



*Options for the Future Supply
and Reimbursement of Generic Medicines
for the NHS*

A Discussion Paper

JULY 2001

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Executive Summary

- i. Generic medicines are crucial to the National Health Service. They play a key part in many treatments in hospital and in the community and make a key contribution to the quality of life of patients up and down the country. They can also release substantial savings in the prices the NHS pays for medicines for redeployment in other areas of healthcare. The growth in use of generics in the NHS is a major success story. Generic prescribing has increased steadily in recent years and now stands at a little over 70%. Generics account for nearly 50% of prescription items dispensed in the community.
- ii. The Government is committed to building on that record. We will only be able to do so if we are able to achieve a secure and consistent supply of both established and new generics and value for money in the prices the NHS pays for them. This paper sets out options for achieving these goals. It invites the views of interested parties. It also consults formally on proposals for information gathering to assist in developing and assessing one of the options.
- iii. The dispensing of generics and other medicines is a central role of community pharmacy contractors and dispensing doctors. Dispensing contractors have a good record of ensuring consistent and ready availability of product. We need to ensure that future arrangements for supply and reimbursement enable them to sustain that record and that patients continue to benefit from good access to community pharmacy services.
- iv. The work that led to these options was prompted by the Government's concern about the supply turbulence in the generics market in 1999. The overall level of prices paid by the NHS increased by around 45% during the course of the year. There were also apparent supply problems across a range of generic preparations which persisted long after we were told that the supply chain had made up the production shortfall. As part of a response to these problems the Government commissioned a fundamental review from Oxford Economic Research Associates (OXERA) in November 1999. OXERA reported in September 2000 and the Government has drawn on their analysis and recommendations in preparing this paper.
- v. In August 2000 the Government put in place a statutory maximum price scheme to protect the position of the NHS from continued high prices and to stabilise the market. We made clear at the time that this does not alter the Government's intention to consider other options for the longer term.
- vi. The Government acknowledges that purchasing and supply arrangements up to December 1998 helped to secure reasonably stable supply conditions and prices. However, it is now also clear that they have a number of significant underlying weaknesses –
 - there is a lack of transparency over the nature of the market and prices. Reimbursement prices often differ significantly from true market prices. Price lists in some cases appear to be produced solely for the purpose of satisfying the requirements of the Prescription Pricing Authority (PPA). Prices and the nature of the market are most opaque to the ultimate payer – the NHS. This is unacceptable.

- The effectiveness of current purchasing and reimbursement arrangements depends on community pharmacies' independence and ability to purchase from whichever supplier can offer them the best deal. Vertical integration has increasingly undermined that independence, weakened the effect of the discount inquiry and further obscured the operation of the market.
 - There is some evidence that the market for certain generics is concentrated in the hands of just one or two suppliers, increasing the vulnerability of the NHS to shortages in the event of production problems. Overall there is a lack of information on how competitive the market is.
 - In addition, the question remains whether present arrangements make the best use of the buying power which the NHS – as the dominant UK customer for such medicines – should be able to exert.
- vii. It is difficult to quantify the effect of these deficiencies. But there appears to be a significant gap between the NHS' total annual expenditure on generics and ex-manufacture prices with the addition of a reasonable distribution margin. Although some of this will be accounted for by branded medicines which are dispensed against generic prescriptions, this is unlikely to account for the whole of the difference, suggesting that significant excess sums remain in the supply chain and are lost to the NHS.
- viii. Our analysis has also identified a number of trends in the supply chain, in particular the likely continued growth of vertical integration between wholesalers and pharmacies and, possibly, between wholesalers and manufacturers. These can be expected to expose the weaknesses of present arrangements further.
- ix. Whatever arrangements we put in place for the purchasing and supply of generics, we see it as essential to obtain better information about the state of competition in the market and to develop measures to encourage entry where necessary. We commissioned some further work on this from OXERA earlier this year. We recognise, too, that encouraging competition has a wider dimension. It involves putting in place arrangements which enable companies to make reasonable returns. The proposals in this discussion document take account of this.
- x. We have assessed a number of options for the future. Many were discarded as not meriting detailed considerations, either as unworkable or unlikely significantly to address the points outlined above. We believe two new approaches for future purchasing and supply merit further detailed discussion –
- a reform option, which leaves present procurement arrangements intact but changes the basis on which reimbursement prices are calculated. It potentially includes an element of statutory price control, and
 - a proposal for the introduction of central purchasing, through competitive tendering, replacing present purchasing arrangements.
- xi. As a further option, the paper assesses the possibility of keeping in place the existing maximum price scheme over the longer term. This would not address a number of the limitations of existing arrangements and if we went down this route we would need to consider how the maximum price scheme could be made to address these concerns.
- xii. The paper evaluates the strengths and weaknesses of each of these options. It does not reach a clear conclusion on the way forward. We believe that the contribution of community pharmacy contractors, wholesalers, Product Licence (PL)-holders, and manufacturers, with their knowledge of the supply chain, is essential to the debate. We would also welcome the views of users of community pharmacy services. We would be willing to consider alternative arrangements which are put to us. We will then take a final decision on which approach best addresses the deficiencies set out above and meets our criteria for supply and reimbursement of medicines detailed in this paper.

- xiii. We would particularly welcome views on –
- the assessment of existing arrangements
 - the options put forward in the paper
 - any other options which have the potential to meet the Government's objectives
 - the partial regulatory impact assessment at *Annex C* to this paper
- xiv. The discussion process will run until Monday 22 October 2001 and we would welcome comments by that date. We will then reach a view on the future course of action and consult on detailed proposals.
- xv. This paper also formally consults interested parties on proposals for two information collection exercises to enable us to refine the reform proposal (see section 7). The consultation period on the proposed collection of a full year's data for 2000-01 ends on Friday 14 September 2001. Subject to the views we receive we will then put the exercise in place quickly. Consultation on the proposed collection of monthly information ends on Monday 22 October 2001. The information we obtain will inform a decision about which option to proceed with, and in what form, and does not in any way pre-judge it.
- xvi. Alongside this paper we have issued an invitation to interested parties to contribute to a review of the maximum price scheme and have consulted on our own proposals. Subject to the outcome of the review, the maximum price scheme will then remain in place pending decisions about longer term arrangements.
- xvii. Generics are only one segment – albeit a significant one – of the supply of medicines to the NHS in the community. Arrangements for the provision and reimbursement of branded medicines fall outside the scope of this paper.

1. Introduction

- 1.1 Generic medicines play an important part in patient care. They account for nearly 50% of prescription items dispensed in the community. They can also release substantial savings in the prices the NHS pays for medicines for redeployment in other areas of healthcare. This paper evaluates present arrangements for the supply and reimbursement of generic medicines for the NHS and puts forward possible alternatives. Its primary purpose is to encourage discussion of future arrangements with all those with an interest so that the Government can take their views into account in reaching decisions on the way forward. It also consults formally on a proposal for the collection of information to allow further development of one of the options for change.

Background

- 1.2 During the course of 1999 the NHS was affected by steep price increases and apparent shortages of many generic medicines. In response the Government commissioned a fundamental review of arrangements for the supply of generic medicines to the NHS from Oxford Economic Research Associates (OXERA) in December 1999. The terms of reference of the fundamental review are at *Annex A*.
- 1.3 The Government also asked the Office of Fair Trading (OFT) to investigate the market for evidence of anti-competitive practice. The OFT inquiry is still under way.
- 1.4 OXERA's work continued through the spring and summer of 2000 and a report and recommendations were delivered to the Department in September 2000. OXERA's report is available on the internet at www.doh.gov.uk/generics or in hard copy from Department of Health, PO Box 777, London SE1 6XH (tel. 08701 555 455). Prior to this, in response to continued high Drug Tariff prices and little evidence that these were justified by increases in the cost base, and in order to protect the position of the NHS, the Government consulted on a statutory maximum price scheme for the main generic medicines. Following consultation, the scheme was introduced with effect from 3 August 2000 and the Category D arrangement in the Drug Tariff was replaced in September 2000. The Government made clear at the time that the introduction of the maximum price scheme did not affect the intention to complete a wider-ranging review, aimed at producing proposals for the longer term.
- 1.5 The analysis and proposals in this paper draw both on OXERA's work and on the Department's experience of the generics supply chain, including the lessons of the last two years and discussions with interested parties during that period. We have also looked at arrangements in a number of other countries to see whether there are models that could be drawn on for the UK.

Scope of the paper

- 1.6 The paper focuses on future arrangements for the supply, pricing and reimbursement of generic medicines for NHS use in the community.
- 1.7 The paper is concerned with the supply of unbranded generic medicines – those not covered by the Pharmaceutical Price Regulation Scheme (PPRS) – and the reimbursement of generically written prescriptions which can be dispensed generically.
- 1.8 The paper does not affect arrangements for determining the prices of branded medicines under the PPRS or the reimbursement of branded prescriptions. Nor does it cover arrangements for the supply of generic medicines to the hospital sector, the over the counter (OTC) market, dispensing in response to private prescriptions, or supply for export.

2. The Government's Objectives

- 2.1 The Government's objectives for the system of distributing medicines to the NHS, published in December 1999 as part of the announcement of the fundamental review, are that it should –
- maintain, and improve, the current quality of service to patients both in hospital and in the community, in particular maintaining a secure and reliable service that meets clinical need
 - minimise the costs of the distribution networks, subject to service level and quality requirements
 - reimburse community pharmacies, overall, as closely as possible to what they actually pay for the medicines they dispense under the NHS
 - have transparent prices
 - support a competitive pharmaceutical market; and
 - secure value for money for the NHS.
- 2.2 We have added another two criteria to these for the purpose of evaluating present supply chain arrangements and possible alternatives.
- 2.3 First, any arrangements for the future would need to work well in the light of both the current characteristics of the supply chain and the way it may evolve over the coming years. Section 4 therefore considers future trends – in the NHS, in different parts of the medicines market, and globally – which are likely to affect the generics supply chain in future.
- 2.4 Second, the cost and complexity of introducing any new arrangements for the supply of generics to the NHS should not be disproportionate for public finances and the NHS or introduce disproportionate burdens on companies.

3. Assessment of Present Arrangements

3.1 This section assesses present arrangements for the supply of generics to the NHS against our criteria. Present arrangements are taken to mean those which were in place prior to the introduction of the maximum price scheme in August 2000. They can be summarised as follows –

- community pharmacies and dispensing doctors act as the agents of the NHS and purchase generics (as well as branded medicines) for dispensing against NHS prescriptions
- there are no restrictions on what product they may purchase or from whom, though suppliers of medicines have to comply with the relevant licensing requirements designed to protect public health through controls on safety, quality and efficacy.
- up to August 2000 there were no direct controls on the *prices* at which generic medicines could be offered to community pharmacies and dispensing doctors
- instead, the reimbursement system for community pharmacies and dispensing doctors is designed to secure cost-effective purchasing and value for money for the NHS by encouraging them to buy lower than the reimbursement price
- the reimbursement (Drug Tariff) price is based on the list prices of a number of major players and is designed to follow competition in the market
- recovery of estimated discount, assessed through regular discount inquiries, is designed to capture the extent to which community pharmacies and dispensing doctors manage to buy at lower prices and ensure that the NHS obtains the financial benefits of such purchasing
- up to August 2000, a drug in short supply at the Tariff price could be placed in Category D, allowing reimbursement at the list price of the supplier endorsed. (With effect from September prescriptions Category D was replaced by arrangements for reimbursement of the brand price where this had to be dispensed against a generic script on account of a shortage of the generic.)

To maintain and improve the current quality of service to patients

3.2 Although a number of factors contribute to perceptions of the quality of pharmaceutical services as seen by patients, a dominant consideration is whether there is a consistent and ready availability of product.

3.3 Community pharmacies and dispensing doctors have a good record on this. The evidence is that even during the turbulence in the generics market in 1999 there were very few instances when patients' needs could not be fulfilled, although pharmacists had to make significantly greater efforts than usual (including measures such as bartering medicines) to achieve this. The question arises whether dispensing contractors' task in 1999 was made harder by the reimbursement system or other features of supply arrangements.

- 3.4 It is clear that, in some cases, the supply problems of 1999 arose because of apparent rather than real shortages, in the sense that sufficient product was being manufactured, but was not available for dispensing to patients. It is probable that speculation and panic-buying both played a part in this and that the situation was exacerbated both by a lack of accurate information for pharmacies about supply conditions and by exploitation of the Category D arrangement. It was for this reason that Category D was abolished with effect from September 2000.
- 3.5 OXERA suggest that the lack of accurate information also made it harder for manufacturers to meet short-term fluctuations in demand. Coupled with relatively long lead-times for production and the need to meet regulatory requirements (in the event that a new supplier wants to enter the market) this limits the flexibility that the generics market – as a commodity market – should ideally be able to demonstrate in responding to sudden increases in demand.

To minimise the costs of the distribution networks

- 3.6 OXERA note that the pharmaceutical distribution system in the UK is effective and that the full-line wholesalers face competition from specialist distributors and from each other. The picture of a competitive distribution market suggests that the NHS should be obtaining value for money.
- 3.7 There are two caveats to this. First, the value for money the NHS obtains depends on the effectiveness of the reimbursement system in securing the benefits of competition in distribution. This is addressed in the next section. Second, it appears that in some cases product does not pass through the supply chain from one level to the next, starting at manufacture and ending with dispensing, but instead circulates around the different levels. It is unclear to what extent this is a by-product of the functioning of the market or the result of poor information on demand in the supply chain.

To reimburse pharmacies and dispensing doctors overall as closely as possible to what they actually pay for the medicines they dispense under the NHS

- 3.8 The question is whether the reimbursement price less the deduction resulting from the discount inquiry closely reflects the average prices paid by community pharmacies and dispensing doctors.
- 3.9 There are clear indications that many reimbursement prices are significantly above real market prices – even after the introduction of the maximum price scheme –
- Category A of the Drug Tariff (which represents the great majority of the top 200 generic preparations by net ingredient cost) is based on a basket of two full-line wholesalers and three manufacturers. As such it no longer gives a representative picture of the market. In particular, the basket excludes specialist generic distributors, who now make up a substantial proportion of generic supply
 - it has become increasingly clear that the price lists submitted to the Prescription Pricing Authority (PPA) for calculation of the reimbursement price show prices which, in many cases, are far removed from real prices paid in the market. Recent examination of price lists suggests that many major wholesalers compete at prices which are often only a fraction of the Tariff price. Some of the lists submitted to the PPA have also been found to be inaccurate or out of date.

- 3.10 Such disparities undermine the credibility of arrangements for setting the reimbursement price. However, they would not in themselves undermine the objective of reimbursing community pharmacies and dispensing doctors accurately if the various discount inquiry and deduction mechanisms were completely effective in clawing back the difference between list prices and prices actually paid by contractors. We do not believe that this is the case. In particular, we believe that the effectiveness of the discount inquiry for community pharmacies is significantly undermined by –
- the effective absence of a contribution from some major players, including Boots, which carries out its own wholesaling and says that it cannot provide a meaningful transfer price between its wholesale and retail arms. The more widespread such exceptions are, the less representative the inquiry becomes
 - the growth in vertical integration between wholesalers and community pharmacies. This makes asking pharmacies for prices paid to wholesalers increasingly meaningless. Similar issues arise in cases where dispensing doctors jointly own wholesale businesses. Vertically integrated companies are able to shift profits from one part of the chain to another according to their objectives. In the generics supply chain, vertically integrated companies could set high transfer prices for sales to their own pharmacies in order to keep profits from effective purchasing at the wholesale level of the chain, where it is hidden from the discount inquiries.
- 3.11 These factors make it unlikely that the inquiry is identifying the full extent of discounts off the reimbursement price. Together with the limitations of the mechanisms for setting the price, this suggests that the reimbursement system is failing, overall, to reimburse those supplying medicines in the NHS the average real cost of the drugs and to derive the full benefit of competition which the Government as the ultimate payer expects on behalf of the taxpayer.

To ensure transparent prices

- 3.12 Price transparency serves three purposes – allowing the Department to assess the performance of the supply arrangements, enabling it to determine an appropriate reimbursement price and enhancing the effective functioning of the supply chain.
- 3.13 The present system largely fails to satisfy the first two of these purposes. We do not believe that current reimbursement arrangements give us transparent information as to the true prices paid in the market. The system yields even less intelligence about the prices at which product is sold to wholesalers by manufacturers. This produces the extraordinary situation where the NHS has no way of telling with any degree of accuracy the prices of the generics for which it reimburses contractors.
- 3.14 It is less clear to us to what extent the various players in the supply chain itself have sufficient transparent price information. But it is doubtful whether the opacity of current arrangements helps those considering entering the market to decide whether it is worth doing so.

To support a competitive pharmaceutical market

- 3.15 Investigation of the market over the last two years has underlined how little information the Department has about the true level of competition in the generics market. Information about the number of Product Licence (PL) holders for different preparations is available. However, information about PL-ownership only tells us about who is permitted to be in the market, and not about who is actually offering product. There is also substantial cross-manufacture in the generics market, with one manufacturer sometimes making product for a number of competing PL-holders. Thus the existence

of a number of PL-holders for a given product can mask the fact that all supply is dependent on the same manufacturing source. The 1999 sales data submitted to the Department under the maximum price scheme has given us a slightly better understanding of the market. However, the turbulence in the market during that year means that the results need to be treated with caution. Until we have better information about where there is good competition in the market and where there is excessive concentration in both active PL-ownership and manufacture we will not be in a position to gauge overall competitiveness.

- 3.16 There are a number of possible explanations for any cases where there is little competition in the market for a particular generic preparation. These include –
- previous competition, which has driven most players out of the market
 - a lack of information and transparency as to price, set out above, which means that potential entrants are not fully aware of the potential of entering the market or are unable easily to assess possible returns
 - difficulties of entry to the market resulting either from the need to meet regulatory requirements or from not having sufficient knowledge about the market infrastructure.
- 3.17 Future arrangements will need to include measures for measuring market concentration, identifying the causes and, as far as possible, taking steps to tackle them.

To secure value for money for the NHS

- 3.18 Securing value for money for the NHS is implicit in the other five objectives. The points put forward in the previous paragraphs are therefore relevant. Even if community pharmacies and dispensing doctors are purchasing efficiently, our view that there are inefficiencies in the distribution chain, that the reimbursement system is proving ineffective in ensuring dispensing contractors are reimbursed, overall, what they pay for generics, that price transparency is inadequate, and that in the case of certain generics there is insufficient competition, leads to the conclusion that the NHS is not securing optimum value for money.
- 3.19 Some support for this comes from an assessment of the value chain for generics. NHS expenditure on generically prescribed medicines (net of discount deduction) appears to be very much greater than estimates of the turnover of the generics suppliers, with the addition of a reasonable wholesale margin, for the same period. Some of the difference will be attributable to branded medicines dispensed against generic prescriptions. However, the likelihood is that some part of the total represents value which is being lost to the NHS on the supply of unbranded generics. One commentator has suggested that the discount in the generics supply chain which is not identified by and clawed back by the reimbursement system amounts to some £90-130 million a year in England. We believe that the sum may be significant.
- 3.20 There is an argument that even if the deficiencies in existing arrangements could be overcome, they would still fail to deliver maximum value for money for the NHS because the health service's huge buyer power is split between a large number of smaller purchasers – community pharmacies and dispensing doctors. This is considered further in section 8, on central purchasing.

Summary

3.21 In summary, under present arrangements community pharmacies and dispensing doctors have continued to be able to supply medicines to patients. However, the arrangements also suffer from a number of significant weaknesses –

- the effectiveness of the reimbursement system in delivering value for money and ensuring community pharmacies are reimbursed what they actually spend on generics overall has been undermined, in particular by vertical integration between wholesalers and pharmacies
- reimbursement prices do not reflect true prices in the market and the resulting lack of transparency of prices does not enhance competition
- there is inadequate information for the Department about the performance of the system and, possibly, for those in the market or wishing to enter

3.22 In addition, there are questions about the extent of competition in parts of the market.

3.23 It could be said that, despite their limitations, the present arrangements have served the NHS well over the long term, that they contributed to a gradual decline in prices up to the end of 1998 and it would be wrong to base conclusions too heavily on the experience of 1999-2000. However, to take this view would be to underestimate the extent to which the turbulence of 1999 made the weaknesses of the reimbursement system plain for all to see. Whereas before some of those weaknesses may not have been perceived by all, now they are well known and therefore all the more likely to be exploited in future.

4. Future Trends in the Supply Chain

4.1 There are a number of trends in the generics market in the UK and globally which are likely to continue in the future and which any future arrangements will need to be robust against. These are –

- continued vertical integration between wholesalers and community pharmacies (vertically integrated pharmacies already make up about a third of the total) and, in future, perhaps also between manufacturers and pharmacies, coupled with increasing horizontal integration at the wholesale and pharmacy level
- increased consolidation and integration of generic markets and industries at both European and global level. To the extent that this increases ease of entry to the UK market for non-UK based companies and therefore contributes to greater competition it is an opportunity. To the extent that it makes it easier for existing suppliers to divert to more favourable overseas market their current supply to the UK market, thus potentially reducing competition, it is a threat.
- an increasing focus on the profitability of individual drugs and on margins, which may lead to more withdrawals from the market for low-margin drugs in future. This makes it all the more important that the Department has arrangements in place to identify products where there is a monopoly or near-monopoly of supply and can take measures to try and encourage new entrants

4.2 A conclusion that can be drawn from this analysis is that if existing reimbursement arrangements – and with them the value for money the NHS obtains from generics – have been undermined by the growth of vertical integration, then they are likely to be undermined even more seriously in future.

5. Options for the Future

- 5.1 We believe that our objectives for the supply and reimbursement of generics will best be served by a healthy and competitive generics market. That view has influenced our choice of options for the future – Where competition in supply exists, our strong preference is to rely on it as the best way to match supply to demand and to deliver prices and margins which bring the best value to the NHS and the taxpayer while allowing companies to make reasonable returns. However, where competition is lacking or fails, we need to be able to regulate the market to ensure stability and to protect the position of the NHS.
- 5.2 In addition, we believe any future arrangements should ensure that –
- the prices paid by NHS reflect real prices in the market
 - if we continue with a system where community pharmacies and dispensing doctors (or their associated companies) purchase generics on behalf of the NHS, they should continue to have incentives to seek out the best deal
- 5.3 At present we do not know with any precision the extent of competition in the generics market, though there is evidence that this varies from one preparation to another. Earlier this year we commissioned a further study from OXERA looking at how we can improve our intelligence about the market. We will draw on this in developing suitable indicators of competition and drawing up an assessment of competitiveness in the market. Information from this, coupled with the outcome of our discussions with interested parties, will determine the future balance between a regulated pricing and reimbursement system for generics and one based on competition.
- 5.4 The following sections put forward two new approaches – reform of present pricing and reimbursement arrangements and a move to central purchasing through competitive tendering – and consider the possibility of retaining present arrangements and rolling forward the current maximum price scheme. A number of other options for the future put forward by OXERA are also considered.

6. A Reference-based NHS Price Scheme with Regulation to Underpin It

6.1 The following paragraphs set out an approach to deliver the Government's objectives while retaining the structure of the existing arrangements – essentially an open market in supply, with community pharmacies and dispensing doctors (or their associated companies) purchasing medicines on behalf of the NHS.

The proposal in summary

6.2 The following arrangements would replace the existing maximum price scheme and reimbursement arrangements for community pharmacies and dispensing doctors –

- an *NHS price* for each presentation falling within the scope of the new arrangements would be calculated from the prices at which wholesalers bought product from PL-holders, with the addition of a wholesale margin set by the Government. The price information would be collected regularly and the NHS price updated monthly
- the reimbursement price for community pharmacies and dispensing doctors would generally be based on the NHS price
- a periodic margins review would be held to ensure that the wholesale margin continued to encourage efficient wholesaling and cost-effective purchasing by pharmacies, while allowing reasonable returns to wholesalers
- price controls would be imposed where there was either insufficient competition to ensure a competitively-derived price or where competition failed
- the arrangements would be backed by powers under the Health Act 1999

6.3 The following paragraphs give a more detailed description of the proposed arrangements and set out issues on which we would welcome views. In order to develop the proposals further, we now need information about the prices at which PL-holders sell to wholesalers from one month to another. Section 7 below sets out these preliminary information requirements and consults on them.

Which presentations would fall within the new arrangements

6.4 We envisage that information on the prices of sales from PL-holders to wholesalers would be collected for most, if not all, unbranded generic presentations and an NHS price set for them. ***We recognise that this could, potentially, mean the collection of information about several thousand lines. We would be willing to discuss the possibility of excluding presentations with the smallest net ingredient cost from the exercise and would welcome views on whether a selective or an all-inclusive approach would be easier for those providing the information.***

- 6.5 Circumstances in which price controls would be applied to these presentations and arrangements for setting the reimbursement price for community pharmacies and dispensing doctors are covered in more detail in the relevant sections below.
- 6.6 When new preparations or new presentations of existing preparations became available in generic form, they would become subject to the new arrangements and their NHS price would be constructed from prices in the market in the same way as for other preparations.

Information needed from the supply chain to calculate the NHS price

- 6.7 Calculation of a meaningful NHS price would call for timely, up-to-date and accurate information about the price at which products were sold by PL-holders to wholesalers and about sales volumes.
- 6.8 Information would need to be collected sufficiently frequently for the NHS price to reflect the latest changes in the market, but bearing in mind the need not to impose an excessive burden on the companies concerned. We envisage requiring information to be submitted monthly, in electronic form, to a central collection point. We would specify how details of individual transactions should be recorded and aggregated.
- 6.9 The information could, in principle, be collected primarily from either PL-holders or wholesalers (though in certain special circumstances – see paragraph 6.15 – we might require information from a different source to the primary one). ***We would welcome views on which primary source would be more appropriate.*** We would also need to reach decisions on whether to set a threshold (based, for example, on a company's turnover of generics) beneath which a company would be exempt from the information collection requirements. A key issue here would be ensuring that the information received covered both the widest possible range of generics and gave representative data for activity in the market.
- 6.10 It is important that the information we collect represents the true level of transactions between PL-holders and wholesalers and is not influenced by mark-ups resulting from trading between wholesalers. In the event that we decided to use wholesalers as our primary source of information, details of sales from one wholesaler to another would therefore be excluded from the exercise.
- 6.11 Regardless of what the primary source of information was, we would require all PL-holders and wholesalers to retain records of transactions for a certain period (probably two years) so that information from one can be checked against the other if necessary.

Setting the wholesale margin

- 6.12 The wholesale margin would be set at a level which fairly reflected the cost of wholesaling, gave wholesalers an incentive to operate efficiently and encouraged community pharmacies to seek out the best deal. It would also need to be constructed in a way which did not favour one segment of the generics market over any others, or require cross-subsidy from one product to another. A margin calculated as a percentage of the aggregated wholesale acquisition price might favour relatively high priced products (to the detriment of lower priced ones). An alternative would be a margin based on a flat fee per item. A combination of the two might also be used. The margin would be reviewed annually. ***We would welcome views on ways of applying the wholesale margin.***

Calculating the NHS price

- 6.13 The NHS price would be calculated monthly from the price information received from PL-holders or wholesalers. The information would be weighted to take account of the volume of transactions and an aggregate transaction price derived. The wholesale margin would be added to this to give the NHS price.
- 6.14 We would need to set the interval between the date of the purchases reported to us and the period of validity of the NHS price derived from them to reflect the stock turnaround times at the wholesale level as closely as possible. It might also be appropriate to use a moving average of price data (using several months' returns) to ensure that the NHS price reflected a range of stock turnaround times and also to smooth sharp fluctuations in price between one month and another. ***We would welcome views on what average turnaround time we should use to set the timetable for pricing and on whether and how a moving average might be used to calculate the NHS price.***
- 6.15 Arrangements might also be needed for special circumstances to ensure that the NHS price reflected true activity in the market. In particular –
- where agency schemes (under which a wholesaler acts as an agent for a PL-holder in return for fee) were in operation, we might need to require the PL-holder to provide information about the volumes and prices of sales to pharmacies for the period concerned as well as the fee paid to the wholesaler. This would enable an equivalent price of a transaction between the PL-holder and wholesaler to be constructed
 - where a PL-holder supplied pharmacies direct, we would require information about actual prices of supply to pharmacies and then deduct the set wholesale margin
 - here a wholesaler purchased from a PL-holder who was a subsidiary of the same company, so that the transaction was in effect an internal transfer, the price posted would reflect company accounting arrangements and might therefore not be directly comparable with the prices posted by others. Such prices might therefore be excluded from the calculation of the maximum price
 - companies submitting information would be required to indicate whether the prices posted reflected the net effect of the transaction, or whether there were other elements of the arrangements – for example rebates, free stock or volume discounts – which needed to be taken into account. Where the latter was the case, the price posted might be weighted to take account of such arrangements.
- 6.16 The calculation used to derive the NHS price will be developed further using hard data about sales volumes and prices which we intend to obtain from the supply chain.

Price controls to protect the position of the NHS

- 6.17 Our expectation is that where there is competition in the market for supply of generics this, along with the incentives for community pharmacies to seek out the best deal, should deliver a competitive and fair NHS price. But where competition turned out to be limited or non-existent, we would need other ways of protecting the position of the NHS.
- 6.18 In such cases we would impose price controls – probably in the form of a statutory maximum price of supply to community pharmacies and dispensing doctors – to ensure that prices did not rise unreasonably. They might be based on the NHS price at the start of the scheme or on an alternative appropriate baseline.

- 6.19 There could be cases where a price increase over and above the statutory maximum was justified – for example where substantial raw material cost increases had driven up production costs. In such cases we would not want to stand in the way of reasonable increases. We would therefore specify that any company which wished to set a price above the maximum would be able to do so with the Department’s agreement, following the submission of a justification. Where a dispensation was granted following such a submission it might remain in place for a certain period.

Verification of information

- 6.20 It would be important to ensure that the arrangements were, as far as possible, robust against flawed data (for example resulting from mistakes in what was posted). ***We would welcome views about procedures which companies should be asked to put in place to ensure that data submitted under the arrangements was authoritative.*** In addition, we would conduct regular checks on prices posted. We envisage –

- investigating increases in prices which were out of line with the trend in prices to check that these did not result from an error, such as incorrect keying in of data or the omission from the data of the effect of a rebate or volume discount
- random comparisons of information posted to us with corresponding information from the other party to the transaction might be carried out to verify the overall accuracy of data submitted. Independent audit of data might also be requested at random
- periodic comparisons of volume data submitted to us with data on volumes of product dispensed by pharmacy contractors and dispensing doctors to check that the companies from whom information was being collected continued to represent the bulk of the market.

Reimbursement of community pharmacies and dispensing doctors

- 6.21 The aim of reimbursement arrangements will continue to be to provide an incentive for community pharmacists and dispensing doctors to seek out the best deal, stimulating competition at all levels of the supply chain, while ensuring that, as a whole, they are reimbursed the net cost of their expenditure on dispensed items.
- 6.22 The reimbursement price would therefore be set in a way which best reflected the real market prices paid by pharmacies and dispensing doctors for each generically available preparation. In most cases we envisage that the NHS price – reflecting the latest market prices of unbranded generics – would be the most appropriate basis. However, there may be cases where a different basis would be preferable, for example where a branded product with suitably wide availability has a list price significantly lower than the NHS price.
- 6.23 Although we envisage collecting information for all packs of preparations in the scheme, we would not necessarily derive reimbursement prices for every pack. As now, we would most likely choose one or more packs per preparation on which to reimburse.

- 6.24 The reimbursement price for a given month's scripts would be posted on a dedicated web-site at the start of the month in question. Prices would also continue to be published in the Drug Tariff but, as now, printing times would mean that reimbursement prices applying to one month would be printed in the Tariff for the following month. Availability of current reimbursement prices on the internet would be of additional use to those contractors with internet access. The Government will make the whole of the Drug Tariff available on the internet in due course.

Arrangements for review

- 6.25 In line with the requirements of the EU Transparency Directive, an annual review of the arrangements would be carried out. This would include reviewing the sources of information and the mechanisms by which the NHS price was derived.
- 6.26 We would also carry out an annual margins review. A sample of reimbursement prices would be compared with wholesalers' selling prices and/or pharmacies' acquisition prices to see whether, overall, the wholesale margin reflected competition in the market, whether pharmacy contractors were being reimbursed their expenditure on generically available preparations and the extent of discount still available to them. We would only take account of prices which had been determined through genuine competition. We would therefore exclude from the review sales by wholesalers to community pharmacies owned by them, or purchases by community pharmacies or dispensing doctors from wholesale companies in which they had an interest. If necessary, the wholesale margin would be adjusted to reflect the findings of the review. ***We would welcome views on how we might best go about carrying out the exercise to ensure that we obtained a representative picture of community pharmacies' and dispensing doctors' acquisition prices.***

Statutory underpinning of the scheme

- 6.27 We would underpin the new arrangements with powers under the Health Act 1999. We would be open to setting up the arrangements as a voluntary scheme under section 33 of the Act. A statutory scheme under section 35 of the Act would be put in place in the event that we were unable to reach agreement on a voluntary scheme with bodies representative of those in the supply chain or to apply the new arrangements to any PL-holders or wholesalers who chose not to sign up to the voluntary scheme or consistently flouted it.
- 6.28 The statutory scheme would differ from a voluntary scheme –
- there would be less price flexibility
 - any representations for increases over the maximum would have to be made in accordance with requirements laid down in regulations. The regulations would also specify the process and time-scales
 - there would be scope for penalties to be imposed in the event of infringements of the scheme.

Transition to the new arrangements

- 6.29 We would aim to refine and test the scheme on the basis of firm market information before implementing it. The intention would be to introduce it simultaneously for all the presentations covered by it.
- 6.30 If current margins in the supply chain are modest then there should be little difference between current reimbursement prices (after taking into account the existing level of discount deduction) and those generated under the new arrangements and little need, therefore, for a transitional period. If, however, it became clear that current reimbursement prices are at a significant premium to those under the new arrangements, there might be a need to consider a transitional period to ensure that demand for product remained stable.

7. Consultation on Proposed Information Requests to Refine the Reference-based Scheme

- 7.1 We will take all views put to us into account in deciding whether to proceed with the scheme and – if so – in further developing the detail of the arrangements. The next stage of development of the scheme will also call for additional information from the supply chain.
- 7.2 This section of the discussion paper sets out our proposals for information collection and formal consults interested parties on them under powers in section 36 of the Health Act 1999.

A full year's data on sales and sources of manufacture

- 7.3 This discussion paper makes clear (see paragraph 5.1) that where there is competition in the market for supply of generics this should help deliver a competitive and fair NHS price under the reference-based scheme, but where competition turns out to be limited or non-existent, we would impose price controls to ensure that prices did not rise unreasonably. We need to establish the extent of competition in the market so that we can decide which preparations should be subject to price control in a reference-based scheme.
- 7.4 We therefore propose to collect information, under powers in section 36 of the Health Act 1999, to give us an accurate picture of market shares at the manufacturing, PL-holding and wholesale level. Such information will also help inform an assessment of where the NHS might be most vulnerable to supply difficulties.
- 7.5 The information we propose to collect will additionally help us assess the size of the gap between market and current reimbursement prices and inform arrangements for the transition to any reference-based NHS price scheme.
- 7.6 The proposed information requirements are in most respects equivalent to those we were proposing to impose for the year 2000 under the existing maximum price scheme. They also draw on work undertaken by OXERA on our behalf.

Who would be required to provide information

- 7.7 We propose to collect information from all PL-holders and wholesalers with sales of unbranded generics of over £1 million. We consider this threshold necessary to ensure we obtain a complete picture of competition in the market for each preparation covered by the exercise.

Information that would be required

- 7.8 We propose to require the submission of the following information –
- *from PL-holders:* for each presentation, information on the total volume and value of sales to wholesalers for the year September 2000 to August 2001. For each such presentation, where the finished product was bought in by the PL-holder and not manufactured by him we also propose to collection information about the source of manufacture and purchase volumes and values

- *from wholesalers:* for each presentation, information on the total volume and value of sales to community pharmacies and dispensing doctors for the year September 2000 to August 2001.

7.9 We propose to draw on experience of the 1999 data collection exercise in setting out the details of the scheme in order to ensure that the returns are consistent and give an accurate reflection of the market. For example, we propose to require that –

- returns from PL-holders should also be required to identify and explain transactions with community pharmacies and dispensing doctors made under agency schemes
- transactions which are internal transfers between two subsidiaries of the same parent should be identified as such;
- returns should take account of and explain any additional discounts or rebates given as part of a transaction
- returns should exclude transactions relating to product for export, for non-NHS use and for supply to NHS hospitals

7.10 We propose that each return should be accompanied by an audit certificate to confirm its accuracy.

Presentations to be covered by the return

7.11 We propose to require information to be submitted in respect of all presentations of unbranded generic preparations with a net ingredient cost (NIC), based on the latest information available, of £250,000 or more. This amounts to around 370 preparations.

Proposed time-scale for submission of information

7.12 Subject to the outcome of the consultation exercise and making of the necessary regulations, we intend to write to PL-holders and wholesalers, probably in October, with details of the information required and to obtain confirmation of whether sales exceed the £1 million threshold.

We would welcome comments from interested parties by Friday 14 September 2001 on all aspects of this proposed data collection. We would also welcome comments to enable us to refine the section of the partial Regulatory Impact Assessment which relates to the proposal (see paragraph 8.4 onwards of Annex C).

Monthly sales/purchase data for a sample of preparations

7.13 The second area where we need further information is about transactions, month by month, between PL-holders and wholesalers, for a sample of unbranded generics. This will enable us to construct the methodology for calculation of the NHS price for the reference-based NHS price scheme.

7.14 We propose to discuss the information request with interested parties. If sufficient of those in the supply chain are prepared to work with us to provide the information, we would be willing to proceed through a voluntary arrangement. However, this consultation relates to statutory arrangements under powers in section 36 of the Health Act 1999 and will proceed with these in the event that a satisfactory voluntary approach is not agreed.

7.15 The details of the proposed information request are as follows.

Who would be required to provide information

7.16 We need sufficient returns to obtain a comprehensive picture of the prices in the market. We may therefore need to collect information from all PL-holders and/or wholesalers with annual sales of unbranded generics for NHS use in the community of over £1 million, based on the latest information available. However, we would be prepared to consider a higher annual sales threshold if we are convinced, following consultation, that it will provide the information we need.

Information that would be required

7.17 For each presentation of a sample of unbranded generic preparations, we propose to require the submission, in electronic form, to the PPA, of PL-holders' monthly sale volumes and prices to wholesalers and/or wholesalers' monthly purchase volumes and prices from PL-holders. ***We would welcome views from interested parties on whether we should collect primarily from PL-holders or wholesalers.*** Subject to the outcome of consultation, we do not rule out collecting information from both levels of the supply chain to enable us to cross-check from one source to the other and supplement any incomplete returns. If the decision is only to collect from one level of the supply chain, we propose to require records of such transactions to be retained by the company concerned for a period of at least a year and to be made available to the Department on request to enable cross-checking to be carried out.

7.18 We want the sample data to give us the most accurate picture possible of sales values and volumes, month on month, while imposing the minimum necessary burden on companies. One option would be to require data to be submitted recording each separate sale or purchase of a given presentation by a company during each monthly period in question. As an alternative, we would be willing to consider receiving data aggregated to give single sales and volume figures for each presentation per month provided we have confidence that the means of aggregation used by companies are consistent and robust. ***We would welcome views from interested parties on which approach would be most appropriate.***

7.19 We propose to set similar ground-rules for submission of information to those for the full year's data collection exercise, set out in paragraph 7.9 above.

7.20 We may also require audit certificates to be submitted periodically or on an occasional random basis to confirm the accuracy of the data

Presentations for which returns would be required

7.21 We propose that returns should be submitted for all presentations of around 30 preparations. A proposed list of preparations is at *Annex B*. The sample has been drawn up to give a broadly representative cross-section of unbranded generics. No preparations which are also available over the counter have been included to eliminate the possibility of sales for over the counter use being included in the returns.

Timetable for data collection and period to be covered by the returns

7.22 Subject to the outcome of consultation and making of the necessary regulations, we propose to write to companies setting out the information requirement in detail.

- 7.23 We propose to require the submission of monthly data, probably starting with that for September or October 2001 and continuing for at least several months. The first few months' data will be required retrospectively. We propose that data relating to months following the coming into operation of the scheme should be submitted to the PPA within two weeks of the end of the month in question. We intend to reach a decision on whether to end the data collection exercise in the light of the first few months' information submitted and following a decision on which longer-term option to proceed with. If a decision is taken to proceed with the reference-based NHS price scheme, we envisage that the data collection will continue up to the implementation date, when it will be expanded to cover all presentations falling within the scope of the scheme.

We would welcome comments from interested parties on all aspects of this proposed data collection, including the questions identified in the text, by Monday 22 October 2001. We would also welcome comments to enable us to refine the section of the partial Regulatory Impact Assessment which relates to the proposal (see paragraph 8.8 onwards of Annex C).

- 7.24 The longer consultation period for this proposal, compared to that for the proposed collection of a full year's data, reflects the fact that this is a new proposal, whereas the proposal for the collection of a year's data is in most respects equivalent to the requirements imposed under the maximum price scheme, and consulted on in Spring 2000 (apart from the addition of information about product bought in from third parties).

Conclusion

- 7.25 We will take comments received during the consultation into account in finalising the information requests. We also propose to hold discussions with representatives of those who would be affected by the requests to ensure that we identify the best way of running the requests – for example the design of templates for returns or the description of presentations – so as to obtain the most accurate results and minimise the work involved.

8. Central Purchasing Through Tendering

- 8.1 Under present supply arrangements for generics (and for other pharmaceuticals used in the community) the NHS has delegated the purchasing function to community pharmacies and dispensing doctors. The effect has been to fragment the health service's substantial purchasing power which arises from the fact that, for most generics, it is the UK's only or dominant purchaser. A move away from fragmentation to a system of central purchasing should enable the NHS to make better use of its purchasing power.
- 8.2 OXERA put forward a number of options for harnessing the NHS' purchasing power through various forms of competitive tendering. This section concentrates on a proposal that the Department should let contracts, by competitive tender, for the exclusive right and obligation to supply a specified volume of a specified preparation(s) at a specified price to community pharmacies and dispensing doctors for the purpose of NHS dispensing. OXERA also explored the possibility of tendering for buffer contracts and for framework contracts for supply (with no volume commitments). We do not propose to take these options further.
- 8.3 The following paragraphs set out how a system of tendering for supply might be constructed to deliver these advantages and overcome the potential disadvantages.

Which segments of the generics market would be put out to tender

- 8.4 We believe that competitive tendering could be an appropriate way of securing supply in all segments of the generics market. For example, tendering could be used for –
- preparations where there appears to be a competitive market among suppliers but where the existing reimbursement system may not be delivering the full benefit of that competition to the NHS
 - preparations where there appears to be little or declining competition and where tendering might offer sufficient certainty as to demand over a period to encourage new entrants into the market. In some cases, it could be appropriate for a tender exercise to be open to suppliers who are still in the process of obtaining a PL and to make award of the contract conditional on their completing the licensing process in a certain time
 - preparations where there is only one supplier and a legally binding contract would give the NHS greater security of supply over the period of the contract than current arrangements, under which a supplier could take a decision – on economic grounds – simply to terminate supply.
- 8.5 Tendering would be appropriate for preparations with a substantial net ingredient cost (NIC) as it would be for those with a smaller NIC. However, we would clearly need to take into account the overheads incurred in carrying out a tender exercise in deciding whether to proceed with tendering for preparations with the lowest NIC.

The construction of the contract for supply

- 8.6 We would let contracts for the right to supply a given preparation to community pharmacies and dispensing doctors for dispensing against generically written prescriptions for a given period. Contracting suppliers would sell product to wholesalers for exclusive use in the NHS. Wholesalers would then sell to community pharmacies and dispensing doctors on the same basis. For their part, the contractor would have an obligation to supply a given volume of product (a range of minimum and maximum volumes would be set). In this respect the arrangements would differ significantly from those for supply to the hospital sector, where the contract itself imposes no requirements as to volume of product.
- 8.7 The ability of contracts to deliver a given volume of demand would depend on contract supply being purchased by the great majority of community pharmacies and dispensing doctors and on the ability of the Department to forecast demand accurately. Our expectation is that the wide availability and advantageous price of the contract supply would ensure that it had a dominant position in the market for the preparation concerned. However, we would also put measures in place to ensure that the NHS got the full benefit if any product that wholesalers obtained from another source had a lower price than that of the contract supply.
- 8.8 OXERA's work indicates that it should be possible to construct sufficiently reliable volume forecasts to inform contracts. Contracts could also include provisions setting out the terms under which additional volumes of product over and above the contracted amount could be secured by the Department in the event of an unexpected increase in demand. The contract would specify that the contractor was paid for the minimum volume specified even if – through no fault of his own – demand did not reach this threshold. It would also set out penalties to apply in the event of default on supply. These would compensate the NHS for the extra cost of having to use the brand equivalent or open up an alternative source of generic supply at short notice.
- 8.9 The winning contractor would be required to sell product into the supply chain at the price agreed in the contract. The expectation would be that he would absorb most subsequent fluctuations in cost. However, the contract might include provision for price flexibility in extreme circumstances beyond the contractor's control, for example a sudden leap in raw material prices.
- 8.10 If we proceed with tendering for supply to the community there would be a strong case for extending it also to cover supply to the hospital sector. Supply to the hospital sector is already put out to tender, but the arrangements differ in certain respects from those proposed here and we would need to consider how they could be best aligned.

Which products the tender exercise would cover

- 8.11 A tender exercise could be designed to cover a single generic preparation, all preparations of a given chemical entity or a basket of products. Our preference would be to tender preparation by preparation. Such an approach should –
- provide price transparency for each preparation, giving information about supply conditions
 - enable several suppliers to remain in the market for a given chemical entity, opening the way for all to tender in subsequent tender exercises and reducing the risk of monopolisation
 - make it easier for a new entrant to come into the market by minimising the initial commitment he would need to make (in comparison with a tender involving a whole chemical entity or basket of products)

- 8.12 Tendering preparation by preparation could result in the loss of some economies of scope, for example from the ability for a supplier to purchase raw materials for use for a range of preparations. However, there would be nothing to *prevent* a supplier from bidding to supply all generic preparations of a given chemical entity.
- 8.13 Neither of the two other approaches would deliver price transparency for individual preparations. Additionally, letting a single contract for the supply of all generic preparations of a chemical entity might increase the risk of monopolisation by making it more likely that there would be smaller pool of contractors who would have the capability to supply in future and might therefore take part in future tender exercises. ***We would welcome views on whether tendering preparation by preparation is the most suitable approach.***

Who would be eligible to bid

- 8.14 Tenders would be open to anyone who could meet certain preconditions. These would generally include holding a valid Produce Licence (PL) or having a firm agreement with another party who held a PL, having confirmed access to manufacturing capability with the necessary regulatory approval and back-up capability to give greater security of supply, and meeting certain requirements as to financial status.
- 8.15 It is possible that, in cases where there is little or no competition in the market for a given preparation, we would open the bidding to those who did not yet have a valid PL but were in the process of applying for one or were considering doing so. In such circumstances, a bidder who did not already hold or have access to a PL might be awarded the contract on condition that he completed the licensing process within a certain period of time.

The tendering process

- 8.16 The tendering system would have to be constructed in a way which minimised the risk of market concentration. If a single tender for the whole supply of a given preparation (or, even more so, product) was let for a long period, other supplies of the same preparation might leave the market. The result, over the medium term, might be a reduction in competition, higher prices and reduced security of supply.
- 8.17 One way of overcoming this, put forward by OXERA, would be to let contracts by means of a system of staggered tendering. For each preparation, total forecast demand would be divided into a certain number of equal tranches. Contracts for each tranche would be let at intervals. Every contract would have a duration of two years. Thus, once the arrangement was up and running at any one point there would be a number of different contracts running, and every few months any supplier would have the opportunity of tendering for a tranche of supply. Appropriate lead times would be built in to the timetable to enable the winning bidder to make the necessary preparations for production.
- 8.18 As a further step to ensure that monopolisation did not occur, the criteria for assessing tenders could be set so that at any one time there were always at least two different suppliers (who relied on different manufacturers) with contracts for supply of a given preparation. To take an example, if the contracts for supply of a number of consecutive tranches of product were won by the same supplier, the tender criteria for the next tranche would specify that the Department would normally consider it not to be most economically advantageous to award the contract to an existing supplier.
- 8.19 Such an arrangement would –
- reduce the risk of monopolies arising from a single supplier winning the sole right to supply the market for a longer period

- enable suppliers who have lost one tender to tender for a contract only four months later
- enable the Department to adjust supply in response to changes in demand every four months by revising the volume tendered for in the next tranche
- however, it is possible that suppliers who lost several consecutive bids for a tranche contract would then leave the market, reducing the pool of potential future bidders

8.20 Another approach would be to let contracts, simultaneously, for supply by different suppliers of a number of unevenly sized tranches of the total demand for a given preparation (say 60%, 30% and 10%). Thus at any one time there would be at least three suppliers in the market and a reasonable prospect that, at the end of the two-year contract period, there would be at least three suppliers in a position to tender for the next set of tranches. Possible disadvantages of this option would be that the different sizes of tranche tendered would mean differing economies of scale and therefore result in big variations in contract prices. This would produce an incentive for purchase of the largest (and probably lowest unit-priced) tranche and disincentive for purchase of the smallest (and probably highest unit-priced), putting volume commitments at risk.

We would welcome views on which of these options would be most appropriate and on any alternative proposals for minimising the risk of market concentration.

8.21 A further objective would be to ensure that price did not become the sole determinant of who won a tender, to the exclusion of service. We would require all those who bid for contracts to demonstrate that they could meet certain minimum standards of service, for example having a back-up source of manufacture in the event that the main manufacturer ran into production difficulties and do not have a record of defaulting on earlier contracts.

Distribution arrangements

8.22 Drawing on OXERA's work, there are two broad approaches to distribution which could be used.

Distribution by any wholesaler

8.23 Under this option the distribution of product sourced through contracts would be open to any holder of a wholesale dealer's licence. Wholesalers would be able to buy supply from a contract supplier and sell on to community pharmacies and dispensing doctors and the latter would remain free to use the wholesaler of their choice. The Department would set a reimbursement price, based on the contract price plus a distribution margin, and wholesalers would be able to compete by offering discounts off the margin and on service. (Various options for payment and reimbursement under contracting are set out in more detail in the next section.)

8.24 A key issue is how such an arrangement for distribution could be squared with helping deliver equal and predictable demand to the different tranche suppliers. We would structure the payment flows in the supply chain in such a way that they did not make it financially more attractive for wholesalers to purchase from one tranche supplier than from another. However, it is questionable whether this would in itself be sufficient to ensure even demand. There might still be other reasons for wholesalers preferring one tranche supplier to another, for example the service or terms of settlement offered. We might therefore also –

- specify in contracts that tranche suppliers could only sell in response to wholesalers' orders allocated to them by a clearing house. The *clearing house*, which would be set up by or on behalf of the Department, would help ensure that demand was spread evenly over all tranche suppliers, *or*
- specify in contracts that each tranche supplier's monthly sales for NHS use should not exceed amounts set out in a schedule which reflected the range of total contract volume. The schedule could be revised periodically to take account of any changes in forecast demand

We would welcome views on whether either of the approaches would be helpful as a way of helping achieve even and consistent demand across the tranches.

Letting a contract for distribution

- 8.25 The second option would involve the Department letting contracts for distribution under which a wholesaler would undertake to buy and distribute the entire supply of a given preparation. Contracts would be awarded on the basis of the distribution fee and service offered (for example ability to ensure swift delivery around the country).
- 8.26 The contract for distribution might specify that the contracting wholesaler would undertake to purchase broadly equal quantities from each of the tranche suppliers, thus giving even and consistent demand across the tranches.
- 8.27 An assessment of the options set out above against the main requirements the distribution arrangements would need to satisfy is at Table 1 below.

Table 1		
	Distribution by any wholesaler	Distribution by designated distributor following tender exercise
Promoting an efficient distribution structure	Yes	Questionable: would mean different distribution arrangements for different products
Transparency with respect to margins and vfm	Would depend on Department's ability to obtain information about distribution margins and adjust the standard margin	Would reveal prices at which wholesalers prepared to distribute and help obtain most competitive price
Not hampering achievement of even and consistent demand from tranche suppliers	Best if clearing house arrangement used; up to a point if tranche suppliers limited to maximum monthly sales in line with contract	Yes
Straightforward for community pharmacies to operate	Yes	For some community pharmacies, would mean a different distributor for the tendered product to their usual one, increasing numbers of orders and deliveries

We would welcome views on the distribution options. A further possibility would be to have single contracts covering both supply and distribution and we would welcome views on whether this would present any significant advantages over the main options set out above.

Payment and reimbursement arrangements

8.28 We have examined a number of possible approaches to payment and reimbursement under tendering. Assuming that we let contracts for supply in a number of tranches for each preparation and accept different contract prices per pack, our preferred payment and reimbursement option is as follows –

Option 1: Wholesalers pay tranche suppliers a *Category T* price (which could be set at the mean of the tranche prices or at the level of the lowest); wholesalers deliver to pharmacies and charge the Cat. T price plus a distribution fee; pharmacies are reimbursed the Cat. T price plus a distribution fee (set by the Department) following receipt of the script at the PPA; the Department periodically settles the difference between the Cat. T price and the contract price with each tranche supplier, basing its calculations on sales volume information from the clearing house (if there is one) or the expected volume of sales for that period (if there is not), with periodic checks on actual sales volumes. If the Cat. T price was at the level of the lowest tranche, the settlement would only involve payments by the Department to the contractors; if the Cat. T price was a mean, settlement might involve such payments or repayment of sums paid by wholesalers to contractors in excess of the contract value

8.29 If we let contracts for supply of a given preparation through a number of *simultaneous* tranches, an alternative approach would be to derive a *single* contract price from the prices put forward in the successful bids. Contracts would then be signed on the basis of this single price. With a single price for all tranche suppliers, payment and reimbursement arrangements would then operate as follows –

Option 2: Wholesalers pay tranche suppliers the single contract price on receipt; wholesalers deliver to pharmacies and charge the tender price plus a distribution fee; pharmacies are reimbursed the single contract price plus a distribution margin (set by the Department) following receipt of the script at the PPA

8.30 An assessment of these options against the main requirements they would need to satisfy is at Table 2 overleaf.

Table 2		
	Option 1	Option 2
Consistent with principle that each player paid following delivery of product to next part of chain	Yes	Yes
Straightforward for community pharmacies to operate	Yes	Yes
Robust against abuse	Provided that Cat. T price is close to contract prices. The lower it is, the greater the risk of product being sold on outside NHS	Yes
Value for money	Would be undermined if product is sold on with the result that the NHS pays for product which is not dispensed against NHS prescriptions	Suppliers might be reluctant to tender if they could not predict the price they would be paid under a contract or might tender high as an insurance against the contract price being driven low by low bids from others. Either way some of the benefits to the NHS could be lost
Reimburses fairly	Yes	Yes
Compatible with supply tendering options	Yes	Only feasible if tranches let simultaneously
Compatible with distribution options	Yes	Yes

- 8.31 The choice of payment and reimbursement arrangement would be influenced by the form of tendering selected. If we opted for staggered tendering Option 1 would be the clear front-runner (it is difficult to see how a single contract price would be feasible under such circumstances). If we opted for simultaneous tendering the choice would be more finely balanced. ***We would welcome views on the matter and proposals for other options.***

Conclusion

- 8.32 The move to central purchasing through tendering would be a major step. If we decide to take this route we would want to start with a modest number of contracts. So, in practice, tendering would operate in parallel with a separate set of arrangements for the purchasing and supply to the NHS of other unbranded generics. It would also allow us to refine the arrangements as we learnt from the experience of the early tender exercises.

9. Existing Reimbursement Arrangements Coupled with the Maximum Price Scheme

- 9.1 A further option would be to continue to roll forward present arrangements for reimbursement of community pharmacies and dispensing doctors coupled with the present maximum price scheme. Under such an arrangement the reimbursement price could, in theory, continue to be set by competition at any level up to the maximum price. This would be consistent with the principle that the price the NHS pays should be set competitively.
- 9.2 A review of the maximum price scheme has been launched at the same time as this discussion paper. Its outcome has to be announced by 21 October 2001. Since we do not expect to have completed the process of developing, consulting on and introducing longer-term arrangements by then, we propose, subject to the outcome of the review, to roll the scheme forward at least once. The question is whether it should form the basis of a long term approach.
- 9.3 The scheme has brought stability to the market and is on course to deliver savings to the NHS which, in a full year, should reverse the effect of price increases in 1999. However, relying on existing reimbursement arrangements and the maximum price scheme for the longer term would not address a number of the limitations of existing arrangements. In particular, we would continue to have to rely on list prices as the basis for reimbursement. Over recent months most list prices posted by suppliers have clustered at or just below the maximum price, producing reimbursement prices fairly close to the maximum and suggesting that competition – where it exists – is on the basis of discounts off list prices. Yet even where there is real competition in the market and real prices are significantly lower than list prices, the limitations of the discount inquiry mean that the NHS will not be reaping the full benefit. In the event that the decision was taken not to proceed with a different option for the longer term, we would need to consider how the maximum price scheme could be made to address these concerns.

10. Other Options put Forward by OXERA

- 10.1 OXERA proposed and assessed a number of other options for reform or radical change of existing arrangements. These are listed below.

Recouping excess profits made in 1999

- 10.2 OXERA discussed the option of a windfall tax on excess profits made in 1999. OXERA's assessment was that introducing a measure which retrospectively hit returns in the supply chain would send a message to companies that such a step might be repeated in future and could discourage investment in the generics sector in the UK, reducing competitiveness in the longer term. It would also be a difficult undertaking given the commodity nature of the market.

Reform of reimbursement

- 10.3 *Expansion of the Drug Tariff basket:* the aim of this would be to bring Tariff prices more closely into line with those paid by community pharmacies and dispensing doctors. It is possible that adding to or even replacing some of the current basket with the major specialist generic distributors could reduce reimbursement prices in the short term. However, examination of the price lists of non-basket suppliers over the past year suggests that many already set high list prices and then use different price lists or offer significant discounts to community pharmacies and dispensing doctors. Once a supplier's price were included in the basket he would also have an incentive to maintain high list prices with the aim of contributing to a relatively high reimbursement price which would then either reduce the overall level of competition or allow a continuation of competition based on discount.
- 10.4 *Removal of Category D:* abolition of Category D accompanied the introduction of the statutory maximum price scheme in 2000.
- 10.5 *Reform of the discount inquiry:* for independent pharmacies, OXERA propose a move to a system where total expenditure on medicines in a given year is compared with the amount paid out by the PPA as reimbursement. For integrated pharmacies (including Boots), OXERA propose that actual prices paid should be identified by requiring the submission of the integrated wholesaler's purchase prices and adding to it an allowable wholesale margin (based either on margins elsewhere, say under the PPRS, or on an assessment of wholesalers' costs).
- 10.6 The proposal for integrated pharmacies is close to the proposal for a reference-based NHS price scheme (described in section 6), with its reliance on wholesaler acquisition prices as a basis for the reimbursement price and an annual margins review drawing on information about competitively derived wholesale margins. We do not see the proposal for independent pharmacies as feasible in the short-term, though over time improved information flows between community pharmacies and the PPA and IT developments within community pharmacies may make it at least worth considering.

Improving information flows

- 10.7 OXERA propose that the Department could obtain a better picture of the working of the market and of true prices and stock-holdings through a range of information requirements and through greater use of IT systems. The Department agrees that it lacks adequate information to enable it to achieve its objectives relating either to value for money or to ensuring secure supply of product. The additional information which would be gathered under the reference-based NHS price scheme would go some way towards overcoming this. The Department does not propose, however, to require endorsement of all prescriptions on account of the resources this would consume at both pharmacy level and at the PPA and the difficulties with auditing the information provided.

IT solutions

- 10.8 We agree with OXERA that developments in information technology have the potential to alter communications within the medicines supply chain and to create new possibilities in relation to information exchange.
- 10.9 The electronic transfer of prescriptions (ETP) between GPs, community pharmacies and the Prescription Pricing Authority is one of the key elements of “Pharmacy in the Future”, the programme for pharmacy announced by Ministers in September 2000. Electronic prescriptions will be routine by 2004, with electronic transfer of data taking place in the large majority of cases by 2008 at the latest. Pilots will start later this year. When ETP is closer to being established we will consider whether it opens up new opportunities for reimbursement. But, as is clear from the timetable, it would be premature to consider these issues now.
- 10.10 As far as communications between suppliers and the Department or PPA are concerned, we envisage making full use of electronic links for transmission of the data which would be needed to set the NHS price under the reference-based NHS price scheme. We will discuss with wholesalers and PL-holders the form that such links should take.

Structural change

- 10.11 OXERA put forward a number of proposals to enable the Department to obtain more accurate information about the true prices paid by community pharmacies, in order to underpin accurate reimbursement, by introducing accounting or structural separation between integrated pharmacies and wholesalers. The Department agrees that vertical integration has undermined the effectiveness of the reimbursement system. Our options for change reflect this. But we believe that to proceed by forcing through changes in the relationships within the supply chain would be complex, time-consuming, could cause disruption to community pharmacy and – given the many forms vertical integration could take – might well prove unsuccessful.

11. Comparison of Options Against The Government's Objectives

11.1 Table 3 compares the two new options and the further option of rolling forward the present maximum price scheme against the Government's objectives for the medicines supply chain and the additional criteria listed in section 2. For completeness, the options are also compared with the option of going back to arrangements prior to August 2000.

Table 3				
Objectives	Reference-based NHS price scheme	Central purchasing through tendering	Existing arrangements (pre-August 2000)	Continue maximum price scheme
Quality of service to patients	Better price information for pharmacies and supply information for Gov't may help	Binding contracts and predictable demand product should improve security of supply. But if tendering produced a single dominant supplier any major production problems could cause difficulties	Yes, but problems evident in 1999 not addressed	As for existing arrangements
Minimise cost to NHS of distribution networks	Yes	Depends on option. Different wholesalers for different contracts could reduce current economies of scale but may still offer a good price to NHS	Yes, but NHS may not be reaping benefits	As for existing arrangements
Reimburse community pharmacies closely	Yes, provided accurate sales information reported by companies and w/sale margin set at realistic level	Yes, provided any w/sale margin set at realistic level	No – many list prices out of line with true prices; discount inquiry has limited effect	Many list prices pegged at max. but some probably remain out of line with true prices
Transparent prices	As above	Yes	No – as above	No – as above
Support a competitive market	Better information for Gov't to assess position and target measures to encourage entry	Yes, provided contracts let in a way which minimises risk of monopolisation	Lack of information to prove either way	Lack of information; if any max. prices are too low competition may reduce over time

Table 3 continued				
Objectives	Reference-based NHS price scheme	Central purchasing through tendering	Existing arrangements (pre-August 2000)	Continue maximum price scheme
Secure VFM for the NHS	Should improve on current position provided accurate information reported	Would allow more efficient production scheduling, hence lower costs Should improve on current position, especially if suppliers make realistic bids and system is robust against abuse	No – given above deficiencies	Has delivered savings for NHS. Controls in place to reduce risk of repeat of rapid price increases of 1999
Robust against future trends	More so than current arrangements provided companies do not devise new forms of vertical integration to get round controls	More so than current arrangements	Likely to expose deficiencies even more	As for existing arrangements
Implementation cost	Costs to companies of supplying regular information and to Gov't of setting up systems for collection	Various costs to Gov't of setting up and running tendering. Benefits should more than outweigh cost to companies of bidding	–	Companies carry some costs of compliance with information requirements

- 11.2 Our view is that reverting to existing arrangements *prior* to the introduction of the maximum price scheme would fail substantially to meet the Government's objectives.
- 11.3 The reference-based NHS price scheme and central purchasing through tendering both have the potential to deliver a better performance against the Government's objectives than present arrangements. Putting a value on the potential savings for the NHS is difficult. Tendering and the reference-based NHS price scheme have the potential to reduce any excessive margins currently being earned in the supply chain. The scale of available savings and where in the supply chain they might come from is unclear (though one commentator has estimated the gap between manufacturers' prices plus a reasonable distribution margin and what the NHS in England pays at about £90-130 million). Each of the options for change would also involve some implementation costs, though these should be outweighed by the savings available.
- 11.4 The maximum price scheme has been effective in stabilising the market and reversing the effect of the price increases of 1999. It is already in place and proven. But it does not tackle some of the underlying deficiencies in existing arrangements and as such has limitations as a longer term option. Subject to the outcome of the review, we intend to roll it forward in order to give us time to complete the process of discussing and deciding on a longer term option. But we would need to find ways of addressing its limitations before we could rely on it beyond this period.

- 11.5 We have not expressed a preference for one or other of the main future options in this paper. We wish to obtain the views of interested parties before reaching a decision and will consider seriously any new proposals which meet the Government's objectives. A combination of options is also possible. For example, if we decided to proceed with tendering, we would start with a modest number of preparations and, for preparations not subject to tender, either roll forward the maximum price scheme, subject to some revisions, or introduce the reference-based NHS price scheme. The pace of the roll-out of tendering would be influenced by the success of whatever other arrangements were in place in meeting the Government's objectives as well as on the success of the early tender exercises.
- 11.6 In choosing between the options the Government will also take into account their regulatory impact on companies, including factors such as the cost of providing information. A partial Regulatory Impact Assessment (RIA) is attached to the paper at *Annex C* and we would welcome any initial views on it. We will develop it in the light of the discussion process and further work on the options and it will form part of the Government's consultation package on its proposal for the way forward.
- 11.7 The proposals are also likely to have an impact on community pharmacy contractors. The Government is committed to maintaining good access to community pharmacy and to developing pharmacy in line with the aims set out in *Pharmacy in the Future*. We will take account of the views of the pharmacy profession in reaching decisions about the way forward for the longer term.
- 11.8 Whichever option for the future is selected, the Government sees a need to obtain a better picture of the state of competition in the market. The approach to this will be influenced by decisions on future options. We will draw on OXERA's latest work. The Government is also committed to ensuring that a good range of both established and new generics is available and will consider what more can be done to encourage entry to the market. It is taking these objectives into account in its approach to the future development of licensing and intellectual property rules in the 2001 review of EU licensing and in its input into the EU High Level Group on Innovation and the Provision of Medicines.

12. Application of the Proposals to the Devolved Administrations

- 12.1 The supply of generics to the health service and reimbursement of community pharmacies and dispensing doctors in Scotland, Wales and Northern Ireland is the responsibility of their respective devolved administrations. In practice, the main elements of arrangements for the purchasing and supply of generics to the health service are broadly the same in all parts of the UK. However, Scotland and Northern Ireland operate their own reimbursement scheme, while England and Wales have a joint system.
- 12.2 The analysis of present arrangements and conclusions reached apply to all parts of the UK and are shared by the Department of Health and the devolved administrations. There is also agreement between them over the possible options for the future. That said, there would be some differences in the way these would be taken forward –
- if the decision is to proceed with a reference-based NHS price scheme, we envisage that the setting of the NHS price and any other elements of the scheme which would be underpinned by powers in the Health Act 1999 would be implemented on a UK-wide basis but that, again, reimbursement would continue to be operated separately for England and Wales, Scotland, and Northern Ireland
 - if the decision is to proceed with tendering for supply to the NHS, it would be for the UK Government and the devolved administrations to decide whether to run a single tender exercise or separate ones for England and Wales, Scotland, and Northern Ireland
 - if the decision is to continue to roll forward present reimbursement arrangements coupled with the present maximum price scheme in some form, we envisage that the statutory maximum price would continue to be set on a UK-wide basis and reimbursement would continue to be operated separately for England and Wales, Scotland, and Northern Ireland
- 12.3 The Scottish Executive and the Department of Health, Social Services and Public Safety in Northern Ireland are separately issuing the proposals in this discussion paper to representatives of community pharmacy contractors and GPs and to others with an interest in the health service in Scotland and Northern Ireland.

13. The Discussion Process and Subsequent Steps

The discussion process

- 13.1 The Government is committed to taking the views of interested parties on future arrangements before reaching a decision on the way forward. We have already received the views of some in the supply chain. This paper is intended to launch a more comprehensive process of discussion. We would welcome views in writing. We would also be willing to meet those who wish to discuss the issues with us or to answer questions. We will be contacting representative bodies with an interest in the matter to offer them a meeting.
- 13.2 Views are invited *by Monday 22 October 2001* on –
- the assessment of existing arrangements
 - the options put forward in the paper
 - any other options which have the potential to meet the Government's objectives
 - specific questions highlighted in the paper
 - the partial Regulatory Impact Assessment (RIA) at *Annex C*
- 13.3 Views are also invited in response to the formal consultation on the proposed information collection exercises to enable us to develop and assess the reference-based NHS price scheme –
- *by Friday 14 September 2001* in the case of the proposed collection of a full year's data for 2000-01 on sales and sources of manufacture (section 7 of the discussion paper) and the assessment of its impact on business (set out in the RIA)
 - *by Monday 22 October 2001* in the case of the proposed collection of monthly sales/purchase data for a sample of preparations (section 7 of the paper) and the assessment of its impact on business (also set out in the RIA)
- 13.4 Comments should be sent by e-mail to generics@doh.gsi.gov.uk or by post to Generic Medicines Project, room 147 Richmond House, 79 Whitehall, London SW1A 2NS.

Timetable following the end of the discussion process and consultations

- 13.5 Subject to the views expressed during consultation, we will proceed quickly to put the information collection exercises in place. The information received will help in the assessment of the reference-based NHS price scheme and in the choice of option for the longer term.

- 13.6 Ministers will then reach decisions on the way forward for the longer term . We will consult formally on any proposals before they are implemented.
- 13.7 Subject to the outcome of the review of the maximum price scheme (covered in a separate document issued alongside this paper) we propose to roll forward the scheme pending a decision on longer term arrangements.

Conclusion

- 13.8 The Government regards the fundamental review as a timely opportunity to look in detail at the supply and purchasing arrangements for generics for the NHS and to identify the most appropriate arrangements to meet the needs of the health service in the 21st century. We believe that the development and implementation of those arrangements will benefit from the active participation of those in the supply chain. We invite all interested parties to play their part in the forthcoming discussion process.

Terms of Reference of Fundamental Review of Arrangements for the Supply of Generic Medicines to the NHS

The fundamental review will –

- carry out and report on a “high level” analysis of the generic manufacturing and supply industry, and the wider pattern of relationships for wholesaling and retail of medicines for the NHS. This will cover –
 - i. a detailed investigation of ownership links
 - ii. an analysis of operational characteristics at all levels of distribution and supply
 - iii. an analysis of how the NHS reimbursement arrangements, and distribution margins, affect participants’ behaviour
 - iv. an understanding of the incentives that exist at each stage in the distribution chain
 - v. a consideration of how these are changing through time
- conduct a competition analysis, covering –
 - i. market boundaries (in particular the interactions between branded and generic markets on either the demand or supply side)
 - ii. market shares and concentration ratios
 - iii. entry barriers
- be intended to support policy analysis and decisions to be taken by the Department of Health about possible reforms to these arrangements. Broadly two perspectives will be taken to this stage of the review –
 - i. a remedial approach, asking whether adjustments to existing arrangements could be made, which would better deliver the Government’s objectives
 - ii. a radical approach, asking how we might do things differently

Annex B

Proposed Sample of Preparations for which Monthly Sales/Purchase Data will be Collected

Paragraph 7.21 of the discussion paper proposes that returns should be submitted for all presentations of the preparations listed below.

Preparation
Allopurinol Tablets 300mg
Amoxicillin Capsules 250mg
Atenolol Tablets 25mg
Beclomethasone Dipropionate Inhaler 100mcg (200 Doses)
Bendrofluazide Tablets 2.5mg
Cimetidine Tablets 400mg
Co-Amilofruse Tablets 5mg 40mg
Co-Amoxiclav Tablets 250mg 125mg
Co-Dydramol Tablets 10mg 500mg
Co-Proxamol Tablets 32.5mg 325mg
Diclofenac Sodium Tablets E C 50mg
Digoxin Tablets 125mcg
Dihydrocodeine Tartrate Tab 30mg
Enalapril Maleate Tablets 10mg
Erythromycin Tablets E C 250mg
Fluoxetine HCl Capsules 20mg
Frusemide Tablets 40mg
Gliclazide Tablets 80mg
Metformin HCl Tablets 500mg
Nitrazepam Tablets 5mg
Penicillin VK Tablets 250mg
Prednisolone Tablets E C 5mg
Ranitidine HCl Tablets 150mg
Salbutamol Nebuliser 100mcg (200 Doses) CFF
Temazepam Tablets 10mg
Thyroxine Sodium Tablets 100mcg
Tramadol HCl Capsules 50mg
Trimethoprim Tablets 200mg
Warfarin Sodium Tablets 1mg
Zopiclone Tablets 7.5mg

Partial Regulatory Impact Assessment (RIA)

Title

- 1.1 Longer-term arrangements for the purchasing and supply of generic medicines for the NHS in the community.

Issue

- 2.1 In 1998 the NHS in England spent around £700 million on generic medicines. During 1999, the NHS was affected by steep price increases and apparent shortages of many generic medicines. In order to protect the NHS from continued high prices (estimated to have cost the NHS in England some £200 million in 1999-2000) and to stabilise the market, the Government put in place a statutory maximum price scheme for the main generic medicines in August 2000.
- 2.2 The turbulence in the generics market in 1999 highlighted the need for the Government to review the arrangements for the purchasing and supply of generic medicines to the NHS. In December 1999 Oxford Economic Research Associates (OXERA) were commissioned to assess existing arrangements and to put forward options for the future. The Government has drawn on their work in developing the discussion paper to which this RIA relates.
- 2.3 A summary of present supply and reimbursement arrangements is at paragraph 3.1 of the discussion paper. The Government's assessment of it is at paragraphs 3.2 – 3.23.

The Government's Objectives

- 3.1 To introduce longer-term arrangements for the purchasing and supply of generics for the NHS in the community which most closely meet the following published objectives –
 - to maintain, and improve, the current quality of service to patients both in hospital and in the community, in particular maintaining a secure and reliable service that meets clinical need
 - to minimise the costs of the distribution networks, subject to service level and quality requirements
 - to reimburse community pharmacies, overall, as closely as possible to what they actually pay for the medicines they dispense under the NHS
 - to have transparent prices
 - to support a competitive pharmaceutical market; and
 - to secure value for money for the NHS.

- 3.2 This includes putting in place the collection annual market share data and monthly sales data for a sample of preparations to allow further development and assessment of one of the options for the future under consideration.

Who would be Affected and Issues of Equity

- 4.1 The Government's decisions on future options will affect manufacturers, Product Licence (PL) holders and wholesalers of generic medicines, as well as community pharmacists and dispensing doctors.
- 4.2 Information collected from companies for the year 1999 indicates that there are about 70 companies holding PLs for generic medicines who were active in the market during that period and some 150 wholesalers of generics. The data indicates that the companies cover a broad spectrum in terms of turnover. We do not have the information to estimate the breakdown into small, medium size and large enterprises.
- 4.3 There are some 9,800 community pharmacy contractors and about 4,500 dispensing doctors in England.
- 4.4 Future arrangements need to strike a balance between delivering value for money and security of supply for the NHS and allowing manufacturers and wholesalers to make reasonable returns.

Options

- 5.1 The discussion paper sets out two main options for the future –
- reforming the reimbursement arrangements through a reference-based NHS price scheme, backed by statutory price control where necessary (*option 1*). (This is set out in detail in section 6 of the discussion paper)
 - introducing central purchasing through competitive tendering (*option 2*) (set out in detail in section 8 of the paper)
- 5.2 As a further possibility, the paper also assesses keeping in place existing purchasing and reimbursement arrangements and rolling forward the present statutory maximum price scheme (referred to below as *option 4*) (covered in section 9 of the paper).
- 5.3 For completeness, these are considered below alongside the option of keeping in place existing purchasing and reimbursement arrangements as they were prior to the introduction of the maximum price scheme in August 2000 (*option 3*)

Benefits and Risks

- 6.1 The table below assesses the options against the Government's objectives and their robustness against future trends

Objectives	Option			
	1 Reference-based NHS price scheme	2 Central purchasing through tendering	3 Existing arrangements (pre-August 2000)	4 Continue maximum price scheme
Quality of service to patients	Better price information for pharmacies and supply information for Gov't may help	Binding contracts and predictable demand for contract product should improve security of supply. But if tendering produced a single dominant supplier any major production problems could cause difficulties	Yes, but problems evident in 1999 not addressed	As for existing arrangements
Minimise cost to NHS of distribution networks	Yes	Depends on option. Different wholesalers for different contracts could reduce current economies of scale but may still offer a good price to NHS	Yes, but NHS may not be reaping benefits	As for existing arrangements
Reimburse community pharmacies closely	Yes, provided accurate sales information reported by companies and w/sale margin set at realistic level	Yes, provided any w/sale margin set at realistic level	No – many list prices out of line with true prices; discount inquiry has limited effect	Many list prices pegged at max. but some probably remain out of line with true prices
Transparent prices	As above	Yes	No – as above	No – as above
Support a competitive market	Better information for Gov't to assess position and target measures to encourage entry	Yes, provided contracts let in a way which minimises risk of monopolisation	Lack of information to prove either way	Lack of information; if any max. prices are too low competition may reduce over time
Secure VFM for the NHS	Should improve on current position provided accurate information reported	Would allow more efficient production scheduling, hence lower costs. Should improve on current position, especially if suppliers make realistic bids and system is robust against abuse.	No – given above deficiencies	Has delivered savings for NHS. Controls in place to reduce risk of repeat of rapid price increases of 1999

Option				
Objectives	1 Reference-based NHS price scheme	2 Central purchasing through tendering	3 Existing arrangements (pre-August 2000)	4 Continue maximum price scheme
Robust against future trends	More so than current arrangements, provided companies do not devise new forms of vertical integration to get round controls	More so than current arrangements	Likely to expose deficiencies even more	As for existing arrangements

6.2 Many of these potential benefits and risks cannot be quantified. What follows is a preliminary assessment of the costs/savings to the NHS, compared with current NHS expenditure, and the costs of compliance for companies. The latter fall entirely into the category of *implementation costs* – those associated with implementation which cannot be directly attributed to a particular policy goal. Where appropriate, the assessment covers the implications for small businesses (defined as those with a turnover of less than £2.8m a year). We will refine the assessment in the light of forthcoming discussions with interested parties and further work to develop the options.

Costs/Savings to the NHS and Costs of Compliance

Option 1

- 7.1 The reference-based NHS price scheme would have the potential to reduce the significant gap that appears to exist between the NHS’ total annual expenditure on generics and ex-manufacture prices with the addition of a reasonable distribution margin. One commentator has estimated this gap at around £90-130 million a year. How much was recouped through the scheme would depend on the real savings available and on a variety of factors such as the accuracy of price information reported to the Government under a reference-based scheme and the level at which the wholesale margin was set. The Government would incur some additional costs associated with operating the scheme.
- 7.2 Costs of compliance would be the recurring costs of complying with ongoing information requirements under the scheme. This would involve the monthly submission to the PPA of details of transactions between Product Licence (PL) holders and wholesalers as well as compliance with any random or periodic inquiries carried out to check the robustness of the arrangements. Costs would depend on who the information was collected from (PL-holders or wholesalers), the number of preparations covered by the arrangements, the amount of information required, the format in which it had to be submitted to the Prescription Pricing Authority (PPA), and the degree to which companies had to adjust and re-present the data available in their own accounts systems. The cost of compliance for small businesses should be in proportion to their size.

Option 2

- 7.3 Competitive tendering has the potential of recouping some of the value currently believed to be lost to the NHS in the supply chain. It might also realise some savings on actual manufacturing costs, resulting from production efficiencies linked to the stable and predictable demand that tendering would produce. The extent of savings would depend on the how much of the market was put out to tender – at present

the Government envisages starting with a small number of products and extending the arrangements in the light of experience – as well as on the robustness of the arrangements put in place for letting contracts and for distribution and reimbursement.

- 7.4 The Government would incur costs associated with running tendering exercises. The costs of compliance to companies would be those of participating in tender exercises. The costs would depend on the number of preparations for which tendering was introduced and the number of tenders in which companies chose to take part.

Option 3

- 7.5 Option 1 would not deliver any savings over and above what is already being achieved under the maximum price scheme. If the maximum price was abolished prices might rise in segments of the market where competition is absent or fails.
- 7.6 There would be no costs of compliance other than the minimal cost to wholesalers and manufacturers of continuing to submit price lists to the Prescription Pricing Authority (PPA) monthly.

Option 4

- 7.7 The maximum price scheme has brought stability to the market and, in a full year, is expected to reverse the effect of price increases in 1999-2000. Its ability to deliver stability over the longer term would depend on the robustness of the arrangements put in place for reviewing prices periodically. Through further adjustment of maximum prices the scheme might have the potential to recover some of the value currently believed to be lost to the NHS in the supply chain .
- 7.8 Costs of compliance would be the cost of providing information required in connection with the scheme. The RIA for the maximum price scheme (finalised in July 2000, following consultation) estimated these costs at between £1000 and £5000 a year per company. The future cost per company would depend on whether any changes were made to the information requirements put in place in 2000. The total cost would depend on how many companies the information was sought from. The impact on small businesses should be in direct proportion to their size.

Cost of Compliance with Proposed Preliminary Information Collection Requirements

- 8.1 Before reaching a decision on which of the options to pursue the Government proposes to refine Option 1 (a reference-based NHS price scheme) and to assess it using data about Product Licence (PL) holders' and wholesalers' sales. The proposed information requirements are set out in full in section 7 of the discussion paper.
- 8.2 The benefit to the Government/tax-payer of the proposed information collection is to ensure that a leading option for securing value for money and security of supply for generic medicines can be fully developed and assessed. Without the proposed information the Government will not be in a position to make a final decision or to be sure that implementation will be smooth and effective.
- 8.3 We estimate that the costs of compliance will be as follows.

A full year's data on sales and sources of manufacture

- 8.4 We propose to require all PL holders with sales of unbranded generics of over £1 million to submit information about their total volumes and values of sales to wholesalers, for the year from September 2000 to August 2001, of each presentation of some 370 generic preparations as well as a breakdown of the source of manufacture of product in cases where it is bought in. We also propose to require wholesalers with sales of over £1 million to submit information about their total volumes and values of sales, to community pharmacies, of the same preparations for the same period.
- 8.5 Based on sales returns for 1999, we estimate that the requirements will apply to 30-40 PL-holders and 30-40 wholesalers.
- 8.6 The main compliance costs will be the staff costs incurred in assembling and providing the information. The costs will be affected by the detail of the information collection arrangement, including the format in which data will be required and the ground-rules which companies will be asked to follow in submitting information. We propose to reach decisions on these points following consultation with interested parties. The costs will also vary depending on the size and structure of PL-holders and wholesalers and their level of business with the NHS. The assumption is that, the smaller the business, the lower its level of NHS business and, therefore, the lower the cost of compliance with the requirements.
- 8.7 The proposed information requirements are in most respects equivalent to those imposed under the existing maximum price scheme (the one additional proposal being the requirement for PL-holders to submit information about product bought in from third parties). Following consultation in 2000, we estimated the costs of compliance with information requirements under the maximum price scheme at between £1,000 and £5,000 a year for each company.

Monthly sales/purchase data for a sample of preparations

- 8.8 We propose to require all PL-holders and/or wholesalers with annual sales of unbranded generics of over £1 million to submit information about monthly sales to wholesalers (in the case of PL-holders) or purchases from PL-holders (in the case of wholesalers) of each presentation of around 30 unbranded generic preparations to the PPA probably for several months beginning in September or October 2001.
- 8.9 The main compliance costs will be the staff costs incurred in assembling and providing the information. The costs will depend on the detail of the information collection arrangement and whether we collect from either PL-holders or wholesalers or from both. The assumption is that, the smaller the business, the lower its level of NHS business and, therefore, the lower the cost of compliance with the requirements.
- 8.10 Whether we require information about each separate transaction or aggregated to give a total figure for each presentation per month may also have a significant impact on costs. We propose to reach decisions on these points following consultation with interested parties.



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