

**DEPARTMENT OF HEALTH, SOCIAL SERVICES AND PUBLIC SAFETY**

**GUIDANCE TO TRUSTS**

**ON**

**REPORTING DEFECTIVE MEDICINAL PRODUCTS**

**June 2001**

Prepared by:

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(This telephone number should not to be used for general contact with the Medicines Control Agency, whose number is: 020 7273 3000 Fax: 020 7273 0676.

**(a) Departmental contacts are:**

**Dr N Morrow, Chief Pharmaceutical Officer  
Tel 028 9052 2952**

**Mr T J Scott, Principal Pharmaceutical Officer  
Tel 028 9052 3282**

**Dr M Mawhinney, Principal Pharmaceutical Officer  
Tel 028 9052 3348**

**(b) Outside office hours, at weekends or Public Holidays:**

**Dr N Morrow,           028 9061 7515**

**Mr T J Scott,           028 9061 0207**

**Dr M Mawhinney,   028 9262 9217**

**To contact MCA:**

**Whitehall Switchboard Operator  
MTS Bureau, HM Treasury  
Parliament Street, London, SW1P 3AG**

**Tel: 020 7210 300 who will contact the Medicines Control Agency Duty Officer.**

5. All information needed by in handling a report, should be made available at first contact. The MCA uses the form reproduced at Appendix 3 to record details reported to it. Boards and Trust are asked to use this form as the means of assembling the information which will be required by the Department and MCA to process the report.
6. The procedure described above does not affect the responsibility of staff to take any necessary local action arising from any incident either before or after notification, that is to say:
  - (a) To prevent further use of a defective or possible defective medicinal product.
  - (b) To preserve evidence against future need as enquiries progress. Material evidence must be preserved and put in the charge of a responsible officer.
  - (c) To prevent interference with equipment used with a defective or possibly defective medicinal product, except for safety reasons or to prevent loss of

samples and where appropriate to witness and record dial readings, position of taps and switches.

7. The defective or possibly defective product must be preserved. If samples are required for analysis or other purposes, they should be obtained from another part of the same batch, using the material implicated only if these other samples would not provide the information needed.

### **Receipt and Handling of Reports of Defective Products**

8. Following the receipt of a Drug Alert issued by the Medicines Control Agency, the Department first despatches the details to the CSA, Boards and Trusts by means of a faxed Pharmaceutical Circular (PhC). This 'Alert' is sent to each of the named recipients listed in Appendix 4. The CSA in turn will transmit, by post, details of the 'Alert' to Community Pharmacists, Dispensing Doctors and other users of an identified defective medicine. In urgent, out-of-hours situations the Department will contact by telephone named individual officers nominated by their Trust. The current list of contacts appears at Appendix 5.
9. The Department uses a standard list of addresses for all alerts put out in connection with this Scheme. Recipients of messages may assume that all other addressees will also receive it.
10. Alerts circulated by the Department will indicate:
  - the name of the product
  - its batch number
  - its date of manufacture and expiry date
  - the nature of the defect
  - the nature of the action to be taken
  - the degree of urgency for any action to be taken
  - any responsibility for onward transmission of the alert

## **APPENDIX 1**

### **MEDICINAL PRODUCT**

Any substance or combination of substances presented for treating or preventing disease in human beings or animals.

Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.

Also included, for the purposes of this Procedure only, are:

- materials used as ingredients of medicinal products, or during their preparation.

***Products which are not defined above must not be reported to the Department or Medicines Control Agency, but elsewhere in the Department, as described in Safety Notice SN(NI) 2001/01.***

**ACCIDENT:** An event which rational consideration could not have foreseen.

**ADVERSE REACTION:** A harmful or non-beneficial symptom or syndrome occurring as the result of the correct clinical use of a product which is not defective. An inherent unwanted property of the product.

**DEFECT/DEFECTIVE:** Not conforming to its specification\*. A shortcoming.

**HAZARDOUS DEFECT:** A defect which has the capability to adversely affect the health of the patient\*.

**MAJOR DEFECT:** A defect which impairs the therapeutic activity of the product. It may not be hazardous\*.

**MINOR DEFECT:** A defect which has no important effect upon the therapeutic activity of the product, and does not otherwise produce a hazard\*.

**ERROR:** A wrong action by a person.

**FAILURE:** Lack of expected clinical response from a product which is not defective.

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\* Based upon definitions in British Standard BS 6001 : 1972 "Sampling Procedures"

## APPENDIX 2

### PROCEDURE FOR ASSESSMENT OF INFORMATION RECEIVED BY OR ARISING WITHIN TRUSTS

This Appendix is set out primarily in the form of diagrammatic representation of what should be done by anyone who has discovered a defect in a medicinal product before any contract is made with the Department (though this should not prevent contact being made to see information or advice which the Department may be able to provide).

The Appendix is addressed to those who:

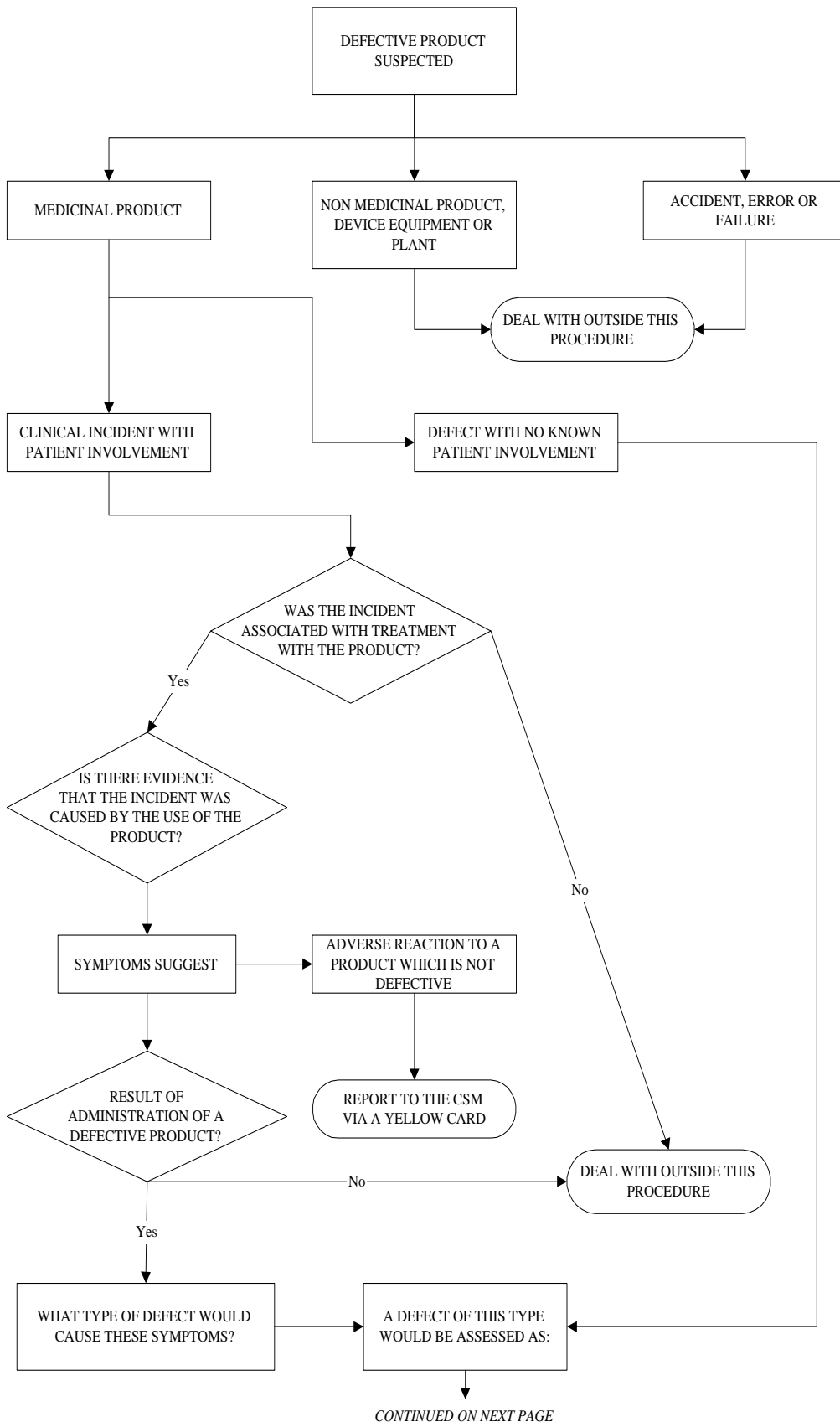
1. In medical, dental or nursing sphere observe clinical symptoms or a patient event, which indicates that a defective medicinal product has been used, or where a defective product might be the explanation of this observation.
2. In the pharmaceutical sphere, recognise that a medicinal product is or may be defective.

It provides a procedure which encompasses all matters which need to be considered, and questions which need to be asked, to enable conclusions to be drawn.

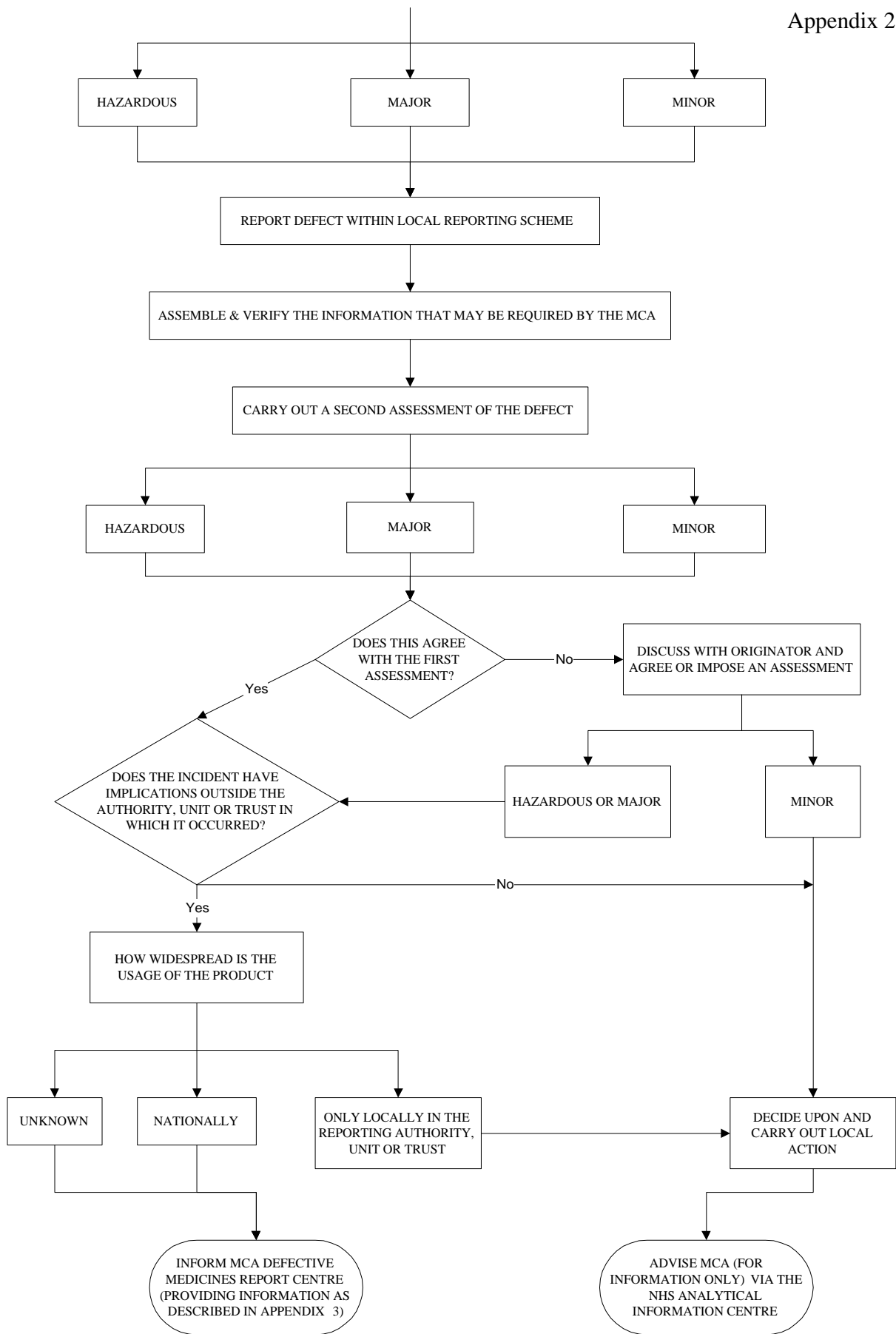
The purpose of the procedure is:

- a. To distinguish events due to defective products from those due to accidents, errors or failures.
- b. To differentiate between events relating to medicinal products from those relating to non-medical plant, and equipment, and medical and non-medical supplies.
- c. To ensure that before any report is made to the Department, all information which will be needed has been assembled.
- d. To provide reporting officers with the means to assess the seriousness of what is to be reported, before contact is made with the Department.
- e. To indicate to reporting officers the need to consider whether events warrant national action in addition to any action taken locally.

**PROCEDURE FOR THE ASSESSMENT OF INFORMATION RECEIVED BY OR ARISING WITHIN HEALTH AUTHORITIES, NHS TRUSTS & PROVIDER UNITS**



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# MEDICINAL PRODUCT DEFECT REPORTING FORM

Reference: MDR: \_\_\_\_\_

Date \_\_\_\_\_ Time \_\_\_\_\_ Message taken by \_\_\_\_\_

1. Report received from:

Name: \_\_\_\_\_ Position/Status: \_\_\_\_\_

Organisation: \_\_\_\_\_

Address (if not Co.): \_\_\_\_\_

Telephone No. (Work): \_\_\_\_\_ Ext \_\_\_\_\_

Home: \_\_\_\_\_

2. Product name: \_\_\_\_\_

Supplier: (from label) \_\_\_\_\_

Manufacturing Site: \_\_\_\_\_

Product Licence No: \_\_\_\_\_

Dosage form: \_\_\_\_\_

Strength: \_\_\_\_\_

Container type/size: \_\_\_\_\_

Batch/Lot No: \_\_\_\_\_

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.

### Appendix 3

4. Medical/nursing contact who can give further information of any clinical incident.  
Name \_\_\_\_\_ Position/Status \_\_\_\_\_  
Address \_\_\_\_\_  
Phone No. \_\_\_\_\_ Ext \_\_\_\_\_
5. Has manufacturer/supplier been informed? YES/NO
6. Other action taken by reporter:
7. Company Contact (to be completed by Defective Medicines Report Centre)  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Telephone No: \_\_\_\_\_ Fax No: \_\_\_\_\_
8. Comments of Duty Pharmaceutical Assessor or Medicines Inspector (all cases)
1. Tell Company of nature of defect.  
Ask Company for:-
  2. Site of manufacture
  3. Date of distribution
  4. Check batch documentation
  5. Batch size
  6. Where it was distributed to
  7. Other similar defects
  8. Retained sample to be tested / examined.
9. Comments of Duty Senior Medical Assessor (where applicable)

**FAX NUMBERS FOR PHARMACEUTICAL CIRCULARS**  
(*Drug Alerts*)

		FAX Nos
CSA	Mr M Nelson	028 90 532963
Eastern Board	Ms A McCollum	028 90 553622
Northern Board	Dr D Morrison	028 25 662076
Western Board	Mrs O'Kane	028 71 611477
Southern Board	Mr M Timoney	028 37 414625
S&E Belfast	Ms A Bowen	028 90 565809
Belvoir Park	R Loughlin	028 90 647206
Musgrave Park	Ms Paula King	028 90 663278
Causeway Trust	Mrs Lundy	028 703 50002
BCH Trust	Mrs C Sonner	028 90 263993
Royal Group	Dr S O'Hare	028 90 263281 & 028 90 263282
Lagan Valley	Debra Paul	028 92 664198
Downe	Sharon Harte	028 44 619162
United Hospitals	Dr M Scott	028 94 424276
Mater Hospital	Mr E Mullaney	028 90 802384
UNDAH	Judith Walwin	028 90 561308
Muckamore	Ms Carmel Tohill	028 94 461768
Craigavon	Mrs Ann Friel	028 38 394142
Whiteabbey	Jill Hutchinson	028 90 552578
Mid Ulster	Miss M Hetherington	028 79 366784

