

EUROPEAN COMMISSION

Directorate-General for Internal Market,

Industry, Entrepreneurship and SMEs

Unit GROW D.4 – Health Technology and Cosmetics

Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8

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1. INTRODUCTION

This document provides additional guidance in relation to the Medical Device Vigilance System that is currently in operation under the Medical Devices Directives. The guidance should complement and be used in conjunction with MEDDEV 2.12-1 rev. 8, 2013.

The document:

- Clarifies some of the existing definitions.
- Introduces a new Manufacturer's Incident Report and the new template for Field Safety Notice.
- Introduces device specific vigilance guidance.
- Provides further detail in relation to the area of the coordination of vigilance issues amongst Competent Authorities.
- Clarifies the differences between the EU NCAR exchange and the IMDRF NCAR exchange.

The document also highlights that the most recent revision of all of the forms that currently support the Medical Device Vigilance System can now be found on the EU commission website rather than the Annexes of the MEDDEV 2.12-1 rev. 8, 2013.

2. DEFINITIONS

Section 4 of MEDDEV 2.12-1 rev. 8, 2013 provides details of the definitions which assist our understanding of many of the terms that are in use in the medical device vigilance system. This section provides clarification of some of the existing definitions and introduces a number of definitions.

2.1. FIELD SAFETY CORRECTIVE ACTION (FSCA)

Section 4.6 of MEDDEV 2.12-1 rev. 8, 2013 provides a definition of Field Safety Corrective Action. The definition below has been modified slightly to highlight that it is both the nature of the action taken, and the reason giving rise to the need for the action which defines whether an action is a FSCA (NOTE 5). It also clarifies that recommended safety related “device inspections “ are also considered as FSCAs (NOTE 1).

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;
- MEDICAL DEVICE inspection/ examination by the device USER;
- MEDICAL DEVICE modification;
- MEDICAL DEVICE exchange;
- MEDICAL DEVICE destruction;
- retrofit by purchaser of MANUFACTURER's modification or design change;
- advice given by MANUFACTURER regarding the use of the MEDICAL DEVICE and/or the follow up of patients, USERS or others (e.g. where the MEDICAL 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 his 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 medical 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:

It is both the nature of the action taken, and the reason giving rise to the need for the action which defines whether an action is a FSCA.

NOTE 6:

This guideline uses the definition of FSCA as synonym for recall mentioned in article 10, paragraph 1b) of the MDD, Article 8, paragraph 1b) of the AIMD and Article 11, paragraph 1b) of the IVD Directive.

2.2. FIELD SAFETY NOTICE (FSN)

Section 4.7 of MEDDEV 2.12-1 rev. 8, 2013 provides a definition of **Field Safety Notice**. This definition has been modified slightly to clarify the target audience for the communication.

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

3. DEVICE SPECIFIC VIGILANCE GUIDANCE

Over the past number of years', member states have developed Device Specific Vigilance Guidance documents which provide additional information to MANUFACTURERS that can assist them to identify incidents and complaints associated with specific medical devices, and help determine if a type of incident is reportable to the Competent Authority. The guidance documents also suggest the method of reporting that should be used e.g. Individual incident reporting, Periodic Safety Reports or trend reports.

Device Specific Vigilance Guidance documents have been developed to complement the requirements of the Medical Devices Directive and MEDDEV 2.12-1 rev. 8, 2013 and should be read in conjunction with those requirements.

Published DSVGs can be found on the Commission website, see:

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

4. MANUFACTURER'S INCIDENT REPORT

Section 5.1.6 of the MEDDEV 2.12-1 rev. 8, 2013 outlines the details that should be included in the MANUFACTURER reports. It should be noted that the Manufacturer's Incident Report Form has been updated.

A copy of the updated form (the latest version) and detailed guidance/ help text that may assist in completing the form are available on the Commission website, see

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

The current version of the MIR Form included a number of new concepts

- The information is presented in a new structure.
- Introduces international IMDRF coding/ terminology.
- Introduces a definition of similar incidents and requires similar incidents trend data in a tabular format.
- In preparation for the future EU MDR it also introduces (not mandatory yet):
 - the concept of SRN which will be utilized greatly in the future under the new regulations.
 - the use of UDI.

The updated version of the MIR Form V 7.2 will become mandatory from January 2020.

A questions and answers document detailing the transition to the new form can be found on the commission website see: https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

5. FIELD SAFETY CORRECTIVE ACTION

This section provides clarification on Field Safety Corrective Actions (FSCA) 5.4.4 MEDDEV 2.12-1 rev. 8, 2013.

FSCA should be implemented in all countries where the affected medical device is on the market or remains in use, and/or where diagnostic result services were provided.

If the medical device is introduced to a new market after implementation of the FSCA, the MANUFACTURER should review whether the risk cited in the Field Safety Notice (FSN) remains relevant. If so, a copy of the FSN should be provided to the new customers as well as the Competent Authority where the device is being introduced to the market after implementation of the FSCA. In addition, a copy of the FSCA should also be provided to the Competent Authority.

The MANUFACTURER should only exclude from FSN distribution a country where the medical device is on the market or in use, if there is a robust and objective rationale for why the risk identified in the FSN could not apply within that country. Such a rationale should be discussed and agreed with the coordinating Competent Authority. It is not sufficient to include in the FSN distribution only countries where adverse incidents have occurred, as the principles of the EU Vigilance System are preventative.

FSCA should be notified to the customers via a FIELD SAFETY NOTICE. See section 8 of this document for more details.

This should include informing sponsors of clinical trials of medicinal products where a FSCA is relevant to medical devices used in the medicinal clinical trial.

The most recent revision of the FSCA form is available on the Commission website, see https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

6. CONTENT OF THE FIELD SAFETY NOTICE

This section provides clarification on the Field Safety Notice section 5.4.4.2 of MEDDEV 2.12-1 rev. 8, 2013.

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. FIELD SAFETY NOTICES, other than those targeted at patients, should follow the details outlined in section 5.4.4.2 of MEDDEV 2.12-1 rev. 8, 2013, or the format given in the FSN template and guidance document provided on the Commission website.

Exceptions should be made only where the guidance in MEDDEV 2.12-1 rev. 8 section 5.4.4.2 or the FSN template does not provide a place for non-standard information that may be unique to a particular FSNA.

The MANUFACTURER should use a distribution means ensuring the appropriate organisations have been informed, e.g. by confirmation of receipt. A standardised customer reply form and distributor reply form are also available on the Commission website for guidance.

The FIELD SAFETY NOTICE should be written in the language(s) accepted by the National Competent Authority(s).

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.

By following the recommendations above and the FSN guidance document, the clarity of FIELD SAFETY NOTICES will be improved. This may reduce the likelihood of Competent Authorities either requesting MANUFACTURERS issue revised FIELD SAFETY NOTICES or issuing separate National Competent Authority communications e.g. for translation/ language issues.

The FSN template, customer reply form and distributor reply form and guidance document are available on the Commission website, see

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

7. CIRCUMSTANCES WHERE A COORDINATING NATIONAL COMPETENT AUTHORITY IS NEEDED

This section clarifies section 6.3.1, 6.3.2 and 6.3.3 of MEDDEV 2.12-1 rev. 8, 2013.

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

- where there is concern regarding a particular incident or cluster of incidents,
- where the appropriateness of the FSCA that is proposed by a MANUFACTURER is in question,
- where a broader opinion on a vigilance issue is required,
- where a CA requires the assistance of the CA where the MANUFACTURER or its AUTHORISED REPRESENTATIVE or the Notified Body is located, e.g. where there is missing information, concerns regarding the MANUFACTURER's vigilance system or no final vigilance report,
- where there would be merit in setting up a taskforce to examine and coordinate a specific issue, e.g. 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 IMDRF NCAR Exchange Program) or information published on a CA website outside the EEA, Switzerland and Turkey.

The Coordinating Authority may consider informing the MANUFACTURER or its AUTHORISED REPRESENTATIVE accordingly.

7.1 SINGLE COORDINATING NATIONAL COMPETENT AUTHORITY

In many instances a brief email exchange, the circulation of an established enquiry form or discussion of the issue on a teleconference may be sufficient to ensure coordination. Such an exchange can ensure that the issue is highlighted, progressed and resolved. In such cases the single coordinating National Competent Authority should be either the CA that raises the issue or the CA where the MANUFACTURER or its AUTHORISED REPRESENTATIVE or the Notified Body is located.

7.2 VIGILANCE TASKFORCE

For the more involved and complex issues the establishment of a specific vigilance taskforce may be required. In such cases **the vigilance taskforce** will take on the coordination role for the issue. The composition of a vigilance taskforce should include the CA with the original concern and several other CAs who support the concern. Also where possible the CA where the MANUFACTURER or its AUTHORISED REPRESENTATIVE is located and the Notified Body are located should be participants or at least included on all of the correspondence. The taskforce should identify a leader to manage the groups work.

7.3 THE ROLE OF A VIGILANCE TASKFORCE

The taskforce should, where relevant:

- Inform the MANUFACTURER / EU representative and the other affected Competent Authorities and the Commission that a taskforce has been established and the composition of same, including the identified leader,
- Inform the MANUFACTURER / EU representative and the other affected Competent Authorities and the Commission of specific concerns,
- Coordinate and monitor the investigation with the MANUFACTURER on behalf of other Competent Authorities,
- Consult with the Notified Body which made the assessment 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 6.6,
- 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 where appropriate to instigate an action within its Member State in accordance with the provisions of the relevant directives. In doing so, the NCA should ensure that the MANUFACTURER / AUTHORISED REPRESENTATIVE, Competent Authorities and the Commission are kept informed about these activities.

8. DISSEMINATION OF INFORMATION BETWEEN NATIONAL COMPETENT AUTHORITIES

This section clarifies section 6.3.5 MEDDEV 2.12-1 rev. 8, 2013.

8.1 NATIONAL COMPETENT AUTHORITY REPORT

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 requests 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 a corrective action is taken by a MANUFACTURER which is not considered to be a field safety corrective action nor is it 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. Where the Competent Authority responsible for the MANUFACTURER or its AUTHORISED REPRESENTATIVE has not conducted an assessment of the issue prior to the circulation of the NCAR or where they do not intend to conduct an assessment of the issue this should be clearly stated in the text of the NCAR and a rationale should be provided (e.g. when the affected medical device is not on the market in their jurisdiction). The NCAR must whenever possible, indicate the Member States (EEA, Switzerland, Turkey) in which the affected medical device has been placed on the market.

The NCAR concerning B) and C) 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.

Competent Authorities must consult the MANUFACTURER when preparing a NCAR relating to A) and B) above and should inform the MANUFACTURER when the NCAR is issued. For NCARs concerning C) it may not be appropriate or justified for the MANUFACTURER to be consulted or informed of the NCAR. When the Competent Authority consults with the MANUFACTURER regarding a NCAR the Competent Authority will provide a deadline for comments. If no comments are received by the deadline the NCAR will be distributed.

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.

8.2 The Format of the Exchange

The format for dissemination of information between National Competent Authorities and the Commission is available on the Commission website

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

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.

NCARS 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 the MDD, Article 15 of the AIMD and Article 19 of the IVDD).

The NCAR exchange outlined in this section relates to the European NCAR exchange. Should a member state wish to communicate with international regulators the IMDRF NCAR exchange should be used. See section 9 of this document.

The most recent revision of the European NCAR form and the instructions for completing same are available on the Commission website, see https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

9. IMDRF NCAR EXCHANGE

When a member state wishes to communicate an issue to the wider international regulatory community they can consider using the IMDRF NCAR exchange. Details regarding the IMDRF NCAR exchange can be found in IMDRF Document **IMDRF/NCAR WG/N14 FINAL:2017 (Edition 2)** “Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form”.

To exchange information via the IMDRF NCAR exchange the member state must be a participant in the exchange and must have completed the necessary training. The member states must also have the appropriate/ necessary bilateral confidentiality agreements in place.

It should be noted that the criteria for exchanging information via the IMDRF NCAR exchange and the mechanism by which information is exchanged differs from the EU NCAR Exchange. Full details are available in the **IMDRF/NCAR WG/N14 FINAL:2017 (Edition 2)**, see <http://www.imdrf.org/documents/documents.asp>.

The most recent revision of the IMDRF NCAR form and the instructions to complete same are available on the Commission website, see https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

10. MEDDEV 2.12-1 rev. 8 – Forms

The most recent revision of the forms referred to in **MEDDEV 2.12-1 rev. 8** are available on the Commission website, see

https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

