



Skipton House
80 London Road
London
SE1 6LH

12 September 2005

Dear

CONSULTATION

REIMBURSEMENT OF “STANDARD” BRANDED GENERIC MEDICINES

A new Pharmaceutical Price Regulation Scheme (PPRS) was introduced on 1st January 2005. The PPRS is a voluntary, non-statutory scheme, which indirectly controls the prices of branded prescription medicines to the National Health Service (NHS) in the UK by regulating the profits that companies can make on these sales. Its objectives are to:

- secure the provision of safe and effective medicines for the NHS at reasonable prices;
- promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
- encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

The new Scheme stated that subject to public consultation, ‘standard’ branded generics would no longer be covered by the PPRS and would be transferred to the new arrangements for the reimbursement of generic medicines. Accordingly, on 20th January 2005 the Department issued a consultation letter proposing that ‘standard’ branded generics should be:

- removed from the Pharmaceutical Price Regulation Scheme (PPRS)
- transferred to new arrangements for the reimbursement of generic medicines; and

- reimbursed at the lesser of either the Drug Tariff (DT) price of the comparable true generic or the list price of the standard branded generic medicine.

A 'standard' branded generic is defined as an out of patent product to which the manufacturer/supplier, who is not the originator company, has applied a brand name and that is comparable to a true generic that is readily available (i.e. currently listed as Category A or M in Part VIII of the Drug Tariff). In the main, other branded generics such as modified release preparations will remain within the scheme. The proposals do not affect the position of out of patent originator branded products, which will remain under the PPRS, irrespective of whether the originator company has transferred the product to another company.

The majority of those who responded supported the Department's proposals whilst also raising a wide range of additional issues. The Department's position on each of these additional issues is summarised at Annex A to this letter. A summary of the responses is also available at:

<http://www.dh.gov.uk/Consultations/ResponsesToConsultations/fs/en>

The Department has concluded that a range of products should be removed from the PPRS and reimbursed at the lesser of either the Drug Tariff price of the comparable true generic or the list price of the standard branded generic medicine.

However, in the light of comments received, including concerns about the accurate identification of 'standard' branded generic medicines that were not in oral solid dose form, the Department will undertake two further rounds of consultation. This, the first, seeks views on a range of proposals, detailed in Annex B concerning the removal from the PPRS of standard branded generic medicines in oral solid dose form listed in Annex C.

A second round of consultation will be undertaken in 2006 and will deal with the complexities associated with the identification of non-oral solid dose standard branded generic medicines.

You are invited to comment on:

- **the proposed revised arrangements detailed within Annex B for removing "standard" branded generic medicines in oral solid dose form from the PPRS.**
- **the products listed in Annex C which details those oral solid dose form medicines currently on the market that would be removed from the PPRS by application of the Department's definition of standard branded generics.**

Please send your responses to Eunice Barnor either by post to:

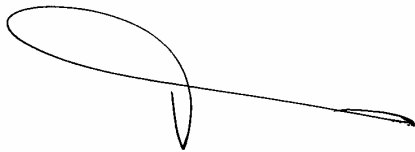
Department of Health
Skipton House
80 London Road
London
SE1 6LH

or via e-mail entitled standard branded generics to generics@dh.gsi.gov.uk by 24th October 2005. As this is a second consultation, a shorter period for responses has been allowed.

If there are any questions on the consultation, please contact Mike Shanahan by e-mail mike.shanahan@dh.gsi.gov.uk or by telephone 020 7972 2960 or by post to the address above.

A list of the organisations being consulted on this proposal is at schedule 1 attached.

Yours sincerely

A handwritten signature in black ink, consisting of a large, stylized loop followed by a horizontal line that tapers to a point.

DR FELICITY HARVEY
Head of Medicines, Pharmacy and Industry Group

SCHEDULE 1

LIST OF RECIPIENTS OF THIS CONSULTATION DOCUMENT

Association of the British Pharmaceutical Industry

British Generic Manufacturers Association

British Association of Pharmaceutical Wholesalers

British Association of European Pharmaceutical Distributors

British Association of Generic Distributors

Pharmaceutical Services Negotiating Committee

The Consumers' Association

Dispensing Doctors' Association

Primary Care Trusts' Chief Executives in England

Health Authorities' Chief Executives in England

General Practitioners Committee - British Medical Association

The Patients Association

National Pharmaceutical Association

Royal Pharmaceutical Society of Great Britain

Company Chemist Association

All Companies listed at Annex C

NOTES

Confidentiality Disclaimer

1. The information you send 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.

Regulatory Impact Assessment

2. As part of modernising Government, the Department of Health is committed to better regulations and the removal of unnecessary ones. A Regulatory Impact Assessment (RIA) helps assess proposals for change and the impact of various options identified. A partial RIA is required as part of the consultation process and this can be found at **Annex R**. The responses will contribute to the final RIA.

Cabinet Office Code of Practice on Consultations

3. This consultation is carried out in the context of the following criteria contained in the *Cabinet Office Code of Practice on Consultation*:
 1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy
 2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses
 3. Ensure that your consultation is clear, concise and widely accessible
 4. Give feedback regarding the responses received and how the consultation process influenced the policy
 5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator
 6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate
4. The Department intends to issue two further consultation letters each covering a period of six weeks seeking additional views. This, the first, seeks views on a range of proposals, detailed in Annex B concerning the removal from the PPRS of standard branded generic medicines in oral solid dose form listed in Annex C.

5. A second round of consultation will be undertaken mid 2006 and will deal with the complexities associated with the identification of non oral solid dose standard branded generic medicines. These will be additional to original consultation period on this matter which provided for the 90 consultation days recommended by Cabinet Office Guidelines.

7. Respondents are invited to comment on the extent to which the criteria have been adhered to and to suggest ways for further improving the consultation process. Comments or complaints about the consultation process should be directed to:

Steve Wells
Consultations Co-ordinator
Department of Health
Skipton House
80 London Road
London
SE1 6LH

E-mail: steve.wells@dh.gsi.gov.uk