OFFICE OF FAIR TRADING

Annexe I

Supplementary analysis

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INTRODUCTION

1.1. This Annexe presents supplementary analysis to that of the report (see Chapter 5) on the following subjects:

- **Section A:** Vertical integration in the medicines industry
- **Section B:** The use of quotas under DTP

SECTION A

Vertical integration in the medicines industry

Introduction

1.2. There is a significant degree of integration in the UK between pharmacy chains and wholesalers, with well over 40 per cent of the pharmacy market accounted for by vertically integrated chains. In addition to representing a barrier to entry at the wholesale level (see Annexe C), manufacturers and integrated pharmacies and wholesalers may be able to gain from DTP as a result of the joint negotiation of distribution fees and the structure of discounts received by pharmacies.

1.3. This section sets out a potential concern that could arise where distribution fees and pharmacy discounts are determined together. This is followed by an examination of the current control mechanisms and an analysis of the current and proposed moves to DTP to establish the extent to which this concern may arise in practice.

Concern arising from vertical integrated wholesalers and pharmacies

1.4. In the traditional model, wholesalers typically purchase branded medicines at a discount of 12.5 per cent from the list price. Wholesalers then determine the level of discount they can offer to external pharmacy customers. The price vertically integrated wholesalers charge to their affiliated pharmacy chains can vary and is essentially an internal transfer price.

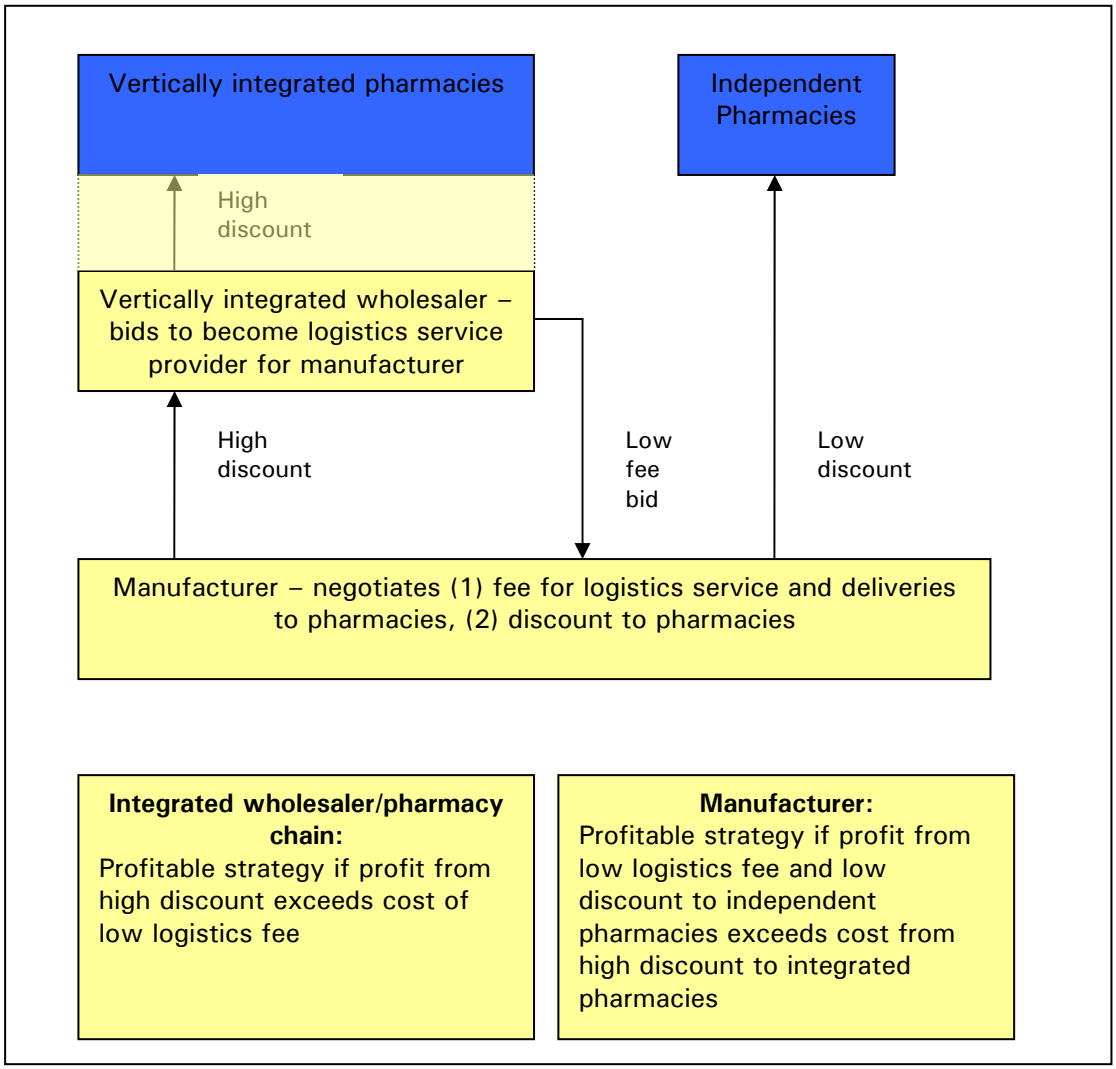
1.5. Under DTP, the system is fundamentally altered as manufacturers now sell their medicines direct to pharmacies. Manufacturers determine the level of discount they offer to both independent and vertically integrated pharmacies and negotiate a fee for distribution with LSPs. The fee for distribution from the wholesale part of the vertically integrated business will typically be determined following a tender process initiated by the manufacturer.

1.6. Under DTP, the profit margins achieved by a vertically integrated business' wholesale and pharmacy operations are both the consequence of negotiation with manufacturers. Given the change in the competitive process implicit in DTP, it is necessary to consider what implications this might have for competition at the wholesale and pharmacy levels of the supply chain.

1.7. It would appear that, given the ability to negotiate distribution fees and pharmacy costs together, vertically integrated wholesalers and pharmacies may have incentives to offer lower distribution fees in return for a larger discount for its own pharmacies. Moreover, one interpretation of the current PPRS arrangements suggests that manufacturers have a financial interest in encouraging such a cross-subsidy. This may be profitable as a subsidy which favours vertically

integrated wholesaler and pharmacy chains may be balanced by lower discounts for independent pharmacies. The manufacturer could still provide some assurance that the aggregate cost of pharmacy discounts would not change. This is explained in the diagram and in more detail in the paragraphs below.

Figure I.1 Representation of concern about vertical integration among wholesalers and pharmacies



How this strategy could be profitable

1.8. **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 likely. 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 forty independent pharmacies in England and does not take account of

vertically integrated pharmacy chains.[1] This is because, in such vertical businesses, it can be difficult to determine a transfer price that is comparable with the purchase price for independent pharmacies, and there are issues of cost allocation which also add to the difficulties in this area. Further, even if such a discount was identified, the clawback scale applied to pharmacies in England and Wales varies by an individual outlet's sales rather than by the size of the pharmacy chain. Consequently, a pharmacy chain with 50 stores each with a turnover of £1 million would be subject to the same clawback rate as a single outlet independent pharmacy with a turnover of £1 million.

1.9. Given that improved terms at the pharmacy level for a vertically integrated chain are not subject to increased clawback, vertically integrated wholesaler and pharmacies 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 the 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.

1.10. **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.

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

Box I.1 Stylised example of how vertical integration might favour manufacturers and vertically integrated wholesalers

Assume Manufacturer A produces a relatively high value medicine and is launching a DTP scheme. It must decide on its discount structure to pharmacies, and which distributor(s) it will use.

For simplicity, assume it has a single product with a list price of £10 and it sells total volumes of 10m to 1000 pharmacies, each purchasing an average of 10,000 units. The total value of sales at list price is therefore £100m.

Under the traditional model, Manufacturer A faces distribution costs equal to 12.5 per cent of its £100m sales, that is £12.5m.

Wholesalers receive a 12.5 percent discount per item, equal to £1.25 off the list price. They

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

retain 25p of this to cover the costs of distribution and pass £1 onto pharmacies, who pay £9 per item. The total value of pharmacy discounts is therefore £1 x 10m = £10m.

Having offered cost neutrality assurances to DH (that is, discounts to pharmacies will equal £10m in total), manufacturer A was planning to offer a flat discount of 10 per cent on all purchases.

On going to tender, manufacturer A receives offers from three wholesalers. One, company Z, is vertically integrated and the other two are not.

Each company offers to distribute the product at a flat rate fee of 25p per item, giving a cost for distribution of £2.5m. However, Company Z, which has 200 pharmacies (out of the total 1000) and purchases 2m units of A's product also makes an alternative offer of a distribution price of 20p per pack, provided that its retail chain receives a discount of 15 per cent rather than 10 per cent.

The impact of these two bids on Company Z's revenues is as follows:

£m	25p per pack, 10% discount	20p per pack, 15% discount
Revenue from distribution fee	2.5	2
Revenue from discounts	2	3
Clawback at 10%	2	2
Total revenue	2.5	3

Manufacturer A notes that offering a 15 per cent discount to the pharmacy chain of Company Z need not affect its revenues from pharmacies overall. Instead, it can introduce tiers into its volume discount structure which will accommodate a 15 per cent discount to Company Z but leave its average discount at 10 per cent. It calculates that this would involve offering a 8.75 per cent discount to other pharmacies who account for purchases of 8m units of its product.

The relative impact of the alternatives available to Manufacturer A is shown below:

Cost to Manufacturer A £m	25p per pack, 10% discount	20p per pack, 15%/8.75% discount
Cost of distribution fee	2.5	2
Discounts to Company Z's pharmacies	2	3
Discounts to other pharmacies	8	7
Total cost of distribution	12.5	12

Manufacturer A's sales would be unchanged if it accepted Company Z's offer, but it would save 5p per pack if all of its medicines are distributed by Company Z. Its profits would therefore be higher.

Manufacturer A appoints Company Z as its exclusive LSP and sets pharmacy discounts ranging from 8.75-15 per cent.

1.12. 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.

Box I.2 DTP discounts to date

The experiences of implementing DTP in practice in the UK are limited. In the case of Pfizer, the process of selecting logistics service partners involved inviting bids from potential logistics service partners and considering these. Such negotiations took place well before Pfizer announced the level and structure of discounts from the list price that it would be offering on its medicines. Similarly, Astra Zeneca has announced the logistics service partners it intends to use, although it has yet to announce the level and structure of discounts from the list price that it would be offering on its medicines.

As a result of the order in which these announcements have been made and their timing, it would not appear likely in these cases that the manufacturers sought to obtain logistics fee quotes which were conditional on particular levels of discount for vertically integrated pharmacies. This would not prevent other manufacturers interested in DTP from tendering explicitly for logistics service bids that are linked to a specified level of discount for an integrated pharmacy chain.

Potential distortion to competition between suppliers

1.13. One existing obstacle to this scenario in the short term may be the lack of operational co-ordination between the retail and wholesale operations that are under common ownership. For example, we understand that within UniChem, Alliance and Boots, the retail and wholesale businesses retain a degree of autonomy. The same can be said of AAH and Lloyds.

1.14. If we assume further operational integration in future, as well as the continued application of the existing negotiation style for the PPRS, there is nevertheless a concern that in the future, competition in medicines wholesaling may be distorted in favour of those wholesale companies that have the most significant interests at pharmacy level. Indeed, in this regard, UniChem, Alliance and Boots' ability to secure further exclusive DTP contracts may be materially enhanced by its position as the leading owner of UK pharmacies (see Annexe C). The extent to which the market structure could become a cause for concern will to some extent depend upon manufacturers' willingness to concentrate appointments of LSPs on the largest vertically integrated wholesalers. Where large vertically integrated pharmacies and wholesalers substantially increase their presence in both markets, there is a concern that this could act as a barrier to entry and may reduce competition in these markets.

Conclusion

1.15. This section has outlined one potential concern that may arise from DTP in that the joint negotiation of pharmacy discounts and wholesale logistics fees may allow the large vertically integrated pharmacies and wholesalers to increase their share of the market and may act as a barrier to entry and 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 detected the reduced profitability of the independent pharmacies. Under this scenario, clawback would decrease even where average discounts to pharmacies were unchanged.

1.16. In practice, the current DTP contracts do not appear to have been negotiated in a simultaneous manner, although this does not preclude such negotiations from taking place in future.

1.17. While the concern outlined in this section is at present theoretical, we note that recommendation one presented in Chapter 6 would alleviate the concerns raised above (irrespective of the implementation options used).

SECTION B

The use of quotas under DTP

Introduction

1.18. DTP enables manufacturers to adopt supply policies whereby individual pharmacy purchase volumes are monitored and restricted. Indeed, as part of its DTP scheme Pfizer now operates a supply policy under which it monitors, and in some cases restricts, purchasing by pharmacies of Pfizer medicines.[2] This section considers the potential implications of the use of supply 'quotas' under DTP and, where possible,[3] considers the impact and application of Pfizer's own supply policy.

1.19. Under the traditional wholesale model, manufacturers do not supply pharmacies directly and cannot generally observe the ordering patterns of 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).

1.20. Pfizer's supply policy essentially comprises monitoring levels of supply, 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.

1.21. A number of stakeholders have 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. Our analysis has found that Pfizer's supply policy does not appear to have been overly restrictive in its implementation so far.

1.22. Quotas may also have the potential to discourage pharmacies from purchasing parallel imports given that quotas may be based on the level of past purchases. This is because purchasing parallel imports would serve to decrease UK requirements, which would in turn 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 costs to the NHS.

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[2] The 'supply policy' referred to throughout this section relates specifically to the monitoring, questioning and in some cases the imposition of quotas at the pharmacy level (Pfizer terminology).

[3] We have not published a detailed analysis of Pfizer's supply policy as it considered this confidential.

1.23. We have identified several potential benefits of the use of quotas under DTP over the traditional wholesale model. Under DTP, manufacturers can manage the allocation of medicines more effectively, particularly in instances of shortages.

1.24. This section considers the following:

- the availability of medicines under the traditional wholesale model
- the benefits of a supply policy under DTP
- analysis of the potential impact on NHS costs and patients.

The availability of medicines under the traditional wholesale model

1.25. Manufacturers and wholesalers of medicines in the UK are obliged to ensure that they are able to meet demand from UK patients. The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789)[4] provide that manufacturers and suppliers shall:

> '…ensure that, within the limits of his responsibility as a distributor of relevant medicinal products, the appropriate and continued supply of such relevant medicinal products to pharmacies and persons who may lawfully sell such products by retail or who may lawfully supply them in circumstance corresponding to retail sale so that the needs of patients in the United Kingdom are covered.'

1.26. A manufacturer's choice of distribution arrangements should comply with this regulation to ensure that patients have continued access to medicines. Distribution arrangements should be able to deal effectively both with fluctuations in demand for medicines and with supply problems.

1.27. Demand for some medicines is not always stable but may fluctuate significantly both at the local and the national level, with the consequence that it is sometimes difficult to predict. In response to changes in demand, manufacturers may not always be able to change the volume of medicines they produce at short notice. Moreover, there may be efficiency gains from managing national stock levels and not producing excess stock.

1.28. On occasion, manufacturers are also subject to supply problems. In general, these come about because many manufacturers manage their operations on a global level, and therefore face complex logistical issues in ensuring that the correct quantity of medicines reach the right location. In addition, manufacturers have argued that issues can arise through wholesalers stockpiling medicines.

[4] Regulations 2(3)(i) and 8(1)(b)

Box I.3: Examples of manufacturer supply problems

- About three years ago, Cardura XL (a Pfizer product) was in short supply as a number of batches encountered production difficulties and delays. This situation persisted and some PCOs suggested that patients should be switched to alternative medication.
- In March 2007, Alliance Pharma Ltd, the supplier of the Atarax active ingredient, had a fire in its factory which gave rise to supply issues. An alternative supplier was found but required reformulation and renewed regulatory clearance. The factory is expected to reopen in 2008. Existing supplies were rationed and supplied to key customers.
- AstraZeneca experienced supply problems in September 2005. Half of a medicine's production line had to be shut down at short notice for quality control testing. Consequently, AstraZeneca calculated that it could only fulfil forty per cent of orders received. AstraZeneca implemented an emergency direct supply line for the medicine to supply to customers that needed it most.

1.29. **Supply of medicines under the traditional wholesale model:** Pharmacies typically have a principal full-line wholesaler and a secondary full-line wholesaler for situations when their principal wholesaler is out of stock. There are exceptions to this, as several pharmacies (particularly some of the larger multiples) source medicines from only one wholesaler.

1.30. In spite of this back-up option being available to pharmacies, shortages and out-of-stock situations occur from time to time under the traditional wholesale model.

1.31. It is quite common for wholesalers to have certain lines unavailable and UniChem, for example, produces a weekly sheet of out-of-stock medicines. This explains the reason for the item being out-of-stock and when new stock is expected.

1.32. In order to manage supply under the traditional wholesale model, several manufacturers, including most of the largest such as Pfizer, AstraZeneca, Novartis, Sanofi-Aventis, Eli Lilly, Merck and Servier among others, have imposed quotas for particular medicines on wholesalers.

1.33. **Parallel trade:** Aside from the management of supply to ensure that patient demand is met, several wholesalers and pharmacies have put to us that manufacturers use such supply policies to seek to restrict the levels of parallel trade for their medicines. A quota may limit the quantity of a medicine which is supplied in the UK and which can be traded for sale abroad, thus safeguarding manufacturer profit in Europe overall. Some medicines prices in the UK are relatively high compared to some countries in Europe and consequently price differentials leading to the exporting of UK medicines may be limited. For certain medicines in certain countries (such as Germany and the Scandinavian countries), however, prices are sometimes high enough to sustain parallel exports from the UK.

1.34. While UK medicines prices may allow limited opportunities for parallel exports from the UK, there are generally more opportunities for pharmacies and wholesalers in the UK to benefit from parallel imports from European countries with lower prices.

1.35. There is also a low level of parallel exports from the UK to outside the EU. It has been suggested that recent legislation passed by Congress in the USA to legalise parallel trade into the USA may provide an additional incentive for manufacturers in the UK to try to restrict parallel trade, particularly given that the USA often has relatively high prices for some medicines. This issue is considered in the box below.

Box I.4: Parallel trade in the USA

It is illegal to import medicines into the USA, either commercially or for personal use. There are two exceptions: manufacturers are allowed to re-import medicines that are manufactured in the USA and then exported to another country, and manufacturers can choose to manufacture their medicines at foreign FDA-approved plants. These exceptions do not allow for parallel importation by third parties.

Over the past few years, however, legislation has been passed that allows for the lawful importation of medicines into the USA. In 2000, the House of Representatives and the Senate passed the Medicine Equity and Drug Safety Act. The Act included provisions for legalising parallel importation of prescription drugs, providing the Secretary of Health and Human Services (HHS) certified that imported drugs posed no additional safety risks and provided significant cost savings to consumers. However, successive Secretaries of HHS have failed to implement the Act, citing that they could not ensure the safety of imported medicine and significant cost savings for consumers using the FDA's current resources.

More recently, legislation has been passed to legalise drug importation into the US, but implementation is no closer. The Medicare Prescription Drug, Improvement and Modernisation Act included provisions to allow the importation of medicines from Canada provided certain conditions were satisfied. The Secretary of the HHS again failed to implement this Act for the reason that the safety of imported medicines and cost savings to consumers could not be assured. One reason why implementation of this legislation is difficult is that it would require the USA Government to ensure that all medicines entering the USA met required safety standards. This exercise may be too costly to warrant implementation given that the margins on parallel traded drugs that accrue to the consumer are likely to be relatively small. For this reason it is hard to see the implementation of this legislation in the foreseeable future.

It is understood that illegal parallel importation to the USA, however, does occur to some extent via Canada. During the course of the study, some stakeholders alleged that medicines were being exported from the UK to the USA via Canada. It appears, however, unlikely that the levels of any such parallel trade would be significant.

Since it appears unlikely that any of the proposed changes in USA legislation will be implemented in the short-term, they have not created anything other than a potential long-term incentive for manufacturers to restrict parallel trade in the EU in order to prevent parallel export to the USA.

1.36. While changes in US legislation appear currently to be of less significance, the aim of restricting parallel trade across the EU appears to be a feasible long term motivation for manufacturers supplying medicines in the UK to implement distribution arrangements that enable greater transparency and easier management at the pharmacy level, such as Pfizer's DTP scheme. These benefits are considered further in the following section.

The benefits of quotas under DTP

1.37. This section looks at the potential benefits of quotas under DTP and of the potential for DTP schemes to result in more effective access to medicines for UK patients.

1.38. Distinct from quotas, there are benefits to DTP schemes which are attributable to the greater control that the shorter and more visible supply chain afforded by DTP allows. These benefits appear to be advantages inherent in the DTP model, and do not necessarily stem from the operation of quotas. These benefits include:

- DTP allows for more effective product recall
- greater transparency of pharmacy demand allows manufacturers to observe and respond to fluctuations in demand more effectively and more quickly.

1.39. **More effective medicine recall:** Manufacturers may be required to be able to recall medicines effectively in instances where there are supply problems or where counterfeits enter the supply chain (this is discussed in more detail in Annexe C). Effective recall requires good knowledge of the location of medicine batches and the ability to remove them from the supply chain swiftly. DTP may allow manufacturers to manage medicine recall more effectively as they retain control over supply in a shorter supply chain and have much greater visibility over the distribution and location of medicines within the shorter supply chain.

1.40. **Greater visibility of demand:** Under DTP, manufacturers have greater visibility of individual pharmacy demand allowing them to ascertain the level of demand nationally and locally with far greater speed and accuracy. Manufacturers would then be able to respond more quickly to shortages by increasing production and/or reallocating existing supplies.

1.41. Depending on how quotas under DTP schemes are implemented, they may also have the potential to further enhance the improved availability of medicines for patients. In general, these benefits arise from individual manufacturer's ability to observe and restrict ordering by pharmacies to ensure that its stock is more

efficiently allocated. These benefits are significant given that shortages are relatively common (due to fluctuations in demand and supply problems).[5]

1.42. The following paragraphs set out in more detail the potential benefits that the use of quotas under DTP may have. At this stage, however, it is difficult to assess the significance of these benefits fully and we have not attempted to do so.

1.43. Depending on how quotas are implemented under DTP, they may have the following potential benefits:

- under the traditional wholesale model, quotas imposed on individual wholesalers may have resulted in misallocations and shortages due to a lack of visibility of pharmacy level demand by the manufacturer. Under DTP, the manufacturer may be able to allocate stocks of medicines more efficiently among regions and across pharmacies

- in the case of shortages, greater control of supply gives the manufacturer a greater ability to supply medicines to where they are needed most. In times of short supply, this may include rationing medicines, and preventing stockpiling orders that could exacerbate shortages

- a number of pharmacies and wholesalers engage in the trade of medicines either within the UK (grey trade) or abroad (parallel trade). Many stakeholders have pointed to the prevention of this trade as being one of Pfizer's motivations for implementing quotas.[6] Given that shortages in some medicines do occur, for a number of different reasons, this trade has the potential to exacerbate availability problems. We recognise that there may be a conflict for manufacturers between the regulatory obligation to ensure medicines are available and allowing parallel and grey trade in their medicines.

Box I.5: Pfizer's supply policy

The stated rationale behind Pfizer's supply policy is that 'it promotes supply chain efficiency and integrity by ensuring that there is adequate supply to meet demand across the UK'. Essentially, by monitoring pharmacy purchasing and imposing limits on those pharmacies that appear to order excessive quantities, Pfizer argues that it will be better able to ensure that there is supply of its medicines in the right place and at the right time to meet demand.

Pfizer has provided an example where the above benefits have been realised through its use of its supply policy under its DTP scheme. Champix is a smoking-cessation prescription medicine that was launched commercially in the UK in January 2007.

[5] See Box I.3 – Supply problems.

[6] A small number of stakeholders complained that Pfizer was using quotas to curtail their legitimate trading on the grey market.

Between the beginning of May and the end of June, national demand for Champix more than quadrupled and rose above the quantity predicted by Pfizer. Consequently, stock shortages occurred at the beginning of July.[7]

Pfizer implemented the following measures to manage supply:

- Prioritisation of remaining stock to areas where there was the highest demand.
- Revision of manufacturing plans so supply was brought forward in time.
- Active management of remaining stock held at UniChem's distribution centres. Prioritisation given to the booking of Champix deliveries above other deliveries.
- Excessive or unusually high ordering by some pharmacies was limited.

The measures were implemented within one working week. Pfizer stated that it believes that this would have taken much longer prior to the implementation of its DTP scheme. This example illustrates the potential for quotas to be used to better enable manufacturers to manage the distribution of stock in the event of medicine shortages.

Impact on NHS costs

1.44. **Parallel importing:** Quotas could affect the levels of parallel imports of branded medicines into the UK due to their effect on pharmacy incentives to purchase parallel imports.[8] This is because pharmacies may be discouraged from purchasing parallel imports if they believe that this may lower their benchmark for quota assessment and therefore put at risk supplies from the relevant manufacturer in the future. Pfizer, for example, calculates a pharmacy's allowable quota by reference to past purchases such that where a pharmacy purchased imported medicines for a time, its allowable quota would be lower in future periods.

1.45. During the course of the study, several pharmacists informed us of their concerns that the purchasing of parallel imports would lower their Pfizer quota benchmark.

1.46. It is difficult to quantify the costs to the NHS that Pfizer's supply policy may have in terms of discouraging parallel importing. Similarly, it is not possible to meaningfully assess the impact of other manufacturers adopting pharmacy level quotas. At this stage, it is unclear to what extent pharmacies will alter their current supply strategies, in particular the levels of recourse to parallel imports. In addition, we recognise that there are several other factors which determine the levels of parallel trade, including the availability of specific parallel imports, the source countries involved and the existence and magnitude of price differentials.

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[7] A number of our pharmacy survey respondents associated shortages of Champix with Pfizer's DTP scheme.

[8] Parallel imports account for around £1.2 billion of annual primary care medicines expenditure and are estimated to provide for NHS savings of around £163 million.

1.47. Given the number of variable factors involved, we cannot meaningfully determine the potential costs to the NHS which could result if pharmacies are in fact discouraged from purchasing parallel imports as a result of quota systems. By way of approximation, we note that if Pfizer's supply policy prevented pharmacies from purchasing any parallel imports of Pfizer medicine, the potential impact on NHS costs could be up to £16 million a year.[9] It is of course very unlikely that the Pfizer supply policy would prevent all or even most parallel imports of Pfizer medicines. In addition, we note that an estimated cost of £16 million per annum is a relatively small amount in the context of the £8 billion that the NHS spends on branded medicines annually.

1.48. **Parallel exporting:** Wholesalers (and pharmacies acting in a wholesale capacity) have the incentive to exploit price differentials for medicines between the UK and other EU countries by engaging in parallel trade. Under the traditional wholesale model, they are able to sell UK medicines to wholesalers in a country with higher prices for the same medicines. While the UK has relatively high prices for most medicines compared to other EU countries, there are some medicines that are priced higher in other counties.

1.49. Pfizer's supply policy under DTP restricts the ability of pharmacies to export Pfizer medicines and prevents wholesalers from doing so. Any wholesaler under a DTP arrangement with Pfizer will be unable to export medicines as it does not retain ownership of the medicine and therefore cannot re-sell to customers.

1.50. A reduction in parallel exporting banded medicines is unlikely, however, to result in any increased costs to the NHS. Any profits made by pharmacies from the trade of medicines are not included in the purchasing profit allowance set out in the Pharmacy Contract.[10] Consequently, any reduction in these profits will not be transferred to the NHS via the clawback mechanism or any other means.

Impact on patients

1.51. Quotas have the potential to impact upon patients if implemented with limited allowance for reasonable changes in pharmacy demand. In the short-term, the

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[9] This figures is based on the following assumptions:

- Parallel imports provide savings of around £163 million per annum to the NHS (note 1).
- Pfizer products account for approximately ten per cent of all medicines prescribed in the UK. We therefore make the assumption that Pfizer products account for ten per cent of the benefits to the NHS provided by parallel imports, i.e. approximately £16 million (note 2).

Note 1: The economic impact of parallel import of pharmaceuticals, Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark, June 2006.

Note 2: Because Pfizer products are relatively high value, easily transportable and have high sales volume, it is likely that they represent a larger proportion of parallel traded products. However, benefits to the NHS are determined by the margins earned by pharmacy on parallel imports rather than the value of the product. We have little information on the relative margins of Pfizer and non-Pfizer parallel imports so assume that benefits to the NHS are proportional to share of sales to the NHS.

application of restrictive quotas may result in supply levels that are insufficient to satisfy patient demand. In the longer term, where quotas affect competition between pharmacies an outcome may be the provision of poorer pharmacy services to the detriment of patients.

1.52. Medicines availability: Pharmacies have informed us that their demand for different medicines can vary significantly from week to week and from month to month.[11] They are therefore concerned that where a manufacturer seeks to impose a fixed quota that reflects a 'normal' level of demand, in a month of high patient demand they will be unable to secure sufficient volumes of affected medicines to satisfy patient requirements.

1.53. Competition between pharmacies: A successful pharmacy can be expected to see its sales and medicines requirements rise over time. Were a number of significant manufacturers to apply strict quotas, pharmacies' ability to compete successfully may be constrained as they would be unable to obtain the volumes of medicines they require to meet demand. Where pharmacies' incentive to compete is dampened, this can be expected to ultimately result, for example, in poorer services to patients.

Conclusion

1.54. We have identified potential benefits relating to the use of such a supply policy under DTP which are not replicated under the traditional wholesale model. However, it is difficult fully to assess the scale and significance of these benefits.

1.55. Quotas have the potential to increase NHS costs and lower patient service standards. However, the significance of either effect depends on how a manufacturer implements its quota system. To that extent, an assessment of whether or not quotas are problematic relies on an examination of how a manufacturer implements its quota system in practice.

1.56. To date, Pfizer's use of quotas does not appear to have had a significant adverse impact on patients or NHS costs.

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[10] The profit allowance is based on the Margin Inquiry which only accounts for margins made from the purchase of pharmaceuticals. Profits made from trade are attributable to the pharmacy's capacity as a wholesaler and so are not included.

[11] This variability can be caused by change to patient requirements, a change in local GP and/or a change to local GP's prescribing preferences.