
MEDICAL DEVICES : Guidance document

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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 1998 as MEDDEV 2.12/1 - rev. 3

Foreword

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.

This document represents a transposition of the views of the Global Harmonisation Task Force (GHTF) on what constitutes a reportable adverse incident into the European vigilance guidance. The Guidelines have been extended to include the reporting of adverse incidents involving *in vitro* diagnostic medical devices (IVDs).

Due to the participation of the aforementioned interested parties and of experts from Competent Authorities, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

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), the Directive for Medical Devices (MDD) and the In Vitro Diagnostic Medical Devices Directive (IVDD). In particular, Article 8 (AIMD), Article 10 (MDD) and Article 11 (IVDD) 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 the Directives are provided in Appendix 8.

A diagrammatic summary of the system for medical devices is given in Appendix 10.

1.1.2 These Guidelines cover the activities of:

- the Commission,
- Competent Authorities,
- 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 II, IV, V, VI, VII of MDD and Annexes III, IV, VI and VII of IVDD). The term "post-marketing surveillance" as referred to in Annexes 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.

1.2 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 (Article 10 of MDD and Article 11 of IVDD). 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 incidents by the user and other professionals involved in the distribution, the delivery or putting in to service of the device. 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 investigation or performance evaluation¹.

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, the Medical Devices Directive and the In Vitro Diagnostic Devices Directive. The procedures are intended to be the same for all the Directives, with respect to the Vigilance system.

2 FOR WHOM THESE GUIDELINES ARE WRITTEN

2.1 MANUFACTURERS

2.1.1 These Guidelines apply to manufacturers placing medical devices on the market in accordance with the AIMD, the MDD and the IVDD. 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.

¹ According to the requirements of Annex 7 of AIMD and Annex 10 of MDD incidents occurring during clinical investigations meeting the same criteria as those reportable under the Vigilance System should be notified to the relevant Competent Authority.

2.2 COMPETENT AUTHORITIES

These Guidelines cover Competent Authorities' responsibilities, in particular under Article 2 of AIMD, MDD and IVDD and Article 8 of AIMD, Article 10 of MDD and Article 11 of IVDD.

2.3 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, MDD 20 and IVDD 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 8.2), 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 Where an incident or near incident occurs as a consequence of the combined use of two or more separate devices (and/or accessories) made by different manufacturers, each manufacturer should submit a report to the relevant Competent Authority.

4.1.6 It is recommended that manufacturers inform their Notified Body of those incidents affecting 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.

4.1.7 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

5.1.1 Extracts from the Annexes of the AIMD, the MDD and of the IVDD 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 three 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

5.2.1 As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reportability of an incident. Any incident which meets the three basic reporting criteria listed below is considered as an adverse incident and should be reported to the relevant Competent Authority. The criteria are that:

- an incident (or potential incident) has occurred (see paragraph 5.4),
- the manufacturer's device is associated with the incident,
- the incident led, or might have led, to one of the following outcomes (see paragraph 5.3):
 - death of a patient, user or other person.;
 - serious injury of a patient, user or other person.

5.2.2 Certain incidents may be exempt from reporting if any one of the criteria described in paragraph 5.5 is applicable.

5.2.3 Those adverse incidents involving particular issues of significant public health concern as determined by the relevant Competent Authority should be reported regardless of exemption criteria. Similarly those adverse incidents which are subject to an exemption become reportable to the Competent Authority if a change in trend (usually an increase in frequency) or pattern is identified.

5.2.4 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 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:

5.3.1 Those which led to a death;

5.3.2 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.

5.3.3 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

testing or examination of the device or the information supplied with the device, or any scientific literature 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.

5.4 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.

5.4.1 Malfunction or deterioration in the characteristics or performance.

A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions. This includes problems caused by unpredicted biological effects relating to the device.

The intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

5.4.2 Inadequate design or manufacture.

This would include cases where the design or manufacturing of a device is found deficient, where such a deficiency could lead to a death or serious injury, regardless whether an incident has occurred.

5.4.3 Inaccuracy in the labelling, instructions for use and/or promotional materials.

Inaccuracies include omissions and other deficiencies. An inaccuracy in the instructions which caused, or could cause misuse or incorrect maintenance or adjustment should be reported.

Omissions do not include the absence of information that should generally be known by the intended users.

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

5.4.4 A significant public health concern.

This can include an incident that is of significant and unexpected nature such that it becomes alarming as a potential public health hazard. These concerns may be identified by either the Competent Authority or the manufacturer.

5.4.5 Other information becoming available.

This can include results of testing performed by the manufacturer on its products, or by the user prior to being used on the patient, or by other parties. This can also include information from the literature or other scientific documentation.

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

5.5 INCIDENTS EXEMPT FROM REPORTING UNDER THE VIGILANCE SYSTEM

If an incident meets the one of the following criteria, the adverse incident does not need to be reported to the Competent Authority by the manufacturer.

5.5.1 Deficiency of a new device found by the user prior to its use.

Regardless of the existence of provisions in the instruction for use provided by the manufacturer, deficiencies of devices that would normally be detected by the user and where no serious injury has occurred, do not need to be reported.

5.5.2 Adverse incident caused by patient conditions.

When the manufacturer has information that the root cause of the adverse incident is due to patient condition, the incident does not need to be reported. These conditions could be pre-existing or occurring during device use.

To justify no report, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious injury. A person qualified to make a medical judgement would accept the same conclusion.

Examples:

- **Orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision due to not following directions.**
- **Early revision of an orthopaedic implant due to loosening caused by the patient developing osteolysis.**
- **A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.**

5.5.3 Service life or shelf-life of the medical device.

When the only cause for the adverse incident was that the device exceeded its service life or shelf-life as specified by the manufacturer and the failure mode is not unusual, the adverse incident does not need to be reported.

The service life or shelf-life must be specified by the device manufacturer and included in the master record [technical file] or, where appropriate, the instructions for use (IFU). Service life or shelf-life is defined as: the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified. Reporting assessment shall be based on the information in the master record or in IFU.

Examples:

- **Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator has shown up in due time according to device specification. Surgical explantation of pacemaker required.**
- **A drill bit was used beyond end of specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.**

5.5.4 Protection against a fault functioned correctly.

Incidents which did not lead to serious injury or death (near incidents), because a design feature protected against a fault becoming a hazard (in accordance with relevant standards or documented design inputs), do not need to be reported.

Examples:

- **An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.**
- **Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm. (e.g., in compliance with relevant standards) and there was no injury to the patient.**
- **During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.**

5.5.5 Negligible likelihood of occurrence of death or serious injury.

Near incidents where the risk of a death or serious injury has been quantified and found to be negligibly small need not be reported if no incident has occurred and the risk has been characterised and documented as acceptable within a full risk assessment.

If an incident resulting in death or serious injury has happened, the incident is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligible,

previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Changes in the trend, usually an increase, of these non-serious outcomes must be reported.

Example:

- **Manufacturer of pacemaker released on the market identified a software bug and quantified the probability of occurrence of a serious injury with a particular setting to be negligibly small. No patients experienced adverse health effects.**

5.5.6 Expected and foreseeable side effects.

Side effects which are foreseeable and clinically acceptable in view of the individual patient benefit, identified in the manufacturer's labeling, and having a certain functional or numerical predictability when the device was used as intended need not be reported.

Some of these incidents are well known in the medical, scientific, or technology field; others may have been clearly identified during clinical investigation or performance evaluation and labelled by the manufacturer.

Documentation, including risk assessment, for the particular side effect should be available in the device master record prior to the occurrence of adverse incidents: manufacturer can not conclude in the face of incidents that they are foreseeable unless there is prior supporting information.

Examples:

- Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.
- **Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.**
- **A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within the range specified in the device master record.**

5.5.7 Adverse incidents described in an advisory notice.

Adverse incidents that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the relevant Competent Authority.

Example:

- **Manufacturer issued an advisory notice and recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarised in quarterly reports concerning the recall action and individual adverse incidents did not have to be reported.**

5.5.8 Reporting exemptions granted by the Competent Authority.

Common and well-documented incidents may be exempted by the Competent Authority from reporting or changed to periodic reporting upon request by the manufacturer.

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

5.6.1 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.

5.7 TIMESCALE FOR THE INITIAL REPORTING OF AN INCIDENT OR NEAR INCIDENT

The report should be made as soon as possible. The timing should be 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

5.8 SYSTEMATIC RECALLS

5.8.1 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 2).

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.

5.8.2 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 or IVDs listed in Annex II or for self-testing, 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, and for devices in Class I or IVDs neither listed in Annex II nor for self-testing, the Competent Authority in the State where the manufacturer's registered place of business under Article 14 is situated. 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 recall action is being initiated.. 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 made to the Competent Authority in the country of occurrence of the incident, with the following provisions 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 and IVDs listed in Annex II or for self-testing and 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 and IVDs neither listed in Annex II nor for self-testing and occurring 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 or Article 10 of the IVDD respectively.

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.

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 number;
- 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;
- name and address of the local distributor in the EEA State to which the report has been sent;
- name of the Competent Authority to which the report has been sent.

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 or fax (eg telephone, e-mail), 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)². In the unusual incident that an initial report is to be disseminated, the Competent Authority should inform the manufacturer prior to issue.

² Other dissemination obligations may exist under the Mutual Recognition Agreements (MRAs). Further guidance will be provided.

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 may determine a single coordinating Competent Authority under the following circumstances:

- incidents of similar types occurring in more than one country within the EEA;
- recalls conducted in more than one country within the EEA, whether or not a reportable incident has occurred.

The following hierarchy should determine the co-ordinating 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.

7.3 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 (Article 6 of AIMD, Article 7 of MDD and Article 7 of IVDD).

7.4 MANUFACTURER ROLE FOLLOWING THE INITIAL REPORT

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

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

7.5 COMPETENT AUTHORITY ROLE FOLLOWING THE INITIAL REPORT

7.5.1 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.

7.5.2 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.

7.5.3 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.

7.5.4 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.

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

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

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

7.5.8 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 8.2.

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 notice, 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, Article 8 of the MDD or Article 11 of the IVDD.

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

Competent Authorities should use their discretion where corrective action is taken by a manufacturer which is not considered to be essential to protect the safety of patients or other users. Under these circumstances a Competent Authority Report may not be necessary. In the case of doubt, however, there should be a pre-disposition on the part of Competent Authorities to disseminate the information.

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 unless otherwise subject to national provisions and practices (Article 20 of MDD and Article 19 of IVDD).

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, Article 8 of MDD and Article 8 of IVDD).

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 [DN: to be updated by the Commission]

APPENDIX 1 LIST OF COMPETENT AUTHORITIES (see attached)

APPENDIX 2 DEFINITIONS

1 ADVISORY NOTICE (Ref EN46001)

A notice issued to provide information and/or to advise on what action should be taken in the use, modification, disposal or return of a medical device (see also Recall).

2 RECALL (Ref EN46001)

When there is a risk of death or serious deterioration to the state of health, the return of a medical device to the supplier, its modification by the supplier at the site of installation, its exchange or its destruction, in accordance with the instructions contained in an advisory notice.

3 SINGLE FAULT CONDITION (Ref EN 60601-1)

Condition in which a single means for protection against hazards is defective or a single external abnormal hazardous condition is present (see Clause 12).

4 MANUFACTURER (Ref. Articles 1, 2(f) of MDD)

... the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations (of this Directive) to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This sub-paragraph does not apply to the person who, while not a manufacturer within the meaning of the first sub-paragraph, assembles or adapts devices already on the market to their intended purpose for an individual patient ...

5 INTENDED PURPOSE (Ref. Article 1.2 (g) of MDD)

.... means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials...

APPENDIX 3 SUGGESTED INCIDENT REPORT FORMATS

INCIDENT REPORT FORMAT FOR INITIAL REPORTS

DESTINATION

1 Competent Authority
Address

2 Reporting firm name:

- a) Manufacturer Authorised representative in EEA
- b) Address

- c) Contact person name
- d) Telephone number
- e) Telefax number
- f) Report date
- g) Name of distributor
- h) Address

3 Manufacturer (if not already provided in point 2)

- a) name
- b) address

4 Information about the incident

- a) Medical device commercial name
- b) (*) Kind of device (e.g. pacemaker, diathermy machine,....)
Class of device (e.g. I, IIa, IIb, III) or category of IVD
- c) Model or catalogue number
- d) Serial number(s) or lot number(s)
- e) Accessories/associated devices (if applicable)
- f) Software version (if applicable)
- g) Identification number of Notified Body involved in conformity assessment (if applicable)
- h) Reporting firm is aware of other similar incidents having an impact on the current report Y/N
- i) If yes, the countries to which these have been reported, and the report reference numbers are listed below

- j) Incident reported by (user or other source)

Address:

Telephone number:

Date reported:
- k) Incident date:
- l) Incident description:

- m) Outcome: [e.g. death, deterioration in health,...]

n) Manufacturer's preliminary comments

o) Current location of device (if known)

p) Expected date of follow-up report

q) Corrective action (if any)

Corrective action agreed to be taken in the following Member States:

r) Projected timing

Note: Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the competent authority that the content of this report is complete or accurate, that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

(*) Please also include nomenclature id. And which nomenclature system used if known

FINAL REPORT FORMAT

DESTINATION

1 Competent Authority Address

2 Reporting firm name:

- a) Manufacturer Authorised representative in EEA
- b) Address

- c) Contact person name
- d) Telephone number
- e) Telefax number
- f) Date of this final report
- g) Name of distributor
- h) Address

3 Manufacturer name

4 Information about the incident

- a) Medical device commercial name
- b) (*) Kind of device (e.g. pacemaker, diathermy machine,....)
Class of device (e.g. I, IIa, IIb, III) or category of IVD
- c) Model or catalogue number
- d) Serial number(s) or lot number(s)
- e) Accessories/associated devices (if applicable)
- f) Software version (if applicable)
- g) Identification number of Notified Body involved in conformity assessment (if applicable)
- h) Reporting firm is aware of other similar incidents having an impact on the current report Y/N
- i) If yes, the countries to which these have been reported, and the report reference numbers are listed below
- j) Incident reported by (user or other source)
- k) This device has been distributed within the following EEA countries:
- | | | | | | | | | | |
|----------------|----|----|----|----|----|----|----|----|----|
| All EEA states | AT | BE | DE | DK | ES | EL | FR | FI | IE |
| | IS | IT | LU | NL | NO | PT | SE | GB | |
| | LI | | | | | | | | |
- l) Date of initial report

m) Result and conclusion of manufacturer's investigation

n) Further investigation (if any)

o) Corrective action (if any)

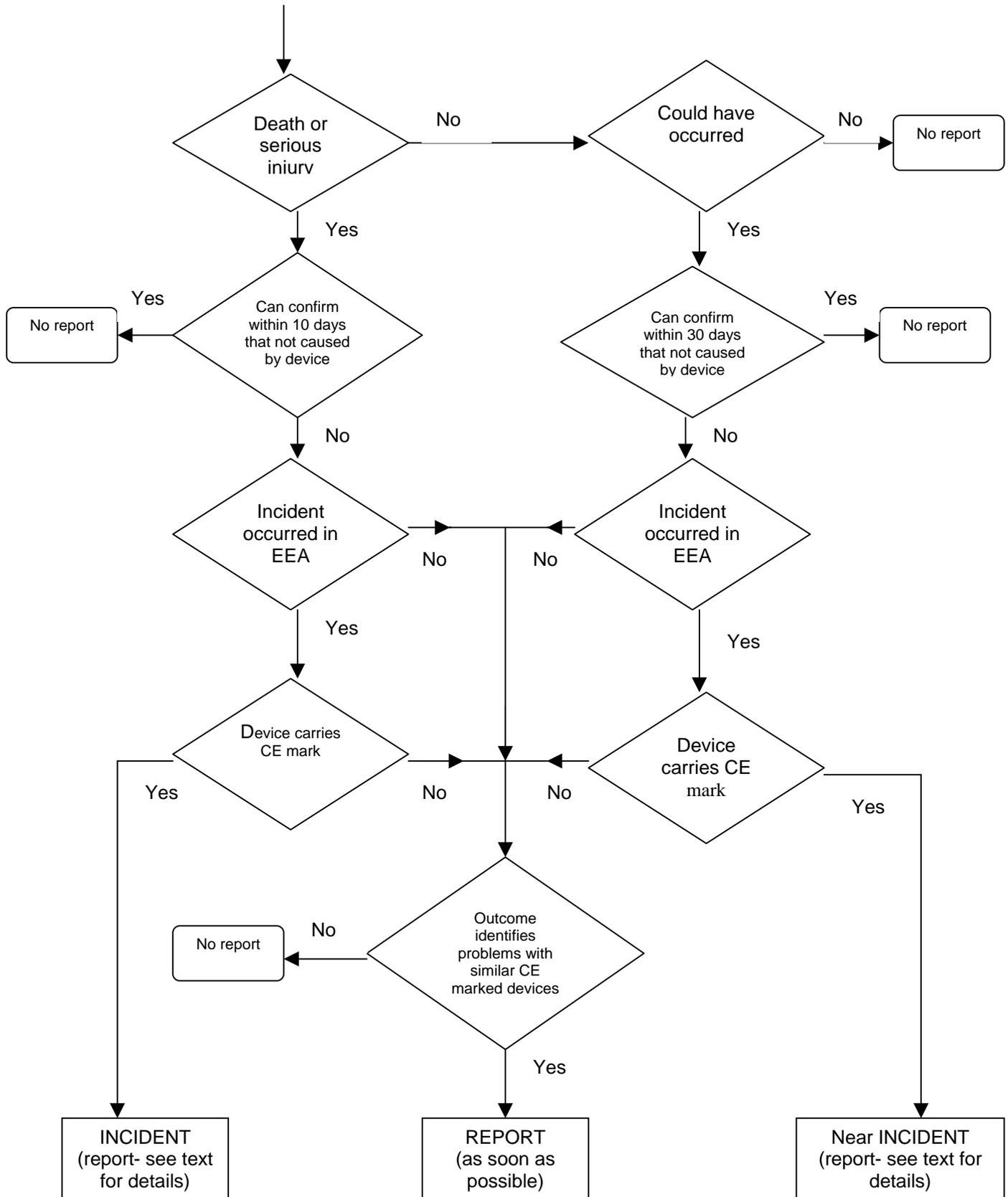
Corrective action to be taken in the following Member States:

p) Projected timing

(*) Please also include nomenclature id. And which nomenclature system used if known

APPENDIX 4 SIMPLIFIED FLOWCHART – ILLUSTRATION OF INCIDENTS TO BE REPORTED

SIMPLIFIED FLOW CHART – IDENTIFICATION OF INCIDENTS TO BE REPORTED BY MANUFACTURERS UNDER THE VIGILANCE SYSTEM
THIS FLOWCHART IS FOR ILLUSTRATIVE PURPOSES ONLY. SEE TEXT FOR DETAILS



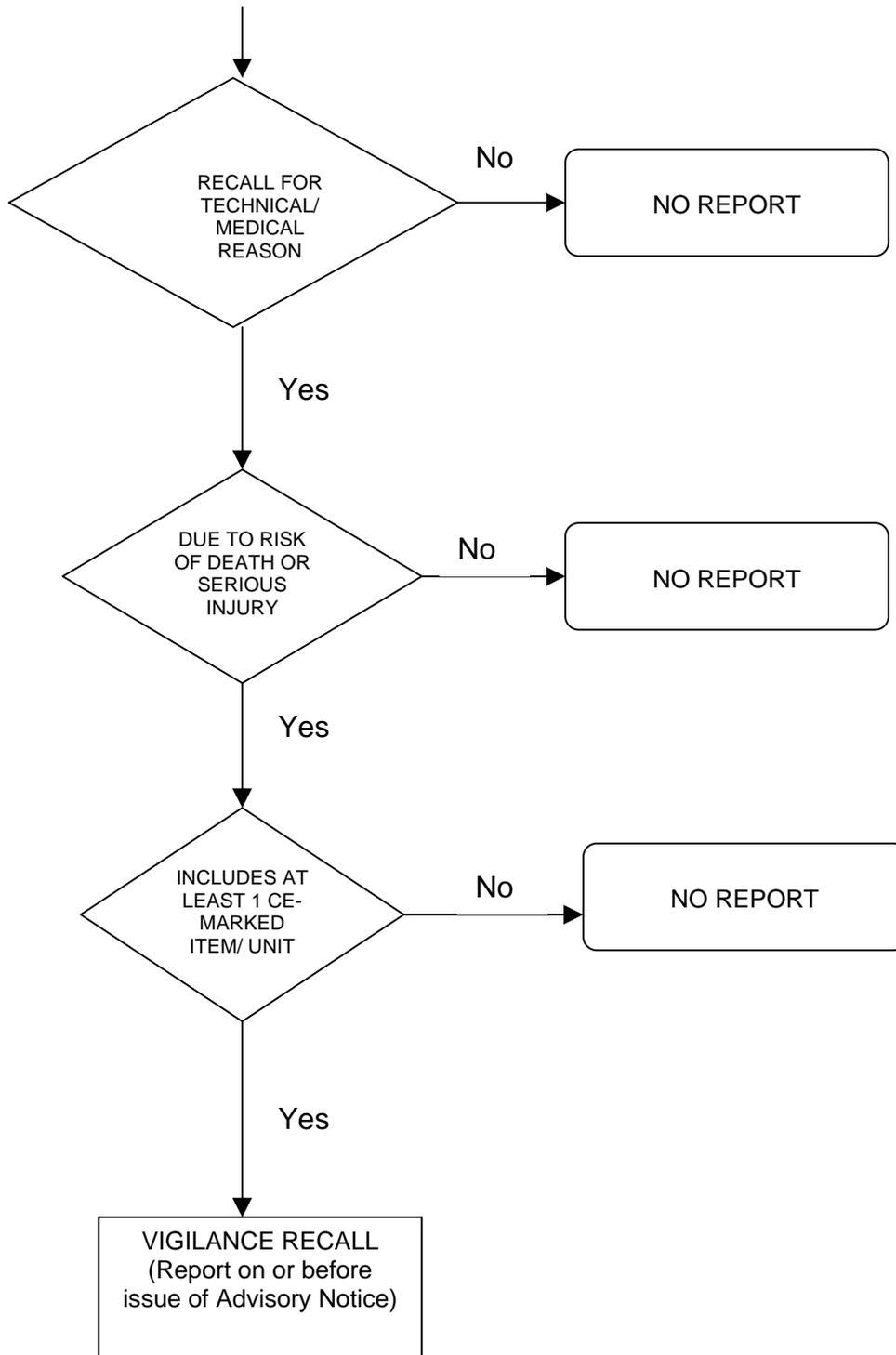
APPENDIX 5 EXAMPLES OF INCIDENTS AND NEAR INCIDENTS WHICH THE MANUFACTURER SHOULD REPORT

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 judgmental element in the decision on whether to report.

1. A patient dies after the use of a defibrillator and there is an indication of a problem with the defibrillator. The incident should be reported.
2. A patient receives a burn during the use, in accordance with the manufacturer's instructions, of surgical diathermy. If the burn is significant, this should be reported as such an injury is not normally expected.
3. 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" as in a different situation it could have caused an injury.
4. 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.
5. An aortic balloon catheter leaked because of inappropriate handling of the device in use, causing a situation which was potentially dangerous to the patient. It is believed that the inappropriate handling was due to inadequacies in the labelling. The incident should be reported as a "near incident".
6. 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".
7. Glass particles are found in a contact lens vial. This should be reported as a "near incident".
8. 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 manufacturer institutes a recall of this batch. The recall should be reported.
9. Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time, although it should have according to device specification. This incident should be reported.
10. On an X-ray vascular system during patient examination, the C arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer's instructions. This incident should be reported.
11. The premature revision of an orthopedic implant is required due to loosening. Although no cause is yet determined, this incident should be reported.
12. The manufacturer of a pacemaker has identified a software bug in a pacemaker that has been placed on the market. The initial risk assessment identified the risk of a serious injury as remote. Subsequent failure results and the new risk assessment carried out by the manufacturer indicate that the likelihood of occurrence of a serious injury is not remote. This should be reported.
13. Fatigue testing performed on a commercialised heart valve bioprosthesis demonstrates premature failure, which resulted in a risk to public health. This should be reported as a "near incident".
14. Manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD.

APPENDIX 6 SIMPLIFIED FLOWCHART ILLUSTRATING THE REPORTING OF RECALLS

DECISION TREE – IDENTIFICATION OF RECALLS TO BE REPORTED BY MANUFACTURERS UNDER THE VIGILANCE SYSTEM



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 centralised 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 II, IV and V

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.

3. Council Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices

A. Article 11 : Vigilance Procedure

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 devices bearing the CE marking is recorded and evaluated centrally:
 - (a) any malfunction, failure 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, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their 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, the medical institutions or the organisers of external quality assessment schemes 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 authorised representative, 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 appropriate measures, including possible withdrawal, have been taken or are contemplated.
4. Where, in the context of notification referred to in Article 10, a device notified, bearing the CE marking, is a "new" product, the manufacturer shall indicate this fact on his notification. The competent authority so notified may at any time within the following two years and on justified grounds, require the manufacturer to submit a report relating to the experience gained with the device subsequent to its being placed on the market.
5. The Member States shall on request inform the other Member States of the details referred to in paragraphs 1 to 4. The procedures implementing this Article shall be adopted in accordance with the procedure referred to in Article 7(2).

B. Annexes III, IV, V and VII

6. The manufacturer shall 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 actions, taking account of the nature and risks in relation to the product.

He shall notify the competent authorities of the following incidents immediately on learning of them:

- (i) any malfunction, failure 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, directly or indirectly, might lead to, or might have led to, the death of a patient or user or other persons or to a serious deterioration in his or their state of health;
- (ii) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

APPENDIX 8 SUGGESTED NATIONAL COMPETENT AUTHORITY REPORT FORMAT

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 2.12/1 3/93-rev 2

This form should be used for the exchange of information between National Competent Authorities only

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

DEVICE DATA	
9. Generic name/ kind of device: _____	
10. Nomenclature id: _____ (which nomenclature)	11. No: _____ (code)
12. Type: _____	
13. Software version: _____	
14. Serial no: _____	15. Lot/batch no: _____
16. Manufacturer/authorized rep: _____ Tel: _____	17. Country: _____

18. Concerned Notified Body no: _____
1. Was the Safeguard Clause used? No Yes
2. Is the device CE-marked? : No Yes
Class: _____

For pt 21-22-23 use additional pages if necessary.

21a. Background information / reason for this report: 21b.: Serious risk to patient safety
--

22a. Conclusions/corrective action: 22b. Corrective action to be taken in the following Member States: CA in _____ is willing to take the lead and coordinate the investigation

23. Recommendation to receivers of this report:
--

24. This report has been sent to the following MDVS Contact Points: All EEA states AT BE DE DK ES EL FR FI IE IS IT LI LU NL NO PT SE GB EC ESA EFTA as well as The manufacturer/ authorized rep: _____ CA in: _____

MEDICAL DEVICES VIGILANCE REPORT FORM

Instructions for filling in the Competent Authority report:

Format – General remarks

This form should be used by *Competent Authorities only* when exchanging information about relevant measures and/ or recommendations relating to the prevention of adverse incidents concerning *medical devices*.

The Competent Authority filling in and sending the form will be *responsible for the quality* of the content as well as the *appropriateness* of sending such a message. The content should normally be considered to be <<commercial in confidence>> and hence handled accordingly.

Before releasing any information from a received report, careful note should be taken concerning the most appropriate way to do this.

Items 1-8 – concerning the Reporter

These items must clearly identify the Competent Authority responsible for this Report and making it possible for the receiving Competent Authority to contact the Originating Competent Authority for further information.

Items 9-17 – Device Data

To make certain the device in question is properly identified by all, these items must give as much accurate information as possible. If the device can be classified in a recognized nomenclature (e.g. GMDN, NKKN, UMDNS) this will be of value (no 10). 14-15 identifies devices affected by this report. Items 16-17 points to who is legally responsible for placing the device in question on the market in the area where the incidents occurred. Telephone number will ease follow-up contact.

Item 16

Manufacturer or Authorized Rep should be deleted as appropriate.

Item 18

Give four digit number of the Notified Body concerned.

Item 19

State here if the Safeguard Clause is used.

Item 20

CE-marking and Risk Class of the device concerned should be notified here.

Item 21 - Reason for this report

Here a description of what has happened, as well as factual background information, should appear. Such information might lead to a better understanding on how to make an appropriate follow-up. Similarly, who has done the investigation leading to this report could be of importance for further action.

Item 22 - Conclusions or corrective actions

This will describe the outcome or the conclusions of the investigation, including any corrective actions, for example recalls. Normally at this stage the investigation will have reached some conclusions or be finalised. There can, however, be reasons for disseminating an alert at an earlier stage, even without conclusive evidence of a serious risk to patient safety. Sometimes an Authority volunteers for a role as a coordinator of any further investigation.

Item 23 - Recommendations to receivers of this report

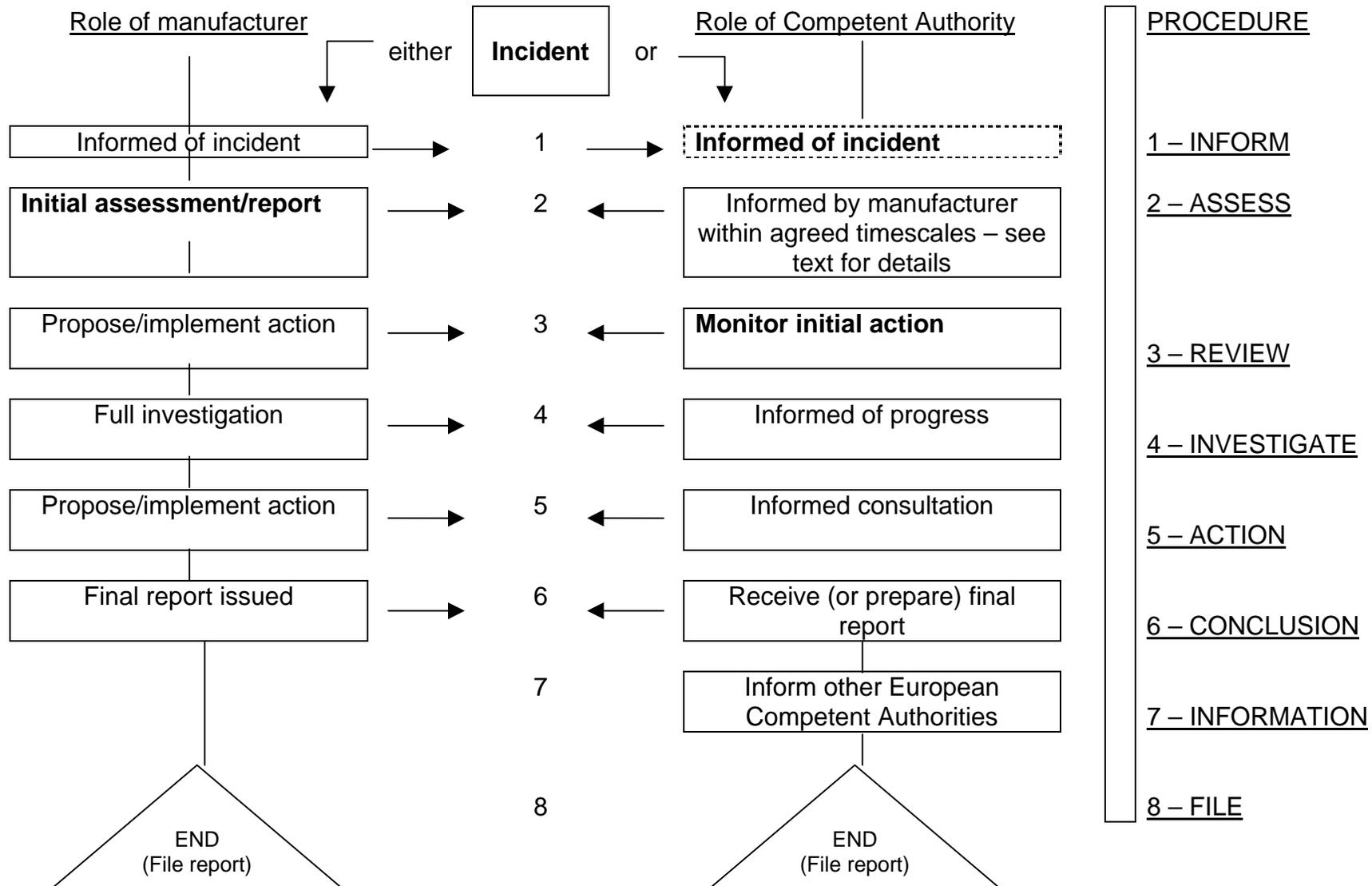
Here should appear what action the receiving Authority is recommended to do nationally upon being informed. If known, it should appear here in which countries the device has been sold.

Item 24 – This report has been sent to the Competent Authorities in

Normally it will be of help, or of support, to know who else has received this Report. The manufacturer, or his authorized representative, should always be provided with a copy.

APPENDIX 9 DIAGRAM OF THE VIGILANCE SYSTEM

MEDICAL DEVICE VIGILANCE – INCIDENT RESPONSE



APPENDIX 10 SPECIFIC REQUIREMENTS FOR IN VITRO DIAGNOSTIC DEVICES

10.1 Introduction

This section deals only with aspects of vigilance reporting that are specific to *in vitro* diagnostic medical devices (IVD). It must be read in conjunction with the generic guidelines.

Vigilance reporting for IVDs may be more difficult since IVDs do not generally come into contact with patients. Therefore, it can be difficult to demonstrate direct harm to patients, unless the device itself causes injury. Harm to patients is more likely to be *indirect* - a result of action taken on the basis of an incorrect result obtained with an IVD. Whether as a result of direct or indirect harm, incidents and near incidents should be reported.

With IVDs, it is common for two or more separate devices (and/or accessories) to be used in combination – often from different manufacturers. In this instance refer to generic guidance (section 4.1.5).

10.2 Direct harm

For incidents and near incidents involving direct harm to patients, users and third parties, manufacturers are directed to the generic vigilance guidelines which provide guidance on which types of incidents and near incidents should be reported.

In addition, the following specific examples should be considered as serious injury:

infection with biological agents (for example, when potentially biohazardous, or toxic material including specimens for analysis enters into a mucus membrane, eye, or open wound or penetrates the skin of a user or other person).

10.3 Indirect Harm:

In these incidents, the IVD does not act directly upon the individual who is harmed or could be harmed. Instead harm occurs as a consequence of the medical decision, or action, taken on the basis of information provided by an IVD. Examples include

- misdiagnosis,
- delayed diagnosis,
- delayed treatment,
- inappropriate treatment,
- transfusion of inappropriate materials.

Note that, for self-testing devices, a medical decision may be made by the user of the device-who is also the patient

Incorrect results obtained with an IVD may arise from a faulty or inappropriately designed IVD, for example, the device does not achieve the claimed sensitivity or specificity or gives rise to user/device interface problems.

It may be difficult to determine if a serious deterioration in the state of a patient's health was or could be the consequence of an erroneous result obtained with an IVD, or if the harm was the consequence of an error by the user or third party.

In the case of potential errors by users or third parties, labelling and instructions for use should be carefully reviewed for any possible inadequacy. This is particularly true for devices used for self-testing where a medical decision may be made by the patient. Inadequacies in the information supplied by the manufacturer that led or could have led to harm to users, patients or third parties should be reported.

In particular, it can be extremely difficult to judge potential near incidents in which no harm was caused, but where harm could result if the incident was to occur again elsewhere. For example, when an incorrect result is obtained with a IVD and no medical action is taken but there could have been severe adverse medical consequences if the result had been acted upon.

10.4 Examples of reportable incidents involving IVDs

- 10.3.1 A batch of out-of-specification blood glucose test strips is released by manufacturer. A patient uses the strips according to the manufacturer's instructions, but the readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization. This incident should be reported.
- 10.3.2 A customer reports a wrong assignment of analytical results to patient codes by an automated analyzer. An evaluation could reproduce the effect and indicated that under specific conditions a data mismatch could occur. Due to the data mismatch a patient suffered from wrong treatment. This incident should be reported.
- 10.3.3 During maintenance of a self-testing analyzer for patients it was detected that a screw which places the heating unit of the analyzer in exact position had come loose. Due to this fact, it may happen that the heating unit leaves its position and the measurement is performed under non exact temperature, which would lead to wrong results. As this could lead to wrong treatment of the patient this should be reported as a near incident.
- 10.3.4 During stability testing of a CRP test the internal quality control found that after several months of storage false increased values are measured with neonatal samples. This could lead to the wrong diagnosis of the existence of an inflammatory illness and to a wrong treatment of the patient. This should be reported as a near incident.