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GUIDELINES

ON A MEDICAL DEVICES VIGILANCE SYSTEM

The present Guidelines are part of a set of Guidelines relating to questions of application of EC-Directives on medical devices. They are legally not binding. The Guidelines have been carefully drafted through a process of intensive consultation of the various interested parties (competent authorities, Commission services, industries, other interested parties) during which intermediate drafts were circulated and comments were taken up in the document. Therefore, this document reflects positions taken by representatives of interested parties in the medical devices sector.
Note : this document is a revision of an earlier document published in March 1993 as MEDDEV. 3/93 rev. 2.

These Guidelines describe an adverse incident notification and evaluation system, to be known as the Medical Devices Vigilance system.

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APPENDICES

1. INTRODUCTION

1.1.1 These Guidelines describe a system for the notification and evaluation of adverse incidents to be known as the Medical Devices Vigilance system. They are intended to facilitate the uniform application and implementation of the Directive for Active Implantable Medical Devices (AIMD) and the Directive for Medical Devices (MDD). In particular, Article 8 (AIMD) and Article 10 (MDD) outline the obligations of Member States upon receipt of incident reports, from manufacturers or other sources, concerning any medical device which carries the CE marking.

These Guidelines also give guidance on those Annexes of the Directives which oblige the manufacturer to report certain types of incident to Competent Authorities.

These Guidelines are not enforceable by law.
Relevant extracts from both Directives are provided in Appendix 7.

A diagrammatic summary of the system is given in Appendix 9.

1.1.2 These Guidelines cover the activities of :

- the Commission,
- Competent Authorities,
- Notified Bodies,
- manufacturers (including their authorised representatives and persons responsible for placing on the market, see Article 14 of the MDD),
- users and others concerned with the continuing safety of medical devices.

For the purposes of Medical Devices Vigilance, Member States are represented by the Competent Authorities listed in Appendix 1.

1.1.3 These Guidelines cover the action to be taken once the manufacturer or Competent Authority receives information concerning an incident. Information on incidents which should be reported under the Vigilance system may come to the attention of manufacturers via the systematic procedure to review experience gained from devices in the post-production phase, or by other means (see Annexes 2, 4, 5, 6, 7 of MDD). The term "post-marketing surveillance" as referred to in Annex 2, 4, 5 in AIMD has the same meaning as the aforementioned "systematic procedure..".

These Guidelines make no recommendations on the structure of the systems by which manufacturers gather information concerning the use of devices in the post-production phase.

1.1.4 This medical devices vigilance system takes precedence over information systems to be installed under the requirements of the Council Directive 92/59/EEC of 29/6/1992 on General Product Safety[1]

1.2 USER AND OTHER INCIDENT REPORTING SYSTEMS

1.2.1 Member States may wish to supplement reports received from manufacturers under the Vigilance system with reporting from other sources. Member States should adopt administrative measures to ensure that the pertinent manufacturers are informed without delay of reports meeting the criteria set out later in these Guidelines (see para 6.4).

1.2.2 In order to enhance the efficacy of the Medical Device Vigilance system, Competent Authorities should encourage the reporting of adverse events by the user. Such reports may be made either directly to the Competent Authority, or to the manufacturer, or to both depending on National practice.

1.3 APPLICABILITY

1.3.1 These Guidelines refer to incidents occurring within the Member States of the European Community and all other States within the European Economic Area (EEA) with regard to:

* devices which carry the CE-mark ;
  and
* devices which do not carry the CE-mark, where such incidents lead to corrective action relevant to CE-marked devices.

Corrective action includes, but may not be confined to: device recall; issue of advisory notice; additional surveillance/modification of devices in use; modification to future device design, components or manufacturing process; modification to labelling or instructions for use.

These Guidelines do not apply to devices under clinical evaluation or investigation - see Annex 7 of AIMD and Annex 10 of MDD.

1.3.2 If incidents which occur outside the EEA lead to corrective action relevant to CE-marked devices which are offered for sale or are in use within the EEA, then manufacturers should notify the relevant Competent Authorities.

1.3.3 These Guidelines are intended to be applicable equally to the Directive for Active Implantable Medical Devices and the Medical Devices Directive. The procedures are intended to be the same for both Directives, with respect to the Vigilance system.

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[1] OJ.C 156/8 of 27 June 1990

2 *FOR WHOM THESE GUIDELINES ARE WRITTEN*

2.1 MANUFACTURERS

These Guidelines apply to manufacturers placing medical devices on the market in accordance with the AIMD and the MDD. The definition of the term "manufacturer" is given in Appendix 2.

2.1.2 Manufacturers should ensure that these Guidelines are made known to their authorised representatives within the EEA, persons responsible for placing devices on the market and any other agents authorised to act on their behalf for purposes related to Medical Devices Vigilance, so that the manufacturers' responsibilities may be fulfilled.

2.2 COMPETENT AUTHORITIES

These Guidelines cover Competent Authorities' responsibilities, in particular under Article 2 of AIMD and MDD, and article 8 of AIMD and Article 10 of MDD.

2.3 NOTIFIED BODIES

Notified Bodies may be consulted by Competent Authorities or manufacturers following incidents involving, for example, medical devices for which they have provided attestations leading to a CE mark.

2.4 HEALTH-CARE ORGANISATIONS AND PERSONNEL

Member States should ensure that organisations and individuals involved in purchasing medical devices and in the provision of health-care are aware that their co-operation is vital in providing the first link in the Vigilance chain. This includes organisations and individuals responsible for providing calibration and maintenance for medical devices.

3 *PURPOSE OF THE VIGILANCE SYSTEM*

3.1.1 The purpose of the Vigilance system is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

3.1.2 The Vigilance system is intended to allow data to be correlated between Competent Authorities and manufacturers and so facilitate corrective action earlier than would be the case if data were collected and action taken on a State by State basis.

3.1.3 Whilst the manufacturer has the responsibility for taking any action necessary, Competent Authorities should also monitor the effectiveness of the manufacturers' follow-up on reported incidents. The Competent Authority should take any further action that may be necessary to supplement the actions of the manufacturer.

3.1.4 Once corrective (or other) action is identified, hospital administrators, medical practitioners and other health-care professionals, and user representatives responsible for the maintenance and the safety of medical devices, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the manufacturer.

3.1.5 Competent Authorities may also monitor experience with devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification.

4. GENERAL PRINCIPLES

4.1.1 Information held by Competent Authorities in connection with the Vigilance System is to be held in confidence, as defined by the relevant Articles of the Directives (AIMD 15 and MDD 20). In order to achieve the purpose of the Vigilance system, any incident report should be available on request, and in confidence, to the other Competent Authorities (see paragraph 7.2).

4.1.2 The act of reporting an incident to a Competent Authority is not to be construed as an admission of liability for the incident and its consequences. Written reports may carry a disclaimer to this effect. (see paragraph 6.2)

4.1.3 The initial report on an incident under the Vigilance system is made by the manufacturer to the Competent Authority for recording and evaluation (see paragraph 6). Each initial report should lead to a final report (see paragraph 8.6), but not every initial report will lead to a corrective action.

4.1.4 The manufacturer should ensure that their authorised representative within the EEA, persons responsible for placing devices on the market and any other agents authorised to act on their behalf for purposes relating to Medical Devices Vigilance, are kept informed of incident reports as appropriate

The manufacturer should consider informing official distributors etc as appropriate during the procedure. This does not affect the right of the manufacturer to determine the person authorised to be the principle contact point for purposes of relating to Medical Devices Vigilance.

4.1.5 It is recommended that manufacturers inform their Notified Body of those incidents which may affect the certification provided by that Notified Body. However, it remains the role of the Competent Authority to monitor the investigation being carried out by the manufacturer.

4.1.6 Depending on the outcome to the investigation, any information necessary for the prevention of further incidents (or the limitation of their consequences) should be disseminated (see paragraph 8.4 and 8.5).

5. *TYPES OF INCIDENTS TO BE REPORTED BY MANUFACTURERS TO COMPETENT AUTHORITIES*

5.1 REQUIREMENTS OF THE ANNEXES

Extracts from the Annexes of the AIMD and of the MDD which define what should be reported by the manufacturer to Competent Authorities are given in Appendix 7. Although the wording of these Annexes to the two Directives is different, the interpretation given in these Guidelines is nevertheless the same.

For example, the Directive for Medical Devices includes the word "serious" as a qualification of "deterioration in his state of health". In these Guidelines, the Directive for AIMDs is interpreted as though the word "serious" were present.

5.2 DECISION PROCESS ON WHAT A MANUFACTURER SHOULD REPORT

The manufacturer should assess the following points when deciding whether an incident should be reported to a Competent Authority:

- the type of incident (or potential incident) - paragraph 5.4;
- whether any medical device may have been involved which was made by that manufacturer or under his authority;
- whether the incident was caused (wholly or partly), or could have been caused, by the device or by shortcomings in the information supplied with the device - paragraph 5.5.

The same considerations apply to a Competent Authority's decision whether to inform a manufacturer of an incident reported via a User Reporting or other system -see paragraph 6.4.

5.3 ACCESS TO THE DEVICE SUSPECTED TO BE INVOLVED IN THE INCIDENT

A manufacturer may consult with the user on a particular incident before a report has been made to the Competent Authority (see paragraph 6.1). The manufacturer may also wish to have access to the device said to be involved in the incident for the purpose of deciding whether the incident should be reported to the Competent Authority. Such access may be affected by the requirements of National Law, and may also be at the discretion of the user or health-care facility concerned.

If the manufacturer gains access to the device, and his initial assessment (or cleaning or decontamination process) will involve altering the device in a way which may affect subsequent analysis, then the manufacturer should inform the Competent Authority before proceeding. The Competent Authority may then consider whether to intervene.

5.4 GUIDELINES ON TYPES OF INCIDENTS TO BE REPORTED

The following paragraphs describe the types of incidents which a manufacturer should report to the Competent Authority.This is illustrated by the simplified flow chart and the examples of such incidents, given in Appendices 4 and 5.

In assessing the type of incident. the manufacturer should consult with the medical practitioner involved or other health-care professional wherever practicable.

Incidents which need to be reported are defined in the Directives as follows:

5.4.1 Those which led to a death;

5.4.2 Those which led to a serious deterioration in the state of health of a patient, user or other person. A serious deterioration in state of health can include:

- life-threatening illness or injury;
- permanent impairment of a body function or permanent damage to a body structure;
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Note: The interpretation of the term serious is not easy, and should be made in consultation with a medical practitioner wherever possible. Many points may need consideration, for example:

- *whether a risk was foreseeable and clinically acceptable in view of potential patient benefit;*
- *whether the outcome was adversely affected by a pre-existing condition of the patient.*

In cases of doubt on this issue, it is suggested that there should be a pre-disposition to report rather than not to report.

5.4.3 Those which might have led to death or serious deterioration in health

Not all incidents which should be reported involve a death or serious deterioration in health which actually occurred. The non-occurrence of such a result might have been due to other fortunate circumstances or to the intervention of health-care personnel.

It is sufficient that:

- an incident associated with a device happened, and
- the incident was such that, if it occurred again, it might lead to death or serious deterioration in health.

OR

- an examination of the device or the information supplied with the device indicated some factor (eg a deterioration in characteristics or performance, or a shortcoming in the information) which could lead to an incident involving death or serious deterioration in health;For the purposes of these Guidelines, such potential incidents are to be known as "near incidents".

For a near incident to be reported, a possible direct link with the device, or with shortcomings in the information supplied, should be clearly established.

5.5 THE INCIDENT OR NEAR INCIDENT AND THE DEVICE OR THE INFORMATION SUPPLIED WITH THE DEVICE

The following paragraphs describe the characteristics of the device, or of the information supplied with the device, which may be associated with an incident which should be reported.

In assessing the link between the device and the incident or near incident, the manufacturer should take account of:

- the opinion, based on available evidence, of health-care professionals;
- the results of the manufacturer's own preliminary assessment of the incident;
- evidence of previous, similar incidents;
- other evidence held by the manufacturer.

5.5.1 Malfunction or deterioration in the characteristics and/or performance of a device.

A malfunction is a failure of a device to perform in accordance with its intended purpose (see Appendix 2) when used in accordance with the manufacturer's instructions. This includes single fault conditions (e.g. component failures) which cause, or could cause, an injury. (The EN 60601-1 definition of single fault is reproduced in Appendix 2 Definitions).

It does not include single fault conditions for which the manufacturer has made provision (in accordance with relevant standards) and which do not cause an injury, or potential injury.Deterioration of the device also includes problems caused by unpredicted biological effects related to the device.

Deterioration does not include the normally expected ageing of implant materials or depletion of batteries which were predicted in the information supplied with the device.

5.5.2 A device which shows no malfunction or deterioration, but nevertheless has a characteristic which could lead to an incident should be reported as a near incident.

5.5.3 Inaccuracies in the instruction leaflet, or instructions for use include omissions and deficiencies.

The terms "instruction leaflet" and "instructions for use" include all information provided on or with the device, such as instruction materials, or user and maintenance manuals.

An example of an omission is a failure to warn of a side effect which may be produced by the device working within specification; an example of a deficiency is a lack of clarity which leads, or could lead to, an injury.

Omissions do not include the absence of information which should generally be known by the intended user.

Any inaccuracy in the instructions which caused, or could cause, misuse or incorrect maintenance or adjustment should be reported.

5.5.4 Reference to the above considerations may be made in the report, or should be kept on file by the manufacturer in the case a decision not to report.

5.6. TIMESCALE FOR THE INITIAL REPORTING OF AN INCIDENT OR NEAR INCIDENT

The report should be made as soon as possible commensurate with determining whether the incident falls within the guidance discussed above. The times given below are the maximum elapsed times for determining the relevant facts and making an initial report.

The time runs from the manufacturer first being informed of the incident, to the relevant Competent Authority receiving the notification from the manufacturer.

Incidents	10 days
Near incidents	30 days

5.7 SYSTEMATIC RECALLS

Recall = withdraw

5.7.1 The Directives require any technical or medical reason for the systematic recall of a device to be notified by the manufacturer to a Competent Authority. The Term "withdrawal" used in the AIMD is interpreted in the same way.

The term "recall" is defined in EN46001 (see Appendix).

Removals from the market for purely commercial reasons are not included.

A simplified flow chart illustrating the types of recalls to be reported is given at Appendix 6.

5.7.2 The manufacturer should issue advisory notices when implementing recalls. Copies of advisory notices should be sent to the Competent Authorities of the countries to which they are applicable, and for devices in Class II or Class III, the Competent Authority in the State where the Notified Body is situated and which made the attestation which led to the CE marking being attached to the device. Manufacturers should consider sending copies of Advisory Notices to Competent Authorities under cover of a report which takes the same structure as the Final Report (see para 8.1.3). Notification to Competent Authorities should be made before or at the same time as the notices are sent to the relevant users. The terms "advisory notice" and "Recall" are defined in EN46001 (see Appendix 2).

6 MAKING AND RECEIVING AN INITIAL REPORT BETWEEN MANUFACTURER AND COMPETENT AUTHORITY

6.1 COMPETENT AUTHORITY TO WHICH AN INITIAL REPORT SHOULD BE MADE

6.1.1 In general, the report should be to the Competent Authority in the country of occurrence of the incident, with the following provisos or exceptions :

i) In the case of an incident involving an implant which occurs in a Member State other than the Member State where the implant was performed, the above principle still applies. In addition, the manufacturer should copy the report to the Competent Authority of the State where the implant was performed, if known.

ii) Reports on incidents concerning devices in Class II or Class III **occurring in countries outside the EEA** and which result in corrective action, should be made to the Competent Authority in the State where the Notified Body is situated and which made the attestations which led to the CE marking being attached to the device.

iii) Reports on incidents concerning Class I devices which **occur outside the EEA** and which result in corrective action, should be made to the Competent Authority of the Member State in which the manufacturer, or the person responsible for placing on the market, has made his notification within Article 14 of MDD.

The list of Competent Authorities is in Appendix 1. The list is correct at the time of writing, but there may have been changes, additions or deletions since.

6.1.2 Where appropriate, manufacturers should notify their authorised representative, persons responsible for placing on the market and any other agents authorised to act on their behalf of incidents reported under the Vigilance System.

Manufacturers should inform their Notified Body of those incidents reported under the Vigilance System which relate to the conformity assessment as carried out be the Notified Body.

6.2 DETAILS TO BE INCLUDED IN INITIAL REPORT

A recommended format for the initial report by the manufacturer to the Competent Authority is given in Appendix 3.

6.2.1 The report should include the following details as appropriate:

- manufacturer's name (and the name of the authorised representative within the EEA, where relevant), address, contact point, telephone number, Fax.
- the date when the incident came to the knowledge of the manufacturer;
- medical device kind, commercial name, catalogue number model, serial/batch/lot number, software version;
- identification number of the Notified Body involved in the conformity assessment procedure (if any), and the date(s) of the attestation(s);
- associated devices and/or accessories involved in the incident (if known);
- details of the incident (to the extent known) including date and patient or user outcome;
- current location of device involved in the incident, if known;
- contact point of user where incident occurred (the patient's full identity should not be reported).(The contact point need not necessarily be the person who actually witnessed the incident. It is recommended that health-care facilities have a contact person for all incidents reported).
- manufacturer's preliminary comments;
- manufacturer's proposed next action, and timescale;
- a statement of whether the manufacturer is aware of similar incidents having an impact on the current report
- if yes, the names of any other Competent Authorities to which these incidents have been reported, and the reference/date of the report (s);
- any other EEA State in which the device is known to be on sale.

6.2.2 If the manufacturer is located outside the EEA, a suitable contact point within the EEA should be provided. This may be the manufacturer's authorised representative, persons responsible for placing devices on the market or any other agent authorised to act on their behalf for purposes relating to Medical Devices Vigilance.

6.2.3 The report should not be unduly delayed because of incomplete information.

If the initial report is made by means other than by letter post (eg telephone, fax), it should be followed as soon as possible by a written confirmation.

6.2.4 The report may also include a statement to the effect that the report is made by the manufacturer without prejudice and does not imply any admission of liability for the incident or its consequences.

6.3 COMPETENT AUTHORITY ACTIONS ON RECEIPT OF AN INITIAL REPORT FROM A MANUFACTURER

6.3.1 The Competent Authority should acknowledge the receipt of the report to the sender.

6.3.2 The Competent Authority should record the report - this should involve categorising the incident, for example:

- by date (of incident, receipt by manufacturer, receipt by Competent Authority);
- by outcome (death, injury or near incident);
- by manufacturer and model;
- by device kind, using appropriate nomenclature;
- by "coordinating" Competent Authority for this type of incident (if any - see paragraph 7.2);
- by the date when the manufacturer's next action is due.

6.3.3 The Competent Authority should evaluate the report and intervene as appropriate, in consultation with the manufacturer if practicable (see para 7).

6.4 COMPETENT AUTHORITY ACTIONS ON REPORTS FROM USER OR OTHER SYSTEMS

6.4.1 A report which appears to meet the criteria of para 5, received by a Competent Authority from a User Reporting system or other source, should be copied by the Competent Authority to the manufacturer without delay. In doing so, patient confidentiality should be maintained.

6.4.2 Once the manufacturer has been so informed, the subsequent procedure is the same, as far as practicable, as that described in Section 7 onwards of these Guidelines.

7. *PROCEDURE FOLLOWING THE INITIAL REPORT*

7.1 PRINCIPLES

7.1.1 The manufacturer normally performs the investigation, while the Competent Authority monitors progress. The Competent Authority may intervene, or initiate independent investigation if appropriate. This should be in consultation with the manufacturer where practicable. (See paragraph 7.4).

7.1.2 In the case of incidents of, groups of incidents, or recalls involving more than one Competent Authority, there may emerge a single coordinating Competent Authority. Most communications should then be between the "coordinating" Competent Authority and the manufacturer. (See paragraph 7.2).

7.1.3 It is possible that the action concerning an incident may be completed without further investigation following the initial report.

Note: The above principles are generalised and do not take account of interventions by judicial or other agencies.

7.2 CO-ORDINATION BETWEEN COMPETENT AUTHORITIES

7.2.1 Initial reports are not normally disseminated between Competent Authorities. In the case of initial reports which confirm that incidents meet the criteria set out in paragraph 8.4.1, information should be disseminated between Competent Authorities and to the Commission at this stage (see paragraph 8.4). In the unusual event that an inital report is to be disseminated, the Competent Authority should inform the manufacturer prior to issue.

However, in order to achieve the purpose of the Vigilance system, any report made by a manufacturer to an individual Competent Authority should be accessible in confidence to the other Competent Authorities on request.

7.2.2 Competent Authorities should determine a single coordinating Competent Authority under the following circumstances:

* incidents of similar types occurring in more than one country within the EEA, and which lead to corrective action;

* recalls conducted in more than one country within the EEA, whether or not a reportable incident has occurred.

The following hierarchy should determine the coordinating Competent Authority, unless otherwise agreed between Competent Authorities:

* the Competent Authority which received the first initial report concerning this type of incident.

* the Competent Authority in the State where the manufacturer or his authorised representative is situated.

* the Competent Authority in the State where the Notified Body which made the attestation leading to CE-marking, is situated;

7.2.3 The coordinating Competent Authority has responsibility for:

* monitoring the investigation and coordinating contacts with the manufacturer on behalf of other Competent Authorities;

* accessing the expertise of the relevant Notified Body and coordinating with other Competent Authorities within the EEA;

* discussing with the manufacturer the principles, need and circumstances of corrective actions to be taken within the EEA;

* disseminating details of incidents which meet the criteria set out in paragraph 8.4.1 to other Competent Authorities and the Commission, including confirming the names of other States affected by recalls etc.

* receiving and pooling data and experience from other Competent Authorities;

7.2.4 Confirmation of a co-ordinating Competent Authority where applicable should be provided on the Competent Authority Report (see paragraph 8.4.2) under "reason for report" (see Appendix 8.).

7.2.5 Such an arrangement would not affect the rights of an individual Competent Authority to perform its own monitoring or investigation, or to instigate action within its Member State in accordance with the provisions of the relevant Directives.

7.2.6 COMMITTEE ON MEDICAL DEVICES

If similar reports are being investigated in different Member States, it is recommended that the Commission should be informed, so that it can facilitate or support measures such as those described above. At the initiative of the Commission or the Member State, the matter may be discussed in the framework of the Committee on Medical Devices.

7.3 MANUFACTURER ROLE FOLLOWING THE INITIAL REPORT

7.3.1 The manufacturer normally performs the investigation following the initial report, keeping the Competent Authority informed of progress as appropriate.

7.3.2 If the manufacturer is not able to perform the investigation of an incident then he should inform the Competent Authority without delay.

7.4 COMPETENT AUTHORITY ROLE FOLLOWING THE INITIAL REPORT

7.4.1 The Competent Authority normally monitors the investigation being carried out by the manufacturer. However, the Competent Authority may intervene at any time. Such intervention should be in consultation with the manufacturer where practicable.

7.4.2 Aspects of the manufacturer's investigation which may be monitored include, for example:-course, or direction the investigation is taking;
- conduct, or how the investigation is being carried out;
- progress, or how quickly the investigation is being carried out;
- outcome, or whether the results are satisfactory.

7.4.3 Facts which may be needed include, for example:
- the number of devices involved;
- the length of time they have been on the market;
- details of design changes which have been made.

7.4.4 Liaison may be needed with:
- Notified Bodies (involved in the attestation leading to the CE marking);
- users;
- other Competent Authorities;
- other independent bodies, test houses etc.

7.4.5 The Competent Authority should consider liaison with other (non-medical device) Competent Authorities, for example if a medicinal product is involved.

7.4.6 The Competent Authority should take coordinating action to ensure an investigation is carried out if several manufacturers are involved.

7.4.7 If the manufacturer cannot for any reason perform the investigation, then the Competent Authority should ensure an investigation is carried out. The manufacturer should be kept informed.

7.4.8 Competent Authorities may also monitor experience with the use of devices of the same kind (for instance, all defibrillators or all syringes), but made by different manufacturers. They may then be able to take measures applicable to all devices of that kind. This could include, for example, initiating user education or suggesting re-classification

8 OUTCOME OF AN INVESTIGATION, AND FOLLOW-UP

8.1 PRINCIPLES

8.1.1 Normally, the manufacturer should take the action necessary following the investigation, including consultation with the Competent Authority and performing any recalls - see paragraph 8.2.

8.1.2 The Competent Authority may take any further action it deems appropriate, consulting with the manufacturer where possible - see paragraph 8.3.

8.1.3 There should be a final report which is a written statement of the outcome of the investigation and of any action. This is made by the manufacturer to the Competent Authority. If the Competent Authority performs the investigation then the manufacturer should be informed of the result - see paragraphs 8.2, 8.3 and 8.6.

8.2 MANUFACTURER ACTIONS

8.2.1 The manufacturer should make a final report to the relevant Competent Authority - see also paragraphs 8.3 and 8.6.

A suggested format for the manufacturer's final report is in Appendix 3.

8.2.2 Outcomes may include, for example:

- no action;
- additional surveillance or follow-up of devices in use;
- dissemination of information to users, eg by advisory notice;
- corrective action on future production;
- corrective action on devices in use;
- recall.

8.3 COMPETENT AUTHORITY ACTIONS

8.3.1 The Competent Authority should receive the final report from the manufacturer concluding the investigation -see paragraph 8.6.

8.3.2 Competent Authority actions should be in consultation with the manufacturer wherever practicable.

8.3.3 The Competent Authority should consider the content and method of dissemination of any advisory note, in consultation with the manufacturer and medical practitioner if appropriate - see paragraph 8.5.

8.3.4 Other Competent Authority actions may include, for example:

- no action;
- gathering more information, for example by commissioning independent reports;
- making recommendations to manufacturers, for example to improve information provided with the device;
- keeping the Commission and other Competent Authorities informed, for example on recalls and other actions to be taken; the information may be in the format of a Competent Authority Report (see paragraph 8.4.2), or similar.
- consulting with the relevant Notified Body on matters relating to the conformity assessment;
- consulting the Commission, for example if it is considered that re-classification of the device is necessary;
- further user education;
- further recommendations to users;
- any other action to supplement manufacturer action.

8.3.5 The Competent Authority may take action in accordance with Article 2 of either Directive, or in accordance with Article 7 of the AIMD or Article 8 of the MD.

8.3.6 The Competent Authority should consider whether action needs to be taken on similar devices, made by the same or different manufacturer.

8.4 DISSEMINATION OF INFORMATION BETWEEN COMPETENT AUTHORITIES

8.4.1 Information should be disseminated between Competent Authorities and copied to the Commission for incidents where:

* corrective action (including recalls) is to be taken;
* there is a serious risk to the safety of patients or other users, but where no corrective action has yet been established although measures are under consideration, or where there is not yet a final report from the manufacturer.;

8.4.2 A recommended format for dissemination of information, using a "Competent Authority Report" and notes for completion of the report are given at Appendix 8. The manufacturer's report may be circulated with the Competent Authority Report.

The appropriate "reason for report" should be identified on the Competent Authority Report. Competent Authorities receiving reports should pay particular attention to the "reason for report" and any "recommendations" given by the Competent Authority issuing the report. A number of reports may not require any immediate further action. Wherever possible, Competent Authorities should direct enquiries arising from the report to the Competent Authority providing the notification, who will co-ordinate communication with the manufacturer or Notified Body.

8.4 3 Competent Authority Reports are intended for dissemination between Competent Authorities and the Commission only, and are **not for onward distribution to users or other interested parties..**

8.4.4 Competent Authorities should consult the manufacturer when preparing a report, and should inform the manufacturer when one is issued.

8.5 DISSEMINATION OF INFORMATION OUTSIDE COMPETENT AUTHORITIES

8.5.1 Careful consideration should be given to the drafting and the dissemination of information by the Competent Authorities. The possible positive and negative effects of the information to be disseminated should be considered when drafting advisory notifications and when selecting the means and medium by which the message is transmitted.

Preference should be given to notification directly to medical practitioner or health-care facilities concerned.

Medical practitioners or other health-care professionals should be consulted where appropriate.

The manufacturer should be consulted wherever practicable.

8.5.2 In exceptional circumstances, and only if other means are not appropriate, dissemination of information direct to the public may be needed. The purpose of such communication will normally be to suggest that patients or users contact their medical practitioner for further, more specific advice

8.5.3 Consideration should be given to the preparation of a statement to the press for use by all Competent Authorities.

8.5.4. The above considerations apply also to dissemination of information by the manufacturer in consultation with the Competent Authorities.

8.5.5 Interfaces with communication media should be coordinated wherever practicable between the manufacturer and the Competent Authorities.

8.6 SAFEGUARD CLAUSE

The application of the Vigilance system does not affect the responsibilities of the Member States laid down in the Safeguard Clause (Article 7 of AIMD and Article 8 of MDD).

The Safeguard Clause procedures remain applicable regardless of the Medical Devices Vigilance system.

8.7 COMPLETION OF THE INVESTIGATION AND CLOSURE OF THE FILE

8.7.1 The Competent Authority should place the manufacturer's final report on file and make any other observations necessary. The file may then be endorsed as "closed".

8.7.2 If a Competent Authority itself conducts an investigation, the manufacturer (and, where appropriate, other Competent Authorities) should be informed of progress and of the results.

8.7.4 The final report should also be copied to any Competent Authorities who were informed of the initial report.

8.7.5 It is possible for a file to be "closed" with no further action after the initial report of the incident.

8.7.6 The Competent Authority should inform the manufacturer when a file is "closed".

8.7.7 Files where action is complete, or for which no further action is intended, should be retained as it is possible that changing circumstances may cause the matter to be re-opened.

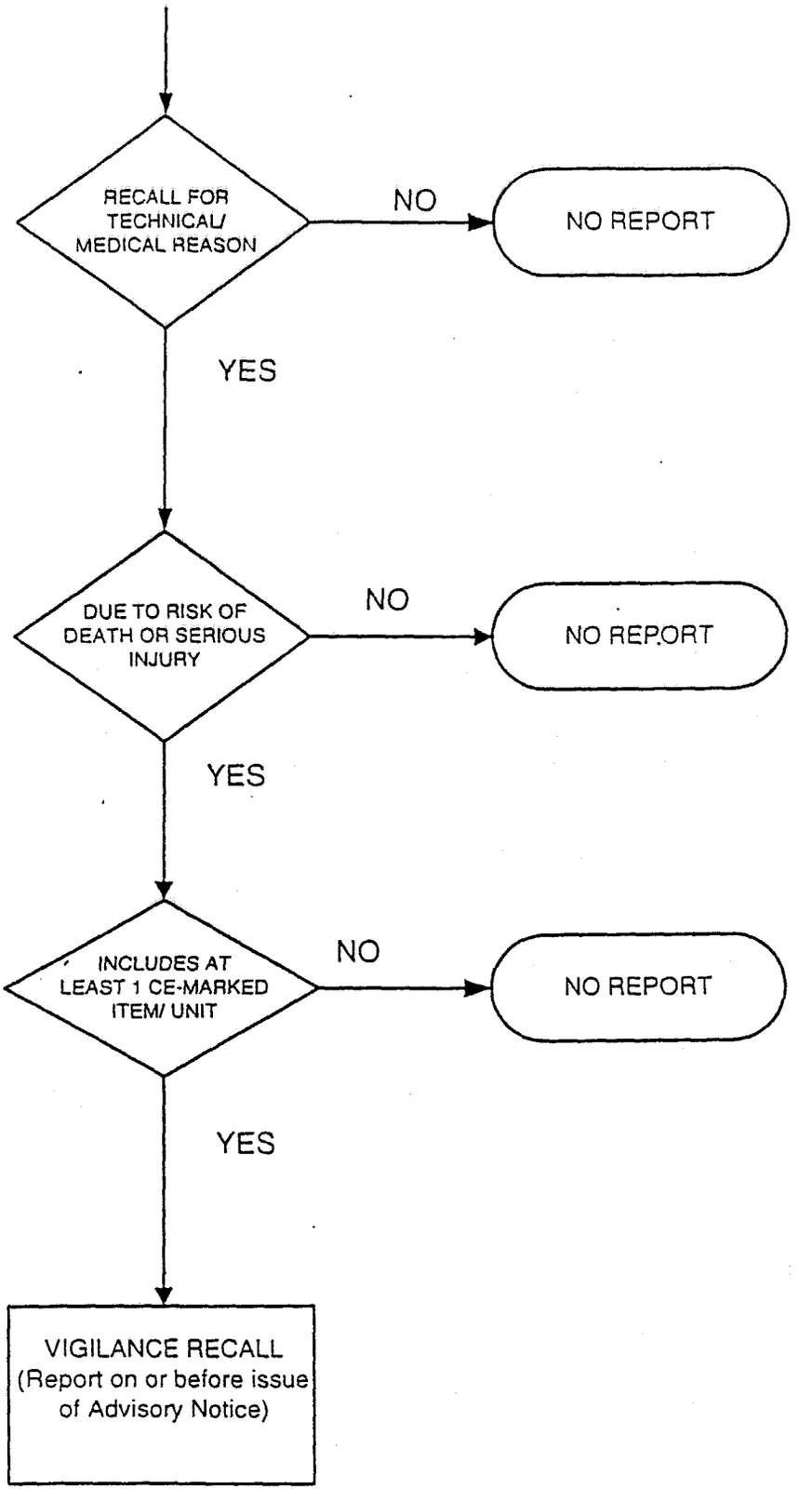
9. *REGISTER OF KEY TERMS*

LIST OF COMPETENT AUTHORITIES (February 1998)

COUNTRIES/ NAMES	COMPANIES	ADDRESSES	PHONE	FAX
AUSTRIA Dr. Ecker, Dr. Neumüller	Federal Ministry of Labour, Health and Social Affairs	Stubenring, 1 A- 1010 Vienna	43/1/711.72.42.06 43/1/711.72.47.60	43/1/715.73.12
BELGIUM Mme Mouyart	The Ministry of Health, Pharmaceutical Inspectorate, Medical Device Vigilance	Vesalius Building – Rijksadministratief Centrum. B- 1010 Brussels	32/2/210.63.58	32/2/210.48.80
DENMARK M. Hans-Kristian Andersen	The National Board of Health Medicines Division *(email = hka@dkma.dk)*	Frederikssundsvej 378 DK- 2700 Brønshøj	45/44/889.111 45/44/889.265 (direct line)	45/44/889.195
FINLAND M. H. Seitsonen	Medical Devices Centre National Agency for Medicines	Mannerheimintie 166 – PO Box 55 FIN- 00301 Helsinki	358/9/4733-4249	358/9/4733-4266
FRANCE Mr. J. Grisoni	Ministère de la Santé; Direction des Hôpitaux *(site matériovigilance : http://www.sante.gouv.fr)*	1 Place Fontenoy F- 75350 Paris 07SP	33/1/40.56.44.35	33/1/40.56.49.63
GERMANY Herrn Stößlein	Bundesinstitut für Arzneimittel und Medizin-produkte; Geschäftsstelle Medizinprodukte	Seestr. 10 – 11 D- 13353 Berlin	49/30/4548.53.84	49/30/786.30.65
GREECE Mr. E. Papadeas	Ministry of Health, Welfare and Social Services Biomedical Technology Department	17 Aristoteleous Street GR- 101 87 Athens	30/1/523.28.21	30/1/522.32.46
IRELAND Mr. B. Ingoldsby	Department of Health	Hawkins House; IRL-Dublin 2	353/1/671.47.11	353/1/671.19.47
ICELAND Mrs. Haraldsdottir	Ministry of Health and Social Service	Laugavegur 116 IS- 150 Reykjavik	35/45/609.700	35/45/519.165
ITALY Dottissa M. Marletta	Ministry of Health, Department II	P. le Industria 20; I-00144 ROMA	39/6/5994.2423	39/6/5994.2111
LUXEMBOURG Dr. Gérard Scharll	Division de la Médecine Curative	4 rue Auguste Lumière L-1950 Luxembourg	352/478.56.33 (478.56.34)	352/480.324
NETHERLANDS P.A. Loekemeijer	Staatstoezicht op de Volksgezondheid, Inspectie voor de Gezondheidszorg	PO Box 5850 NL-2280 HW Rijswijk	31/70/340.62.41	31/70/340.71.59
NORWAY Mrs. Hagerup-Jenssen	National Board of Health *(email : ingeborg.hagerup-jenssen@helsetilsynet.dep.telemax.no)* *(website : http://www.helsetilsynet.no/)*	PO Box 8128 Dep. N- 0032 Oslo	47/22/24.89.53 47/22/24.89.40	47/22/249.017

COUNTRIES/ NAMES	COMPANIES	ADDRESSES	PHONE	FAX
PORTUGAL a) non-active devices : Mrs. ABREU b) active devices : Mr. Faria Gomes	INFARMED INSA	Parque de Saúde de Lisboa; Av. do Brasil, 53 P-1700 Lisboa Av. Padre Cruz P-1699 Lisboa Codex	351/1/790.85.00 351/1/757.35.57	351/1/795.91.16 351/1/757.36.71
SPAIN Carmen Abad Luna	Ministerio de Sanidad y Consumo Dirección General de Farmacia y Productos Sanitarios	Paseo del Prado 18/20 E-28071 Madrid	34/1/596.40.22	34/1/596.44.00
SWEDEN : Bo C. Höjdefors	National Board of Health and Welfare, Medical Devices	S- 106 30 Stockholm	46/8/783.34.99	46/8/783.32.94
SWITZERLAND Dr. Peter Frei	Office fédéral de la Santé Publique	CH-3003 Bern	41/31/322.98.03	41/31/322.76.46
UNITED KINGDOM Ron Dale	Adverse Incident Center, Department of Health, Room 1201	Hannibal House, Elephant and Castle; UK-London SE1 6TQ	44/171/972.80.80	44/171/972.81.09
COMMISSION CONTACT Norbert Anselmann	DG III.D.2 (Medical devices sector, SC15 3/133),	200, rue de la Loi; B-1049 Brussels	32/2/295.93.39 32/2/295.91.54 (Secretarial)	32/2/296.70.13

APPENDIX 4
DECISION TREE - IDENTIFICATION OF RECALLS TO BE REPORTED BY MANUFACTURERS UNDER THE VIGILANCE SYSTEM



This flow chart is provided for illustrative purposes only.
Consult text for authoritative statement.

APPENDIX 5

EXAMPLES OF INCIDENTS WHICH THE MANUFACTURER SHOULD (OR SHOULD NOT) REPORT

The following examples are for illustrative purposes only, and are for the guidance of the manufacturer in determining whether a report should be made to a Competent Authority. The examples are intended to show that there is a considerable judgemental element in the decision on whether to report.

1. A patient dies after the use of a defibrillator:
   - where there is no indication of any problem with the defibrillator or its instructions, then the incident should not be reported, as death is not an improbable outcome in such a situation.
   - where there is an indication of a problem with the defibrillator or its instructions, then the incident should be reported.

2. A patient receives a burn during the use, in accordance with the manufacturer's instructions, of surgical diathermy:
   - depending on the significance of the burn, this should normally be reported, as such an injury is not normally expected.

3. A patient receives a burn during the use in an emergency of an external defibrillator:
   - depending on the significance of the burn, this should not normally be reported, as the risk of such burns may have been accepted in view of potential patient benefit.

4. An infusion pump stops, due to a malfunction, but gives an appropriate alarm:
   - this should not be reported, as it is a single fault condition, for which the manufacturer has made provision.

5. An infusion pump stops, due to a malfunction of the pump, but fails to give an appropriate alarm; there is no patient injury:
   - this should be reported as a "near incident": in a different situation it could have caused an injury.

6. An infusion pump delivers the wrong dose because of an incompatibility between the pump and the infusion set used:
   If the combination of pump and set used was in accordance with the instructions for use for either pump or set, then the incident should be reported;
   If the combination was used against the instructions for use for both pump and set, then the incident should not be reported.

7. An aortic balloon catheter leaked because of inappropriate handling of the device in use, causing a situation which was potentially dangerous to the patient.
   If the inappropriate handling was in any way due to inadequacies in the labelling, then the incident should be reported as a "near incident".
   If the labelling clearly indicated that such handling was inappropriate, then the incident need not be reported.

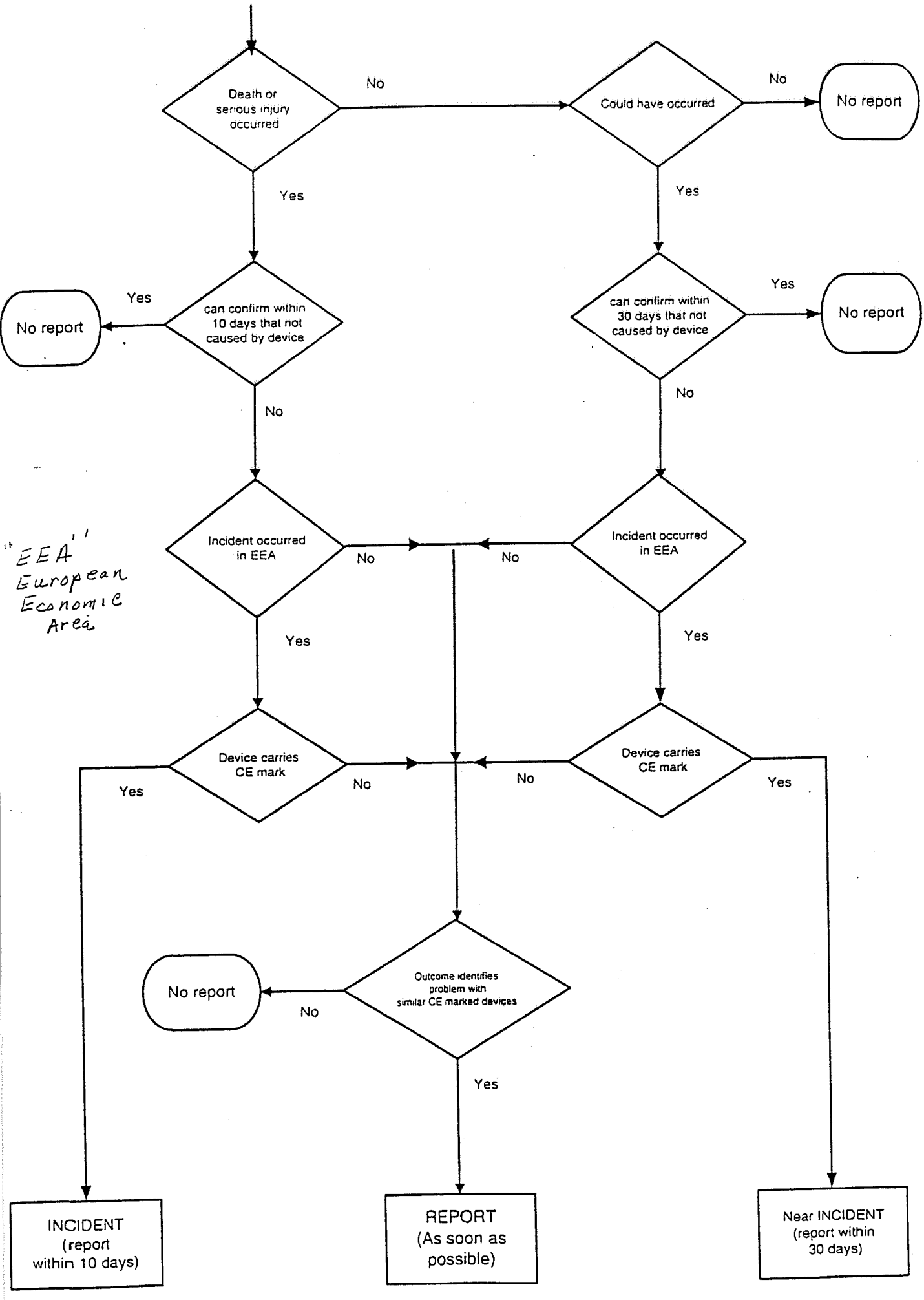
8. A catheter fractured during insertion, with no suggestion of inappropriate handling. The fracture occurred in such a position that the broken part could easily be withdrawn. However, this was clearly a fortunate circumstance as if the catheter had fractured in a slightly different position then surgical intervention would have been necessary to retrieve the broken end.
This should be reported as a "near incident".

9. Glass particles are found in a contact lens vial -
This should be reported as a near incident.

10. A defect is discovered in one (hitherto unopened) sample of a batch (lot) of a contact lens disinfecting agent that could lead to incidence of microbial keratitis in some patients.
The recall of this batch should be reported.

APPENDIX 6

SIMPLIFIED FLOW CHART - IDENTIFICATION OF INCIDENTS TO BE REPORTED BY MANUFACTURERS UNDER THE VIGILANCE SYSTEM



"EEA" European Economic Area

APPENDIX 7

EXTRACTS FROM DIRECTIVES RELATING TO
"MEDICAL DEVICES VIGILANCE"

"1. **Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relative to active implantable medical devices**

A. Article 8

1. Member States shall take the necessary steps to ensure that information brought to their knowledge regarding the incidents mentioned below involving a device is recorded and evaluated in a centralized manner :

   a) any deterioration in the characteristics and performances of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient or to a deterioration in his state of health;
   b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

2. Member States shall, without prejudice to Article 7, forthwith inform the Commission and the other Member States of the incidents referred to in paragraph 1 and of the relevant measures taken or contemplated.

B. Annexes 2, 4, 5

Extracts :

- an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system. The undertaking shall include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them :

  i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in his state of health;
  ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

A. Article 10 : Information on incidents occurring following placing of devices on the market

1. Member States shall take the necessary steps to ensure that any information brought to their knowledge in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally :

   a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
   b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative established in the Community, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

B. Annexes 2, 4 and 5

Extracts :

- an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them :

  i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or a serious deterioration in his state of health;
  ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same by the manufacturer.

APPENDIX 8

SUGGESTED COMPETENT AUTHORITY REPORT FORMAT
THE MEDICAL DEVICES VIGILANCE SYSTEM REPORT
Ref AIMD 90/385/EEC, art 8,MDD 93/42/EEC, art 10 and MEDDEV 3/93-rev 2
This form should only be used for the exchange of information between National Competent Authorities (NCA)

1. Report from CA of: (country)	2. Ref no: (national seq. no)	3. Sent by: (date) (sign)
4. Contact point:	5. Contact person:	
6. Tel:	7. Fax:	8. E-Mail__not to be used_____

DEVICE DATA:

9. Generic name/ kind of device:	18. Was the Safeguard Clause Used: No Yes
10. Nomenclature id.: (which nomenclature) 11. No: (code)	
12. Kind: (model Name/No)	19. Relevant Notified Body No:
13. Software version:	20. Is the device CE marked? No Yes Class:
14. Serial no: 15. Lot/batch no:	
16. Manufacturer/ authorized rep: (telephone/fax No) 17. Country:	

21. Reason for report: Serious risk to patient safety; corrective action; recall; additional information.

For pt 22-23 use additional pages if necessary

22. Background information:

23. Conclusions/corrective actions:
CA of ..... is willing to take the lead and coordinate the investigation .

24. Recommendations to receivers of this report :

25. This report has been sent to the following MDVS Contact Points:

All EEA states AT BE DE DK ES FI FR GB GR IE
IS IT LI LU NL NO PT SE EC ESA EFTA as well as

The manufacturer/
authorized rep: