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MEDICAL DEVICES: Guidance document

MEDDEV 2.12-1 rev 8

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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.

Revision 8 of MEDDEV 2.12-1 explicitly includes IVF/ART devices within the scope of the vigilance system and provides clarity in relation to devices that are not intended to act directly on the individual. The revised guidance will be applicable as of July 2013.

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1 FOREWORD

These guidelines on the Medical Device Vigilance System are part of a set of Medical Device Guidelines that promote a common approach by MANUFACTURERs and Notified Bodies involved in the conformity assessment procedures according to the relevant annexes of the directives, and by the National Competent Authorities charged with safeguarding public health.

They have been carefully drafted through a process of consultation with various interested parties during which intermediate drafts were circulated and comments were taken up in the documents. Therefore, it reflects positions taken in particular by representatives of National Competent Authorities and Commission Services, Notified Bodies, industry and other interested parties in the MEDICAL DEVICEs sector.

The guidelines are regularly updated accordingly with regulatory developments. The latest version of the guidelines should always be used. This revision of these guidelines has:

- carefully considered and transposed into the European context the Global Harmonisation Task Force (GHTF)[1] international regulatory guidance documents on vigilance and post market surveillance;
- addressed the introduction of European medical device database *EUDAMED*;
- amended the document in light of experience with previous clauses.

These guidelines are not legally binding. It is recognised that under given circumstances, for example, as a result of scientific developments, an alternative approach may be possible or appropriate to comply with the legal requirements.

Nevertheless, due to the participation of the aforementioned interested parties and of experts from National Competent Authorities, it is anticipated that the guidelines will be followed within the Member States and, therefore, work towards uniform application of relevant directive provisions and common practices within Member States.
However, only the text of the Directives is authentic in law. On certain issues not addressed in the Directives, national legislation may be different from these guidelines.

2 INTRODUCTION

These guidelines describe the European system for the notification and evaluation of INCIDENTs and FIELD SAFETY CORRECTIVE ACTIONS (FSCA) involving MEDICAL DEVICEs, known as the Medical Device Vigilance System.

The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, USERs and others by reducing the likelihood of reoccurrence of the INCIDENT elsewhere. 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.

These guidelines are intended to facilitate the uniform application and implementation of the Medical Device Vigilance System requirements contained within:

- the Directive for Active Implantable Medical Devices (AIMD), 90/385/EEC
- the Directive for Medical Devices (MDD), 93/42/EEC
- the In Vitro Diagnostic Medical Devices Directive (IVDD), 98/79/EC.

[1] A list of the used abbreviations is listed in annex 10

FIELD SAFETY CORRECTIVE ACTION (FSCA), FIELD SAFETY NOTICE (FSN), USE ERROR and ABNORMAL USE are concepts used in this guideline to enhance and clarify the European Medical Device Vigilance System while promoting harmonisation with GHTF provisions.

The Medical Device Vigilance System is intended to facilitate a direct, early and harmonised implementation of FIELD SAFETY CORRECTIVE ACTION across the Member States where the device is in use, in contrast to action taken on a country by country basis.

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

3 SCOPE

These guidelines describe the requirements of the Medical Device Vigilance System as it applies to or involves:

- MANUFACTURERs[2]
- National Competent Authorities (NCA)
- the European Commission
- Notified Bodies
- USERs and others concerned with the continuing safety of MEDICAL DEVICEs

These guidelines cover the actions to be taken once the MANUFACTURER or National Competent Authority receives information concerning an INCIDENT involving a MEDICAL DEVICE. Information on INCIDENTs which should be reported under the Medical Device 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 cover Article 8 (AIMD), Article 10 (MDD) and Article 11 (IVDD) outlining the obligations of Member States upon the receipt of INCIDENT reports, from MANUFACTURERs or other sources, concerning any MEDICAL DEVICE. They also include guidance to National Competent Authorities about the issue and receipt of information from National Competent Authorities outside Europe who are involved in the GHTF National Competent Authority Report (NCAR) exchange programme.

These guidelines are relevant to INCIDENTs occurring within the Member States of the European Economic Area (EEA), Switzerland and Turkey with regard to:

- a) devices which carry the CE-mark
- b) devices that do not carry the CE-mark but fall under the directives scope (e.g. custom made devices)
- c) devices that do not carry the CE mark because they were placed on the market before the entry into force of the medical devices directives.

[2] including their Authorised Representatives and persons responsible for placing on the market, see section 4 on definitions.

- d) devices that do not carry the CE-mark but where such INCIDENTs lead to CORRECTIVE ACTION(s) relevant to the devices mentioned in a), b) and c).

These guidelines cover FIELD SAFETY CORRECTIVE ACTION relevant to CE-marked devices which are offered for sale or are in use within the EEA, Switzerland and Turkey.

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, of which the Medical Device Vigilance System is an integral part. Such recommendations are outside the scope of this document.

3.1 GENERAL PRINCIPLES

3.1.1 FOR MANUFACTURERS

- The MANUFACTURER or his AUTHORISED REPRESENTATIVE shall notify the relevant National Competent Authority about INCIDENTs and FIELD SAFETY CORRECTIVE ACTIONs when the reporting criteria are met (see section 5.1 and 5.4).
- The MANUFACTURER has the responsibility for investigating INCIDENTs and for taking any CORRECTIVE ACTION necessary (see section 5.2 and 5.3).
- The MANUFACTURER should ensure that these guidelines are made known to their AUTHORISED REPRESENTATIVEs within the EEA, Switzerland and Turkey, 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.
- The MANUFACTURER should ensure that their AUTHORISED REPRESENTATIVE within the EEA, Switzerland and Turkey, 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.
- Where an 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 National Competent Authority (see section 5.1*)*
- MANUFACTURERs must keep the Notified Body advised of issues occurring in the post production phase affecting the certification (see the relevant annexes of the relevant directives and section 7 of this document). This would include relevant changes derived from the vigilance system.

The act of reporting an INCIDENT to a National 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.

When placing on the market of a particular model of MEDICAL DEVICE ceases, the MANUFACTURER’s vigilance reporting obligations under the Medical Device Directives remain. However, a MANUFACTURERs legal trading arrangements change with mergers and acquisitions etc. Where the vigilance and other post market surveillance obligations are being transferred to another legal entity it is important that post market surveillance activities continue and that Competent Authorities are appraised of the implications and provided with new contact details as soon as possible, so that any detrimental effects on the functioning of the vigilance system are minimised.

For a complete description of the MANUFACTURER’s role in the Medical Device Vigilance System, see section 5 of these guidelines.

3.1.2 FOR MANUFACTURERS OF DEVICES THAT ARE NOT INTENDED TO ACT DIRECTLY ON THE INDIVIDUAL

Vigilance reporting may be more difficult for medical devices which do not generally come into contact with patients. For example, for the majority of diagnostic devices, IVDs and IVF/ART medical devices, due to their intended use, it can be difficult to demonstrate direct HARM to patients, unless the device itself causes deterioration in state of health. HARM to patients is more likely to be indirect - a result of action taken or not taken on the basis of an incorrect result obtained with an IVD, a diagnostic device or as a consequence of the treatment of cells (e.g. gametes and embryos in the case of IVF/ART devices) or organs outside of the human body that will later be transferred to a patient. Software qualified as medical devices may also lead to indirect HARM (incorrect information generated by software).

Any event which meets all three basic reporting criteria A – C listed under section 5.1.1 is considered an INCIDENT and must be reported to the relevant National Competent Authority. Where the manufacturer of an IVD, IVF/ART or diagnostic medical device identifies such an event that has or could result in INDIRECT HARM (as defined in section 4.11) and that led or might have led to death or serious deterioration in state of health, they should submit a Manufacturer's INCIDENT Report (in accordance with section 5.1.6) to the relevant Competent Authority.

Any action taken by the manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a MEDICAL DEVICE that is already placed on the market should be reported through a Field Safety Corrective Action Report (as defined in section 5.4.4). Such actions, whether associated with direct or indirect harm, should be reported.

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 a diagnostic device, the consequence of an inappropriate treatment of reproductive cells with an IVF/ART device or the consequence of an error by the USER or third party. In cases of doubt a report should be submitted (see section 5.1).

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 events in which no HARM was caused, but where HARM could result if the event was to occur again elsewhere.

3.1.3 FOR NATIONAL COMPETENT AUTHORITIES

For the purposes of Medical Devices Vigilance System, Member States are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site:

http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm

- The National Competent Authority monitors the investigation of the INCIDENT carried out by the MANUFACTURER.
- The National Competent Authority should take any further action that may be necessary to supplement the actions of the MANUFACTURER.
- 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 by the National Competent Authority.
- 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. In order to enhance the efficiency of the Medical Device Vigilance System, National Competent Authorities should encourage the reporting of INCIDENTs by the USER and other professionals involved in the distribution, the delivery or putting in to service of the device. This includes organisations and individuals responsible for providing calibration and maintenance for MEDICAL DEVICEs. Such reports may be made directly to the MANUFACTURER or to the National Competent Authority as well depending on national practice.

Information held by National Competent Authorities in connection with the Medical Device Vigilance System is to be held in confidence, as defined by the relevant articles of the directives[3]. However, any INCIDENT report should be available on request, and in confidence, to the other European Competent Authorities and to other National Competent Authorities participating in the GHTF exchange programme.

For a complete description of the National Competent Authority's role in the Medical Device Vigilance System, see section 6 of this guideline.

3.1.4 FOR USERS

- USERs should report INCIDENTs with MEDICAL DEVICEs to the MANUFACTURER or to the National Competent Authority depending on national practice.
- 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.

For a complete description of the USER's role in the Medical Device Vigilance System, see section 9 of this guideline.

4 DEFINITIONS

4.1 ABNORMAL USE

Act or omission of an act by the OPERATOR or USER of a MEDICAL DEVICE as a result of conduct which is beyond any means of risk control by the MANUFACTURER.

Reference: EN IEC 60601-1-6

4.2 AUTHORISED REPRESENTATIVE

[3] AIMD 15, MDD 20 and IVDD 20

Any natural or legal person established in the Community who, explicitly designated by the MANUFACTURER, acts and may be addressed by authorities and bodies in the Community instead of the MANUFACTURER with regard to the latter's obligations under the directive.

4.3 CORRECTIVE ACTION

Action to eliminate the cause of a potential nonconformity or other undesirable situation.

NOTE1: There can be more than one cause for non-conformity.

NOTE 2: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

Reference: EN ISO 9000:2000, 3.6.5

4.4 DRUG / DEVICE COMBINATION PRODUCT

A MEDICAL DEVICE incorporating a medicinal product or substance where the action of the medicinal product or substance is ancillary to that of the device. In this case, the lead directive are the Medical Devices Directives (AIMD, MDD).

4.5 EUDAMED

The European database for MEDICAL DEVICEs EUDAMED is to centralise:

- data relating to registration of MANUFACTURERS and MEDICAL DEVICES placed on the Community market,
- data relating to certificates issued, modified, supplemented, suspended,,withdrawn or refused,
- data obtained in accordance with the vigilance procedure,
- data concerning clinical investigations.

Reference: Article 14a of MDD and article 10 of IVDD.

4.6 FIELD SAFETY CORRECTIVE ACTION (FSCA)

A FIELD SAFETY CORRECTIVE ACTION is an action taken by a MANUFACTURER to reduce a risk of death or serious deterioration in the state of health associated with the use of a MEDICAL DEVICE that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a FIELD SAFETY NOTICE.

NOTE 1:

The FSCA may include

- the return of a MEDICAL DEVICE to the supplier;
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of MANUFACTURER's modification or design change;
- advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients, users or others (e.g. where the device is no longer on the market or

has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices).

NOTE 2
A MANUFACTURER can as part of ongoing quality assurance or an investigation at the manufacturing site identify a failure of a device to perform according to the characteristics specified in the information for use provided by the MANUFACTURER. If the failure might lead to or might have led to death or serious deterioration in the state of health associated with the use of a MEDICAL DEVICE and has an impact on a product that has already been placed on the market the MANUFACTURER must initiate a FSCA.

Examples of failure modes may include software anomalies (e.g. incorrect correlation between patient sample and the obtained result), invalid controls, invalid calibrations or reagent failures (e.g. contamination, transcription errors and reduced stability).

NOTE 3
A device modification can include:

□ permanent or temporary changes to the labelling or instructions for use.
For example:
- advice relating to a change in the way the device is used e.g. MANUFACTURER advises revised quality control procedure such as use of third party controls or more frequent calibration or modification of control values for the device.
- changes to storage conditions for sample to be used with an IVD
- advice issued to users relating to a change in the stated shelf life of an IVF/ART device e.g. IVF/ART MANUFACTURER informs users of an error on the labelling of their device which indicates a shelf life longer than the validated shelf life for the product.

□ software upgrades following the identification of a fault in the software version already in the field. (This should be reported regardless of whether the software update is being implemented by customers, field service engineers or by remote access)

NOTE 4
Advice given by the manufacturer may include modification to the clinical management of patients/samples to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device.
For example:
- for implantable devices it is often clinically unjustifiable to explant the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return, constitutes FSCA.
- for diagnostic devices (e.g. IVD, imaging equipment or devices), corrective action taking the form of the recall of patients or patient samples for retesting or the review of previous results constitutes FSCA.

NOTE 5:
This guideline uses the definition of FSCA as synonym for recall mentioned in article 10(1), paragraph 1b) of the MDD and Article 11 IVD Directive since there is no harmonised definition of recall.

4.7 FIELD SAFETY NOTICE (FSN)

A communication to customers and/or USERs sent out by a MANUFACTURER or its representative in relation to a Field Safety Corrective Action.

4.8 HARM

Physical injury or damage to the health of people, or damage to property or the environment.

Reference: ISO/IEC Guide 51:1999

4.9 IMMEDIATELY

For purposes of this guideline, IMMEDIATELY means without any delay that could not be justified.

4.10 INCIDENT

"Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling 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."

Reference: Article 10 of the MDD

Note 1: There is a similar definition in Article 8 of the AIMD and Article 11 IVD Directive with minor wording differences.

Note 2: A description of "serious deterioration in the state of health" is given in section 5.1.1. (C) of this document.

4.11 INDIRECT HARM

In the majority of cases, diagnostic devices IVDs and IVF/ART medical devices will, due to their intended use, not directly lead to physical injury or damage to health of people (HARM – see section 4.8). These devices are more likely to lead to indirect harm rather than to direct harm. HARM may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device or as a consequence of the treatment of cells (e.g. gametes and embryos in the case of IVF/ART devices) or organs outside of the human body that will later be transferred to a patient.

Examples of indirect harm include

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

Indirect harm may be caused by

- imprecise results
- inadequate quality controls
- inadequate calibration
- false positive or
- false negative results.

For self-testing devices, a medical decision may be made by the USER of the device who is also the patient.

4.12 INTENDED PURPOSE

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.

Reference: Article 1.2 (h) of the IVDD and Article 1.2 (g) of the MDD

4.13 MANUFACTURER

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.

Reference: Article 1.2 (f) of the IVDD and Article 1.2 (f) of the MDD

4.14 MEDICAL DEVICE

For the purpose of the Medical Devices Directives 90/385/EEC, 93/42/EEC and 98/79/EEC, any instrument, apparatus, appliance, material or other Article, whether used alone or in combination, including the software necessary for its proper application intended by the MANUFACTURER to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

4.15 OPERATOR

Person handling equipment.

4.16 PERIODIC SUMMARY REPORTING

PERIODIC SUMMARY REPORTING is an alternative reporting regime that is agreed between the MANUFACTURER and the National Competent Authority for reporting similar INCIDENTs with the same device or device type in a consolidated way where the root cause is known or an FSCA has been implemented..

4.17 SERIOUS PUBLIC HEALTH THREAT

Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action.

This would include:

- events that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the National Competent Authority or the MANUFACTURER.
- the possibility of multiple deaths occurring at short intervals.

Reference: GHTF SG2 N54

4.18 TREND REPORTING

A reporting type used by the MANUFACTURER when a significant increase in events not normally considered to be INCIDENTs according to section 5.1.3. occurred and for which pre-defined trigger levels are used to determine the threshold for reporting.

NOTE: Appendix C of GHTF SG2 document N54 "' Global Guidance for Adverse Event Reporting for Medical Devices" provides useful guidance.

4.19 UNANTICIPATED

A deterioration in state of health is considered UNANTICIPATED if the condition leading to the event was not considered in a risk analysis.

NOTE: Documented evidence in the design file is needed that such analysis was used to reduce the risk to an acceptable level, or that this risk is well known by the intended USER.

4.20 USE ERROR

Act or omission of an act, that has a different result to that intended by the MANUFACTURER or expected by the OPERATOR of the MEDICAL DEVICE.

4.21 USER

The health care institution, professional, carer or patient using or maintaining MEDICAL DEVICES.

5 MANUFACTURERS´ ROLE

5.1 INCIDENT REPORTING SYSTEM

The MANUFACTURER or their AUTHORISED REPRESENTATIVE must submit an initial INCIDENT report to the National Competent Authority for recording and evaluation. Each initial report must lead to a final report unless the initial and the final report are combined into one report. But not every INCIDENT report will lead to a corrective action.

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.

Reference to the following 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.

INCIDENTs which occurred outside the EEA, Switzerland and Turkey do not lead to a FIELD SAFETY CORRECTIVE ACTION relevant to these geographic areas do not need to be reported. Incidents which occurred outside the EEA , Switzerland and Turkey led to a FIELD SAFETY CORRECTIVE ACTION relevant to the above-mentioned geographical areas must be reported as a FIELD SAFETY CORRECTIVE ACTION.

Where appropriate, MANUFACTURERs should notify their AUTHORISED REPRESENTATIVE, persons responsible for placing devices on the market and any other agents (e.g. distributors) authorised to act on their behalf of INCIDENTs and FSCA reported under the Medical Device Vigilance System.

If the MANUFACTURER is located outside the EEA, Switzerland and Turkey, a suitable contact point within 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.

Any report should not be unduly delayed because of incomplete information.

5.1.1 CRITERIA FOR INCIDENTs TO BE REPORTED BY MANUFACTURERS TO COMPETENT AUTHORITIES

Any event which meets all three basic reporting criteria **A – C** listed below is considered as an INCIDENT and must be reported to the relevant National Competent Authority. The criteria are that:

A: An event has occurred

This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

Typical events include, but are not limited to:

a) A 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.

b) For IVDs where there is a risk that an erroneous result would either (1) lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual’s offspring, or (2) cause death or severe disability to the individual or fetus being tested, or to the individual’s offspring, all false positive or false negative test results shall be considered as events.

For all other IVDs, false positive or false negative results falling outside the declared performance of the test shall be considered as events.

c) Unanticipated adverse reaction or unanticipated side effect

d) Interactions with other substances or products

e) Degradation/destruction of the device (e.g. fire)

f) Inappropriate therapy

g) An inaccuracy in the labelling, instructions for use and/or promotional materials.
Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended USERs.

NOTE: see ISO TS 19218 adverse event type and cause/effect coding for further details on events.

B: The MANUFACTURER's device is suspected to be a contributory cause of the INCIDENT

In assessing the link between the device and the INCIDENT the MANUFACTURER should take account of:

- the opinion, based on available evidence, of healthcare professionals;
- the results of the MANUFACTURER's own preliminary assessment of the INCIDENT;
- evidence of previous, similar INCIDENTs;
- other evidence held by the MANUFACTURER.

This judgement may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have caused or contributed to the INCIDENT and the MANUFACTURERs should err on the side of caution.

C: The event led, or might have led, to one of the following outcomes:

- death of a patient, USER or other person
- serious deterioration in state of health of a patient, USER or other person.

A serious deterioration in state of health can include (non exhaustive list):

a) life-threatening illness,
b) permanent impairment of a body function or permanent damage to a body structure,
c) a condition necessitating medical or surgical intervention to prevent a) or b).
   Examples: - clinically relevant increase in the duration of a surgical procedure,
   - a condition that requires hospitalisation or significant prolongation of existing hospitalisation.
d) any indirect harm (see definition under section 4.11) as a consequence of an incorrect diagnostic or IVD test result or as a consequence of the use of an IVF/ART device when used within MANUFACTURER´s instructions for use (use errors reportable under section 5.1.5.1 must also be considered).
e) foetal distress, foetal death or any congenital abnormality or birth defects.

NOTE :

Not all INCIDENTs lead to death or serious deterioration in health. The non-occurrence of such a result might have been due to other fortunate circumstances or to the intervention of healthcare 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.

Examples of reportable INCIDENTs are given in Annex 1.

5.1.2 CONDITIONS FOR PERIODIC SUMMARY REPORTING UNDER THE MEDICAL DEVICE VIGILANCE SYSTEM

There are a number of occasions when a National Competent Authority may accept from a MANUFACTURER or AUTHORISED REPRESENTATIVE periodic summary or trend reports, after one or more initial reports have been issued and evaluated by the manufacturer and the National Competent Authority. This should be agreed between MANUFACTURERs and individual National Competent Authorities and submitted in an agreed format and frequency for certain types of device and INCIDENT.

When a MANUFACTURER has received the agreement of a National Competent Authority to switch to periodic summary reporting or trend reports, he shall inform the other concerned CAs of the agreement and of its modalities. Periodic summary reporting can only be extended to other competent authorities upon agreement of the individual national competent authority.

A form for Periodic Summary Reporting is provided in Annex 6 .

5.1.2.1 INCIDENTS DESCRIBED IN A FIELD SAFETY NOTICE

INCIDENTs specified in the FIELD SAFETY NOTICE that occur after the MANUFACTURER has issued a FIELD SAFETY NOTICE and conducted a field safety corrective action need not be reported individually. Instead, the MANUFACTURER can agree with the coordinating National Competent Authority on the frequency and content of the Periodic Summary Report. The Periodic Summary Report must be sent to all affected National Competent Authorities and the coordinating National Competent Authority.

Example:

A MANUFACTURER issued a FIELD SAFETY NOTICE and conducted a FIELD SAFETY CORRECTIVE ACTION 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 FIELD SAFETY CORRECTIVE ACTION and individual INCIDENTs did not have to be reported.

5.1.2.2 COMMON AND WELL-DOCUMENTED INCIDENTS

Common and well-documented INCIDENTs (identified as such in the risk analysis of the device and which have already led to incident reports assessed by the MANUFACTURER and the relevant National Competent Authority) may be exempted from reporting individually by the National Competent Authority and changed to PERIODIC SUMMARY REPORTING. However, these INCIDENTs shall be monitored and trigger levels determined. Trigger levels for interim reporting should also be agreed with the relevant National Competent Authority. An interim report should be made whenever trigger levels are exceeded.

Periodic summary reporting can only be extended to other competent authorities when it has the agreement of individual national CA's.

5.1.3 CONDITIONS WHERE REPORTING UNDER THE MEDICAL DEVICE VIGILANCE SYSTEM IS NOT USUALLY REQUIRED

5.1.3.1 DEFICIENCY OF A DEVICE FOUND BY THE USER PRIOR TO ITS USE

Regardless of the existence of provisions in the instructions for use provided by the MANUFACTURER, deficiencies of devices that are always detected (that could not go undetected) by the USER prior to its use do not need to be reported under the vigilance system.
This is without prejudice to the fact that the user should inform the MANUFACTURER of any deficiency identified prior to the use of a MEDICAL DEVICE.

Examples:

- **The packaging of a sterile single use device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.**

- **Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.**

- **A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.**

- **In an IVD testing kit a bottle labelled lyophilised is found to be fluid, this is discovered by the USER prior to use.**

5.1.3.2 EVENT CAUSED BY PATIENT CONDITIONS

When the MANUFACTURER has information that the root cause of the event is due to patient condition, the event 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 deterioration in state of health. A person qualified to make a medical judgement would accept the same conclusion. It is recommended that the MANUFACTURER involves a clinician in making the decision.

Examples:

- **Early revision of an orthopedic implant due to loosening caused by the patient developing osteolysis, which is not considered a direct consequence of the implant failure. This conclusion would need to be supported by the opinion of a medical expert.**

- **A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure, the MANUFACTURER's investigations revealed the device to be functioning as claimed and the INCIDENT was not attributed to the device.**

5.1.3.3 SERVICE LIFE OR SHELF-LIFE OF THE MEDICAL DEVICE EXCEEDED

When the only cause for the event was that the device exceeded its service life or shelf-life as specified by the MANUFACTURER and the failure mode is not unusual, the 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] and, where appropriate, the instructions for use (IFU) or labelling, respectively. Service life or shelf-life can include e.g.: the time or usage that a device is intended to remain functional after it is manufactured, put into service, and maintained as specified. Reporting assessment shall be based on the information in the master record or in the 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.**

- **Insufficient contact of the defibrillator pads to the patient was observed. The patient could not be defibrillated due to insufficient contact to the chest. The shelf life of the pads was labelled but exceeded.**

- **A patient is admitted to hospital with hypoglycaemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the MANUFACTURER.**

5.1.3.4 PROTECTION AGAINST A FAULT FUNCTIONED CORRECTLY

Events which did not lead to serious deterioration in state of health or death, 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. As a precondition, there must be no danger for the patient to justify not reporting. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.

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 deterioration in state of health of 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.**

- **A laboratory analyser stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the USER. An intervention by the user or an immediate remote intervention by the**

manufacturer allowed the analyser to resume the analysis, resulting in correct results.

5.1.3.5 EXPECTED AND FORESEEABLE SIDE EFFECTS

Expected and foreseeable side effects which meet **all** the following criteria:

- clearly identified in the MANUFACTURER's labelling;
- clinically well known* as being foreseeable and having a certain qualitative** and quantitative predictability when the device is used and performs as intended;
- documented in the device master record, with an appropriate risk assessment, prior to the occurrence of the INCIDENT and
- clinically acceptable in terms of the individual patient benefit

are ordinarily not reportable.

It is recommended that the MANUFACTURER involves a clinician in making this decision.

If the MANUFACTURER detects a change in the risk-benefit-ratio (e.g. an increase of frequency and/or severity) based on reports of expected and foreseeable side effects that led or might lead to death or serious deterioration of state of health, this must be considered as a deterioration in the characteristics of the performance of the device. A trend report must be submitted to the NCA where the MANUFACTURER or its AUTHORISED REPRESENTATIVE has his registered place of business.

Rationale: At the moment side effects are not covered by the INCIDENT definition in the directive unless the change in the risk-benefit-ratio is considered as a deterioration in the performance of the device.

NOTES:

** Some of these events are well known in the medical, scientific, or technology field; others may have been clearly identified during clinical investigation or clinical practice and labelled by the MANUFACTURER.*

*** The conditions that lead to the side effect can be described but they may sometimes be difficult to predict numerically.*

Conversely, side effects which were not documented and foreseeable, or which were not clinically acceptable in terms of individual patient benefit should continue to be reported.

Examples:

- **A patient who is known to suffer from claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured. Potential for claustrophobia is known and documented in the device product information.**

- **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 range specified in the device master record.**

- **A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.**

- **Patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died. Risk assessment documents that endocarditis at this stage is clinically acceptable in view of patient benefit and the instructions for use warn of this potential side effect.**

- **Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.**

5.1.3.6 NEGLIGIBLE LIKELIHOOD OF OCCURRENCE OF DEATH OR SERIOUS DETERIORATION IN STATE OF HEALTH

INCIDENTs where the risk of a death or serious deterioration in state of health has been quantified and found to be negligibly small need not be reported if no death or serious deterioration in state of health occurred and the risk has been characterised and documented as acceptable within a full risk assessment.

If an INCIDENT resulting in death or serious deterioration in state of health has happened, the INCIDENT is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligible small previous 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 a pacemaker released on the market identified a software bug and quantified the probability of occurrence of a serious deterioration in state of health with a particular setting to be negligible. No patients experienced adverse health effects.**

5.1.4 TREND REPORTS

On identifying a significant increase or trend of events or INCIDENTs that are usually excluded from individual reporting as per chapter 5.1.3 a report should be made to the relevant National Competent Authority. To enable this, the MANUFACTURER should have suitable systems in place for proactive scrutiny of trends in complaints and INCIDENTs occurring with their devices.

A trend report to the National Competent Authority where the MANUFACTURER or its AUTHORISED REPRESENTATIVE has its registered place of business should be made where there is a significant increase in the rate of:

- already reportable INCIDENTs
- INCIDENTs that are usually exempt from reporting
- events that are usually not reportable

irrespective of whether PERIODIC SUMMARY REPORTING has been agreed.

A form for Trend Reporting is provided in Annex 7 .

5.1.5 REPORTING OF USE ERROR AND ABNORMAL USE

As with all reported device complaints, all potential USE ERROR events, and potential ABNORMAL USE events dealt with in paragraph 5.1.5.3, should be evaluated by the MANUFACTURER. The evaluation is governed by risk management, usability engineering, design validation, and corrective and preventive action processes.

Results should be available, upon request, to regulatory authorities and conformity assessment bodies.

5.1.5.1 REPORTABLE USE ERRORS

USE ERROR related to MEDICAL DEVICEs, which did result in death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT, should be reported by the MANUFACTURER to the National Competent Authority.

USE ERRORs become reportable by the MANUFACTURER to the National Competent Authority when a MANUFACTURER:

- notes a significant change in trend (usually an increase in frequency), or a significant change in pattern (see appendix C of GHTF SG2 N54) of an issue that can potentially lead to death or serious deterioration in state of health or public health threat)
- or initiates a FSCA to prevent death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT

5.1.5.2 USE ERROR WHERE REPORTING UNDER THE MEDICAL DEVICE VIGILANCE SYSTEM IS NOT USUALLY REQUIRED.

USE ERROR related to MEDICAL DEVICEs, which did not result in death or serious deterioration in state of health or SERIOUS PUBLIC HEALTH THREAT, need not be reported by the MANUFACTURER to the National Competent Authority. Such events should be handled within the MANUFACTURER's quality and risk management system. A decision to not report must be justified and documented.

5.1.5.3 CONSIDERATION FOR HANDLING ABNORMAL USE

ABNORMAL USE needs not be reported by the MANUFACTURER to the National Competent Authority under the reporting procedures. ABNORMAL USE should be handled by the health care facility and appropriate regulatory authorities under specific appropriate schemes not covered by this document.

If MANUFACTURERs become aware of instances of ABNORMAL USE, they may bring this to the attention of other appropriate organisations and healthcare facility personnel.

5.1.6 DETAILS TO BE INCLUDED IN MANUFACTURER REPORTS

Annex 3 comprises the essential details of an INCIDENT to be included in any report made by a MANUFACTURER, AUTHORISED REPRESENTATIVE or person(s) responsible for placing on the market on their behalf to a National Competent Authority and should be used for Initial, Follow-up and Final Incident Reports. In the interests of efficiency, reporting by electronic means (email, on-line database system, xml etc.) is encouraged.

If the initial report is made by oral means (e.g. telephone), it should always be followed as soon as possible by a written report by the MANUFACTURER or the AUTHORISED REPRESENTATIVE.

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.

5.1.7 TIMESCALE FOR THE INITIAL REPORTING OF AN INCIDENT

Upon becoming aware that an event has occurred and that one of its devices may have caused or contributed to that event, the MEDICAL DEVICE MANUFACTURER must determine whether it is an INCIDENT.

The following time lines apply in a case of:

Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the MANUFACTURER of this threat.

Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.

Others: IMMEDIATELY (without any delay that could not be justified) after the MANUFACTURER established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potentially reportable INCIDENT there is still uncertainty about whether the event is reportable, the MANUFACTURER must submit a report within the timeframe required for that type of INCIDENT.

All report times refer to when the National Competent Authority must first be notified. The relevant contact points are available from the Commission’s web site.

5.1.8 TO WHOM TO REPORT

In general, the report should be made to the National Competent Authority in the country of occurrence of the INCIDENT unless specified differently in this guideline.

5.2 HANDLING OF USER REPORTS SUBMITTED TO THE MANUFACTURER BY A NATIONAL COMPETENT AUTHORITY

If the MANUFACTURER receives a USER report from a National Competent Authority he shall check this report against the reporting criteria of chapter 5.1 and

- submit an Initial INCIDENT (or Follow-up/Final) Report to the relevant National Competent Authority, if the event fulfils the relevant reporting criteria or
- if the MANUFACTURER considers the event not to fulfil the reporting criteria, provide the National Competent Authority with a justification why this is not reportable to the National Competent Authority with details of what use will be made of the information. (e.g. added to complaints file).

5.3 INVESTIGATIONS

5.3.1 PRINCIPLES

The MANUFACTURER normally performs the investigation, while the National Competent Authority monitors progress. Timeframe(s) for follow up and/or final reports should be defined.

If the MANUFACTURER is not able to perform the investigation of an INCIDENT then he should inform the National Competent Authority without delay.

The National Competent Authority may intervene, or initiate independent investigation if appropriate. This should be in consultation with the MANUFACTURER where practicable.

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

5.3.2 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 National Competent Authority (see section 6.1). The MANUFACTURER may also need to have access to the device suspected to have contributed to the INCIDENT for the purpose of deciding whether the INCIDENT should be reported to the National Competent Authority. The MANUFACTURER should in such cases make reasonable efforts to gain access to the device and may request support from the Competent Authorities to gain access to the device so that testing can be performed as soon as possible. Any delay can result in loss of evidence (e.g. loss of short term memory data stored in the device software; degradation of certain devices when exposed to blood) rendering future analysis of the root cause impossible.

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 National Competent Authority before proceeding. The National Competent Authority may then consider whether to intervene. Due to the frequency of these requests, a statement introduced in the Initial Vigilance report should cover this requirement, e.g. “The MANUFACTURER will assume destructive analysis can begin 10 days following issuance of this Initial INCIDENT Report, unless the National Competent Authority contacts the MANUFACTURER within this time frame opposing a destructive analysis of the device”.

NOTE: This section also applies to samples and any other useful information associated with the INCIDENT.

5.4 OUTCOME OF AN INVESTIGATION AND FOLLOW-UP

5.4.1 PRINCIPLES

The MANUFACTURER shall take the action necessary following the investigation, including consultation with the National Competent Authority and performing any FSCA - see section 5.4.

The National Competent Authority may take any further action it deems appropriate, consulting with the MANUFACTURER where possible - see section 6.2.3.

5.4.2 FOLLOW-UP REPORT

The MANUFACTURER shall provide a follow-up-report to the National Competent Authority if the investigation time reaches the time line given to the National Competent Authority within the initial report.

5.4.3 FINAL REPORT

There shall be a final report which is a written statement of the outcome of the investigation and of any action.

Examples of actions may include:

- no action;
- additional surveillance of devices in use;
- preventive action on future production;
- FSCA.

The report is made by the MANUFACTURER to the National Competent Authority(ies) to whom the MANUFACTURER sent the initial report.

If the National Competent Authority performs the investigation then the MANUFACTURER shall be informed of the result.

A recommended format for the MANUFACTURER's final report is given in annex 3.

5.4.4 FIELD SAFETY CORRECTIVE ACTION

The Medical Device Directives require the MANUFACTURER to report to the National Competent Authority any technical or medical reason leading to a systematic recall of devices of the same type by the MANUFACTURER. Those reasons are 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 to a serious deterioration in his state of health.

The term "withdrawal" used in the AIMD is interpreted in the same way. This guideline uses the definition of a FIELD SAFETY CORRECTIVE ACTION as a synonym for recall or withdrawal since there is no longer a harmonised definition of these terms.

Removals from the market for purely commercial non-safety related reasons are not included.

In assessing the need for the FSCA the MANUFACTURER is advised to use the methodology described in the harmonised Risk Management standard EN ISO 14971: 2000. In case of doubt, there should be a predisposition to report and to undertake a FIELD SAFETY CORRECTIVE ACTION.

FSCA taken on a basis of INCIDENTs occurred outside the EEA, Switzerland and Turkey affecting devices covered by the MDD are included in this guideline.

FSCA should be notified to the customers via a FIELD SAFETY NOTICE.

Where a Notified Body was involved in the conformity assessment procedure of the device, it is recommended to inform them about the FIELD SAFETY CORRECTIVE ACTION.

5.4.4.1 NOTIFICATION TO NATIONAL COMPETENT AUTHORITIES

The MANUFACTURER should issue a notification (see below) to the Competent Authorities of all countries affected at the same time and also to the National Competent Authority responsible for the MANUFACTURER or AUTHORISED REPRESENTATIVE. Use the format recommended in annex 4.

This notification should include all relevant documents necessary for the National Competent Authority to monitor the FSCA, e.g.

- Relevant parts from the risk analysis
- Background information and reason for the FSCA (including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.)
- Description and justification of the action (corrective/preventive)
- Advice on actions to be taken by the distributor and the USER (include as appropriate:
    - identifying and quarantining the device,
    - method of recovery, disposal or modification of device
    - recommended patient follow up, e.g implants, IVD
    - a request to pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period.
    - a request for the details of any affected devices that have been transferred to other organisations, to be given to the MANUFACTURER and for a copy of the FIELD SAFETY NOTICE to be passed on to the organisation to which the device has been transferred.)
- Affected devices and serial / lot / batch number range
- In the case of an action concerning lots or parts of lots an explanation why the other devices are not affected
- Identity of the MANUFACTURER/AUTHORISED REPRESENTATIVE.

MANUFACTURERs should also include a copy of the FIELD SAFETY NOTICE to the Competent Authorities along with the notification. This should be done before or at the same time as FSCA is being issued.

The MANUFACTURER or other responsible on his behalf should inform the coordinating Competent Authority once the FSCA has been completed in both, the EEA, Switzerland and Turkey. This should include information on the effectiveness of the action per country involved (e.g., percentage of devices recalled)

It is recommended that MANUFACTURERs should provide a draft of the Field Safety Notification to a relevant National Competent Authority, e.g. where the MANUFACTURER or the AUTHORISED REPRESENTATIVE has his registered place of business, where most of the affected devices are on the market or any other appropriate National Competent Authority.

Normally, the MANUFACTURER should allow a minimum of 48 hours for receipt of comment on the Field Safety Notification unless the nature of the FSCA dictates a shorter timescale e.g. for SERIOUS PUBLIC HEALTH THREAT.

It is recommended to copy the FIELD SAFETY NOTICE to the Notified Body involved in the conformity assessment procedure of that device.

5.4.4.2 CONTENT OF THE FIELD SAFETY NOTICE

Unless duly justified by the local situation, a uniform and consistent FIELD SAFETY NOTICE should be offered by the MANUFACTURER to all affected EEA member states, Switzerland and Turkey.

The MANUFACTURER should use a distribution means ensuring the appropriate organisations have been informed, e.g. by confirmation of receipt.

The FIELD SAFETY NOTICE should be on a company letterhead, be written in the language(s) accepted by the National Competent Authority(s) and include the following:

1. A clear title, with “Urgent FIELD SAFETY NOTICE” followed by the commercial name of the affected product, an FSCA-identifier (e.g. date) and the type of action (e.g. see chapter 4 definition of a FSCA).

2. Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.

3. A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, USER or other person and any possible risks to patients associated with previous use of affected devices.

4. Advice on actions to be taken by the USER.
   Include as appropriate:
   - identifying and quarantining the device,
   - method of recovery, disposal or modification of device
   - recommended review of patients previous results or patient follow up, e.g implants, IVD
   - timelines.

5. A request to pass the FIELD SAFETY NOTICE to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period.

6. If relevant, a request for the details of any affected devices that have been transferred to other organisations, to be given to the MANUFACTURER and for a copy of the FIELD SAFETY NOTICE to be passed on to the organisation to which the device has been transferred.

7. If relevant, a request that the recipient of the FIELD SAFETY NOTICE alerts other organisations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.

8. Confirmation that the relevant National Competent Authorities have been advised of the FSCA.

9. Any comments and descriptions that attempt to
   a) serve to play down the level of risk in an inappropriate manner
   b) advertise products or services

should be omitted.

10. Contact point for customers how and when to reach the designated person.

An acknowledgment form for the receiver might also be included (especially useful for MANUFACTURER's control purposes).

By following the recommendations above the clarity of FIELD SAFETY NOTICEs will be improved. This will reduce the likelihood of Competent Authorities either requesting MANUFACTURERs issue revised FIELD SAFETY NOTICEs or issuing separate National Competent Authority communications.

A template for a FIELD SAFETY NOTICE is provided in annex 5.

6. RESPONSIBILITIES OF NATIONAL COMPETENT AUTHORITY

The National Competent Authority should send an acknowledgement of receipt of the report to the sender.

The National Competent Authority shall evaluate the report in consultation with the MANUFACTURER, if practicable (see section 5.2 and 5.3), advise as appropriate and intervene if necessary.

6.1 ACTIONS ON A REPORT FROM USERS OR OTHER SYSTEMS

A report which appears to meet the criteria of section 5.1.1, received by a National Competent Authority from a USER reporting system or other source, shall be copied by the National Competent Authority to the MANUFACTURER without delay or translation. In doing so, patient confidentiality should be maintained.

Once the MANUFACTURER has been so informed and has determined that the event fulfils the three basic reporting criteria of section 5.1.1, the subsequent procedure is the same, as far as practicable, as that described in section 5 of these guidelines.

6.2 RISK EVALUATION AND SUBSEQUENT ACTIONS

6.2.1 RISK EVALUATION BY THE NATIONAL COMPETENT AUTHORITY

The risk assessment of an INCIDENT or FSCA reported may include where relevant:

- Acceptability of the risk, taking into account criteria such as: causality, technical/other cause, probability of occurrence of the problem, frequency of use, detectability, probability of occurrence of HARM, severity of HARM, INTENDED PURPOSE and benefit of the product, requirements of harmonised European standards, the Medical Device Directives safety principles (see annex I, clause 2 of the directives 93/42/EEC and 98/79/EC and clauses 5 and 6 of directive 90/385/EEC), potential USER(s), affected populations etc.

- Need for (what) corrective action

- Adequacy of measures proposed or already undertaken by the MANUFACTURER

This assessment should be carried out in cooperation with the MANUFACTURER.

6.2.2 MONITORING OF MANUFACTURERS SUBSEQUENT ACTIONS

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

Aspects of the MANUFACTURER's investigation which may be monitored include, for example:

- course (direction the investigation is taking);
- conduct (how the investigation is being carried out);
- progress (how quickly the investigation is being carried out);
- outcome (whether the results of device analysis are satisfactory).

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.

Liaison may be needed with:

- Notified Bodies (involved in the attestation leading to the CE marking);
- USER(s);
- other Competent Authorities;
- other independent bodies, test houses etc.

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 harmonised measures applicable to all devices of that kind. This could include, for example, initiating USER education or suggesting re-classification.

6.2.3 NATIONAL COMPETENT AUTHORITY ACTIONS

For drug device combination products regulated under the medical device directives, the National Competent Authority receiving the INCIDENT report should establish a link with any other relevant National Competent Authority or the EMEA, if required.

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

National Competent Authority´s actions as a result of a report of the MANUFACTURER or AUTHORISED REPRESENTATIVE may include, for example:

- no further 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 FSCA and other actions to be taken). The information may be in the format of a National Competent Authority Report (see annex 8) 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 USER(s);
- any other action to supplement MANUFACTURER action.

6.3 CO-ORDINATION BETWEEN COMPETENT AUTHORITIES

6.3.1 CIRCUMSTANCES WHERE A COORDINATING NATIONAL COMPETENT AUTHORITY IS NEEDED

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

- INCIDENTs of similar types occurring in more than one country within the EEA, Switzerland and Turkey;
- FSCA conducted in more than one country within the EEA, Switzerland and Turkey, whether or not a reportable INCIDENT has occurred.
- information available on a FSCA conducted outside the EEA, Switzerland and Turkey where there is uncertainty whether the FSCA affects the member states within the EEA, Switzerland and Turkey or not, e.g. a Competent Authority Report issued outside EEA Switzerland and Turkey (for example via the GHTF NCAR Exchange Program) or information published on a CA website outside the EEA , Switzerland and Turkey.

6.3.2 DETERMINATION OF THE COORDINATING NATIONAL COMPETENT AUTHORITY

The co-ordinating Competent Authority should be the one that is responsible for the MANUFACTURER or his AUTHORISED REPRESENTATIVE, unless otherwise agreed between Competent Authorities e.g. the National Competent Authority:

- which has a particular high interest in consulting other Competent Authorities or is already undertaking investigation on INCIDENTs and therefore initiates the co-ordination.
- in the State where the Notified Body which made the attestation leading to CE-marking, is situated.

6.3.3 THE TASKS OF THE CO-ORDINATING NATIONAL COMPETENT AUTHORITY

The coordinating National Competent Authority should, where relevant:

- inform the MANUFACTURER, the other affected Competent Authorities as described in 6.3.1 and the Commission about taking the lead;

- coordinate and monitor the investigation with the MANUFACTURER on behalf of other Competent Authorities;
- consult with the Notified Body which made the attestations which led to the CE marking and coordinate with other National Competent Authorities within the EEA, Switzerland and Turkey;
- discuss with the MANUFACTURER the principles, need for and circumstances of corrective actions to be taken within the EEA, Switzerland and Turkey ;
- reach agreement, where possible, with MANUFACTURER and amongst National Competent Authorities about implementing a uniform FSCA in all affected European countries;
- Feedback to the Competent Authorities and the Commission the conclusion from inquiries within the EEA member states, Switzerland and Turkey e.g. with respect to multiple INCIDENTs in different countries which do not lead to corrective actions at the latest with the closure of the file; MANUFACTURER will be informed according to section 6.4;
- Agree with the MANUFACTURER about content and periodicity of PERIODIC SUMMARY REPORTING for INCIDENTs covered by FSCA
- Distribute the closure information.

Such an arrangement would not affect the rights of an individual National 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. In doing so, the coordinating National Competent Authority and the Commission should be kept informed about these activities.

6.3.4 SAFEGUARD CLAUSE

The application of the Medical Device 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.

6.3.5 DISSEMINATION OF INFORMATION BETWEEN National COMPETENT AUTHORITIES

Information shall be disseminated between National Competent Authorities and copied to the Commission when:

A) a FSCA is performed by the MANUFACTURER;
B) a National Competent Authority requires the MANUFACTURER to perform an FSCA or to make changes in an FSCA that the MANUFACTURER has already initiated;
C) 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;
D) the MANUFACTURER does not provide a final report in a timely manner.

This information is called National Competent Authority Report (NCAR).

National 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 National Competent Authority Report may not be necessary. In cases of doubt there should be a pre-disposition on the part of National Competent Authorities to disseminate the NCAR.

The NCAR concerning A) above should be disseminated by the National Competent Authority responsible for the MANUFACTURER or its AUTHORISED REPRESENTATIVE.

The NCAR concerning B), C) and D) above should be disseminated by the National Competent Authority requesting the FSCA or changes within the FSCA, or identifying the serious risk and considering measures, or expecting the final report, respectively.

This NCAR should be distributed by the NCA IMMEDIATELY (without any delay that could not be justified) but not later than 14 calendar days after being informed by the MANUFACTURER.

The format for dissemination of information between National Competent Authorities and the Commission is given in Annex 8 and is the GHTF SG2 N79 format with minor changes. The MANUFACTURER's report may be circulated with the Competent Authority Report. The use of Eudamed to exchange NCARs is mandatory.

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

National Competent Authority Reports are intended for dissemination between National 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).

Competent Authorities must, where appropriate, consult the MANUFACTURER when preparing a NCAR, and must inform the MANUFACTURER when one is issued.

6.3.6 DISSEMINATION OF INFORMATION OUTSIDE National COMPETENT AUTHORITIES by a National Competent Authority

Careful consideration should be given to the mode of communication, the drafting and the dissemination of information by the National 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.

When the MANUFACTURER has informed one or multiple National Competent Authorities in advance of the start of an FSCA (see section 5.4) this information should be held confidential by the National Competent Authority until the information becomes public.

In general, preference should be given to notification communicated directly to medical practitioner or health-care facilities concerned, over communication to the public.

In some cases dissemination of information directly to the public may be needed e.g. to suggest that patients or USERs contact their medical practitioner for further, more specific advice.

Where appropriate, it is recommended that the communication includes a statement indicating that medical practitioners or other health-care professionals should be consulted and that the information is intended for medical professionals only.

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

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

Interfaces with communication media should be coordinated wherever practicable between the MANUFACTURER and the National Competent Authorities.

6.4 COMPLETION OF THE INVESTIGATION

The National Competent Authority shall place the MANUFACTURER's final report on file and make any other observations necessary. The files investigation may then be endorsed as "complete".

If a National Competent Authority itself conducts an investigation, the MANUFACTURER (and, where appropriate, other National Competent Authorities) shall be informed of progress and of the results.

The MANUFACTURER’s final report shall also be copied to any National Competent Authorities who were informed by a National Competent Authority of the initial report.

The National Competent Authority should inform the MANUFACTURER when the investigation is complete, or if no investigation by the MANUFACTURER is required by the National Competent Authority (Note: this does not preclude the MANUFACTURER investigating as part of their ongoing quality assurance procedures).

Records of INCIDENT reports shall be retained to enable the investigation to be reopened if necessary, and to facilitate systems for trend analysis.

7 THE ROLE OF THE NOTIFIED BODIES

Even though the Notified Bodies do not play a key operational role in the Medical Device Vigilance System, the overall performance of the Medical Device Vigilance System is supported by the Notified Body activity in the following areas:

- Assessment of vigilance procedures
- Audit of the implementation of the vigilance procedures, and link with other systems e.g. Corrective and Preventive Action (CAPA) , FSCA
- Assessment of the impact of vigilance issues on the certification granted
- Liaise with the National Competent Authority if required, e.g. specific investigations/audits based on a request of the National Competent Authority

Further guidance on these areas is provided by Notified Bodies Operation Group documents or Notified Body recommendations.

8 THE ROLE OF THE COMMISSION

The Commission shall ensure that appropriate coordination and cooperation is put into place between the Competent Authorities of all Member States to allow the Medical Device Vigilance System to deliver the high level of protection for the health and safety of patients and USERs.

- In order to reinforce a common understanding and a common approach towards the identification and resolution of vigilance cases, the Commission shall:

- facilitate the exchange of experience and best practices between the National Competent Authorities of the Member States,
- facilitate the transmission of relevant data through the appropriate data exchange system,
- when appropriate, in cooperation with National Competent Authorities, develop and organise training programs.

9 USERS ROLE WITHIN THE VIGILANCE SYSTEM

There is no legal requirement within the directives obliging USERs to have an active role in the Vigilance System. Yet for the successful operation of the vigilance system their involvement is vital. It is through the USERs that suspected INCIDENTs are made known to the MANUFACTURERs and it is with their close involvement and co-operation that the implementation of FSCAs is made possible.

The involvement of USERs is promoted and encouraged through the relationship the MANUFACTURER develops with his customer (the USER). Annex 11 details some key areas that the MANUFACTURER should promote with the USER. These areas may also be reinforced by separate advice from National Competent Authorities.

ANNEXES

10.1 ANNEX 1- EXAMPLES OF INCIDENTS AND FIELD SAFETY CORRECTIVE ACTIONS 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 National Competent Authority. The examples are intended to show that there is a considerable judgmental element in the decision on whether to report.

EXAMPLES OF REPORTABLE INCIDENTS

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 a serious deterioration in state of health is not normally expected. The INCIDENT should be reported.

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 in a different situation it could have caused a serious deterioration in state of health. The INCIDENT should be reported.

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.

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. The INCIDENT should be reported.

7. Glass particles are found by the user in a contact lens vial. The INCIDENT should be reported.

8. 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. The INCIDENT should be reported.

9. 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.

10. The premature revision of an orthopaedic implant is required due to loosening. Although no cause is yet determined, this INCIDENT should be reported.

11. User discovers that insufficient details are provided on cleaning methods for reusable surgical instruments used in brain surgery, despite obvious risk of transmission of CJD. The INCIDENT should be reported.

12. 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. This INCIDENT should be reported.

13 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 a data mismatch could occur. Due to the data mismatch a patient may obtain a wrong diagnosis / treatment. This INCIDENT should be reported.

14. 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 incident should be reported.

15. A user discovers that an IVF culture medium is contaminated resulting in degeneration of the cells. This INCIDENT should be reported.

EXAMPLES OF REPORTABLE FSCA.

15. 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 deterioration in state of health as remote. Subsequent failure results and the new risk assessment carried out by the MANUFACTURER indicate that the likelihood of occurrence of a serious deterioration in state of health is not remote. The FSCA should be reported.

16. Fatigue testing performed on a commercialised heart valve bio prosthesis demonstrates premature failure, which resulted in a risk to public health. The FSCA should be reported.

17. 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 initiates a FSCA of this batch. This should be reported as an FSCA.

18. 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. The MANUFACTURER issues information to the field that a reduced onboard stability has to be taken into account. The FSCA should be reported.

19. A MANUFACTURER has noticed that starting from control lot XX a lower recovery is obtained and re-assigns the control value. Users are informed of this new value by means of warning stickers and a customer communication. The FSCA should be reported.

20. A MANUFACTURER of an immunohematology analyzer received complaints of an ABO blood grouping system results being attributed to the wrong patient identification. The error proved to be due to the analyzers software, which was subsequently updated. The FSCA should be reported.

21. IVF/ART MANUFACTURER informs users of an error on the labelling of their device which indicates a shelf life longer than the validated shelf life for the product. The FSCA should be reported.

10.2 ANNEX 2- EXTRACTS FROM DIRECTIVES RELATING TO "MEDICAL DEVICES VIGILANCE"

I. 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

Extracts :

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. 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 authorised representative, is also informed of the incident.

3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 7, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents.

B. Annexes 2, 4 and 5

Extracts :

The manufacturer shall make an application for evaluation of his quality system to a notified body. The application shall include:

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 :

a) 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;

b) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

II. 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

Extracts :

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, V, VI and VII

Extracts :

The manufacturer shall make an application for evaluation of his quality system to a notified body. The application shall include:

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 :

a) 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;

b) 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.

III. 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. Annex III

Extracts :

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:

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 other persons or to a serious deterioration in his or their state of health;

b) 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.

10.3 ANNEX 3 - REPORT FORM FOR MANUFACTURER'S TO THE NATIONAL COMPETENT AUTHORITY

Report Form
Manufacturer's Incident Report

Medical Devices Vigilance System

10.4 ANNEX 4 - REPORT FORM FOR FIELD SAFETY CORRECTIVE ACTION

Report Form

Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System

10.5 ANNEX 5 - Template for a Field Safety Notice

Urgent Field Safety Notice

Commercial name of the affected product,
FSCA-identifier (e.g. date)
Type of action (e.g. chapter 4 definition of a FSCA).

Date:

Attention: ///////////////

Details on affected devices:
Specific details to enable the affected product to be easily identified e.g. type of device , model name and number, batch/ serial numbers of affected devices and part or order number.
Insert or attach list of individual devices.
(Possible reference to a manufacturer web site.)

Description of the problem:
A factual statement explaining the reasons for the FSCA, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person.
Any possible risk to patients associated with previous use of affected devices.

Advise on action to be taken by the user:

Include ,as appropriate:

- *identifying and quarantining the device,*
- *method of recovery, disposal or modification of device*
- *recommended patient follow up, e.g implants, IVD*
- *timelines.*
- *Confirmation form to be sent back to the manufacturer if an action is required (e.g. return of products)*

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

Name / organisation, address, contact details.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

(Closing paragraph)

Signature

10.6 ANNEX 6 - Manufacturer's PERIODIC SUMMARY REPORT FORM

Report Form

Manufacturer's Periodic Summary Report (PSR)

Medical Devices Vigilance System

10.7 ANNEX 7- MANUFACTURER'S TREND REPORT FORM

Report Form
Manufacturer's Trend Report
Medical Devices Vigilance System

10.8 ANNEX 8 - NATIONAL COMPETENT AUTHORITY REPORT FORMAT

v.01.13

NATIONAL COMPETENT AUTHORITY REPORT

This form should be used for the exchange of medical device information between NCAR participants only. Completed forms should not be released to the public.

1. Is this report confidential? Yes [ ] No [ ]

Reference and Reporter Data

2. NCA report ref. no.:	3. Local NCA reference no.:	4. Related NCA report nos.: (if any)
5. Manufacturer Ref/Recall no.:	6. Sent by: (Name and Organization)	7. Contact person: (if different from 6)
8. Tel:	9. Fax:	10. E-mail:

Device Data

11. Generic name/kind of device:	
12. Nomenclature id:	13. No.:
14. Trade Name and Model:	
15. Software version:	
16. Serial no.:	17. Lot/batch no.:
18. Manufacturer:	19. Authorized rep:
Country:	Country:
Full Address:	Full Address:
Contact:	Contact:
Tel:	Tel:
Fax:	Fax:
E-mail:	E-mail:

20. CAB/Notified Body no.:
21a. Device approval status: 21b. Risk Class:
22. Action taken: [ ] None [ ] Safeguard Action [ ] Field Safety Corrective Action [ ] Other (specify)

Event Data

23a. Background information and reason for this report: 23b. Is the investigation of the report complete? [ ]Yes [ ] No
24a. Conclusions: 24b. Have the manufacturer's actions been made public? [ ]Yes [ ]No 24c. The originator of this NCAR will take the lead and co-ordinate the investigation [ ]Yes [ ]No
25a. Recommendation to receivers of this report: 25b. Device known to be in the market in (include copy of manufacturer's letter): 25c. Device also marketed as (trade name):

Report Distribution

26a. This report is being distributed to: [ ] The NCAR Secretariat for further distribution to FULL NCAR PARTICIPANTS. [ ] The NCAR Secretariat for further distribution to ALL NCAR PARTICIPANTS. [ ] EEA states, EC, and EFTA [ ] The following targeted NCAs: [ ] The manufacturer / authorized rep.: 26b. The last NCAR distributed by this NCA was (>>>>>>>>>>>>>>)

Instructions for Filling in National Competent Authority Report

The form should be completed in English

The NCAR participant filling in and sending the NCAR is responsible for the quality of the content as well as the appropriateness of sending such a message and the scope of its distribution. Guidance on

which issues should be selected for exchange between NCAR participants is given in Section 5 above. Before releasing any information, careful note should be taken of the SG2 N8 (Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices).

This form should be completed by NCAR participants only, when exchanging safety information about relevant measures and/or recommendations relating to the prevention of adverse incidents concerning medical devices. This form is designed for exchanging information between NCAR participants; it should not be passed directly on to patients, users, third persons or the public – instead, if there is a need to communicate to this audience another form of notice should be used. It is not to be used for advising of single incidents, unless those incidents have a clear implication for public health. In such cases, the implied recommendation is for other NCAs to be aware and take such local actions they find appropriate.

If the NCAR report concerns a specific manufacturer's device, then the manufacturer or authorized representative should be consulted about the NCARs content and distribution prior to it being sent – preferably by providing a copy for the manufacturer or authorized representative to comment on. This will help to ensure the accuracy of the NCAR. An appropriate time frame for receiving manufacturer's comments should be communicated. However, this process should not be allowed to cause unnecessary delay. If an NCAR concerns a range of devices from different manufacturers then the NCA should make efforts to contact and obtain comment from all relevant manufacturers or authorized representatives known to be on their markets.

There are differing reporting obligations for various NCAR participants. In general, NCAR participants shall send reports directly to the NCAR Secretariat for appropriate global distribution. The NCAR secretariat will include the originator of the NCA report as confirmation of distribution.

The EEA States must exchange reports with each other in accordance with current European Directives for medical device. They should also send the report to the NCAR Secretariat for further distribution to all other (non EEA) NCAR participants. There are instances where reports are sent only to EEA participants of the NCAR program. This may cause a discontinuity in the numbering of reports received from EEA participants. When an NCAR is not to be distributed to all NCAR participants a note of this should be made on the next NCAR that is issued by the originating NCA to all NCAR participants (see Notes on Field 26b).

On the rare occasions-when there are time critical issues of significant public health threat or concern-in addition to sending the report to the NCAR Secretariat, NCA's may send reports directly to countries participating in the NCAR exchange who are known to have the subject device in national distribution. In such circumstances, the issuing NCA should ensure that the form is completed fully and contains the correct sequential reference, preferably by contacting the NCAR Secretariat.

Field:

1 - Please be sure to check Yes or No for confidentiality. This tells the recipient NCA if the information provided can be released publicly or must be held strictly confidential.

2 - Use the rules for numbering NCARs,(* use the ISO 3166 for country codes) which incorporates a two-letter code of the issuing country to fill in this item. For example: CA-2004-10-19-004 is a report from Canada sent 19 October 2004 and is the 4th report for 2004. Each NCAR should be given a new, unique NCAR number. If an NCAR relates to a previously exchanged NCAR (i.e : is an update), the original NCAR number should be specified in field 4.

3 - Insert any local reference number used by your NCA relevant to this report, here.

4 - If there have been previous NCARs exchanged relating to this one, regardless of source, insert their NCA exchange numbers here.

5 - Insert the manufacturer's reference/recall number here, if applicable.

6 - Identify person and organization sending the NCAR. This should be the single point of contact, previously identified to the NCAR Secretariat.

7 - Identify contact person for any information / technical discussion of the topic.

8-10 - Telephone, Fax and e-mail of person in (7) above.

11 - Kind of device or generic descriptor.

12 - Identify the nomenclature system used (e.g. GMDN Global medicaldevice nomenclature, etc) .

13 - Number or code to identify the device based on the nomenclature system identified in (12).

14 - Trade name / Brand name AND Model number

15 - Self Explanatory 16-17 If there are many lot/batch numbers or serial numbers (ie: more than 3 or 4), a detailed list should be appended to the bottom of the report.

18 - Manufacturer of device - full address, including country, fax, phone numbers and e-mail.

19 - Identify the authorized representative in reporting country (who is legally responsible for placing the subject device on the market where the incidents occurred), full address, including country, fax, phone numbers and e-mail.

20 - Indicate name or code number of Conformity Assessment Body/Notified Body involved, if applicable.

21 - a.) Identify approval status of the device in the region where the report originates. For example: CE-marking, approval number or licence number

b.) Device risk class according to the jurisdiction of the issuing NCA can also be included.

22 - Identify any regulatory, legal or company-initiated action taken in advance of sending out the report. This could, for instance, refer to a Recall or the use of Safeguard action.

23a - .Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (SECTION 5 ABOVE), describe the reason for the report and why you want to inform other NCAs about these events. Such information will lead to a better understanding by the recipient on what is considered to be appropriate follow-up.

23b - Indicate if the investigation of the report is complete or not.

24a - Describe the outcome or conclusion of the investigation, to date. If useful, include a copy of any manufacturer or NCA advisory notice(s) associated with the NCAR and make reference to them within the NCAR.

24b - Indicate whether the manufacturer's actions have been made public.

24c - Indicate whether originating NCA is willing to take the lead in co-ordination of the investigation.

25a - Recommendations to receivers of this report.

25b - List all countries known to have received the device. Put considerable care and effort into obtaining accurate information from the manufacturer for this field.

25c - List the marketed trade name(s) in other countries, if different.

26a - Indicate to whom the report has been sent. Care should be taken to indicate the correct distribution for the NCAR. Confidential NCARs should only be sent via the NCAR Secretariat to full NCAR participants not all NCAR participants. EEA European Economic Area , EC European commission and EFTA European federation trade associates NCAR participants should indicate direct distribution of the NCAR to EEA states, EC and EFTA NCAs in accordance European Medical Device Directives. NCAs outside the exchange program that are being sent the NCAR by the originating NCAR participant should also be listed.

26b - Where NCAR report numbers are not sequential, participants should include the number of the last report issued to all NCAR participants

Form N79R11 can be downloaded as well from: http://www.imdrf.org/documents/doc-ghtf-sg2.asp

10.9 ANNEX 9 - TITLES OF GLOBAL HARMONISATION TASK FORCE STUDY GROUP 2 DOCUMENTS USED IN THE DEVELOPMENT OF THIS MEDDEV AND/OR CITED

- SG2-N8 Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
- SG2-N79 Medical Devices: Post Market Surveillance: National Competent Authority Exchange Criteria and Report Form.
- SG2-N54 Global Guidance for Adverse Event Reporting for Medical Devices :

NOTE: All these documents can be downloaded from http://www.imdrf.org/documents/doc-ghtf-sg2.asp

10.10 ANNEX 10- LIST OF THE USED ABBREVIATIONS

AIMD	Active Implantable Medical Devices Directive
CAPA	Corrective and Preventive Action
EEA	European Economic Area
FSCA	FIELD SAFETY CORRECTIVE ACTION
FSN	FIELD SAFETY NOTICE
GHTF	Global Harmonisation Task Force
IVD	In Vitro Diagnostic Device
IVDD	In Vitro Diagnostic Medical Devices Directive
MDD	Medical Devices Directive
NB	Notified Body
NCA	National Competent Authority
NCAR	National Competent Authority Report

10.11 ANNEX 11- GUIDANCE TO MANUFACTURERS WHEN INVOLVING USERS IN THE VIGILANCE SYSTEM

Reporting Guidance

What: Encourage users or those given specific responsibility for reporting incidents that have occurred with medical devices and that meet the criteria within these guidelines to report the incidents to the Manufacturer and or to the Competent Authority in accordance with national guidance.

When: Encourage users to report all adverse incidents as soon as possible. Serious cases ought be reported by the fastest means possible. Initial incident reports should contain as much relevant detail (e.g. equipment type, make and model) as is immediately available, but reporting ought not be delayed for the sake of gathering additional information.

How: Encourage the user the use reporting forms in accordance with national guidance and to provide contact details when reporting to the manufacturer or the Competent Authority.

What to do with the device: All items, together with relevant packaging materials, ought to be quarantined; they ought not be repaired, or discarded. The device should be returned to the manufacturer in accordance with their instructions unless otherwise required by national or other legal requirements. In some member states the Competent Authority may be required to be given opportunity then to carry out its own investigation. Medical devices ought not to be sent to Competent Authorities unless it has been specifically requested. Users ought to contact the manufacturer to obtain information relating to the procedure for returning the suspect device. The device should be appropriately decontaminated, securely packaged, and clearly labelled, including the CA or manufacturer reference number if needed.

Further local information: Encourage reporters to cooperate with the manufacturer and the Competent Authority by providing further information concerning incidents should they become available e.g. relevant outcomes of internal investigations concerning the device or patient outcomes e.g. subsequent death.

Field Safety Corrective Action Guidance

Importance of FSNs: Field Safety Notices are an important means of communicating safety information to medical device users in all healthcare areas. Field Safety Notices may also be used to provide updated information and request feedback.

It is therefore important that users are encouraged to develop effective closed loop systems that ensure the dissemination of the Field Safety notices and the timely completion of the actions outlined.

Distribution: Healthcare organisations should be encouraged to help ensure that the FSN reaches all in the organisation that needs to be aware and/or take the recommended action.

Action: encourage users responsible for the maintenance and the safety of medical devices to take the actions advised in the manufacturer's field safety notice. These actions ought to be taken in co-operation with the manufacturer where required. They may also include associated actions recommended by the Competent Authority in connection with the FSCA, including providing any requested feedback.

Access to devices: Encourage users responsible for the maintenance and the safety of medical devices to a) facilitate manufacturer access to the device if this is required, and b) work with the manufacturer when needing to balance the individual risks and benefits for any dependent patients using affected devices.