

Overview

This paper:

- describes the origins of the fundamental review of the supply of generics;
- sets out the options put forward for reform of the existing arrangements;

It finds that:

- although it is not possible to prove from the available data it appears that any change to the existing arrangements will benefit some pharmacists and disadvantage others ;
- both main options will reduce the scope for pharmacists benefiting or losing from the way they procure generics. In particular, the tendering option appears likely to remove all risks of paying too much *i.e.* more than the reimbursement price;
- the precise way in which either of the two main options is implemented is critical for an estimate of their impact on community pharmacy;
- this round of reform should be seen as the start of a process of extended market management by the Department of Health of the way that the NHS procures generics. This may involve intervention in the manufacturing side as well as the wholesale and retail distribution.

Origins of the Fundamental Review

The Review 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 the supply chain had made up the production shortfall.

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. It then commissioned a fundamental review from Oxford Economic Research Associates (OXERA) in November 1999. OXERA reported in September 2000. Their analysis forms the basis of the Government's discussion paper.

(Department of Health, Options for the Future Supply and Reimbursement of Generic Medicines for the NHS - A Discussion Paper. July 2001, Executive Summary p3)

This briefing draws on the discussion paper and the background analysis on which it is based.

The Problem: Weaknesses in Existing Arrangements

The Government acknowledges that purchasing and supply arrangements up to December 1998 helped to secure reasonably stable supply conditions and prices. However, the discussion paper identifies a number of weaknesses in those arrangements:

- 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. OXERA point out that at no stage in the supply chain are the actual prices paid visible.
- 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. (pps 3 and 4)

As far as the last of these points is concerned, the discussion paper states that 'there appears to be a significant gap between what the NHS spends on generics and the manufacturing prices plus a distribution margin'. That gap – put at around £100 million with a wide margin of error round that figure - represents the possible scale of the benefits to the NHS of an improved scheme. Although these words are not used, the paper in effect is stating that there are excess profits in the supply chain but it does not identify exactly which part of it is enjoying them - manufacturing, wholesale distribution or retail. The data in the OXERA report that they may be spread across all three main stages in the supply chain.

Objectives for a New Scheme

The paper sets out six broad objectives:

- 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. (p 8)

It also points out that any option for change must be evaluated against likely changes in the supply chain – ex the extent of integration between manufacture, wholesale and retail distribution and also against a value for money test. As far as the first of these is concerned, the paper makes it clear that the existing arrangements have relied on effective competition to supply generics to pharmacists and dispensing GPs and that the Government prefers to rely on competition in future. In some instances however it may be necessary to actively promote competition.

Evaluation of Existing Arrangements

The paper assesses existing arrangements against the above criteria. It concludes that although these have managed to ensure that patients did get the medicines they needed, even during the time when the market was 'turbulent', the current system suffers from four main 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;
- in addition there are questions about the extent of competition in parts of the market. (p 13)

Trends in the Market

Any consideration of options must take into account the way the overall market is changing. The paper identifies three main trends:

- 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. (p 14)

The paper argues 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. It concludes therefore that 'no change' is not an option: the current weaknesses will only get worse.

[SH - query]

The Options

The discussion paper puts forward two main options:

- 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 radical option which introduced central purchasing, through competitive tendering, entirely replacing present purchasing arrangements. (Executive Summary, p 4)

These are the main options explored in the paper. However the OXERA report identified a range of other possibilities which are briefly mentioned; some of these might be used in conjunction with the two main options.

The Main Options

Option 1. A reference-based NHS price scheme underpinned by regulation

This option would work as follows:

- 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 to impose price controls. (p 16)

The paper recognises that this option could fail the value for money test by virtue of the large amount of information that would have to be collected and also that competition may not be adequate. Hence price controls would still have to be retained as a reserve measure.

The paper argues that reimbursement arrangements should continue to provide community pharmacists and dispensing doctors to seek out the best deal. It therefore proposes that:

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. (p 19)

The paper explicitly considers the transition issue, recognising that if the new arrangements result in much lower prices, there would be a need to consider a transitional arrangement.

Option 2. Central purchasing through tendering

The starting point for this option is that the NHS current purchasing power is dispersed. Centralising it should allow that purchasing power to be used to better effect.

OXERA put forward a number of ways in which this might be done. The paper favours one which requires the Department of Health to let contracts by competitive tender for the exclusive right and obligation to supply a specified volume of a specific preparation at a specified price to community pharmacists and dispensing GPs for the purpose of NHS dispensing.

It argues that this approach could be used for all parts of the market and in different ways:

- 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. (p 26)

The paper notes that if this option is pursued 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 new arrangements differ in certain respects and hence the new and the existing would have to be aligned in some way. (p 27)

If tendering is introduced, the next question is: what is the 'unit' for procurement. The paper prefers a preparation by preparation approach as this would:

- 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). (p 27)

Within this option two broad approaches to distribution might be used:

By wholesaler - under this option the distribution of product sourced through contracts would be open to any holder of a wholesale dealer's licence. (p 29)

By contract for distribution - 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). (p 30)

The OXERA report notes that under the tendering option, reimbursement for the cost of drugs could be done away with as the suppliers could be paid directly by the Department of Health. This would mean however that pharmacists had no incentive to hold sensible stock levels and would open the way for illegal activity.

Transition - the paper notes that the move to tendering would be a major step and hence this option would be phased in through a modest number of contracts.

A Variant

OXERA suggest that the tendering option could focus on the key current weakness in the supply chain *i.e.* price volatility and uncoordinated supply in the face of shortage. This would mean that the Department would take over responsibility for ensuring the supply of Category D goods.

Other Options

The paper notes briefly that other options are available. It considers explicitly the following:

Existing arrangements plus maximum price scheme:

Under this option present arrangements for reimbursement of community pharmacies and dispensing doctors would continue alongside 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.

Reform of reimbursement:

This option consists of a series of relatively small measures designed to bring the reimbursement price in line with the actual price by improving the basis on which the latter is calculated, modifying the Category D element, and modifying the calculation of the discount/clawback.

Better Information:

The OXERA report confirms that the Department has available to it only limited information of how the market works. It makes a number of suggestions as to how the gaps might be filled.

IT solutions

OXERA point out that if electronic transfer becomes more common, it will be possible to put reimbursement on a better footing.

Structural change

Following the model of other regulated industries, OXERA raise the possibility of introducing measures to counter the trends towards vertical integration through the introduction of accounting or even structural separation of the various stages.

Implications for Community Pharmacy

Neither the discussion paper nor OXERA make proposals for the reform of pharmacy payments as a whole. The assumption underlying the options is that there will continue to be a reward for processing prescriptions.

OXERA note a number of problems with the current arrangements as perceived by pharmacists:

- it is hard to understand
- it is hard to audit payments from the PPA
- Category D endorsement is difficult and time-consuming
- payment delays put up overdraft costs.

The impact of the two main options depends critically on:

- how pharmacists procure generics now
- the precise way in which any scheme is structured.

The supporting report by OXERA considers how the existing system works, as far as community pharmacists are concerned. It points out that the payments received by pharmacists in the current system are among the lowest in the world and that the existing system provides an incentive for pharmacists to seek out low prices (except for category D goods).

OXERA assume that there are in effect two classes of pharmacists, trading and non-trading. The former are active in seeking out the best deals - and hence may make profits out of the current reimbursement system. The second are not active and may pay more than they are reimbursed. These are likely to be the smaller chains, for which the

effort involved in seeking out the best prices may not be justified. Hence they may well make a loss on generic prescribing.

Underlying this analysis is the view that drug tariff prices are higher than market prices but although the consultants strongly believe this to be the case, they have no direct evidence for it. That could only be obtained through an analysis of invoices paid for drugs - which has not been carried out. However the consultants interpret the complaint of pharmacists they interview that the discount/clawback compels them to seek out better prices as evidence that the current scheme does have, from the viewpoint of the NHS, the right incentives.

The options and the precise way they are implemented have other implications. Some examples are:

- in some versions of tendering pharmacies would have to deal with more suppliers putting up transaction and delivery costs;
- time spent looking for the best deal would be reduced in nearly all variants;
- there would be cash flow implications in some variants (positive or negative);
- under tendering the appearance of the drugs obtained may vary from order to order (if tenders are let in time tranches).

The Longer Term

The OXERA report makes it clear that the way that generics are manufactured and supplied has been changing and will probably continue to change. The role that community pharmacy has played (or has been assumed to play) in keeping prices down is no longer adequate.

Although the main options put forward for discussion do not directly address structural issues, they are clearly identified in the OXERA report and will not go away. These include:

- increasing competition in the manufacture of generics through for example report of product licensing and mutual recognition arrangements;
- treating the supply of generics as a 'public utility' and developing a regulatory regime analogous to that for telecoms, power and water.

The tendering option starts to move the Department of Health in the direction of OFDRUG. At the moment the Department would clearly prefer to move only very slowly in that direction.