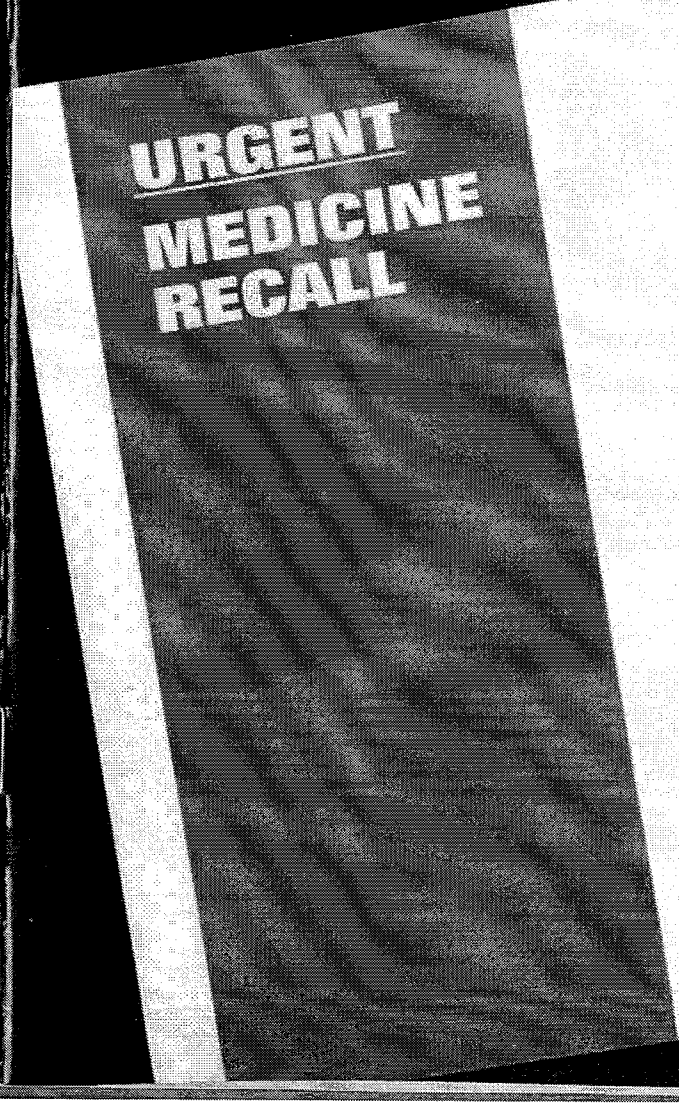
Batch recall of pharmaceutical products



Batch recall of pharmaceutical products

2ND EDITION SEPTEMBER 1994

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The Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY

Telephone: 020 7930 3477
Fax: 020 7747 1411
E-mail: abpi@abpi.org.uk
Website: www.abpi.org.uk

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Introduction

The Association has prepared this document as a general guide to the management of batch recall or product withdrawal by companies in the UK pharmaceutical industry. Consequently, it is most likely that the affected product will be restricted by law to supply by, or on the prescription of, a doctor or dentist, and its stocks held at various points in the distribution chain for the purpose of NHS use. Similar considerations may be appropriate to the management of recall of pharmacy and general sale list medicines, having due regard in each case to the nature of the product concerned and its distribution outlets.

Effective batch recall or product withdrawal assumes that the product has been conveyed in accord with good distribution practice through legitimate channels.

It is essential that recalls and withdrawals are managed promptly from the time of reporting of a possible defect, in a manner commensurate with the degree of potential risk to the patient. As a prerequisite, therefore, the necessary procedures will already have been put in place, tested, reviewed (especially at times of relocation and management change), and made known to all concerned in the recall process.

A company cannot conduct a batch recall or product withdrawal in isolation, however. It relies on its customers and agents, including health authorities, to act with due diligence at the time of discovery of a possible defect; to provide all reasonable assistance in locating and, if necessary, embargoing the suspect material; to supply a sample if available immediately on request for the purpose of examination and analysis; and to co-operate as appropriate in the dissemination of recall information.

The second edition of this guidance reflects changes in legislation with respect to the manufacture and distribution of medicinal products in the European Economic Area.

As this publication was going to press the MCA was consulting on the implementation of the new European licensing procedures for medicines, the 'Future Systems'.

It is likely that new powers under the centralised procedure, for instance will give further statutory force to the good practice already pertaining in the UK as advocated in this guidance. Any such changes introduced will be notified to member companies via the normal channels. Companies are advised to take due account of all relevant legislative changes.

1. Scope of the guidance

The scope of the guidance offered in this booklet applies to medicines for human use that are licensed medicinal products as defined in the Medicines Act 1968, and which are withdrawn or recalled from sale or supply for safety, quality or efficacy reasons. It does not cover withdrawal from sale or supply for commercial reasons, even though the licence holder is obliged to notify the Medicines Control Agency (MCA) of such a withdrawal. If a company is discontinuing a product without immediate withdrawal of stock then the market will be notified accordingly.

The principles of this guidance may be applied, where appropriate, to unlicensed medicinal products such as clinical trials material and to incidences where tampering is suspected.

If it is suspected that a product is a counterfeit (see Glossary) then companies should refer to Appendix 1 for further guidance.

2. Legislation

2.1 Medicines Act Regulations

Regulations made under the Medicines Act 1968 impose certain obligations on licence holders with regard to withdrawal and recall from sale.

The following extract is taken from Part I, Schedule 1 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No. 972), as amended.

para 6 The licence holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which the licence relates.

para 7 Where the licence holder has been informed by the licensing authority that any batch of any medicinal product to which the licence relates has been found not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period not exceeding six weeks as may be specified by the licensing authority.

para 8 The licence holder shall notify the licensing authority forthwith of any decision to withdraw from sale, supply or exportation any medicinal product to which the licence relates and shall state the reason for that decision.

Schedule 2 to the Regulations (Standard Provisions for Manufacturers Licences including Manufacturers Licences of Right) was amended in 1992 by SI No. 2846, in order to implement Directive 91/356/EEC 'Principles and Guidelines of Good Manufacturing Practice for Medicinal Products for Human Use' (the GMP Directive). The holder of the manufacturer's licence is required to have in place a system for recording and reviewing complaints and for recalling medicinal products in the distribution system. The manufacturer must inform the Defective Medicines Report Centre (DMRC) of the MCA immediately of any defect that could result in a recall or restriction of supply.

Where the product is manufactured by a contract manufacturer, then it is advisable that the product licence holder should clearly define the roles and responsibilities for a recall or withdrawal in the contract between the two parties. The product licence holder should be informed at the earliest opportunity if a problem arises that could result in a recall or withdrawal.

Amendments to Schedule 3 to the Regulations (Standard Provisions for Wholesale Dealers Licences including Wholesale Dealers Licences of Right) place requirements on holders of wholesale dealers licences to have recall plans and to assist in the event of a recall.

Implementation of Directive 92/25/EEC on wholesale distribution requires wholesale dealers to assist in the recall of a medicinal product and a special role is established for the Responsible Person. Further guidance will be found in the current Code of Good Pharmaceutical Wholesale Distribution Practice, published by the British Association of Pharmaceutical Wholesalers alongside the European Commission's guidelines on good distribution practice (OJ C.63 of 1.3.94).

2.2 Liability

Civil liability issues should be taken into account when considering the necessity for a batch recall or product withdrawal.

Claims under common law negligence could allege a failure by the manufacturer to discharge his duty of care to consumers by not initiating a batch recall or product withdrawal and that, as a result, injury was caused to the claimants (Walton v British Leyland). It is more likely, however, that claims would be based on strict liability under the Consumer Protection Act, 1987 which provides for liability in the event of injury or damage caused by a defective product. There

is no need to prove that the manufacturer was negligent and a product is to be deemed defective, 'if the safety of the product is not such as persons generally are entitled to expect'. While liability under the Act is strict, it is not absolute and a manufacturer may, in appropriate circumstances, rely on the so-called development risks defence whereby there will be no liability if, at the relevant time, the state of scientific and technical knowledge was such that the defect could not have been detected. Compensation levels under both negligence and the 1987 Act are unlimited.

Whatever decision is taken by the recall committee (see section 4 below), it is important from a liability point of view for the committee to be seen to have acted reasonably and on the basis of an informed risk-benefit analysis.

3. Complaints logging and monitoring

A potential batch recall or product withdrawal may be initiated by receipt of a complaint from customers, distributors, the company's own quality control organisation or from the DMRC. It is consequently essential for an effective procedure to exist in order to respond to all customer complaints in a timely manner. The existence of such a procedure should be made clear to all company employees (including representatives, receptionists, and possibly security staff) and agents who may be the first recipient of a complaint.

3.1 Receipt

Complaints cover a range of concerns and may be broadly divided into 'product' complaints (eg. quality or efficacy) or 'service' complaints (eg. marketing or distribution). They may be received either orally or in writing from various sources by a wide variety of individuals and departments within the company.

There must exist a defined procedure that prescribes the route for directing complaints to those assigned the responsibility for handling them. The procedure should require prompt notification to all relevant personnel, including a Qualified Person.

A system must be developed which allows for the recording of complaints and their individual identification. In the case of an oral complaint, a written record of the contact should be made and the complainant identified. Companies are advised to have a pro forma on which relevant data is entered. The pro forma should form part of the company's recall documentation.

Receipt of a complaint should be acknowledged without prejudice pending an investigation. If it is necessary to seek clarification, or relevant to recover any material associated with the complaint, this should be requested at this

juncture. It is reasonable to expect that samples will be supplied promptly unless there is insufficient of the possibly defective material. In such an event the company should be informed immediately and, as set out in the NHS Management Executive Guidance (HSG (93) 13), the company should also be informed of the result of any analytical tests performed. Steps should be taken to replace or credit alleged faulty material and reimburse postage and other expenses.

Complaints which are related to medical effects (alleged adverse reactions or ineffective treatment) must be referred to the medically qualified individual assigned this responsibility.

Complaints which indicate possible problems that could lead to a recall must be immediately referred to the recall committee (see section 4 below).

3.2 Investigation

Complaints must be thoroughly investigated by the nominated person or persons in a timely fashion in order to determine their validity and potential risks. The person named on the manufacturer's licence as responsible for quality control should be involved in the review of product quality complaints. The investigation should include the laboratory evaluation of any returned material along with the control keeping sample of the specific batch, if known. Other batches may also need to be checked (particularly any batches containing rework of the defective batch).

An internal technical report containing full details of the complaint, nature of complaint, material returned and laboratory findings should be prepared and referenced to the corresponding batch records. Possible causes of the complaint should be explored and corrective actions identified.

Previous complaints of a similar nature should be reviewed to help determine if the complaint is an isolated occurrence or if a pattern or trend exists. Where the investigation indicates that corrective action is necessary, management should review the results of the investigation to determine and implement the required actions.

3.3 Response

All complaints should be responded to regardless of their validity. The company must be sensitive to customers' perception of the quality of its products by being responsive to their concerns. The reply to the complainant should be based upon the internal technical report and contain sufficient detail as is reasonable to satisfy the complainant of

the company's concern and determination to assure the safety and efficacy of its products. In this regard, account should be taken of the particular source of complaint (e.g. patient, pharmacist, doctor, health authority or DMRC).

Copies of all correspondence, including the investigation summary, must be retained for a period consistent with the company's documentation retention policy. If samples either accompanied the complaint or were obtained subsequently, they also need to be retained for a defined period.

3.4 Complaint Analysis

A regular written summary report of the number and type of formal complaints received should be prepared for presentation to management. The data should be analysed in such a manner as to render visible any additional corrective action required.

4. Risk assessment

The company should have effective procedures for the efficient batch recall or product withdrawal of any of its products from the market. Designated senior executives, or their appointed deputies with a responsibility for patient safety and/or quality assurance, may perform the risk assessment. If a 'Recall Committee' is appointed to perform this task it may consist of some or all of the following as appropriate: – medical director, technical director, territorial business operations director, a Qualified Person, persons named on the manufacturer's licence as responsible for production and quality control, regulatory affairs manager, distribution manager, legal affairs manager, public affairs manager and product strategy manager.

The risk assessment requires an assessment of incoming reports which call for consideration of a need for a batch recall or product withdrawal. It should include consideration of the level of the batch recall or product withdrawal in the distribution chain and the possible need for patient awareness.

If a company is unsure whether a batch recall or product withdrawal is required, stocks at wholesalers and hospitals may be quarantined pending further investigation. The DMRC should be informed of such an action.

4.1 Classification of Defects

All product defects should be classified according to the nature of the fault and the potential risk it may present to a user. The appropriate classification may be discussed with the DMRC.

CRITICAL DEFECTS

Are those defects which can be life threatening and require the company to take immediate action by all reasonable means, whether in or out of business hours.

This defect category is defined as 'hazardous' ('a defect which has the capability to adversely affect the health of a patient') in the MCA 'Guidance on Reporting Accidents with, and Defects in, Medicinal Products'. It would result in the DMRC issuing a Class 1 Drug Alert.

MAJOR DEFECTS

Are those defects which may put the patient at some risk but are not life threatening and will require the company to initiate the batch recall or product withdrawal within 48 hours.

This defect category is defined as 'major' ('a defect which impairs the therapeutic activity of the product, it may not be hazardous') in the MCA Guidance. In this case the DMRC would issue a Class 2 Drug Alert.

Examples of each classification of defects are listed. *This list is not exhaustive and it is intended as guidance only.* For instance, non-compliance with product specification is generally regarded as a major defect, but in particular cases might be regarded as critical or minor. The appropriate action to be taken will be determined by the recall committee.

CRITICAL DEFECTS

- Product labelled with incorrect name.
- Product labelled with incorrect strength where there may be serious medical consequences.
- Microbiological contamination of a sterile product.
- Chemical contamination with serious medical consequences.
- Product mix up between two or more products or different strengths of products which could lead to serious medical consequences.
- Wrong active ingredient or wrong strength in a multi-component product leading to serious medical consequences.
- Counterfeit or deliberately tampered-with product.

MAJOR DEFECTS

- Any labelling/leaflet misinformation (or lack of information) which represents a significant hazard to the patient.
- Microbiological contamination of non-sterile products which may have medical consequences.
- Chemical/physical contamination by impurities, cross-contamination or particulates.
- Mix up between two or more products or different strengths of product which would not necessarily have serious medical consequences.
- Non-compliance with specification (ie. assay, stability, fill weight).
- Insecure closure which may lead to serious deterioration of product and/or which may result in serious medical consequences (e.g. faulty child resistant closure).

Continued overleaf

MINOR DEFECTS

Are those defects which present only a minor risk to the patient. Any batch recall or product withdrawal would normally be initiated within a period of 5 working days.

This category is defined as minor ('a defect which has no important effect upon the therapeutic activity of the product, and does not otherwise produce a hazard') in the MCA Guidance. A recall would result in a Class 3 Drug Alert being issued by the DMRC.

CAUTION IN USE

Are those minimal defects which do not present a hazard to the patient and do not require a batch recall or product withdrawal but the DMRC consider that a 'caution in use' letter (a Class 4 Drug Alert) should be issued to the distribution chain.

MINOR DEFECTS

This classification embraces defects which may not pose a significant hazard to health and therefore do not justify a Class 1 or Class 2 Drug Alert. A recall may have been initiated for other reasons, however, perhaps not required by the regulatory authority. Examples may include readily visible, isolated packaging/closure faults or contamination which may cause spoilage or dirt, and where it is concluded that there should be minimal risk to the patient.

CAUTION IN USE

A minimal defect which does not present a hazard to the patient, for example an occasional, empty tablet blister or discoloured tablet coating. A letter may be sent to the distribution chain which may advise return of stock to the manufacturer, depending on the defect and the scale of the problem.

4.2 Decision to Recall a Batch

The decision to recall a batch or withdraw a product may be taken for any of the following reasons:-

- If the quality of the product does not conform to the registered specification during its shelf life, for example the quality of the active ingredients or excipients in the product, or the degree of degradation on storage.
- If the packaging of the product is found (or can be expected) to lead to deterioration of the product within its declared shelf life.
- If the statement made on a label or leaflet is not in accordance with the requirements for the product as registered.
- As a result of adverse reactions that may have been reported as occurring with the product.
- Any other factor which might render the product unsuitable for the intended use and which may present a hazard to the user.
- If the product is known or suspected to be counterfeit or tampered with (see Appendix 1).

5. Procedures for recall

5.1 Recommendation for Batch Recall or Product Withdrawal Procedures

The Association makes the following recommendations with a view to the establishment of practices which would ensure the efficient operation of batch recall or product withdrawal procedures.

5.2 Company Responsibilities

Responsibility for the decision to recall a batch or withdraw product must remain with the company holding the United Kingdom product licence, irrespective of how the product is distributed and by whom. For parallel imported products the PL(PI) holder is responsible for placing the product on the market and for cooperating with the DMRC in the event of a recall. However, the DMRC has given an undertaking that it will inform the company marketing the corresponding UK product so that it may take any action necessary to protect its position and may consider whether that product may be affected.

5.3 Liaison with the DMRC

Liaison with the DMRC should be established at an early stage. The information required by the DMRC in the event of a batch recall or product withdrawal is set out in the form shown in Appendix 2. This information is normally given over the telephone. In cases of patient risk immediate notification to the DMRC is essential. The DMRC has 24 hour telephone lines in operation as noted in Appendix 2 and as stated in the current edition of the MCA 'Guidance on Reporting of Accidents with, and Defects in, Medicinal Products' and in the British National Formulary.

The DMRC will inform by facsimile the Health Authorities and the Department of Health of a Drug Alert.

The DMRC will also inform other EC Member States via the 'rapid alert system', if appropriate. Other EC Member States may similarly inform the DMRC of recalled or withdrawn product.

5.4 Written Procedures

Each company should ensure that its batch recall or product withdrawal systems and procedures are set out in written form and their details made known to all who may be concerned in their operation.

5.4.1 Such written procedures should nominate a responsible individual, or group of individuals (the recall committee) to deal with all incoming reports which call for consideration of a need for batch recall or product withdrawal (see section 4.0, Risk Assessment). The procedures should include named deputies and/or out of hours contacts (eg. security staff). The contact details of the responsible individual, the deputy and out of hours contacts should be known to the DMRC. The DMRC maintains a file of these contacts which is updated. Companies are advised to review their contacts' details as appropriate and notify the DMRC of any changes, since they are of critical importance to the DMRC when it needs to communicate urgently.

The recall committee should appoint a 'recall co-ordinator' with appropriate secretarial assistance in order to co-ordinate all the necessary actions and communications and to keep a detailed log of events and the precise time at which they occur.

5.4.2 The procedures should be revised at regular intervals to take account of changes in procedure and the recall committee listed therein.

5.4.3 The procedures should be validated at regular intervals to assess effectiveness.

5.4.4 Immediate Action Upon Receipt of a Report Suggesting a Need for a Batch Recall or Product Withdrawal

Reports should be referred immediately on receipt to the recall committee for risk assessment (see section 4) and appropriate action.

5.4.5 Batch Recall or Product Withdrawal Communications

The procedures should identify the person or persons responsible for communicating the need for a recall; the communication methods to be used eg. media (tv, radio, press), direct mail shot (see below), Electronic Data Interchange (EDI) etc; and to whom the recall or withdrawal notification should be sent. Appropriate liaison with the DMRC is advisable regarding the content of the recall notification and the communication methods to be used. The company may need to communicate the recall or withdrawal notification to hospital customers, including Health Authority – nominated representatives, and to direct account customers. Companies should ensure that staff giving advice, including telephone advice, are familiar with the DMRC Drug Alert text and that the advice given is consistent with this.

Depending on the situation, consideration should be given to providing telephone back-up (a hotline or pre-recorded messages) to supply further information.

Where appropriate, if distribution is primarily carried out through the wholesale dealer network, it is recommended that the 'cascade' system is used. The company may fax the recall communication to the wholesale dealer, addressed to the Responsible Person. Wholesalers agree to embargo their stocks and to advise all customers at the earliest opportunity (by telephone, electronic message or message on delivery note) to segregate and return stocks for credit or replacement. This is consistent with Articles 6 and 8 of Council Directive 92/25/EEC, on the wholesale distribution of medicinal products for human use. The company may also by prior agreement ask the wholesale dealer to include a copy of the complete communication with its delivery notes to all customers. All communication should be directed at the person responsible for dispensing medicines. Costs incurred by wholesalers issuing credit for returned stock will normally be met by the manufacturer/parallel importer which instigates the recall or withdrawal.

Once the decision to recall or withdraw has been made then notifications sent by post should be despatched by first class mail in a readily identifiable envelope, an example of which can be seen in Appendix 3.

5.4.6 In every recall or withdrawal, it is essential that adequate information be provided to purchasers and users, as below:

Name of product.
Presentation(s) involved.
Strength(s) of presentation.
Pack size(s).
Batch/lot number(s).
Expiry date.
Date of first distribution.
DMRC Drug Alert unique reference number.

Mention of the need for an immediate embargo on issues of remaining stocks of the relevant batches.

Reasons for the recall or withdrawal with indication of the health risk and urgency involved, where relevant.

The level in the distribution chain of the recall or withdrawal.

Reference to other recall or withdrawal notification activities (e.g. press, tv).

A telephone hotline number (if provided) for further information.

Methods of recovery and compensation by the manufacturer.

The wording of the recall or withdrawal notification and of the DMRC Drug Alert should be consistent.

5.4.7 Where circumstances make it appropriate, the notification should remind purchasers or users of the need to take into account goods in transit to them when the recall is initiated.

5.4.8 Steps should be taken to quarantine any returned products.

5.4.9 It is recommended that in the event of a decision to recall or withdraw a pharmaceutical product in the UK all overseas subsidiaries, associates and agents of the UK company should also be informed immediately and given the relevant information shown in 5.4.6 in order that they may take appropriate action where necessary.

5.4.10 Monitoring Systems

A system for monitoring the progress of the batch recall or product withdrawal should be instituted to ensure, as far as possible, that the original batch quantity is reconciled with the amount which is either embargoed or returned from purchasers or users as a result of recall or withdrawal action.

Where there is patient risk, such arrangements are particularly essential to provide information, both for the company and for the DMRC, on the extent of the risks for patients which may remain. An initial statement should be prepared giving the amount packaged, the amount distributed and the quantity remaining in stock.

5.4.11 Distribution Records

Adequate distribution records are essential to the efficient operation of the measures outlined above. The records should contain sufficient information on wholesale dealers and direct customers and be readily available to the recall committee.

There may be special customer requirements to record batch documentation for Large Volume Parenterals and Vaccines.

Companies engaged in cross-border distribution are advised to ensure that an efficient batch traceability system is in place.

5.4.12 Post Recall or Withdrawal Review

A final analysis of the recall or withdrawal operation should be produced and a copy sent to the DMRC.

6. Glossary of Terms

Batch	a defined quantity of finished product processed in one process or series of processes so that it could be expected to be homogeneous.
Batch issue system	this system enables the supplier to identify the period during which a particular batch is issued and a check of the relevant sales records for that period will identify those to whom the batch has been supplied.
Batch number	a distinctive combination of numbers and/or letters which specifically identifies a batch or lot and permits its history to be traced.
Counterfeit product	is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with an insufficient quantity of active ingredient or with fake packaging.
Expiry date	the date after which the product must not be used.
Manufacturer	the holder of a manufacturer's licence.
Medicinal Product	a medicinal product as defined by the Medicines Act 1968 and regulations made under it.
Qualified Person	the person who is named on the manufacturer's licence as being responsible for carrying out the duties specified in Article 22 of Directive 75/319/EEC.
Recall	the removal from the market of specified batch or batches of product.
Responsible Person	the person named on the wholesale dealer's licence as being responsible for ensuring that the provisions of the licence and additional guidelines are met.
Withdrawal	the total withdrawal of the product from the market.
Wholesale dealer	the holder of a wholesale dealer's licence.

Appendix 1

Extract from 'Counterfeit Pharmaceuticals – The Association's Policy Document and Action Plan', April 1992.

1. The prime responsibility for prevention and control of counterfeiting lies with government regulation of the healthcare infrastructure and distribution chain.
2. If the authorities suspect that a product is counterfeit, the information should be communicated immediately to the company producing the genuine product. Whilst the primary responsibility for analysis in this case rests with the authorities, the company will offer appropriate co-operation. Any inspection and analysis should be completed as quickly as possible.
3. Since the manufacturer of counterfeit products is generally unknown, the appropriate authority (the DMRC) will generally issue a recall notice. In the interests of patients, the company producing the genuine product will co-operate in any recall.
4. Where the authorities intend to issue a statement or recall notice, the company should receive an advance copy in order to satisfy itself and confirm to the authorities that its legitimate interests are being protected.
5. Any notices should include information, where possible, as to how the counterfeit can be differentiated from the authentic product, and any information available as to the likely danger to, or effect on, the patient brought about by the use of the counterfeit version. The company should endeavour to arrange a fully-manned information line to handle enquiries from the professions and public.
6. Since by definition the company did not put the counterfeit product on the market, it will not be obliged to accept returned counterfeit goods, or to exchange them, or to issue credit notes in respect of them.
7. A company maintains the right to undertake its own investigation and/or to take direct legal action to protect all aspects of its business.

Appendix 2

MEDICINAL PRODUCT DEFECT REPORTING FORM

Reference: MDR

Date: Time:

Message taken by:

1. Report received from:

Name:

Position/Status:

Organisation:

Telephone No: Ext

2. Product Name:

Supplier (from label):

Manufacturing Site:

Product Licence Number:

Dosage Form:

Strength:

Container Type/Size:

Batch/Lot Number:

Expiry date (if known):

First Distributed (if known):

Is sample available for Department of Health arranged testing? YES/NO

3. Reported defect and details of any associated clinical incident.

Notes

DMRC address, fax and telephone numbers are as follows:

Defective Medicines Report Centre
Room 1801
Market Towers
1 Nine Elms Lane
London SW8 5NQ

DMRC 24 hour telephone lines are:

Normal business hours 8.30 am – 5.30 pm – 0171 273 0574
Outside normal business hours – 0171 210 5368/5371
Fax – 0171 273 0676

Appendix 3

RECALL ENVELOPE

The colour block is printed in 'Signal Red' (Pantone PMS 179), positioned 10mm from the left hand edge of the envelope. The colour, which is 65mm wide, is bled off the top and bottom of the envelope. The front cover illustration is the correct size.

There is a 10mm space between the top edge of the envelope and the top of the word 'URGENT'.

Enquiries regarding availability of recall envelopes should be directed to one or other of the main pharmaceutical mailing houses. The Association will provide a sample of the style of envelope shown below on request.