New long-term arrangements for reimbursement of generic medicines

Scheme M

June 2005

Department of Health

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DH INFORMATION READER BOX

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Preamble

The Department of Health and the British Generic Manufacturers Association, representing the British generic pharmaceutical manufacturing industry, recognise that each has a part to play in creating and maintaining a competitive and vibrant generic medicine market in the UK. The responsibilities of each are reflected in this agreement.

The industry recognises that it has a role, crucial to the continuing success of the National Health Service (NHS), particularly in primary care, in providing low-cost, high-quality medicines after expiry of patent protection enjoyed by the original brand.

In return, the Department will continue to promote policies that enable the immediate launch of generic medicines following the patent expiry of the original brand.

Introduction

1. The Department of Health and Scheme members have a common interest in ensuring that safe and effective generic medicines are available to the NHS via a supply chain that provides a reasonable return for all those involved.

Objectives

2. The objectives of the Scheme are that it should:

- maintain and, where possible, improve the quality of service to patients in the community, in particular maintaining a secure and reliable service which meets clinical need;
- achieve a transparent operation of the generic medicines market;
- promote a competitive pharmaceutical market;
- secure value for money for the NHS;
- ensure that the arrangements work well in the light of the characteristics of the supply chain and the way it may evolve over the duration of the Scheme;
- ensure that the cost and complexity of arrangements for the supply of generics to the NHS is neither disproportionate for public finances and the NHS nor places disproportionate burdens on companies.

Membership

3. Scheme M applies to manufacturers, ie those companies that manufacture generic medicines for use in the NHS.

4. The term 'manufacturer' falls under the meaning of supplier within the meaning of the Health Act 1999. Companies may hold product licences allowing for both manufacture and distribution. It is, therefore, important that each Scheme M member is certain about the nature of its membership when joining the Scheme. For example, a single company may elect to assume responsibilities as both a manufacturer and a wholesaler of the same or different generic medicines. Such a company will be required to join two schemes: Scheme M as a manufacturer and Scheme W as a

wholesaler. Manufacturers and wholesalers shall have different obligations under each scheme.

5. In cases of difficulty, the determination of which scheme to join should be guided by the linking of manufacturers/importers to marketing authorisations and by the linking of wholesalers to wholesaler dealing licences.

6. Arrangements for membership of each Scheme are covered by voluntary agreements under Section 33 of the Health Act 1999. All companies supplying generic medicines are able to join the relevant scheme. Those that decide not to do so shall be subject to a statutory scheme under Sections 34 to 38 of the Health Act 1999.

7. 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 shall not apply to members of voluntary schemes.

8. No manufacturer will be exempt from the statutory Scheme if it fails to join the voluntary Scheme.

Effective date of the Scheme

9. The Scheme will operate for not less than five years from 1 April 2005 unless varied or terminated as set out below.

Review of the Scheme

10. The Scheme will continue to operate subject to six months' notice of termination of the Scheme, in whole or in part, given by the Department or any party representing Scheme members.

11. Any party may request a review of the Scheme no earlier than 12 months into the Scheme and at annual intervals thereafter. Following such a review, the terms of the Scheme may be varied with the agreement of the relevant representative body or bodies and the Secretary of State for Health. 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.

Compliance with the Scheme

12. Any company that fails to comply with the Scheme or fails to provide information required under the terms of Scheme membership, or in any other way acts in a manner that would breach the Scheme, will be required to leave the Scheme. That company shall then be subject to the terms of the statutory Scheme. This provision applies to integrated companies of Scheme members.

Consultation arrangements

13. Apart from the mid-term review, meetings will take place between representatives of Scheme members and the Department every six months to consider the operation of the Scheme. This is in addition to any formal process of consultation required in relation to procedures referred to in the Health Act 1999. The Department or parties representing Scheme members may consult one another at any time to discuss or resolve any issues of concern to either side.

Products covered by the Scheme

14. The Scheme applies to all generic, licensed NHS medicines dispensed in the community in England that previously qualified to fall under category A of the Drug Tariff.

15. Within the Scheme, the term 'generic medicine' has a specific meaning. A generic medicine shall be understood to be 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 (rINNs) or any list of similar standing.

16. The Scheme applies to all packs, strengths and dosage forms of a generic medicine except:

- a pack solely 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;
- products included in the list of substances which may not be prescribed and dispensed in primary care on the NHS (drugs listed in Schedule 1 to the National Health Service (General Medical Services Contracts (Prescription of Drugs…) Regulations 2004).

Information to be provided by members

17. Manufacturers shall 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 (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;
    - up-to-date lists of trade prices.

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

18. In the case of a new generic medicine launched following patent expiry of a branded medicine with which it will compete, a manufacturer may be required to submit monthly details of the information above for the first two quarters following launch.

19. In cases of uncertainty about the source of a medicine discovered within the market, the Department may also, from time to time, request that a Scheme member identify the manufacturer of a specified generic medicine.

20. The information submitted to the Department will remain confidential to the Department and the Scheme member.

Pricing and submission of data

21. The Scheme allows freedom of pricing subject to the following provisions:

    - Any Scheme member supplying a generic medicine to the NHS may alter the price at which that medicine is sold to wholesalers or dispensing contractors without any prior requirement to discuss such changes with the Department of Health. This freedom is allowed on the condition that, if requested to do so, a Scheme member shall provide the Department of Health with information sufficient to explain the reasons for charging such prices.
    - New generic products introduced following the granting of a marketing authorisation may be sold at a price decided at the discretion of the supplier upon entering the market, provided that the price is no more than that of the equivalent branded medicine at the date of its patent expiry.

- Scheme members shall submit quarterly information for net generic medicines' income revenues and volumes of transactions.
- Scheme members shall, on request, submit copies of all price lists that they provide to wholesalers and dispensing contractors.

Setting the Category M drug tariff for generic medicines

22. Category M of the drug tariff for a generic medicine is based on a calculation that incorporates the volume-weighted, average price charged by manufacturers. In the interests of ensuring value for money for the NHS, any changes in the drug tariff will be closely aligned to reductions in market price after the market launch of a new generic medicine.

23. At the start of the Scheme, the existing drug tariff prices will be converted to the new basis. This will be achieved by adjusting reimbursement prices so that the relativities in the new drug tariff for generic medicines take account of the net, volume-weighted, average prices charged by the relevant manufacturers.

24. Thereafter, reimbursement prices will increase or decrease by an amount (expressed in currency rather than percentage terms) that will be determined from data including the volume-weighted average selling price derived from the information supplied by the manufacturers. Where such data is not received from manufacturers, the amount may be determined from information provided by wholesalers.

25. In cases, such as imported products, where data on factory gate prices is not made available to the Department, the reimbursement price may be derived from wholesaler purchase prices. The reimbursement prices of all other products will remain unchanged until each subsequent adjustment unless information received by the Department indicates that these prices should be reviewed.

26. In addition to the above there will be periodic readjustments, for example to incorporate the relativities and prices of new generic medicines that become available each year.

27. To determine the drug tariff for new generic products introduced following the granting of a marketing authorisation, the list pricing will be allowed at the discretion of the company on entering the market, subject to a maximum equal to the price of the originating brand product. An interim drug tariff will be calculated on the basis of that list price until such time as information is made available to allow a proper determination using market information. In the case of a new generic medicine

launched following patent expiry of a branded medicine with which it will compete, the Department may request monthly information to be submitted for the first two quarters following launch.

28. Wherever possible, the Department will allow changes in market prices to be influenced by existing market mechanisms. This means that where there is effective competition in respect of any given generic medicine then the Department will not interfere in the operation of the market for that medicine. However, should the Department identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the Department from significant increases in expenditure, then the Department may intervene to ensure that the NHS pays a fair price for the medicine(s) concerned.

29. To allow the consideration of prices and reimbursement, a Scheme member shall provide to the Department on reasonable request information such as the following:

- An analysis of the direct and indirect manufacturing and/or supply costs of the product or products which have increased in price. 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.
- The Department may also require a company to show that their profit margins on sales of other products are fair and reasonable to the NHS. The auditable evidence required in respect of these profit margins shall cover the same aspects as those noted in the section above.

30. In its examination of the reasonableness of a company's costs and prices, the Department 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 any integration of a manufacturer/wholesaler 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.

31. To support this data, the Department may also request details of actual sales of the product for the previous year, a forecast for the current year and an estimate for the following year.

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

Entry into the Scheme

33. The Scheme applies to all manufacturers of licensed, generic NHS medicines that are prescribed by medical or dental practitioners, nurses or others qualified to prescribe. Companies that supply NHS medicines and do not elect to be Scheme members, or cease to be Scheme members, are 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. Those sections do not apply to Scheme members.

34. Those companies which elect to be Scheme members shall signify their membership with the Certificate of consent for voluntary Scheme M to be treated as applying as shown at Annex A.

Arbitration

35. The Department, Scheme members and the relevant representative bodies will undertake to operate the Scheme so that issues arising between a member and the Department may be normally resolved by discussion between them. However, significant issues between a member and the Department may arise that cannot be resolved in this way. In such instances either party may refer the issues to arbitration.

36. Where a Scheme member or the Department decides to go to arbitration it will be required to give written notice to the other party of its intention within 21 days of an event. Examples of issues that may be referred to arbitration include 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 shall provide the arbitration panel with reasoned statements of their position with regard to the dispute within 28 days of the notice of arbitration. Statements shall be made available to both parties and may be supplemented in response to questions arising during the arbitration procedure.

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

38. Before or at a hearing, the panel may request supplementary written information from either party to the dispute if this is considered necessary to properly understand the issues. The parties will normally 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 will be available to all parties. The panel will 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 will not be relied upon in the future operation of any of the Scheme.

39. The arbitration panel will comprise:

- a Chair appointed by the Secretary of State for Health with the agreement of the representative bodies;
- one member appointed by the Secretary of State for Health and one other appointed by the appropriate representative body involved in the dispute.

40. The Secretariat to the panel will be provided jointly by the Department and the appropriate representative bodies of the Scheme members involved in the dispute.

41. The costs of the arbitration panel will be shared equally by the Department and the representative bodies. The parties to each dispute would be responsible for paying their own costs. The confidentiality of commercially sensitive information will be assured.

Exit from agreements

42. Under the Health Act 1999, the Secretary of State for Health may serve notice on a manufacturer that the Scheme is no longer to apply to that company. He or she 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 NHS generic 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.

43. The Secretary of State shall also normally regard it as relevant if it has been necessary to impose penalties or take other enforcement action provided for in regulations for breaches of provisions under regulations or directions made under the Health Act 1999, particularly where this appeared to show a pattern of behaviour.

44. A company may, at any time, withdraw consent for the voluntary Scheme to be treated as applying to it.

Re-entry to the Scheme

45. A company that manufactures NHS medicines has the right to be a Scheme member unless, having ceased to be a Scheme member, for whatever reason, any of its obligations under the Scheme remain undischarged.

Audit arrangements

46. The Department may require that information and data supplied by Scheme members is independently audited.

Report to Parliament

47. The Department will normally report to Parliament once a year and provide aggregated details of the operation of the schemes. The confidentiality of commercially sensitive information will be assured.

ANNEX A
Section 33(2) and Section 33(6) of the Health Act 1999

CERTIFICATE OF CONSENT FOR VOLUNTARY SCHEME M TO BE TREATED AS APPLYING

Name.....
(name of company, partnership, etc)

Address .....

.....

.....

1. I ..... (name of person signing and capacity in which signing, eg director, partner or other) certify that the above-named company/partnership/person hereby consents to the voluntary Scheme made between the British Generic Manufacturers Association and the Department of Health in June 2005 (to which there are modifications/and additions made between [the company/ partnership/ [name] and the Department of Health on …) being treated as applying to it/him.

2. I wish to elect to join Scheme M.

3. I am duly authorised to sign this certificate.

Signed.....

Date .....

ANNEX B

CERTIFICATE OF WITHDRAWAL OF CONSENT FOR VOLUNTARY SCHEME M TO BE TREATED AS APPLYING

Name.....
(of company, partnership, etc)

Address .....

.....

.....

Date on which the consent now being withdrawn was given

.....

1. I ..... (name of person signing and capacity in which signing, eg director, partner or other) certify that the consent of the above-named company/partnership/person to the voluntary Scheme made between the Department of Health and the British Generic Manufacturers Association in June 2005 is hereby withdrawn.

2. I am withdrawing from Scheme M in my capacity as a manufacturer.

3. I am duly authorised to sign this certificate.

Signed.....

Date .....

Schedules

Scheme members will be provided with a web link to enable them to access Schedules of Information to be provided by manufacturers.

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Copies are available from:

Department of Health
Pricing and Supply
Room 456.D
Skipton House
80 London Road
London
SE1 6LH

Or email generics@dh.gsi.gov.uk

The Scheme is available on the Department's generic medicines website at:

www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/GenericMedicines/fs/en