



The Association of the
British Pharmaceutical Industry



Department
of Health



Ensuring Best Practice in the Notification of Product Discontinuations

Best Practice Guidelines

May 2001

Foreword

Discontinuing a medicine is a decision that most pharmaceutical companies will take at some point.

The Department of Health and the ABPI want to ensure that the impact of such a decision on patients is minimised and therefore we have worked together – and with industry representatives and healthcare professionals – to produce these good practice guidelines. They make recommendations about who to tell, when and what information will be needed. The emphasis is very much on early timing and information exchange and dissemination. And to help companies further, a central contact point has been established within DH; the details are on the pro-forma in these guidelines.

We believe that these guidelines will establish good practice across the industry and the NHS and allow discontinuations to be managed with as little inconvenience and worry as possible for patients. We very much hope that you will adopt them within your company.



Philip Hunt
Health Minister
Department of Health



Trevor Jones
Director General
ABPI

Introduction

Every product has a limited medical or economic life cycle and the decision to delete a product can be made for a variety of reasons including:

- Change in medical practice and availability of newer and better drugs
- Change in marketing strategy
- Commercial decisions
- Parent company decisions
- Manufacturing capacity restraints
- Revision of quality, regulatory or compliance requirements
- Problems in procurement of active ingredient

To ensure that the deletion of a product does not cause unnecessary problems for patients and prescribers, it is important that sufficient notice is given so that alternative sources of supply can be located, or patients switched to alternative therapies.

These guidelines have been drawn up jointly by the Department of Health (DH) and the ABPI. They are designed to ensure best practice in managing the phase out of products, especially the timing and recipients of notifications of the deletion.

If a product is being withdrawn for reasons of safety, quality or efficacy companies will be aware of their legal obligations to notify the Medicines Control Agency (MCA).

Notification of Product Deletions

Where a product is being withdrawn and there is no therapeutic alternative, the company should seek a meeting with DH at least – if possible – 12 months before the product is discontinued. When considering the availability of therapeutic alternatives, the company should think about the possibility of unlicensed uses and try to determine the extent of these. The meeting with DH will be informal and confidential and focus on exchanging information. The reasons for deletion should be discussed and DH may want to explore options for continued production such as using another manufacturer, importation or NHS production. DH will not share any information outside the Department, which includes the MCA, without the agreement of the company.

Deletion from Market Date

Once a company has made the decision to delete a product, they should assess how much stock of the product remains within the company and how long this is likely to last, based on current usage patterns. This will determine the deletion from market date. The deletion from market date is the date that the company will no longer supply the product. It does not affect the stock that may already be in the distribution chain in wholesalers and pharmacies.

Once a deletion from market date has been agreed, stock levels should be closely monitored. If it appears that there will be a change in the proposed deletion date due to a reduction or increase in ex-factory sales, the impact on the notification schedules should be considered urgently.

Timetable

At least 12 months prior to Deletion from Market Date

Initiate discussions with DH on products for which there are no therapeutic alternatives.

At least 3-6 Months Prior to Deletion from Market Date

Department of Health

DH should be formally notified of the proposed deletion 3-6 months prior to the deletion from market date. The pro-forma attached to these guidelines should be used. Six months notice would be ideal although it is recognised that this may not always be possible; three months should be taken as the minimum notice period. The information that the DH requires is:

- company details and contact;
- product details;
- which formulations or presentations are being deleted and which remain;
- licensed and unlicensed uses;
- the proposed timing;

- the reason for deletion;
- possible alternative therapies; and
- whether or not the deletion is UK, Europe or world-wide.

It will be assumed that this information can be shared widely with the NHS, with other companies, the Royal Colleges and groups with an interest (including patient groups) unless the company specifies otherwise. DH will contact the company with any feedback they receive regarding the deletion. This will enable the company to target the notifications more effectively.

Medicines Control Agency

The MCA should be notified of the proposed deletion 3-6 months prior to the deletion from market date. Six months notice would be ideal although it is recognised that this might not always be possible; three months should be taken as the minimum notice period. The letter should include:

- the reason for the deletion;
- the proposed timing;
- alternative therapies.

The Irish Medicines Board has its own best practice guidance for discontinued medicines and that should be followed if the discontinuation also applies to Eire.

Three Months Prior to Deletion from Market Date

Regional Medicines Information Centres and NHS Purchasing & Supply Agency

The Regional Medicines Information Centres and the NHS Purchasing & Supply Agency (PASA) should be notified of the proposed deletion three months prior to the deletion from market date. The letter should include: the proposed timing of the deletion; whether the deletion is UK or world-wide; and alternative therapies. This information will then be disseminated via usual communication channels.

Specialist Groups

Feedback from the DH together with internal company knowledge will enable notifications to be targeted at specific specialist groups (eg doctor, pharmacist, patient) depending on the product being deleted. A letter, similar to that sent to the Regional Medicines Information Centres and PASA, should be sent out to the groups with a particular interest.

Two Months Prior to Deletion from Market Date

Media

The company should issue a press release regarding the product deletion, including a request that the product monograph be removed. In timing this, the company needs to consider the deletion from market date and what stock remains in the distribution chain. The press release should be sent to the following media depending on the market concerned (copy deadline is in brackets):

- MIMS UK* (1st of preceding month);
- e-MIMS*;

- Chemist & Druggist Price List* (10th of preceding month);
- BNF** (mid-December for March issue, mid-June for September issue);
- The Pharmaceutical Journal;
- medical press as appropriate;
- professional bodies/organisations.

It is also suggested that the company has a list of Q&As regarding the product deletion, which can be used in any telephone queries. A copy of the Q&A should be sent to DH.

Product Information Compendiums

The company should ensure that the following annual compendium entries are updated to remove SPCs for deleted products:

- ABPI;
- Chemist and Druggist;
- ABPI Electronic Medicines Compendium website.

GP Databases

In the UK 90% of GPs have electronic clinical management systems and 70% of them use the computer during the consultation and to produce the prescription. To ensure that a deleted product is removed from the GP database, a letter should be sent to the NHS Information Authority (formerly the NHS Centre for Classification and Coding) who will then include the information in the update discs that are issued to the GP system suppliers. The process of having a product removed from a GP database can take anything from eight to twelve weeks depending on the cut-off date for the inclusion of new information on the discs that are issued. Alternatively, a company could notify each GP system supplier individually, which may speed up the process. Again in timing this, the company needs to consider the deletion from market date and what stock remains in the distribution chain.

DH aims to have all computerised GP practices connected to PRODIGY, the computer-based decision and learning support tool for GPs. Information about discontinued products can be disseminated quickly by updating the PRODIGY website, informing suppliers that an urgent interim release is required and through the PRODIGY National Dissemination Office releasing special e-mail notices alerting GPs to the changes.

One Month Prior to Deletion from Market Date

Wholesalers

Wholesalers should be notified of the deletion one month prior to the deletion from market date. This notification is left until one month prior to the deletion date to ensure that the product is not removed from the wholesalers' computer systems prematurely which would prevent the wholesalers from ordering further product from the company.

* If stock is anticipated to run out before the 15th of the month, then the product will be removed from that month's issue. If, however, stock is anticipated to run out after the 15th of the month, the product will be removed from the following month's issue.

** If stock is anticipated to run out before March/September, the product will be removed from the corresponding issue. If, however, it is anticipated that there will still be stock available in March/September and beyond, the product is to be removed from the following edition. This will mean however that product may still be listed in the latest BNF despite no longer being available.

Pro-forma for Product Discontinuation

To: by e-mail: MB-discontinuedmedicines@doh.gsi.gov.uk

by fax: +44 (0)20 7972 2932
Mrs Isabelle Izzard
Principal Pharmaceutical Officer
Department of Health

by post: Mrs Isabelle Izzard
Principal Pharmaceutical Officer
Department of Health
Room 607
Eileen House
80-94 Newington Causeway
London
SE1 6EF



Company details

Company name:
Company contact:
Contact telephone number:
Contact fax number:
E-mail address:

Product Details

Product name:
MA number:
Active Ingredient:
Licensed/unlicensed uses:
Presentation:
Presentations remaining:
Proposed date of discontinuation:
(3-6 month's notice if possible, 12 months if there is no therapeutic alternative)
Proposed date to inform medical/pharmaceutical press:

please turn over

Reason for Discontinuation

Please tick (✓) any that apply

- Raw material/sourcing difficulty
- Manufacturing plant closure/transfer
- Manufacturing capacity issues
- Safety issues
- Low volume product
- Other (please state):

Possible alternative product(s):

Interim arrangements:
eg named patient supply

Market(s) Affected

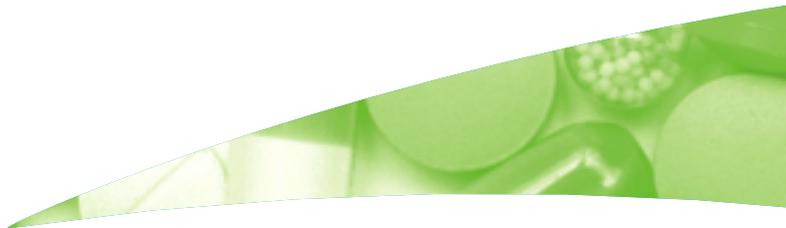
Please tick (✓) any that apply

- UK only
- Europe
- World-wide

If the discontinuation relates to safety, quality or efficacy

Date of notification to MCA:

Name of contact at MCA:



© Crown Copyright
Produced by Department of Health

23732 1p 2k Apr 01

CHLORINE FREE PAPER

Further copies of this document are available free from:
Department of Health, PO Box 777,
London SE1 6XH.

Or you could call the NHS Response Line
on: 0541 555 455

It is also on websites: www.dh.gov.uk/discontinuedmedicines
www.abpi.org.uk