdsley's retail director John Davies said the agreement to exchange ideas and expertise would benefit the wholesalers by increasing their influence... Wholesale chiefs predicted further alliances between distributors in the future.'*⁸⁹
- 5.31 In summary, we do not consider that the potential changes in the wholesale sector discussed above, which may necessitate different business models, are necessarily problematic. We note that there appear to be both opportunities and time for wholesalers to consider whether and how to adapt their business models.

Availability of small manufacturers' medicines

- 5.32 Smaller manufacturers have expressed concerns that the moves to DTP may make it more difficult or expensive for them to distribute their medicines. This concern arises from two issues:
- 5.33 First, DTP removes the cross-subsidy inherent in the traditional wholesale model (which is discussed in more detail in Annexe C and Chapter 3), by which margins on high value and frequently dispensed medicines subsidise the distribution of low value and less frequently dispensed medicines. As a result, manufacturers of less frequently used medicines may find that they will have to pay more for the distribution of their medicines.⁹⁰

⁸⁹ Chemist and Druggist, 6 October 2007.

⁹⁰ We recognise that the removal of this inherent cross subsidy element which appears in the traditional wholesale model results in distribution charges which more closely reflect the actual costs involved. This issue is discussed in Chapter 3.

- 5.34 Second, smaller manufacturers are in a weaker bargaining position in relation to wholesalers than large manufacturers. Under the traditional wholesale model, the relative bargaining power of manufacturers and wholesalers is less of an issue since the 12.5 per cent discount convention governs the terms on which wholesalers are supplied and full-line wholesalers' business is based on stocking nearly the complete range of medicines. Some manufacturers are concerned that, in a situation where wholesalers are looking to cut their costs or increase their revenues, their weaker bargaining position will mean they have to pay more to persuade wholesalers to stock their medicines. This assumes a degree of market power among wholesalers.
- 5.35 The smaller manufacturers may be able to counter potential issues by considering changes in their business strategy and, as a result, the business models of wholesalers. For example, one trade article stated that:
- 'Smaller manufacturers, without the ability to run a direct-to-pharmacy model themselves, will find it increasingly difficult to get new products to the market. Some could conceivably form a distribution joint venture, like Oriola-KD in Scandinavia.'*^{91, 92}
- 5.36 To some extent, the issue of access to market for low value medicines may represent less of a problem if there are fewer full-line wholesalers present in the sector. If the big three full-line wholesalers gain at the regional full-line wholesalers' expense, this should place them in a better position to deliver smaller manufacturers' medicines, through economies of scale and scope. For example, as UniChem now has accounts with all pharmacies in the UK, there appears to be an incentive for it to take on additional DTP contracts, increasing the volumes it delivers and increasing the profitability of its delivery routes by spreading the fixed costs of distribution over a larger portfolio of medicines. This larger range of medicines also makes UniChem more attractive as a principal full-line wholesaler.
- 5.37 In summary, there appear to be incentives for LSPs and wholesalers to continue to want to distribute medicines from smaller manufacturers.

Potential entry

- 5.38 The ease of entry into the wholesale sector is examined in detail in Annexe C where we identify a number of factors that could act as barriers to entry in this sector. These include the cost of establishing a new full-line business capable of providing a reliable twice-daily delivery service, which pharmacists value highly, as well as obtaining sufficient customer revenue to cover the start-up and ongoing costs. The ability to obtain customers is hampered in this sector by the prevalence of vertically integrated wholesalers and pharmacy chains. On the other hand, given the large number of businesses in the UK that hold wholesale dealer licences, obtaining one would not appear to pose a significant barrier to a business considering entry into this sector.

⁹¹ Pfizer Shakes Up Wholesaling Status Quo in UK, 11 June 2007.

⁹² Oriola-KD distributes and sells pharmaceuticals in Finland, Sweden, Denmark, Estonia and Latvia. The healthcare segment of Oriola-KD markets and sells products used in healthcare facilities and laboratories throughout Finland, Sweden, Denmark, Estonia, Latvia and Lithuania. In Sweden, Oriola-KD also distributes healthcare products to manufacturers in the sector, outsources logistics for healthcare products and provides regional home distribution services for healthcare products. On 1 July 2006, Oriola-KD was created from the Wholesale and Distribution Division of the Orion Group that Oriola Oy, Kronans Droghandel AB and their subsidiaries were part of.

- 5.39 There are also some other features of the sector that could assist potential entrants, including the current and likely future growth in the sector and the possibilities for entry on a smaller scale as a second full-line wholesaler or as a short-line wholesaler.
- 5.40 Although DTP may make entry less attractive as it affects the viability of existing full-line wholesalers, it may also make entry easier in some respects, as DTP manufacturers could sponsor entry of other businesses, including those active in other logistics or wholesaling activities.
- 5.41 Even without sponsored entry there are a number of potential new entrants in this sector, including other logistics, wholesale or delivery companies, as well as pre-wholesalers.⁹³ There is also the possibility of expansion or mergers and acquisitions among regional full-line wholesalers and short-line wholesalers.
- 5.42 However, balanced against all of the above is the fact that there has been little recent entry in the sector and more of a trend towards consolidation among wholesalers in recent years.
- 5.43 Overall, there are clearly many features of the wholesale sector that might deter new entry, not least that regional wholesalers are currently losing business. On the other hand, these barriers do not appear to be insurmountable, particularly for those with experience of wholesaling in other markets and/or if entry could be sponsored by a manufacturer. However, the credibility of entry in this way has yet to be tested in practice and there has been no new entry for many years. Our view therefore is that although new entry does appear to represent a credible threat in the wholesale sector, we cannot be confident that barriers to entry are sufficiently low that further concentration in the market would not give rise to significant market power.

Market developments

- 5.44 Competition in medicines distribution could be harmed if there is continued consolidation within the wholesale sector over time as a result of restrictions on the number of wholesalers used. In particular, the widespread use of exclusive contracts could lead to one wholesaler becoming significantly larger than its rivals putting it in a position where it is effectively an inevitable trading partner for manufacturers, with the ability to exercise market power in relation to service levels or price. Such market power could be passed through as additional costs to the NHS.
- 5.45 Overall, given current wholesaler market shares and the scale and nature of changes in distribution so far announced, we do not view the establishment of a dominant wholesaler as inevitable. We also note that barriers to entry are not insurmountable so there is a possibility of entry if prices rise.

⁹³ Pre-wholesalers are companies that organise and collate the delivery of a manufacturer's products to wholesale distribution companies. See Annex C for details.

Vertical Integration

- 5.46 We have also considered how the extensive vertical integration that exists between wholesalers and pharmacies may influence the impact of DTP on competition in this market. Our analysis of this issue is summarised in the box below, and is outlined in detail in Annexe I.

Box 5.2: Vertical Integration and DTP

We have considered the potential impact of DTP given the widespread vertical integration in the wholesale and retail sectors. The degree of vertical integration increased with the recent acquisition by Boots Group plc of Alliance UniChem plc.⁹⁴

This box summarises our analysis which is presented in detail in Annexe I.

Under DTP, the profit margins achieved by a vertically integrated business' wholesale and pharmacy operations are each the consequence of negotiations with manufacturers. They negotiate on the discount they receive on the manufacturer's medicines and on the fee to be paid for distribution. It would appear that, given the ability to negotiate distribution fees and pharmacy costs together, vertically integrated wholesaler and pharmacies may have incentives to offer lower distribution fees in return for a larger discount relating to the supplies of medicines for their own pharmacies. At the same time, one interpretation of the current PPRS arrangements suggests that manufacturers have a financial interest in encouraging such a cross-subsidy. Such a strategy may be profitable as manufacturers can maintain the overall level of discounts by offering higher discounts to vertically integrated chains and lower discounts to other pharmacies.

Integrated wholesaler and pharmacy: From the integrated business' perspective, there are various characteristics of the market that suggest such a strategy may be profitable and therefore more likely to be adopted. First, it is apparent that having negotiated a favourable discount for its pharmacy business, this may not be detected by the NHS given that, at present, the DH discount inquiry is focused upon a survey of around 40 independent pharmacies in England and does not take account of vertically integrated pharmacy chains.⁹⁵

Given that improved terms at the pharmacy level for a vertically integrated chain are not subject to increased clawback, vertically integrated wholesaler and pharmacy chains appear to have incentives to offer lower fees for distribution in return for a greater pharmacy discount. In doing so, they can offer wholesale fees that are, to some extent, subsidised by their pharmacy operations and, other things being equal, at a discount to those offered by competing wholesalers that do not have significant ownership of retail pharmacies.

Manufacturers: The situation described above will only be realised by integrated wholesaler and pharmacies if it is also profitable for manufacturers to adopt terms whereby the discount to vertically integrated pharmacies subsidises the fee for logistics service provision.

If we assume that manufacturers moving to DTP continue to offer assurances to DH that, on average, the value of their discounts to pharmacies will be unchanged, it would be profitable for manufacturers to give higher pharmacy discounts to vertically integrated businesses in return for a lower fee for logistics service provision. In doing so, manufacturers can reduce discounts to

⁹⁴ See Annexe B for details.

⁹⁵ We note that the discount inquiry in Scotland does attempt to measure margins for vertically integrated pharmacies.

other pharmacies such that they offer the same average discounts overall, while at the same time reducing the costs incurred in supplying the market.

In practice, the market shares of vertically integrated retail pharmacy chains (see Annexe C) appear to make it relatively straightforward, in theory at least, for manufacturers to discriminate between different pharmacy chains by implementing discount structures that are dependent on volume. For example, Alliance Boots and AAH / Lloyds are the owners of the largest chains of pharmacies and both are vertically integrated wholesalers and pharmacies. A manufacturer could choose to favour Alliance Boots and AAH / Lloyds by adopting a discount volume threshold that only companies of such a size could achieve through buying medicines centrally.

Conclusion: One concern that may arise from DTP is therefore that, given the joint negotiation of pharmacy discounts and wholesale logistics fees, the largest vertically integrated pharmacies and wholesalers may be able to increase their share of the market and this may act as a barrier to entry and to reduce effective competition. The joint negotiation would also be likely to increase the costs borne by the NHS insofar as the discount inquiries were unable to detect the increased profitability of the vertically integrated pharmacies, but did detect the reduced profitability of the independent pharmacies.

Potential efficiencies

- 5.47 The sections above have considered the potential impact on competition and on the structure of the sector of reducing the number of wholesalers used by manufacturers. The following analysis considers the potential efficiencies associated with moves to DTP, including potential gains related to a model involving fewer wholesalers as well as comparing the level of potential efficiencies as between DTP and the traditional wholesale model.
- 5.48 **Efficiency gains from DTP and fewer wholesalers in the market:** The fact that some full-line wholesalers may be excluded by manufacturers is a result of manufacturers exerting their ability to choose which wholesalers to supply. Under DTP and restricted forms of the traditional wholesale model, manufacturers select the wholesalers they wish to supply, and for non-exclusive arrangements, pharmacies can also select from the appointed LSPs or wholesalers.
- 5.49 As a result of the implementation of DTP or restricted forms of the traditional wholesale model, there may be manufacturer-driven efficiency gains in the market. These could be achieved where manufacturers consider that the current level of service is not cost effective. In this case, gains could be made from manufacturers specifying in DTP contracts the level of service that they expect and are willing to pay for. One argument in favour of such efficiency gains is the following:
- 'By taking control of the supply chain away from competing intermediaries (i.e. the wholesalers), the manufacturers have removed the motivation to compete by over-servicing – hence making efficiency and minimisation of supply chain costs realistic goals for the first time. The key question that remains is how the residual value thus created can be shared amongst the players.'*
- 5.50 There may also be transaction cost savings to manufacturers using fewer wholesalers/LSPs. In particular, under a DTP model where the manufacturer wishes to monitor and control the distribution of their medicines (see Box 5.3 below), it may be simpler and more cost effective to use fewer LSPs.

- 5.51 We acknowledge that new arrangements for medicines distribution may lead to efficiency gains and take the view that it is vital that any benefits of this efficiency should be shared with the NHS.

Efficiency gains from using purchase volume quotas

- 5.52 Under the traditional wholesale model, some manufacturers apply volume quotas and limit the purchases that a wholesaler may make of certain medicines. Under DTP, manufacturers have access to pharmacy level purchase data and can apply quotas to pharmacy purchase volumes. Since implementing its DTP scheme, Pfizer has implemented a system whereby it monitors and sometime constrains the volumes of its medicines that pharmacies may purchase. Pfizer has argued that this approach enables it to manage the distribution of stock more efficiently. The implications of such quota systems are summarised in Box 5.3, and considered in detail in Annexe I.

Box 5.3: Volume quotas

DTP enables manufacturers to adopt supply policies whereby individual pharmacy purchase volumes are monitored and restricted. As part of its DTP scheme Pfizer now monitors, and in some cases restricts, purchasing of Pfizer medicines by pharmacies.

Under the traditional wholesale model, manufacturers do not supply pharmacies directly and cannot generally observe or constrain ordering by individual pharmacies. Under DTP, manufacturers have visibility and control of the supply of their medicines at individual pharmacy level. Consequently they are able to monitor purchases by pharmacies and have scope to impose constraints on the quantity of medicines that a pharmacy can purchase (a quota).

Pfizer's supply policy essentially comprises monitoring the volumes of medicines supplied, questioning the volume of orders from individual pharmacies and in some cases the imposition of quotas on pharmacies which it believes have ordered excessive quantities of a medicine. Pfizer argues that the use of quotas allows the manufacturer to manage the allocation of medicines more effectively in order to ensure that its medicines reach the right patients at the right time.

A number of stakeholders expressed the concern that if quotas are set in a way that is too restrictive to allow for reasonable fluctuations in demand or pharmacy growth, patient access to medicines and competition between pharmacies may be adversely affected.

Quotas may also have the potential to discourage pharmacies from engaging in parallel imports where their levels are based on the volumes of past purchases. This is because parallel imports would decrease UK requirements which would have an impact on future quota levels. If purchases by pharmacies of parallel imports were to fall as a result of quotas this has the potential to increase NHS costs.

We have identified potential benefits of the use of quotas under DTP in terms of the ability to better manage the allocation of medicines more effectively, particularly in instances of shortages.

Overall, the extent of any adverse effects depends on how a manufacturer implements its policy. The more restrictive a manufacturer's quotas are, the more likely it is that concerns will arise. The benefits of quotas will depend on the patient access issues that would exist their absence.

Chapter conclusion

- 5.53 The argument has been put to us that large numbers of wholesalers will exit the wholesale sector in the short run following manufacturers' rationalisation of the number of wholesalers they use. Our view, having considered the evidence, is that a short-run effect of this kind is unlikely. The evidence relating to the implementation of Pfizer's DTP scheme is that customer switching has been more limited than expected by some wholesalers. Whether similar changes by other manufacturers and further restrictions will cause such exit in the future depends on the scale and nature of future manufacturer-led distribution changes, and the scope of any additional incentives that these changes create for pharmacies to switch their business.
- 5.54 It may be the case in the future that a point is reached where a large number of manufacturers have rationalised the number of wholesalers or LSPs they supply with the effect that large scale switching by pharmacies becomes rational to maintain their required delivery service levels and related patient service offering. However, we do not consider this to be an inevitable consequence of changes in distribution arrangements given that most manufacturers are currently choosing to appoint more than one LSP/wholesaler.
- 5.55 We acknowledge that the changes taking place in distribution are likely to affect wholesalers' businesses in the longer term, particularly regional full-line wholesalers. If, as seems likely, the industry is moving gradually to DTP or reduced numbers of wholesalers, we believe it likely that there is still time for wholesalers to consider and to achieve cost savings, and to implement more fundamental changes to their business models if necessary and where possible. Some of these possible changes have been outlined above.
- 5.56 Even if these changes did cause some wholesalers to exit the market, this would not necessarily be a significant competition concern. In 2006, before the introduction of Pfizer's DTP scheme, the three largest wholesalers already had a combined share of nearly 90 per cent by volume for medicines distribution,⁹⁶ and therefore the competitive constraint of some of the smaller and regional wholesalers was already muted.
- 5.57 While we note the possibility of further consolidation and moves to DTP giving rise to one wholesaler that is larger and more significant than its rivals, the evidence on the impact of Pfizer's DTP scheme does not lead us to consider this to be an inevitable consequence of changes in distribution arrangements. This issue is discussed further in Chapter 6.
- 5.58 In terms of efficiency, we do not draw any firm conclusions about the relative efficiency of the DTP model relative to the traditional wholesale model. Our concern is that any gains in efficiency are allocated appropriately in the market so that some of the benefits are shared by the taxpayer and patients.

⁹⁶ See Annexe F for detailed volume-based market shares.

6 RECOMMENDATIONS

Introduction

- 6.1 This chapter explores possible remedies to address the concerns and risks we have identified as arising from further use of DTP and the appointment of limited numbers of wholesalers/LSPs.
- 6.2 By way of context, we first discuss some of the advantages and disadvantages of the traditional wholesale model and consider the value of enhanced transparency of medicines prices, distribution costs and of service standards.

The traditional wholesale model

- 6.3 While we have primarily focused in this study on the impact of the changes that are taking place in relation to the distribution of medicines, we have also considered the effectiveness of the traditional wholesale model.
- 6.4 There are many stakeholders, in particular pharmacies and wholesalers, who believe the traditional wholesale model has served patients very well for over 50 years and that recent changes will lead to a less efficient outcome with lower quality service to patients. However, manufacturers express concern that under the traditional wholesale model the costs of distribution are not transparent. Manufacturers typically give a standard 12.5 per cent discount to wholesalers but since a significant proportion of the discount is passed on to pharmacies it is difficult for manufacturers to know the true cost of distribution.
- 6.5 The manufacturers also contend that the traditional wholesale model results in cross-subsidy at the wholesale level with margins on high value or fast moving medicines being used to fund the cost of distributing low value or infrequently prescribed medicines. The 12.5 per cent discount generally given by manufacturers is determined solely by the price of the medicine and does not take into account how much the medicine actually costs to distribute. Where a medicine has a very low value, the 12.5 per cent discount may not fully cover distribution costs, so wholesalers will cover the costs of distributing these medicines from margins on more expensive medicines.
- 6.6 We also note that there is low visibility of the actual prices paid by pharmacies for branded medicines under current arrangements. The PPRS constrains the list price of a medicine and pharmacies receive the list price when reimbursed by the NHS for their medicines purchases. However, due to the discounts negotiated with, and received from, wholesalers under the traditional wholesale model, pharmacies frequently pay prices for medicines that are below list prices. The NHS uses the clawback mechanism to take back some of the profits pharmacies make by purchasing medicines at below the price at which they are reimbursed.
- 6.7 While this system ensures that the NHS receives the benefits of the lower prices paid by pharmacies, it does mean that the actual price paid by pharmacies for any particular medicine is not known by manufacturers and DH. This also presents difficulties for those administering the PPRS if they are to ensure that price cuts are effective and have an impact on actual transaction prices as well as list prices.
- 6.8 We acknowledge that the traditional wholesale model appears to have generally worked well and that pharmacies, in particular, have experienced a high level of service from wholesalers due to the competitive process at the wholesale level to attract pharmacies' business. However, we also see that there are concerns relating to the traditional wholesale model, particularly concerning the lack of transparency of the true costs of distribution.

Box 6.1: The value of transparency

In our market study on the PPRS, we identified some high-level objectives that we felt should guide the design of a pricing scheme for branded medicines. One of the key objectives was transparency and we noted that this is important for a number of reasons. First, because companies must understand the risks to which they are exposed and the incentives that arise out of them if they are to respond efficiently to a well-designed scheme. Secondly, to gain the support of stakeholders a scheme should not only work well but be seen to work well. Companies, NHS bodies and patients should all be confident that decisions are made on a fair and equitable basis, with the reasoning clearly set out. Further, the interests of the taxpayer should also be met in ensuring there is proper accountability for the use of public resources.

- 6.9 The box above explains why transparency in the pricing of medicines is important. We consider that transparency is also important in relation to the costs of distribution so that efficient choices can be made between alternative distribution methods. Similarly, there are benefits in having some clarity about what is being paid for in terms of service standards so that any changes (whether up or down) can be properly discussed and reflected in prices. If efficiency gains are made, then the benefits of these should be shared with the NHS and not all accrue to the industry.
- 6.10 If there is greater transparency, both in relation to distribution costs and service standards, manufacturers can make much more informed economic and commercial strategic decisions about which distribution model will achieve the required standards at the lowest possible cost – this could be a traditional wholesale or DTP model.
- 6.11 Although we have identified risks associated with DTP or reductions in the number of wholesalers/LSPs used, these arise because the current PPRS framework, and related arrangements dealing with the remuneration of pharmacies, have been set up and evolved in the context of the traditional wholesale model. The recommendations discussed below are aimed at creating an enhanced system that provides the same outcome to the NHS in terms of costs and service levels, whichever distribution model is used.
- 6.12 The risks we have identified in this study as potentially resulting from DTP and/or reductions in the number of wholesalers used are:
- discounts to pharmacies are likely to decrease as a result of DTP, and this can be expected to result in an increase in the cost of medicines to the NHS,
 - under DTP manufacturers specify service levels, which may result in lower service standards to pharmacies, and
 - the exclusive appointment of a wholesaler/LSP results in weak incentives to deliver high service standards and this could result in increased concentration in the wholesale sector and less competition both for DTP contracts or traditional wholesaling services.
- 6.13 In this chapter we recommend a number of options that we consider would be appropriate to address these concerns. Where possible, we also consider potential issues relating to the implementation of each option and propose possible solutions. Where appropriate and by way of guidance, we draw on practice and experience in other countries to indicate where our recommended approach is already used. If DTP schemes cannot be used to circumvent pricing arrangements agreed under the PPRS or to change service levels unilaterally without cost reductions, we can be more confident that, when adopted, such schemes will lead to efficiency gains.

- 6.14 Our study has not considered explicitly the relative efficiency of DTP schemes and the traditional wholesale model. We are concerned to ensure that competition will remain in the wholesale sector so that each manufacturer will be able to select the method of distribution it would prefer, as well as the wholesalers and/or LSPs that it would prefer to use.
- 6.15 We have chosen not to open an investigation under the CA98 at this point. The reason for this is set out fully in Annexe H. While we have identified some concerns with DTP and reductions in the number of wholesalers, these arise primarily because current pricing arrangements pursuant to the PPRS are set up in the context of, and reflect, the traditional wholesale model. Our view is that the most appropriate way to deal with this is to enhance the PPRS pricing regime so that it can accommodate different distribution methods. We do not believe that the additional concerns which relate to the exclusive agreement⁹⁷ which we have assessed to date are sufficient to warrant action under CA98 at this point in time. However, this conclusion does not preclude the possibility that the OFT might take action under CA98 in the future, in particular if there are agreements which give rise to significant competition concerns which are not covered and/or addressed by our recommendations.
- 6.16 We have also decided not to refer the market to the Competition Commission. This is because we consider that the concerns identified are best dealt with by recommendations to Government, and an investigation by the Competition Commission is unlikely to result in a different outcome.

Applicability of the recommendations

- 6.17 The remit and focus of this study has been on branded medicines dispensed by pharmacies and dispensing doctors. Consequently, we limit the scope of the following recommendations to this area. We would of course encourage the Government to consider whether there is merit in the wider application of our recommendations to areas we have not considered directly in this study. Such areas could include generic medicines and the supply of medicines other than to pharmacies and dispensing doctors, for example hospital deliveries and home care services.

Recommendation one – safeguarding the cost of medicines to the NHS

- 6.18 In Chapter 3 we outline how DTP is likely to result in a decrease in pharmacy discounts. The 12.5 per cent discount convention adhered to by manufacturers under the traditional wholesale model appears to have served the NHS well. Competition between wholesalers has resulted in significant discounts being available to pharmacies which the NHS is able to claw back. There is no such convention for the discount that is applied under a DTP scheme, and there are clearly incentives for manufacturers to seek to offer lower discounts than are currently available to pharmacies under the traditional wholesale model.
- 6.19 Some manufacturers have questioned the appropriateness of the 12.5 per cent discount and, in light of the *GlaxoSmithKline v Department of Health*⁹⁸ Judgement, its adoption may face pressure in future (see Chapter 3). This means that cost increases to the NHS may be a risk even under the traditional wholesale model. Accordingly our recommendations would safeguard discounts under both the traditional wholesale and DTP models.

⁹⁷ Or, similarly, from those agreements that limit the number of appointed wholesalers.

⁹⁸ *Glaxosmithkline v Department of Health*, [2007] EWHC 1470 (Comm), 21 June 2007.

- 6.20 Since DTP schemes have not so far been widely adopted, the ability of the PPRS framework to identify and deal with the anticipated reduced discounts has not been tested. It is not possible to calculate with precision the amount by which discounts received by pharmacies may be reduced under DTP schemes or how much such lower discounts might cost the NHS. We do not, however, consider the risk of cost increases to be purely theoretical given the lack of transparency of discounts received by pharmacies and the views expressed to us by some manufacturers. We note that the sums involved are potentially large. In Chapter 2 we attempt to estimate what proportion of branded medicines expenditure might be affected by the anticipated cost increases to the NHS and consider the impact of different scenarios.
- 6.21 On the basis of our wholesaler survey (which suggests that discounts to pharmacies on branded medicines are on average about 10 – 10.5 per cent of list price), under the most extreme possible scenario where all manufacturers of branded medicines adopted DTP schemes and offered no discount to pharmacies, costs would increase by over £500 million a year. In practice, we do not think this extreme scenario is likely to occur as many manufacturers may choose not to move to DTP and/or, although potentially able to, they would almost certainly not lower discounts to such an extent. However, this scenario establishes the limit of possible cost increases to the NHS associated with discount changes. A single percentage point decrease in the discount received by pharmacies relating to branded medicines would equate, therefore, to an increase in NHS costs of over £50 million a year.
- 6.22 A more realistic estimate of potential costs to the NHS can perhaps be calculated by considering the implications of half of the relevant medicines by value going to DTP and discounts being halved. In this scenario we would estimate a cost increase of over £100 million a year to the NHS.
- 6.23 We present two options below which would safeguard the NHS from such cost increases. It is noteworthy that our recommendations provide this protection regardless of the distribution model adopted.

Option one: Reduce list prices by an amount equivalent to current pharmacy discounts

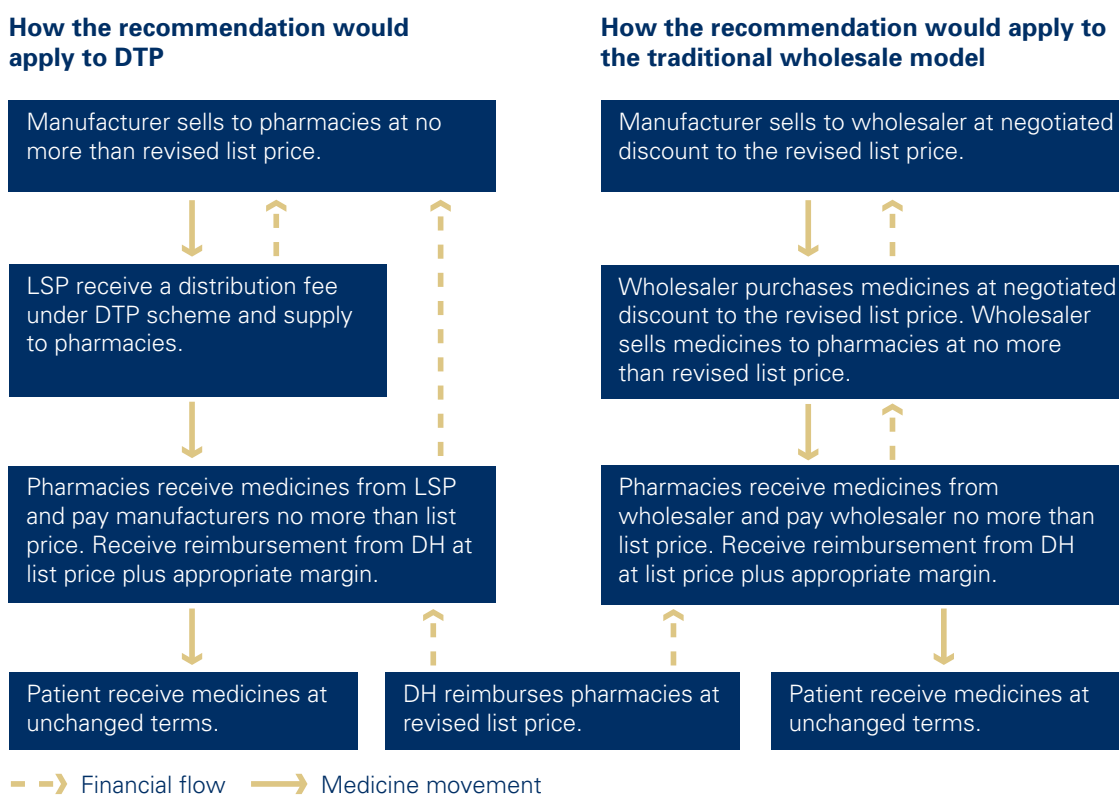
- 6.24 As outlined in Chapter 3, there is a high risk that DTP schemes will enable manufacturers to appropriate the margins currently received by pharmacies and recovered by the NHS through the clawback mechanism. Option one would see these discounts removed from the list price.⁹⁹
- 6.25 By a combination of profit and price controls, the PPRS constrains the list price of medicines. This list price sets the initial pharmacy reimbursement level, though the clawback rate determines the actual reimbursement price realised by pharmacies and paid by the NHS. The list price does not therefore generally correspond to any meaningful transaction price that is realised within the supply chain.
- 6.26 Option one would effectively alter the level in the supply chain at which the list price of medicines is set. The price agreed under the PPRS would be that at which medicines are sold to pharmacies (regardless of whether they are bought from wholesalers or manufacturers).¹⁰⁰

⁹⁹ The extent of the price cut would be formulated by reference to the discounts earned by pharmacies under the traditional wholesale model.

¹⁰⁰ To apply this scheme to wholesalers would require a change to the remit of the PPRS. Further, this option, with its implication that distribution payments to pharmacies would be separated from list prices, could equally be implemented under reforms to the PPRS proposed in the OFT's market study of the scheme (published in February 2007, see http://www.of.gov.uk/advice_and_resources/resource_base/market-studies/). According to those recommendations, list prices for branded medicines would be set on the basis of their relative therapeutic efficacy compared to alternative treatments (where available).

- 6.27 This change would make PPRS pricing arrangements sufficiently flexible so as to accommodate a choice by manufacturers of either DTP or the traditional wholesale model. Manufacturers using the traditional wholesale model would, for example, sell to wholesalers at a negotiated discount to the new lower list price, and wholesalers would then sell to pharmacies at any level up to the new list price. Manufacturers using DTP would pay their LSPs a distribution fee and sell their medicines to pharmacies at any level up to the new list price. As the list price corresponds to the transaction price to pharmacies, the costs of distribution¹⁰¹ are transparent and this enables manufacturers to make an informed choice between different distribution options. In addition, the list prices of medicines would be much closer to the price actually paid by the NHS, giving greater transparency of the true costs of medicines.
- 6.28 By allowing discounts from the new list price, this option retains the incentive for pharmacies to procure medicines as efficiently as possible, as they will benefit from some or all of the profits from so doing (see paragraphs 6.30 to 6.35 below that discuss the application of the clawback mechanism).

Figure 6.1: Summary of the scope of option one



¹⁰¹ Manufacturers can observe the charges they incur under DTP, or determine the traditional wholesale model distribution margin by calculating the difference between their price to wholesalers and the new list price.

Implementation issues for option one

- 6.29 Option one would necessitate certain practical changes to the existing framework of pharmacy reimbursement. In particular, as discussed below, in relation to:
- Maintaining pharmacy income.
 - The desirability of maintaining the clawback mechanism.
- 6.30 **Maintaining pharmacy income:** Under this option the list price reimbursed to pharmacies would no longer be expected to provide for any contribution to retained margin.¹⁰² We have considered two ways in which this issue may be resolved.
- 6.31 First, the NHS could compensate pharmacies for the lost purchasing profits through a direct payment from Primary Care Organisations to pharmacies based on the number of prescriptions dispensed. The amount of such payments could be determined by the aggregate loss in purchasing margin among all pharmacies in the UK.
- 6.32 Second, it is also possible to compensate pharmacies for lost purchasing profits through adjustments to the established payment mechanisms. This would involve DH increasing the reimbursement prices of generic medicines in Category M.
- 6.33 We have not considered the relative merits of these methods, though note that pharmacies may prefer to receive margin across the portfolio of medicines. Where profits are only available on dispensing generic medicines, this may give rise to greater fluctuations in the level of profits earned by different pharmacies.
- 6.34 The desirability of maintaining the clawback mechanism: We are aware that option one reduces substantially the discounts that pharmacies would receive on branded medicines and hence the need for the clawback mechanism to exist. This is likely to provide for more accurate reimbursement than a system that relies on ex-post investigation of margins and adjustments to the clawback.
- 6.35 There may therefore be less need for the clawback mechanism to remain if this recommendation were accepted. However, to the extent that pharmacies might still pay lower prices on some medicines through negotiating discounts or by buying parallel imports, some form of clawback might be appropriate and could be included in option one. However, given that clawback would be of less significance, it may be possible to hold fewer discount inquiries thereby lessening the associated burden upon the NHS and affected pharmacies.

Option two – negotiate with pharmaceutical suppliers to agree a minimum list price discount to pharmacies

- 6.36 There has been general adherence to the 12.5 per cent discount to wholesalers under the traditional model. However, there is no equivalent benchmark or required discount that applies to manufacturers' sales to pharmacies under DTP (see paragraph 2.70 in Chapter 2).
- 6.37 A second option to protect against increased costs to the NHS would therefore be to negotiate with manufacturers under the PPRS (and possibly wholesalers) to agree a minimum discount from the PPRS list price on sales to pharmacies. The minimum discount would

¹⁰² Pharmacies would only earn purchase profit where they were able to negotiate a discount to the new list price.

be formulated by reference to the discounts earned by pharmacies under the traditional wholesale model. This approach could be adopted under the current PPRS or if the scheme were reformed to set prices on value-based principles.

- 6.38 As with option one, this system could accommodate both the traditional wholesale model and DTP. If the minimum discount to pharmacies applied to wholesaler's prices, manufacturers using the traditional wholesale model would, for example, sell to wholesalers at a negotiated discount to the list price, and wholesalers would sell to pharmacies at a price no higher than the list price minus the prescribed minimum discount. Manufacturers using DTP would pay their LSP(s) a distribution fee and obtain up to the new list price minus the prescribed minimum discount on selling their medicines to pharmacies. If the minimum discount to pharmacies could not be agreed with wholesalers, they could continue to operate within the traditional wholesale model receiving the conventional 12.5 per cent discount, although this discount might have to be written explicitly into the PPRS.
- 6.39 Option two represents a simpler way of safeguarding the costs to the NHS, as it would not require the changes to the existing pharmacy reimbursement arrangements necessitated by option one.
- 6.40 Both option one and option two would also address the vertical integration concerns outlined in Box 5.2, the NHS cost increases described in Chapter 3 and to some extent the competition concerns outlined Chapter 5:
- Under these options, manufacturers could only increase discounts to pharmacies at their own expense. It would not be possible for them to offer higher pharmacy discounts to integrated chains in return for a lower fee for distribution (see Box 5.2) for further explanation).
 - Under the current system, the NHS would bear the costs of higher distribution charges for manufacturers of low value/volume medicines. Under our options these costs would be passed on to the manufacturer or perhaps borne by the NHS and manufacturers after negotiation.
 - Since prices to pharmacies would be capped, manufacturers would be unable to decrease pharmacy discounts in response to increased distribution costs. This may heighten manufacturers' incentive to preserve competition among wholesalers/LSPs, as the higher distribution costs associated with lessened competition would be borne by the manufacturers, rather than the NHS.

Evaluation of options one and two

Table 6.1: Advantages and disadvantages of options one and two

	Option one	Option two
Advantages	<p>Greater transparency of medicine prices – through removing some of the complexity of the current system of payments and clawback</p> <p>Greater transparency of distribution costs from the manufacturers' perspective</p>	<p>Simple and quick to implement – avoids need to change list prices, pharmacy payment levels and clawback</p> <p>Greater transparency of medicines costs but less than with Option one</p> <p>Greater transparency of distribution costs from the manufacturers' perspective</p> <p>Need not apply to wholesalers</p>
Disadvantages	<p>More complex and time-consuming to implement as it involves changing list prices and may require additional negotiation between relevant parties and DH</p> <p>Applies to wholesalers as well as manufacturers</p>	<p>Less transparency than option one.</p> <p>Requires 'prices' to be set at three levels, list prices, discounts to pharmacies and potentially, discounts to wholesalers</p> <p>Retains the need for clawback</p>

- 6.41 The table above indicates some of the issues to be considered in determining which of options one or two would be preferable. While we note the advantages and disadvantages of both options, the resulting simplification of the current PPRS and related pharmacy reimbursement mechanism and the resulting greater transparency of distribution costs make option one our preferred long-term solution.
- 6.42 We note however that moves to DTP and limited wholesaler models are already taking place, so consequently there may be a more pressing case for taking simple and swift action to safeguard the costs of medicines distribution for the NHS. This may argue in favour of the use of option two as a transitional measure which may be more straightforward to negotiate and agree with the relevant parts of the industry in the short-term. An agreement on what discounts will be offered to pharmacies could take the place of more general assurances such as that given by Pfizer as to the overall level of discount to be offered.
- 6.43 We recognise that neither of the above options is entirely straightforward but some complexity is unavoidable if the risks we have identified are to be satisfactorily addressed. Given its knowledge of the supply chain and its role in negotiating the prices of medicines under the PPRS framework, we consider that it is appropriate for DH to take a view on which of these options it considers most appropriate to address the concerns we have identified, or indeed, whether alternative options might exist that would safeguard against future cost increases.

- 6.44 Given that the PPRS is in the process of being renegotiated, this would appear to present a good opportunity to implement changes that will deal with the issues we have identified. Greater transparency of costs and prices in the distribution chain would also be beneficial to the operation of the PPRS more generally. Given the complexities discussed above, some temporary increase in the resources available to the DH PPRS team may therefore be required if our recommendations are to be adopted.
- 6.45 Finally, we note that a system that focuses on transaction prices realised by manufacturers is already established in some European countries. Our international study (see Annexe G) considered the distribution systems in France, Germany, Netherlands and Sweden, and found that each country's pricing controls apply to the transaction prices paid by pharmacies and/or charged by manufacturers.

Experiences in other countries

Table 6.2: price and margin regulation in other countries¹⁰³

Country	Price regulation	Margin regulation
France	Manufacturer selling prices agreed through negotiation.	Wholesaler mark-ups are fixed according to a regressive scale and added to the manufacturer selling price. Pharmacy mark-ups are similarly specified and added to the manufacturer selling price.
Germany	Free pricing at the manufacturer level. Price paid by public also includes wholesaler and pharmacy mark-up.	Both wholesaler and pharmacies have a fixed scale of mark-ups that apply dependent on the manufacturer price.
Netherlands	Reimbursement controls based on clinical and cost effectiveness. Prices are set at the pharmacy purchase level.	Wholesaler margins are unregulated. Pharmacies receive the maximum purchase price plus a flat rate dispensing fee for medicines dispensed.
Sweden	Prices set using the pharmacy purchase level by an independent government agency.	Wholesalers mark-up is not regulated. Pharmacies receive the regulated pharmacy purchase price plus a statutory mark-up.

Source: Study of medicines distribution in other countries, prepared for OFT by D MacArthur, December 2007. See Annexe G for details.

Recommendation two – safeguarding against a possible deterioration in service standards as a result of DTP

- 6.46 At paragraphs 4.17 to 4.42 we established that through DTP schemes manufacturers may in the future seek to offer lower delivery service standards than are available today. We note that Pfizer has continued to offer twice-daily delivery but some concern has been expressed about cut-off times, although we consider that DH, Scottish Government and Department of Health, Social Services and Public Safety Northern Ireland are best placed to reach a view,

¹⁰³ The references in this table are generally to gross margins. In these circumstances the actual margin wholesalers receive will depend on the discount offered to pharmacies. For further information see Annex G.

overall, on whether this represents a significant concern. We have not, however, as part of this study assessed whether the traditional wholesale model is the most efficient way of providing satisfactory service standards or whether current service standards are optimal. To the extent that the NHS is concerned to prevent service levels falling as a result of DTP, we have made recommendations that would prevent such problems occurring.

- 6.47 We consider that there would be benefits from having greater clarity about the service level the NHS is effectively paying for when agreeing the price of medicines under the PPRS framework. If the NHS wishes to prevent service levels being eroded in future, we recommend that, in consultation with relevant stakeholders, the NHS should determine the minimum level of service to pharmacies and dispensing doctors that it considers appropriate. This minimum service level would need to be included in all contracts between manufacturers and LSPs for the distribution of medicines. The level of costs incurred by the NHS should reflect any changes in the service levels received by pharmacies.
- 6.48 We consider that DH, The Scottish Government and The Department of Health, Social Services and Public Safety Northern Ireland are best placed to consider the value of different service level standards and to decide on the appropriate minimum level. In particular, they are able to consider the relative value of such services versus other healthcare requirements.
- 6.49 We do not envisage the need for any burdensome or detailed regulatory scrutiny of the implementation and practical application of this recommendation. Once a minimum service level has been determined, the implementation of this recommendation could involve seeking the voluntary agreement of members of the ABPI that they will adhere to the minimum service level specified in their contracts with LSPs.
- 6.50 One possible implementation issue concerns the likelihood that different medicines may warrant different minimum service levels, such that it may not be possible to specify a single minimum service level to apply to all branded medicines. This may arise as medicines are used in a range of different ways and treat a large number of different conditions. Furthermore, some have specific requirements with regard to storage and distribution. Bespoke arrangements may therefore be necessary for certain classes of medicine.

Implications of exclusive LSPs

- 6.51 At Paragraph 5.43 we established that the appointment of an exclusive LSP/wholesaler might be expected to result in a deterioration in service standards because there is no threat of business being lost in the short-term if service standards are low or variable. We also note in Chapter 5 that the administrative burden on pharmacies is likely to be higher where there is no choice of which LSP/wholesaler to use. While in the longer term an LSP or wholesaler could lose its exclusive status if its service is not satisfactory, it will not always be easy for manufacturers to monitor compliance and to know when there are genuine reasons for problems with service. We note that, for now, only Pfizer has adopted an exclusive DTP scheme and that other manufacturers have chosen to appoint at least two LSPs/wholesalers. If however, more manufacturers seek to appoint an exclusive LSP/wholesaler, this issue would become more significant. Furthermore, more widespread use of exclusive contracts risks significantly dampening competition at the wholesaler level, as discussed in chapter 5.
- 6.52 We believe the risks we have identified with exclusivity should also be of concern to manufacturers. If they appoint an exclusive LSP, they may find it more difficult to ensure that the service standards they require are maintained. Giving pharmacies a choice of supplier

gives real incentives to LSPs/wholesalers to offer a good service since they will lose business if standards are not satisfactory. By appointing more than one LSP/wholesaler, manufacturers can in effect transfer some of the effort of monitoring service standards on to pharmacies. They can also provide the certainty of having a back-up supplier if for some reason one supplier is unable to deliver a medicine.

- 6.53 As the purchaser of medicines, DH also has incentives to ensure that it achieves value for money and that its service level expectations are realised by pharmacies to the benefit of patients. To that end, were DH concerned that the exclusive appointment of a LSP/wholesaler was serving to undermine its service requirements, it may wish to impose additional requirements upon manufacturers to ensure that pharmacies receive services of the required standard. Various options may be available to DH, but possibilities may, as relevant, include making lower payments for lower service standards and/or a requirement for additional, more effective monitoring measures on the part of manufacturers using a single LSP/wholesaler.
- 6.54 Moreover, it is not in manufacturers' interests for the intensity of competition among potential LSPs/wholesalers to reduce significantly. If this occurred, they could find themselves ultimately unable to obtain competitive bids from LSPs/wholesalers to distribute their medicines. We are highlighting these findings to the industry in the expectation that manufacturers will take them on board. If more manufacturers do opt for exclusivity in distribution in such a way that competition in the sector is reduced significantly, future intervention by the OFT may be necessary.

Chapter conclusion

- 6.55 We consider the potential impact of recent changes in distribution of medicines to be significant in terms of costs to the NHS and patient service standards.
- 6.56 We have suggested approaches that we consider to be an effective means of protecting against cost increases. We recognise however, that alternative approaches may exist, not least given that the PPRS is in the process of being renegotiated. Given the extent of the potential increases in the cost of medicines to the NHS, it is important that some safeguards are put in place. We also note that our recommendations on pricing would bring greater transparency of medicine prices and of the true costs of distribution. We believe that our proposed approaches could be implemented whether or not the future PPRS takes account of the recommendations we made in the PPRS market study.
- 6.57 On service levels, we have suggested that, if Government feels service level reductions are a problem, it should seek voluntary agreement from manufacturers to adhere to the service levels it considers appropriate. In any event, deterioration in service levels should be reflected in the prices paid for medicines. We have noted the risks associated with manufacturers appointing exclusive LSPs and highlight these findings to the industry in the expectation that it will take steps to prevent long term problems arising without the need for intervention by the OFT.

Published by the Office of Fair Trading
Printed in the UK on at least 50% recycled paper
Product code OFT967
Edition 12/07
© Crown copyright 2007