ARRANGEMENTS FOR THE FUTURE SUPPLY AND REIMBURSEMENT OF GENERIC MEDICINES FOR THE NHS

CONSULTATION DOCUMENT

September 2003
Executive Summary

This Consultation Document invites comments from interested parties in the pharmaceutical industry, the NHS and others on the Government’s proposed arrangements for the long-term supply and reimbursement of generic medicines to the NHS in primary care in England. The proposal when implemented would also replace the current Maximum Price Scheme for generic medicines. This consultation will run until 31 October 2003 and we would welcome views by that date.

The document provides an update on discussions since the publication of the Discussion Paper “Options for the Future Supply and Reimbursement of Generic Medicines for the NHS” in July 2001. It sets out the proposal in detail, how it applies to each part of the generic supply chain namely manufacturing, wholesaling and community pharmacy, and seeks views on specific issues.

Discussions towards development of the proposal have been extensive. All parts of the supply chain have been involved in these discussions. In developing these proposals the Government has considered the interests of the NHS as well as those of all sectors involved in the supply of generic medicines to NHS patients.

The scheme would be based on a voluntary agreement under section 33 of the Health Act 1999 and those that opt out of such a scheme would be subject to a statutory scheme under sections 34 to 38 of that Act. Under the scheme issues that are not resolved amicably between the Department and industry, would be referred to an arbitration body. The Department would intend to report to Parliament annually on the scheme.

General comments and views on the specific parts listed overleaf are invited, and should be sent either by email to:

generics@doh.gsi.gov.uk

please title your e-mail “generic consultation”

or by post to:

Trudi Rwababi
Generic Medicines
Room 133
Richmond House
79 Whitehall
London
SW1A 2NS

to arrive no later than 31 October 2003.
Representative groups should make it clear in their responses who their members are or who they represent.

The information you send to us may need to be passed to colleagues within the Department of Health and/or published in a summary of responses to this consultation. We will assume that you are content for us to do this and if you are replying by e-mail, that your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us.

A partial Regulatory Impact Assessment is included in this document at Annex A and the Code of Practice on Written Consultation is included in this document at Annex B.

The consultation document is available on our website at www.doh.gov.uk/generics
List of issues the document seeks views on

<table>
<thead>
<tr>
<th>Issue</th>
<th>Relevant paragraph</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different arrangements for manufacturers/importers, wholesalers and community pharmacy</td>
<td>11</td>
</tr>
<tr>
<td><strong>Manufacturers</strong></td>
<td></td>
</tr>
<tr>
<td>Whether there is any justification for exempting any manufacturers from the scheme</td>
<td>14</td>
</tr>
<tr>
<td>Whether generics with relatively low sales to the NHS should be outside the scheme and covered by other arrangements and more generally on the medicines that it is proposed should be covered by the scheme</td>
<td>19</td>
</tr>
<tr>
<td>Pricing of products where there are many manufacturers and whether 10% is an appropriate margin for price changes below which no explanation would be requested</td>
<td>25</td>
</tr>
<tr>
<td>Pricing of generics on entry into the market and what, if any, limitations should the scheme place on the companies in the pricing of such products</td>
<td>28</td>
</tr>
<tr>
<td>Measures to ensure integrity of new arrangements</td>
<td>29</td>
</tr>
<tr>
<td>Proposals covering products where there is concentration or a limited number of suppliers</td>
<td>35</td>
</tr>
<tr>
<td>Provisions for the submission of information by manufacturers</td>
<td>40</td>
</tr>
<tr>
<td>Arrangement for selling on products where only one manufacturer supplies a product</td>
<td>42</td>
</tr>
<tr>
<td>Companies' agreement to be bound by the scheme at least 3 months prior to the introduction of a new Drug Tariff</td>
<td>43</td>
</tr>
<tr>
<td>Proposals to review the scheme</td>
<td>45</td>
</tr>
<tr>
<td><strong>Wholesalers</strong></td>
<td></td>
</tr>
<tr>
<td>Whether all wholesalers dealing in generics should be covered by the scheme and suggestions on what should be the parameters and what regime there should be for those excluded on the basis of excessive regulatory burden</td>
<td>48</td>
</tr>
</tbody>
</table>
The scope of the generic medicines to be included within the scheme 53
Arrangements for submission of information by wholesalers 56
Review of the scheme and invitations to accept any new terms proposed 59
Identification of those contractors invited to join the scheme 62

Community Pharmacies and Dispensing Doctors
The scope of the generic medicines to be included within the scheme 67
Arrangements for converting existing Tariff prices and time criteria for introducing these arrangements 71
Mechanisms for adjusting prices after the start of the scheme 72
Options for implementing changes in reimbursement 74
Two options for obtaining market intelligence from a sample of pharmacies 75-77
Review of the terms of the scheme 82

All arrangements
Arrangements for arbitration 91
Exit from agreements 94
Reporting on the operation of the scheme 95
Six monthly meetings with scheme members to discuss potential problems during operation of the scheme and whether matters discussed should be published 97
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
<td>ii</td>
</tr>
<tr>
<td>List of issues the document seeks views on</td>
<td>iv</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Background</td>
<td>1</td>
</tr>
<tr>
<td>Scope of the paper</td>
<td>2</td>
</tr>
<tr>
<td>The Government’s objectives</td>
<td>3</td>
</tr>
<tr>
<td>The proposal in Summary</td>
<td>4</td>
</tr>
<tr>
<td>The Proposal in more detail</td>
<td>6</td>
</tr>
<tr>
<td><strong>Manufacturers</strong></td>
<td></td>
</tr>
<tr>
<td>Companies covered by these arrangements</td>
<td>8</td>
</tr>
<tr>
<td>Products to be covered by the arrangements</td>
<td>9</td>
</tr>
<tr>
<td>Setting the drug tariff for generic medicines</td>
<td>10</td>
</tr>
<tr>
<td>Pricing products where there are many active manufacturers</td>
<td>10</td>
</tr>
<tr>
<td>Pricing of new products</td>
<td>12</td>
</tr>
<tr>
<td>Pricing of products where there is a limited number of manufacturers</td>
<td>13</td>
</tr>
<tr>
<td>Information to be provided by scheme members</td>
<td>15</td>
</tr>
<tr>
<td>Products sold on</td>
<td>16</td>
</tr>
<tr>
<td>Start of Scheme</td>
<td>17</td>
</tr>
<tr>
<td>Provision for review of scheme</td>
<td>17</td>
</tr>
<tr>
<td><strong>Wholesalers</strong></td>
<td></td>
</tr>
<tr>
<td>Companies covered by these arrangements</td>
<td>18</td>
</tr>
<tr>
<td>Products covered by these arrangements</td>
<td>19</td>
</tr>
<tr>
<td>Information to be provided by scheme members</td>
<td>20</td>
</tr>
<tr>
<td>Start of scheme</td>
<td>21</td>
</tr>
<tr>
<td>Provision for review of scheme</td>
<td>22</td>
</tr>
<tr>
<td><strong>Community Pharmacies and Dispensing Doctors</strong></td>
<td></td>
</tr>
<tr>
<td>Community pharmacies and dispensing doctors covered by these arrangements</td>
<td>22</td>
</tr>
<tr>
<td>Products to be covered by these arrangements</td>
<td>23</td>
</tr>
<tr>
<td>Calculation of reimbursement price</td>
<td>24</td>
</tr>
<tr>
<td>Adjustment of reimbursement price</td>
<td>25</td>
</tr>
<tr>
<td>Incentives for community pharmacy</td>
<td>25</td>
</tr>
<tr>
<td>Information to be supplied by community pharmacies and Dispensing Doctors</td>
<td>26</td>
</tr>
<tr>
<td>Start of scheme</td>
<td>28</td>
</tr>
<tr>
<td>Review of scheme</td>
<td>28</td>
</tr>
</tbody>
</table>
All arrangements
Arbitration 28
Exit from Agreement 30
Report to Parliament 31
Discussion with scheme members during the operation of the schemes 31

Annexes
Partial Regulatory Impact Assessment Annex A
Code of Practice on Written Consultation: The Consultation Criteria Annex B
Introduction

1. Generic medicines continue to play an important role in the delivery of patient care. In 2002, 76% of NHS prescriptions were written generically and generic medicines accounted for 53% of prescription items dispensed in the community.

Background

2. In July 2001 the Department of Health published a Discussion Paper “Options for the Future Supply and Reimbursement of generic medicines for the NHS”. The paper put forward two options for the supply and reimbursement of generic medicines to the NHS. These were:

- a reference-based NHS price scheme with regulation to underpin it;
- central purchasing through tendering.

3. The paper also made a commitment for the Department to consult formally on any proposals before they are implemented.

4. Since the conclusion of the last consultation we have considered all the representations put to us and had lengthy discussions with the representative bodies of the manufacturers of generic medicines, pharmaceutical wholesalers and community pharmacies. This paper sets out the reimbursement arrangements which the Government has concluded, subject to the results of the consultation, should be introduced in England for generic medicines. The Government also proposes that the statutory Maximum Price Scheme for generic medicines which was introduced in August 2000 should be abolished on the date that the new arrangements are introduced.
Scope of the Paper

5. This paper fulfils the commitment made in “Options for the Future Supply and Reimbursement of Generic Medicines for the NHS” and sets out for comment proposed pricing and reimbursement arrangements for generic medicines for the NHS in the community that the Government believes should replace the existing arrangements in England, including the Maximum Price Scheme. The paper is concerned with the supply of unbranded generic medicines and the reimbursement of generically written prescriptions which can be dispensed generically. It does not affect the arrangements for determining the prices of branded medicines under the Pharmaceutical Price Regulation Scheme or the reimbursement of branded prescriptions. It also does not cover the arrangement for the supply of generic medicines to the hospital sector, the over-the-counter market or dispensing against private prescriptions.
The Government’s Objectives

6. The Discussion Paper published in July 2001 outlined the Government’s objectives for the system of distributing medicines to the NHS 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;

- 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;

- secure value for money for the NHS;

- ensure any arrangements for the future would work well in the light of both the current characteristics of the supply chain and the way it may evolve over the coming years;

- ensure 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.

7. The responses that the Department received to the Discussion Paper from manufacturers, wholesalers and pharmacy contractors acknowledged the need for the NHS to secure value for money from future arrangements for the
reimbursement of generic medicines. At the same time all sectors of the supply chain for these medicines emphasised the importance of being able to obtain a fair return on its NHS generic medicine business. The Pharmaceutical Services Negotiating Committee urged the Government to recognise the link between the viability of some community pharmacies and the discount on generic medicines that is not being recovered by the Discount Inquiry. In the light of these representations and the discussions that have taken place with all sectors of the supply chain for NHS generic medicines, the Government has clarified that it fully accepts that all sectors of that chain should be able to earn a fair return and thereby secure the supply of generic medicines to the NHS.

8. The proposal that is set out in this paper has been designed to achieve these objectives.

The Proposal in Summary

9. The following arrangements would replace the Maximum Price Scheme and the current reimbursement arrangements for community pharmacies in England. These arrangements make a distinction between manufacturers and wholesalers which is easier to identify in practice than in principle given that companies hold product licences allowing for both manufacture and distribution. Indeed it is possible for a single company to be both a manufacturer and a wholesaler of the same or different generic medicines. In what follows we shall use the terms manufacturer and wholesaler rather broadly, but it should be remembered that both terms fall under the meaning of supplier within the meaning of the 1999 Health Act.

- The arrangements would apply to all licensed generic NHS medicines dispensed in the community which would otherwise fall under category A of the existing Drug Tariff\(^1\)

---

\(^1\) Part VIII of the drug tariff contains a range of generic items and pack sizes, all of which have been agreed between the Department of Health and PSNC, and which are there, basically, to facilitate the generic prescribing of drugs and
• Where many “active” manufacturers supply a generic medicine to the NHS, they would be able to alter the price at which the medicine is sold to wholesalers or dispensing contractors without any prior requirement to discuss such changes with the Department of Health.

• Where there is a limited number of manufacturers of a generic medicine or the supply is concentrated, manufacturers would be required to seek the Department’s agreement to any price increase.

• New generic products introduced following the granting of a marketing authorisation could be sold at a net price decided at the discretion of the manufacturer(s) upon entering the market provided that the drug tariff was less than the equivalent branded medicine. At the same time, the Department may consider provisions that would prevent companies exploiting this freedom to their advantage.

• The drug tariff would be linked to the net prices charged to wholesalers and dispensing contractors by manufacturers.

• Manufacturers and wholesalers would be required under the arrangements to submit quarterly information for generic medicines income revenues, cost of purchases and volumes of transactions.

also to control the NHS Drugs Bill. There are four categories of drugs and each category has its own basis of payment:-

• Category A - drugs which are commonly available from a number of suppliers therefore the price is calculated using Unichem, AAH, APS, Alpharma and Ivax Pharm.

• Category B - drugs that are "older" and less commonly-used. The prices are calculated using (in the order shown) Unichem, then (if not in Unichem) AAH, then Celltech Pharma and finally Thornton & Ross.

• Category C - drugs which are commonly available but generally as branded items. Prices based on specific brands or suppliers.

• Category E - relatively little used extemporaneously dispensed items.
- The arrangements would be covered by voluntary agreements under Section 33 of the Health Act 1999. All companies supplying generic medicines would be able to join the relevant scheme. Those that decide not to do so would be likely to be subject to an alternative statutory scheme under Sections 34 to 38 of the Health Act 1999.

- There should be incentives for pharmacies to benefit from procurement decisions where these also benefit the NHS.

**The Proposal in more detail**

10. The following paragraphs give a more detailed description of the proposed arrangements and set out the issues on which we would welcome views. The Department envisages that the new scheme should distinguish between arrangements for

- those companies that manufacture or in any other way originates the supply of generic medicines for the use of the NHS;

- those companies that deliver a wholesaling service;

- community pharmacies that purchase generic medicines from wholesalers and dispense them to NHS patients.

11. The Department would welcome views on how this distinction could best be incorporated into the provisions of the new arrangements. For example, would it be possible to link the agreement for manufacturers/importers to marketing authorisations and second category holders of wholesale dealers’ licences?

12. The remainder of the paper refers to the term “manufacturer” which is intended to include all companies involved in the manufacture or importation of generic medicines for the NHS, “wholesalers” to refer to those companies
that provide a wholesaling service; and “community pharmacies” for those
community pharmacies that dispense generic medicines to NHS patients.
Manufacturers

Companies to be covered by these arrangements

13. It is proposed the arrangements should apply to all manufacturers of NHS generic medicines that are prescribed in England by medical or dental practitioners, nurses or others approved by the Secretary of State to prescribe. A manufacturer would be a company which in whole or part through the conduct of its day to day business supplied wholesalers with generic medicines which were made, imported or bought in by that company. These arrangements would be set out in a voluntary agreement under Section 33 of the Health Act 1999 which we would intend to conclude with organisations representing manufacturers of generic medicines. This would apply to all members of those organisations as well as those companies that are not members of one of these bodies. All manufacturers of NHS generic medicines would be invited to join the scheme. Companies which supply generic NHS medicines and do not elect to be scheme members, or cease to be scheme members under the agreed procedures would fall to be treated under the arrangements relating to the control of the prices of medicines and profits set out in Sections 34 to 38 of the Health Act 1999, referred to as the statutory scheme. Sections 34 to 38 of the Health Act 1999 govern the price that may be charged for NHS medicines and the level of profit derived from their sale through statutory schemes. Such schemes may be implemented by regulation or direction and may require the submission of information. Additionally, section 37 allows for financial penalties if a supplier of NHS medicines fails to comply with the requirements of any statutory scheme. These sections would not apply to members of the voluntary scheme members.

14. We would welcome comments on whether there is any justification for any manufacturers being exempt from such a scheme that would not prejudice their operation or disadvantage companies that elect to join the scheme.
Products to be covered by the arrangements

15. The Government proposes that the scheme should apply to all generic licensed NHS medicines dispensed in the community in England which would otherwise fall under category A of the existing Drug Tariff.

16. For this purpose, the term “generic medicine” would refer to any human pharmaceutical product for which a marketing authorisation has been awarded and to which the proprietor does not apply a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International Non-proprietary Names (INN) or any list of similar standing.

17. The scheme would apply to all packs, strengths and dosage forms of a generic medicine except:

- a pack that was intended for sale to the public without a prescription and the price of which was not generally accepted as a basis for the pricing of FP10 prescriptions;

- sales of medicines which a company showed to be derived predominantly from private prescriptions;

- products that were included in the list of substances which GPs may not prescribe on the NHS.

18. Where a medicine is sold as a generic medicine on prescription and over the counter (OTC), only the proportion that is prescribed would be subject to the provisions of the scheme.

19. We would welcome comments on the medicines that it is proposed should be covered by the scheme and whether generic medicines with
relatively low sales to the NHS should be outside the scheme and covered by other arrangements and more generally on the medicines that it is proposed should be covered by the scheme.

Setting the drug tariff for Generic Medicines

20. The Government has concluded that, wherever possible, the arrangements of establishing the drug tariff for any given generic medicine should reflect existing market mechanisms. This means that where there is effective competition between manufacturers of a given generic medicine then the Government would not intend to interfere in the operation of that market for that medicine. However there are a number of generic medicines where there is a limited number of manufacturers. In these circumstances there may not be effective competition and it may be necessary to make arrangements to ensure that the NHS pays a fair price for the medicine concerned. The following paragraphs set out proposals for setting the drug tariff for:

- existing generic products where there are many “active” manufacturers;
- new generic products introduced following the granting of a marketing authorisation;
- existing generic products where there is a limited number of manufacturers.

Products where there are many active manufacturers for a generic medicine

21. Where there are many “active” manufacturers simultaneously supplying a generic medicine to the NHS and the supply of NHS medicines is not concentrated scheme members will be able to increase or decrease the price at which the medicine is sold to wholesalers or dispensing contractors.
The conditions under which it is proposed that this should not apply are stated at paragraph 30 below. A manufacturer will be considered to be “active” where it has supplied the generic medicine to a wholesaler or dispensing contractor intended for dispensing in England or Wales during, say, the previous twelve months. The important point is that there should be simultaneous supply of the medicine by sufficient manufacturers to ensure that the prices charged by manufacturers are constrained by competition.

22. Prior to the price increases that took place in 1999 and 2000, the Department received no information about the structure of the market for generic medicines and prices and volumes in that market at each stage of the generics supply chain. Accordingly it was impossible for it to monitor market trends and react if necessary.

23. Proposals to provide the Department with information on all stages of the generics market are set out in paragraphs 36-39, 54-55 and 75-79. In summary, manufacturers would be required to submit quarterly information on income generated for each generic medicine and the volume (e.g. by pack) sold.

24. The nature of the market at the manufacturer/wholesaler interface is such that there will be day to day variations in the prices charged by manufacturers. Nonetheless, if the Department found that the average price charged by the manufacturers of a particular pack size of a given strength and dosage form of a generic medicine had changed significantly, say by 10% or more, between two quarterly returns then the Department may ask all scheme members that have sold that pack size of the medicine in the previous two quarters for an explanation of the price change. The Department would also ask for such information in circumstances where there were increases in the price of a medicine over several quarters where the cumulative change was similarly significant.
25. The Department would welcome views on the proposals for allowing manufacturers to vary prices and at comment on the level of price change that should trigger a request for an explanation.

Pricing of New Products

26. It is proposed in paragraph 68 that the drug tariff for a generic medicine will be a function of the volume-weighted, average price charged by manufacturers. There is a problem with the determination of the drug tariff for new generic products introduced following the granting of a marketing authorisation. The calculation requires information concerning sales to be available before any sales have taken place. This matter might be dealt with by not publishing the associated drug tariff until the information becomes available, but this would mean uncertainty for dispensers who would not know the amount that would be subsequently reimbursed and it would introduce a delay in processing payments. An alternative might be to allow list pricing at the discretion of the company on entering the market subject to a maximum equal to a percentage of the price of the originating brand product or its parallel import. An interim drug tariff could then be calculated on the basis of that list price until such time information became available to allow a proper determination using market information. In the interests of ensuring value for money for the NHS the Department will wish to ensure that any changes in the Drug Tariff are more closely aligned to reductions in market price after the market launch of a new generic medicine than the current arrangements.

27. Line extensions relating to such new products may also be priced at the discretion of the company, subject to the same limitations with respect to the price of the equivalent branded product. Similarly, manufacturers would not be permitted to price varied strengths of existing formulations at a level other than in proportion to existing formulations.
28. We would welcome views on the determination of the drug tariff for generic medicines on market entry and what, if any, limitations should the scheme place on the companies in the pricing of such products.

29. The Government would intend to adhere to these terms provided that they are not used by companies in a way that could jeopardise the overall scheme or result in the NHS not benefiting from the dispensing of generic medicines. We believe therefore that the scheme will need to include provision that would prevent companies jeopardising its operations in any way and for ensuring that there is a smooth transition from the existing arrangements to a new scheme. We would welcome views on the measures necessary to ensure the long-term integrity of the new arrangements.

Pricing of products where there is a limited number of manufacturers

30. Where the supply of a particular generic medicine is concentrated the manufacturers concerned would be required to seek the Department’s agreement to any price increase for that medicine. In this context a market could be deemed to be concentrated if there are few suppliers (e.g. less than 2 or 3 suppliers) or by adopting the 40% benchmark for a one firm concentration ratio (commonly adopted by the competition authorities). The medicines could be defined in terms of the chemical entity of the form (i.e. capsule/ tablet, cream, injection of liquid). In considering such applications the Department would propose to take into account:

- An analysis of the direct and indirect manufacturing and supply costs of the product or products for which a price increase is claimed. These costs should be supported by auditable evidence such as invoices, discounts offered and received, analyses of manufacturing costs and apportionment of overheads. Companies must also be able to show that any increases in costs could not have been reasonably avoided.
• DH may also require manufacturers to show that their profit margins on sales of other products are fair and reasonable to the NHS. The evidence required in respect of these profit margins shall cover the same aspects as those noted in the section above.

31. In its examination of the reasonableness of a company’s costs and proposed prices, DH would have regard to factors such as the following:

• trends in previous prices reported by the company and other companies for the same product;

• any special features of the company’s operation with particular reference to the integration of the manufacturer with any wholesalers and/or pharmacists and any associated transfer prices;

• any ratios inferred from the company’s non-generics business;

• each company’s reported costs and profit margins and the average of other similar manufacturers;

• data from external sources that relate to the generics industry across companies.

If DH agrees that a price increase of more than 30% is justified, then it reserves the right to negotiate the price increase over a reasonable period.

32. In all cases, where a company wished to increase the price of any generic medicine it would be required to give the Department not less than eight weeks notice of this request. This notice would state the amount of the proposed increase and the reason in sufficient detail to satisfy the Department that the increase is justified. Each company would be required to submit with its application actual sales of the product for the previous year, a forecast for the current year and an estimate for the following year. A manufacturer could
reapply for a further increase in the price of any product after this time. This right could pass to any other manufacturer should it meet the concentration condition. However, an additional manufacturer may enter the market and thereby create the conditions under which freedom of pricing would normally apply. In such instances a product increased in price by under the above noted arrangements could not normally be allowed freedom of pricing for a period of three years after the previous price increase.

33. If the Department was in any doubt as to whether such changes were acceptable, it would be able to request further information. The Department could require that any information and data submitted to it should be independently audited where appropriate.

34. No manufacturer that qualified for a price increase under these arrangements would be awarded a price increase within a period of twelve months after a preceding authorised price increase.

35. We would welcome comments on the proposals covering products where there is concentration or a limited number of suppliers.

Information to be provided by scheme members

36. It is envisaged that the agreement would allow scheme members freedom of pricing for the majority of their sales intended for the primary care sector of the NHS subject to any limitations that might be included in the scheme. The Department of Health has a responsibility to monitor this market to see that it is balancing the interests of patients, the taxpayer and scheme members.

37. To enable the Department to fulfil this responsibility scheme members would send to the Department the following information for the quarters ending 31 March, 30 June, 30 September and 31 December of each year:
• the income generated for each generic medicine by strength, presentation, and pack size, net of all discounts and rebates that are allocated to specific products;

• the volume (e.g. by pack) sold for each generic medicine by strength, presentation and pack size;

• the level of any other rebate or discount not attributed to specific products but that accrue to those sales in the relevant quarter;

• a list of the customers to which each generic medicine has been sold and the value of that business by customer and medicine.

38. The information would be submitted to the Department within 30 days of the end of each quarter.

39. The information submitted to the Department would remain confidential to the Department and the scheme member.

40. We would welcome comments on the proposed provisions for the submission of information by manufacturers.

Products sold on

41. Manufacturers sometimes need to change the structure of their product portfolios and may decide to sell a product to another manufacturer. In circumstances where there is only one manufacturer supplying a generic medicine it is important that there should not be disproportionate price increases. Accordingly, when a product covered by this agreement is sold on:

• the manufacturer transferring the product and the acquiring manufacturer would be required to notify the Department of the
product and the name of the acquiring manufacturer within 14 days of the transfer;

- the acquiring manufacturer would not be allowed to increase the price for 3 months after notification;

- if at the end of the 3 months the acquiring manufacturer wishes to increase the price of the product concerned it should seek the Department’s approval;

- the Department would consider the application under the conditions for approving price increases. Where the increase would be more than 30%, the Department would reserve the right to negotiate the increase over a reasonable period.

42. We would welcome comments on the proposed arrangement for selling on products where only one manufacturer supplies a product.

Start date for the scheme

43. The scheme would operate from a date to be agreed between the Department of Health and scheme members. We envisage that companies would agree to be bound by the terms of the scheme at least 3 months before the introduction of a new Drug Tariff. This is necessary to allow sufficient time for the collection of the data necessary to calculate reimbursement prices and the calculation and promulgation of the new Tariff. We would welcome comments on these proposals.

Provision for review of the scheme

44. The scheme would continue to operate subject to six months notice given by either party to the agreement.
45. Either party would be able to request a review of the scheme no earlier than 12 months into scheme and at annual intervals thereafter. Following such a review, the terms of the scheme could be varied with the agreement of the relevant representative body(ies) and the Secretary of State. If the terms of the agreement were to be so altered, scheme members would be invited to accept the new terms. They would have the option of leaving the scheme if they decided not to accept the amendments. We would welcome comments on the proposals to review the scheme.

Wholesalers

46. The following voluntary scheme would apply to wholesalers.

Companies to be covered by these arrangements

47. It is proposed the arrangements should apply to all wholesalers in England of NHS generic medicines that are prescribed by medical or dental practitioners, nurses or others approved by the Secretary of State to prescribe. A wholesaler would be a company which in whole or in part during the conduct of its day to day business distributed generic medicines purchased by that company to pharmacy contractors. These arrangements would be set out in voluntary agreements under Section 33 of the Health Act 1999 which we would intend to conclude with organisations representing holders of wholesale dealers licences. They would apply to all members of those organisations as well as those companies that are not members of one of these bodies. All wholesalers of NHS generic medicines would be invited to join the scheme. Companies which supply generic NHS medicines and do not elect to be scheme members, or cease to be scheme members under the agreed procedures would be liable to be treated under the arrangements relating to the control of the prices of medicines and profits set out in Sections 34 to 38 of the Health Act 1999, referred to as the statutory scheme. Sections 34 to 38 of the Health Act 1999 govern the price that may be charged for NHS medicines and the level of profit derived from their sale through statutory schemes. Such schemes may be implemented by regulation or direction and may require the...
submission of information. Additionally, Section 37 allows for financial penalties if a supplier of NHS medicines fails to comply with the requirements of any statutory scheme. These sections would not apply to members of voluntary schemes.

48. We would welcome comments on whether there are genuine grounds for exemption from such a scheme that would not prejudice the operation of, or otherwise disadvantage companies that elect to join the scheme. For example, should all wholesalers dealing in generic medicines be covered by the scheme, or could some small companies be excluded on the basis of excessive regulatory burden? If some companies were not required to become members, what should be the parameters and what should be the regime for those companies so excluded?

*Products to be covered by these arrangements*

49. The Government proposes that the scheme should apply to all generic licensed NHS medicines dispensed in the community in England which would otherwise fall under category A of the existing Drug Tariff

50. For this purpose the term “generic medicine” refers to any human pharmaceutical product for which a marketing authorisation has been awarded and to which the proprietor does not apply a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International non-proprietary Names (INN) or any list of similar standing.

51. The scheme would apply to all packs, strengths and dosage forms of a generic medicine except:

- a pack that is intended for sale to the public without a prescription and the price of which is not generally accepted as a basis for the pricing of FP10 prescriptions;
sales of medicines which a company shows to be derived predominantly from private prescriptions;

products that are included in the list of substances which GPs may not prescribe on the NHS.

52. Where a medicine is sold as a generic medicine on prescription and over the counter (OTC), only the proportion that is prescribed would be subject to the provisions of the scheme.

53. We would welcome comments on the medicines that it is proposed should be covered by the scheme and would also welcome comments on whether generic medicines with relatively low sales to the NHS should be outside the scheme and covered by other arrangements.

Information to be provided by scheme members

54. The Department has a responsibility to monitor the market for the supply of generic medicines to the NHS to ensure that it is operating effectively for patients, the taxpayer and scheme members. To enable the Department to fulfil this responsibility, scheme members would be asked to send to the Department of Health the following information for the quarters ending 31 March, 30 June, 30 September and 31 December of each year:

Generic medicines purchased

- Total sums paid to all generic manufacturers for each generic medicine by strength, presentation and pack size net of all discounts and rebates that are allocated to specific products.

- The volume (e.g. by pack) for each generic medicine by strength, presentation and pack size.
• The level of any other rebate not attributed to specific products but that
crue to those sales in the relevant quarter.

• A list of the suppliers of each generic medicine covered by the scheme.

Generic medicines sold to pharmacy contractors and dispensing doctors

• The income generated for each generic medicine by strength,
presentation and pack size, net of all discounts and rebates that are
allocated to specific products.

• The quantity (e.g. by pack) sold for each generic medicine by strength,
presentation and pack size.

• The level of any other rebate or discount awarded not attributed to
specific products that accrue to those sales in the relevant quarter.

The Department may also consider it necessary from time to time to ask some
or all wholesalers to supply a list of their customers either in total or for a
specific medicine.

55. The information would be submitted to the Department within 30 days
of the end of each quarter.

56. We would welcome comments on the proposed arrangements for the
submission of information by wholesalers.

Start date for the scheme

57. The scheme would operate from a date to be agreed between the
Department of Health and scheme members. We envisage that companies
would agree to be bound by the terms of the scheme at least 3 months before
the introduction of a new Drug Tariff. This is necessary to allow sufficient time for the collection of the data necessary to calculate reimbursement prices and the calculation and promulgation of the new Tariff.

*Provision for review of the scheme*

58. It is proposed that the scheme would continue to operate subject to six months notice given by either party to the agreement.

59. Either party would be able to request a review of the scheme no earlier than date 12 months into the scheme and at annual intervals thereafter. Following such a review, the terms of the scheme could be varied with the agreement of the relevant representative body(ies) and the Secretary of State. If the terms of the agreement were to be so altered, scheme members would be invited to accept the new terms. They would have the option of leaving the scheme if they decided not to accept the amendments. We would welcome comments on proposals to review the scheme.

**Community Pharmacies and Dispensing Doctors**

60. The following arrangements would apply to community pharmacies and dispensing doctors.

*Community pharmacies and dispensing doctors covered by these arrangements*

61. The new arrangements would cover all generic medicines (as defined in paragraphs 63 - 66 below) and therefore all community pharmacies and dispensing doctors dispensing those medicines against NHS prescriptions in England would be covered by these arrangements.

62. These arrangements would be set out in a voluntary agreement under Section 33 of the Health Act 1999 which we would intend to conclude with Pharmaceutical Services Negotiating Committee (PSNC). The likely
obligations of individual pharmacies under such a scheme are set out in paragraphs 75-78 below. The practical difficulties of asking all community pharmacies to join the scheme may be considerable. We would therefore welcome views on whether it would be desirable to:

- ask all pharmacy contractors to join such a scheme by indicating their agreement to abide by the terms of the scheme;

- limit the requirement for pharmacy contractors to agree to the scheme to those with five or more pharmacies.

**Products to be covered by the arrangements**

63. The Department proposes that the scheme should apply to all generic licensed NHS medicines dispensed in the community in England which would otherwise fall under category A of the existing Drug Tariff.

64. For this purpose, the term "generic medicine" would refer to any human pharmaceutical product for which a marketing authorisation has been awarded and to which the proprietor does not apply a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International Non-proprietary Names (INN) or any list of similar standing.

65. The scheme would apply to all packs, strengths and dosage forms of a generic medicine except:

- a pack that was intended for sale to the public without a prescription and the price of which was not generally accepted as a basis for the pricing of FP10 prescriptions;

- sales of medicines which a company showed to be derived predominantly from private prescriptions;
• products that were included in the list of substances which GPs may not prescribe on the NHS.

66. Where a medicine is sold as a generic medicine on prescription and over the counter (OTC), only the proportion that is prescribed would be subject to the provisions of the scheme.

67. We would welcome comments on the medicines that it is proposed should be covered by the scheme and whether generic medicines with relatively low sales to the NHS should be outside the scheme and covered by other arrangements and more generally on the medicines that it is proposed should be covered by the scheme.

*Calculation of the reimbursement price*

68. It is proposed that the reimbursement price of each medicine as identified by indication, strength and pack size, would be related to the selling price ("ex-factory") of the manufacturers for that medicine. Information derived from manufacturers would be used to calculate the volume weighted average price.

69. At the start of the new arrangements it would be necessary to convert the existing Drug Tariff prices to the new basis. To achieve this reimbursement prices would be recalibrated so that the relativities in the new Drug Tariff for generic medicines take account of the net, weighted-average, prices charged by the relevant manufacturers. For example, if the average ex-factory price of one medicine is 25% more than another, then the reimbursement price would, in principle, also be 25% higher.

70. The Department believes that a formula as simple as this would aid the transparency of the new system. Nevertheless, it could give rise to some significant price changes compared to those derived from the present arrangements. To reduce changes to an acceptable level and to minimise the
degree of turbulence in the market, the Department has concluded that it may be necessary to phase in prices calculated under the new system over time. This could be achieved by setting parameters above and below which the reimbursement prices of individual medicines would not be allowed to rise or fall at one time.

71. The Department would welcome views on

- the proposed arrangements for converting existing Tariff prices to a new basis;

- whether the new arrangements for calculating reimbursement price should be introduced at one time or phased in over a period of months;

- if it is decided to phase in the introduction of the new arrangements, what would be the acceptable limit of price change at one time and how many months should be allowed for the introduction of the new arrangements?

Adjustment of prices after the start of the scheme

72. Reimbursement prices would increase or decrease by an amount (expressed in currency rather than percentage terms) as the volume weighted average selling price derived from the information supplied by the manufacturers. It is also envisaged that there would be periodic readjustments to incorporate the relativities of new generic medicines that became available each year.

The Department would welcome comments on mechanisms for adjusting prices in this way.

Incentives for community pharmacies
As already outlined one of the Government’s objectives for the new arrangements is that it should support a competitive market. To achieve this, the Government recognises that the new arrangements for the reimbursement of generic medicines should include incentives for community pharmacies and dispensing doctors to enable them to benefit from procurement decisions where these also benefit the NHS. The Government is considering ways by which this could be achieved.

Following a change in the price by the manufacturers for a specific medicine, the change in the reimbursement price could:

- be delayed for a specific period after the change has been derived from the information submitted by the manufacturer; and/or
- be less than that change.

The Department would welcome views on the above aspects of implementing changes in reimbursement.

Information to be provided by community pharmacies and dispensing doctors

To complete the picture of market intelligence the Department of Health would need to receive information that enabled it to estimate the overall margin achieved by community pharmacies and dispensing doctors differentiating between the cost of procurement from wholesalers, or in some cases manufacturers, and the sums reimbursed for generic medicines by the Prescription Pricing Authority. The number of pharmacies and dispensing doctors means that it would only be possible to obtain data from a sample of contractors. The Department is considering two options and would welcome views on both of them.

Option 1 - Submission of invoices by a sample of contractors
76. Assessment of margins earned on generic medicines would be determined from a statistically valid sample of pharmacies which would provide the Department or an agreed third party with copies of their invoices on an agreed basis – probably quarterly. The medicine description, volume and price data would be keyed in to create a database on generic medicine prices and volumes. Data would be segmented to allow differentiation between “independent” pharmacies, small chains and integrated chains.

Option 2 - Assessment of margins

77. This option would assess the margin earned on generic medicines dispensed. It could be based on data from the following sources:

- Figures for the total turnover of a sample of pharmacies (reimbursement and remuneration income from NHS business plus sales revenue from non-NHS business) and the total margin earned by each business.

- The Prescription Pricing Authority would provide data for each pharmacy of the total amount of reimbursement and remuneration paid that related to NHS business.

78. From these two sources it would be possible to deduce how much of each pharmacy’s total turnover was attributable to NHS and non-NHS business. Statistical analysis would then be used to estimate the percentage margin earned on NHS turnover and non-NHS turnover that, on average, best reflects the total margin earned on the business as a whole. This would then be refined to ascertain that part which related to generic prescriptions.

79. This method would be relatively simple to operate and require minimal compliance costs. A sample of pharmacies would be required to submit annual figures for their total turnover and total margin, which the Department believes could be obtained fairly easily from annual accounts. Careful testing
would be required to demonstrate that this method provided a reasonable estimate of the amount of margin earned. A system would be put in place to ensure that no individual pharmacy could be identified. A pilot of this option is currently being undertaken.

*Start date of the scheme*

80. The scheme would operate from a date to be agreed between the Department of Health and scheme members.

*Provision for review of the scheme*

81. The scheme would continue to operate subject to six months notice given by either party to the agreement.

82. Either party would be able to request a review of the scheme no earlier than 12 months into scheme and at annual intervals thereafter. Following such a review, the terms of the scheme could be varied with the agreement of the relevant representative body(ies)) and the Secretary of State. If the terms of the scheme were to be so altered, scheme members or their representatives would be invited to accept the new terms. They would have the option of leaving the scheme if they decided not to accept the amendments. We would welcome comments on the proposals to review the scheme.

*All agreements*

*Arbitration*

83. The Department and members of schemes and the relevant representative bodies would undertake to operate this agreement so that issues arising between the company and the Department were normally resolved by discussion between the scheme members and the Department. Nevertheless, significant issues between a member and the Department might arise that
could not be resolved in this way. Such issues could be referred by either party to the arbitration arrangement set out below.

84. Where a scheme member or the Department decided to go to arbitration it would be required to give written notice to the other party of its intention within 21 days of an event. Examples of “events” in this context would be refusal by the Department to agree a price increase under the scheme or a dispute concerning interpretation of information submitted under the agreement. Both parties would need to provide the arbitration panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of arbitration. Statements would be made available to both parties. They could be supplemented in response to questions arising during the arbitration procedure.

85. The arbitration panel would give each party to the disagreement the opportunity to put forward its case on the issue(s) in dispute at an oral hearing. The panel would be expected to hold the hearing within 30 days of the receipt of the written statements from both parties. Both parties would be free to decide their representation at the oral hearing.

86. Before or at the hearing the panel would be able to request supplementary written information from either party to the dispute where it considered this necessary to properly understand the issues. The parties would be required to provide this information within 15 days of the request. All information provided to the arbitrators and the arbitrators’ reasoned opinion and decision would be available to all parties. The panel would be expected to make its decision known to both parties within 30 days of the oral hearing or within 45 days where it had been necessary to obtain additional written information from either party. The decision would not be relied upon in the future operation of any of the schemes.

87. The Department proposes that the arbitration panel should comprise:
• a Chairman appointed by the Secretary of State with the agreement of the representative bodies;

• two members, one appointed by the Secretary of State and the other by the representative bodies.

88. The Secretariat to the panel would be provided jointly by the Department and the representative bodies.

89. The costs of the arbitration panel would be shared equally by the Department and the representative bodies. The parties to each dispute would be responsible for paying their own costs.

90. The confidentiality of commercially sensitive information would be assured.

91. The Department would welcome comments on the proposed arrangements for arbitration.

Exit from Agreement

92. Under the Health Act 1999, the Secretary of State may serve notice on a manufacturer or supplier that the scheme is no longer to apply to that company. He may do this where, for example, any acts or omissions of the company have shown that in the scheme member’s case, the scheme is ineffective either for the purpose of limiting prices for the supply of generic NHS medicines or where there is evidence that a scheme member has manipulated the information provided under the scheme in a way that may be disadvantageous to the NHS. The Secretary of State will have regard to any relevant decision of the arbitration panel when considering whether to serve a notice under that provision of that Act.
93. The Secretary of State would also normally regard it as relevant if it had been necessary to impose penalties or take other enforcement action provided for in regulations for breaches of provisions under regulations or directions made under that Act, particularly where this appeared to show a pattern of behaviour.

94. A company would be able, at any time, to withdraw consent for the voluntary scheme to be treated as applying to it. The Department would welcome comments on these proposals.

Report to Parliament

95. The Department would normally intend to report to Parliament once a year and provide aggregated details of the operation of the schemes. These details would include aggregated data submitted and adjustments made. The Department would welcome comments on ways in which the operation of the scheme could be reported.

Discussion with scheme members during the operation of the schemes

96. The Department anticipates that most business under each scheme will be conducted on a bilateral basis with the relevant scheme member. Nevertheless it is likely that issues will arise that concern all or a significant number of companies which require discussion across the board. To deal with such issues effectively, the Department would propose to have a periodic meeting at around six monthly intervals with each of the representative bodies of scheme members.

97. The Department would welcome comments on such meetings and whether the matters discussed should remain confidential or published on the internet.
Annex A

PARTIAL REGULATORY IMPACT ASSESSMENT (RIA)

1. **Title:** Arrangements for the supply and reimbursement of generic medicines to the NHS.

2. **Purpose and intended effect**

**Objective:** To introduce new arrangements for the pricing and reimbursement of generic medicines to the NHS in the community in England. They will affect manufacturers and wholesalers of generic medicines, as well as community pharmacists and dispensing doctors.

The proposed arrangements are designed 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;

- reimburse community pharmacies in line with what they actually pay for the medicines they dispense under the NHS;

- secure value for money for the NHS;

- provide information on prices throughout the supply chain;

- support a competitive pharmaceutical market with minimal interference;

- maintain incentives for market players to seek value for money in their purchasing.


Background:

The NHS in England spent £1.3 billion on generic medicines in the community in 2002. In 1999 and early 2000, there were apparent shortages and significant price increases in the list price of many generic medicines. Overall prices increased by around 35%. As a result, in August 2000 the Government introduced a statutory Maximum Price Scheme for the main generic medicines used in the community. The scheme, which was intended as a short-term measure, has restored stability to the generics market and overall returned prices to their pre-increase levels. Following a fundamental review of the generics market by Oxford Economic Research Associates (OXERA), the Government published a discussion paper “Options for the Future Supply and Reimbursement of generic medicines for the NHS”, in July 2001, which put forward options for consultation. Since then, the Government has held bilateral discussions with the main stakeholders - the British Generic Manufacturers Association representing the main manufacturers, the British Association of Pharmaceutical Wholesalers representing full-line wholesalers, the Pharmaceutical Services Negotiating Committee representing community pharmacies and the British Association of Generic Distributors - on an alternative scheme acceptable to all parties. It is proposed that this will replace the maximum price scheme.

Risk assessment:

The turbulence in the generics market in 1999-2000 is estimated to have cost the NHS in England £200 million in higher prices for generic medicines. The maximum price scheme has restored stability to the generics market and overall returned prices to pre-price increase levels. The NHS is at risk of a significant increase in expenditure on generic medicines without longer-term arrangements to provide price stability, continuity of supply and value for money for the NHS.
3. Options

The Discussion Paper published in July 2001 identified four options:

Option 1: a reference-based NHS price scheme backed by statutory price control, which would place a fixed distribution margin on the ex-manufacturer price of medicines. There is a high risk of litigation inherent in a statutory scheme. Many stakeholders opposed this option.

Option 2: central purchasing through tendering. There is a risk of monopolisation with single dominant suppliers and shortages. It is administratively burdensome. Most stakeholders opposed this option.

Option 3: a return to the arrangements prior to the introduction of the maximum price scheme (pre-August 2000). This does not address the underlying problems and risks a return to significant price increases and shortages as in 1999-2000.

Option 4: to continue the maximum price scheme. It does not deal with new products and does not link market prices with reimbursement prices.

Following discussions with the main stakeholders, a further option has been developed.

Option 5:

- To allow, wherever possible, the reimbursement price of generic medicines to be set through market forces but require manufacturers to seek the Department’s agreement to any price increase where there is a limited number of manufacturers and to submit quarterly information on the value and volumes of medicines sold.
- To require wholesalers of NHS generic medicines to submit quarterly information on the value and volumes of medicines purchased and sold.

- To introduce a new reimbursement scheme for community pharmacists and dispensing doctors with the reimbursement price linked to the "ex-manufacturer" selling price of the medicine.

4. Benefits

**Option 1:** the provision of better information on prices and setting of realistic wholesaler margins have the potential to close the gap between market prices and reimbursement prices to the benefit of the NHS but could remove incentives for community pharmacies to buy medicines economically.

**Option 2:** the potential to recoup value lost in the NHS supply chain and possible manufacturing efficiencies as a result of the stability and predictability of tenders.

**Option 3:** the players in the generic market benefit from no regulation but at a cost to the NHS.

**Option 4:** the NHS benefits from price restraint and the scheme is administratively simple. It is currently delivering savings of some £330 million a year.

**Option 5:**

- Is based on existing market mechanisms and enables the NHS to benefit from the competition that exists between manufacturers for most medicines. Linking reimbursement prices to those charged by manufacturers would enable the NHS to benefit more quickly from the falls in the market price of generic medicines in the months after the patent expires than occurs under the present system;
• provides regular information that would enable DH to monitor the market and take corrective action as necessary;

• reduces the risk of litigation inherent in a statutory scheme and avoids the administrative costs for DH and the stakeholders that would result from the introduction of central tendering.

**Business Sectors affected**

The business sectors affected are:

• Manufacturers of generic medicines. There are 14 main manufacturers supplying generic medicines to the UK market plus a number of smaller firms.

• Wholesalers of generic medicines, of which there are two types:
  • full-line wholesalers, which supply the whole range of pharmaceutical products. There are 13 full-line wholesalers (3 national and ten independent regional).
  • short-line wholesalers, which supply only a limited range of more profitable, frequently prescribed products. There are a small number of relatively large short-line wholesalers and a large number of companies including community pharmacies and pharmacy chains engage in short-line wholesaling activities. There are more than 1,000 companies with a wholesale licence.

• Community pharmacists and dispensing doctors. There are some 9,800 community pharmacies and some 4,500 dispensing doctors in England.
**Issues of equity and fairness**

The proposal is designed to ensure that the NHS obtains value for money from all sectors of the supply chain - manufacturers, wholesalers and community pharmacies.

**5. Costs**

**Compliance Costs**

**Option 1:** 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 manufacturers 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 (manufacturers 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. Two responses to the discussion paper estimated costs at £50,000 and £250,000 a year dependent on the detail required.

**Option 2:** 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. Responses to the discussion paper gave no quantification of costs.
Option 3: 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: 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 £1,000 and £5,000 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.

Option 5: Manufacturers and wholesalers will incur administrative costs in providing quarterly information to the Department. The costs will be affected by the degree to which businesses have to adjust and re-present the data available in their own accounts systems. Information on the costs of compliance with the information requirements is being sought as part of the consultation process.

Manufacturers will also incur costs supplying information to the Department to justify price increases for products where there is a limited number of suppliers. The costs involved would depend upon the number of price applications submitted.

A sample of community pharmacists and dispensing doctors - around 200 to 300 will be required to submit financial information to the Department. Two options are under consideration – either copies of invoices or financial accounts. Compliance costs are estimated to be minimal. These costs fall into the category of implementation costs – those associated with implementation, which cannot be directly attributed to a particular policy goal.

Other costs
The Government would incur additional costs associated with operating options 1, 2 and 5. Option 2 (tendering) would incur substantial costs.

**Costs for a typical business**

It is difficult to identify costs for a typical business as manufacturers, wholesalers and community pharmacies vary in the size of their operation, as explained in the section on business sectors affected.

**6. Consultation with small business: the Small Firms’ Impact Test**

Discussions have been held with the representative bodies of the manufacturers of generic medicines, pharmaceutical wholesalers and distributors and community pharmacies. They represent businesses of all sizes and the regulatory impact assessment included in the earlier discussion paper was discussed with the Small Business Service.

The consultation document of which this RIA forms a part seeks views on whether small companies or products should be exempt from the scheme.

**7. Competition Assessment**

The markets affected by the proposed changes in regulation are the generic manufacturing market, the generic wholesale market and the retail pharmacy market.

These markets are generally characterised by low levels of concentration and market power, with many competing firms. Retail pharmacies compete mainly on location, while manufacturers and wholesalers tend to compete on the range, price of products (discounts) offered and frequency of delivery. Information on the discounts available in these markets is often unclear. Rapid technological change is not an integral feature of these markets.
**Option 1:** Fixing wholesale margins would provide better information on the transaction prices in the supply chain, but would seriously limit the freedom of wholesalers to set prices. It could also damage the competitive process that ensures pharmacies have the incentive to buy economically.

**Option 2:** Tendering may result in competitive prices in the short run. It could, however, create barriers to entry for potential firms, with established firms finding it easier to win tenders. In addition the market is likely to become more concentrated with fewer firms actively engaged in the market. Companies that do not win the tenders will be excluded from the market. Wholesalers and pharmacies would be restricted in the choice of supplier to those that win the tenders. Prices would be fixed (or heavily constrained) during the period of the contract.

**Option 3:** With an unregulated market, firms have the advantage of freedom of pricing. However the NHS, as the purchaser, may be unable to establish what the true market price is (after discounts etc) and hence may not be able to be benefit from the competitive processes.

**Option 4:** By maintaining the maximum price scheme, artificial inflation of prices by basket suppliers is capped. The scheme however limits the freedom of manufacturers and wholesalers to choose the price of their products.

**Option 5:** Re-calibration of generic reimbursement levels would prevent artificial inflation of prices by basket suppliers. It would allow freedom of pricing in the supply chain (with the exception of products where there is a limited number of suppliers) who will need approval for significant price changes). Information on discount levels would be more readily available to the Department. In practice it would alter the margins available on individual medicines as reimbursement prices more closely reflected manufacturer prices, but the effect on competition is likely to be small.
8. **Enforcement and sanctions**

The arrangements would be covered by voluntary agreements under Section 33 of the Health Act 1999. All companies supplying generic medicines would be able to join the relevant scheme. Those that decide not to do so would be likely to be subject to a statutory scheme under Sections 34 to 38 of the Health Act 1999.

9. **Monitoring and review**

The scheme would operate subject to six months notice given by either party to the agreement.

Either party would be able to request a review of the scheme no earlier than date 12 months into scheme and at annual intervals thereafter. Following such a review, the terms of the scheme could be varied with the agreement of the (relevant representative body (ies) and the Secretary of State. If the terms of the agreement were to be so altered, scheme members or their representatives would be invited to accept the new terms. They would have the option of leaving the scheme if they decided not to accept the amendments.

It is also planned to have periodic meetings with the representative bodies to review progress. DH will also monitor prices in the supply chain as an integral part of the arrangements to ensure that the scheme is meeting its objectives and carry out cross-checks to ensure that data provided by companies are consistent.

10. **Consultation**

(i) Within government

HM Treasury and Office of Government Commerce.

(ii) Public consultation
The discussion paper in July 2001 was sent to manufacturers, wholesalers, community pharmacies and other interested parties of all sizes. Views were sought on all aspects of the proposed options including specifically on data collection for the reference-based scheme. Some 60 responses were received from generic manufacturers, wholesalers, community pharmacies, trade associations and the NHS. A dozen expressed views on the collection of a full-year’s data but only two quantified the estimated costs.

Since then lengthy and detailed discussions have been held with the representative bodies of the manufacturers of generic medicines (British Generic Manufacturers Association), pharmaceutical wholesalers (British Association of Pharmaceutical Wholesalers), community pharmacies (Pharmaceutical Services Negotiating Committee) and the British Association of Generic Distributors.

The consultation paper and partial RIA are part of a further consultation on the Government's proposed arrangements. It is being published following some 12 months of detailed discussions with the representative bodies. Accordingly the Government has concluded that a consultation period of 8 weeks would be appropriate.

11. Summary and recommendation

Awaiting outcome of consultation.
Annex B

Code of Practice on Written Consultation: The Consultation Criteria

The criteria in the “Code of Practice on Written Consultation” published by the Cabinet Office apply to all UK national public consultations on the basis of a document in electronic or printed form.

The criteria, which have been and will continue to be followed, wherever possible, in this consultation exercise, are reproduced below:

1. Timing of consultation should be built into the planning process for a policy (including legislation) or service from the start, so that it has the best prospect of improving the proposals concerned, and so that sufficient time is left for it at each stage.

2. It should be clear who is being consulted, about what questions, in what timescale and for what purpose.

3. A consultation document should be as simple and concise as possible. It should include a summary, in two pages at most, of the main questions it seeks views on. It should make it as easy as possible for readers to respond, make contact or complain.

4. Documents should be made widely available, with the fullest use of electronic means (though not to the exclusion of others), and effectively drawn to the attention of all interested groups and individuals.

5. Sufficient time should be allowed for considered responses from all groups with an interest. Twelve weeks should be the standard minimum period for a consultation.

6. Responses should be carefully and open-mindedly analysed, and the results made widely available, with an account of the views expressed, and reasons for decisions finally taken.

7. Departments should monitor and evaluate consultations, designating a consultation co-ordinator who will ensure the lessons are disseminated.