IMDRF/NCAR WG (PD1)/N14R4

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

Title: Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form.

Authoring Group: National Competent Authority Report Working Group

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.

Introduction

This document was developed by the IMDRF National Competent Authority report (NCAR) Exchange Program Working Group as an update to the original document (N79) authored by Study Group 2 of the Global Harmonisation Task Force (GHTF).

This document concerns a two way communication system involving confidential information for serious public health issues.

This document will provide guidance, procedures and forms for exchange of reports between IMDRF members. Other forms of information exchange may be addressed in the future.

1. Scope

This document provides guidance on:

- the criteria to be used for deciding when to exchange information,
- the procedures to follow when exchanging information,
- the forms to use for exchanging information,
- the requirements for IMDRF members participation in the exchange of NCARs.

2. References

The latest revision of GHTF SG2 N57 Medical Devices Post Market Surveillance: Content of Field Safety Notices.

3. Definitions

NCAR Secretariat

The organization which maintains and monitors the exchange of NCARs between reporting National Competent Authorities (NCAs) and other NCAR participants in accordance with this guidance. The NCAR Secretariat is the recipient and repository of all NCARs.

The organization shall ensure the quality and consistency of the Exchange Program and shall circulate NCARs in line with the provisions of section 6.1 of this guidance. The secretariat will produce statistical analysis /reports regarding participation and report exchange on a periodic basis. The secretariat will also maintain a complete list of participants in the Exchange Program.

The secretariat will not assess or propose action on the NCARs received but rather, when applicable, this is the responsibility of the originator and recipients of the NCAR.

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. Such actions should be notified via a field safety notice

In assessing the need of the FSCA the manufacturer may use the methodology described in the harmonised standard EN ISO 14971.

This may include:

- Return of a medical device to the manufacturer or its representative;
- Device modification[1];
- Device exchange;
- Device destruction;
- Advice given by manufacturer regarding the use of the device (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)

Device modifications may include:

- Retrofit in accordance with the manufacturer's modification or design change;
- Permanent or temporary changes to the labelling or instructions for use;
- Software upgrades including those carried out by remote access;
- Modification to the clinical management of patients to address a risk of serious injury or death 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.
    - For any diagnostic device (e.g. IVD, imaging equipment or devices) the retesting of affected patients, samples or the review of previous results.
- Advice on a change in the way the device is used (e.g. IVD manufacturer advises revised quality control procedure -use of third party controls or more frequent calibration).

Serious Public Health Threat

Any event which results in imminent risk of death, serious injury or serious illness that requires prompt medical action.

A serious injury is either:

- A life threatening illness or injury

[1] Note: device modifications may need to be approved by the NCA or third parties.

- A permanent impairment of a body function or permanent damage to a body structure[2]
- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Unanticipated

A condition leading to an event that was not considered in a risk analysis performed during the design and development phase of the device

Note:

The reportable event may be unanticipated because of:

- A lack of historical information (rare),
- A change in the situation in which it is occurring,
- A change in the patient, health-care professional or user outcome.

4. Reporting guidelines.

The exchange program will be used to exchange information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions, but have not yet resulted in recalls or Field Safety Corrective Actions (FSCAs)

4.1 Exchange criteria

4.1.1 EVENTS LEADING OR HIGHLY LIKELY TO LEAD TO UNANTICIPATED SERIOUS PUBLIC HEALTH THREAT.

Reportable events, associated with a medical device that have led or are highly likely to lead to unanticipated serious public health threat and full fill the following criteria:

- Death of a Patient, User or Other Person.
- Serious Injury of a Patient, User or Other Person.
- No Death or Serious Injury Occurred but the Event Might Lead to Death or Serious Injury of a Patient, User or Other Person if the Event Recurs. Some jurisdictions refer to these events as near incidents.

Notes:

The reportable event may be unanticipated because of:

- A lack of historical information (rare),

[2] Means irreversible impairment or damage to a body structure or function excluding minor impairment or damage.

- A change in the situation in which it is occurring,
- A change in the patient, operator or user outcome.

The interpretation of "serious" in the context of serious public health threat may be difficult to assess and should be determined in consultation with a medical practitioner when appropriate.

Examples:

(a) A contaminated eye rinsing solution is used during eye surgery. The possible outcome is serious vision impairment or blindness. The issue was not identified until testing was conducted following several reports of patients having infection and visual problems. The size of the concerned batch is such that the contaminated solution is likely to be distributed in different geographical areas/regions.

(b) A spinal disc prosthesis is inserted between two cervical vertebrae to treat the pain and numbness associated with the collapse of the disc space. Cases of implanted patients suffering from paralysis several months following surgery have been reported. The investigation concluded that the root cause of the paralysis is mechanical failure of the disc, resulting in the disc moving out from between the vertebrae. Subsequent investigation shows that there is no warning for when the disc might break. Advice provided is that all implanted patients should have the disc replaced.

(c) An IVD manufacturer had identified a problem with his HIV test which can result in the generation of false negative results. The problem is not detected by the device control and therefore the incorrect false negative result could be given to medical staff and the patient. The device is widely used across the world and in some jurisdictions it is used for testing prior to blood / organ donation.

4.1.2 OBSERVATIONS FROM NATIONAL TREND ANALYSIS

A trend noticed by a Regulatory Agency is reportable when:

- The frequency of the event associated with the device is significantly higher than the frequency recorded in the manufacturer's file or significantly higher than the frequency observed with similar devices; and
- The event has led or is highly likely to lead to a serious public health threat.

Examples:

(a) The review of data from a national registry, complemented by adverse event data indicates a potential concern regarding high revision rates for hip prosthesis that have Metal on Metal (MoM) articulations. The consequence for implanted patients can be permanent impaired mobility and/or the need for surgical re-intervention to avoid further impairment.

(b) Review of adverse event data and literature for a specific atrial septal occluder device indicated an increase in tissue erosion compared with other devices in this category. This type of device failure has not been seen in similar devices to treat this condition. This

erosion can require immediate interventional surgery to remove the device and repair the erosion.

4.1.3 REQUEST AND/OR SHARE OF INFORMATION

An NCA may request and/or share information about a specific device or class/group of devices concerning:

- An event or events
- An increased seriousness or frequency to what was previously reported to the NCA
- Major weaknesses and/or major deviations regarding a manufacturer's PMS/QMS
- Regulatory status changes of a device(s)

The consequences of which:

- Have led or are highly likely to lead to serious public health threat; and
- May affect other jurisdictions.

The concerned NCA can ask whether other NCAs participating to the Exchange Program have similar experience and what actions were initiated or are being discussed to address the issue, e.g. recalls or Field Safety Corrective Actions (FSCA).

Examples:

(a) An NCA has received an increasing number of reports for thrombosis in association with a particular Left Ventricular Assist Device (LVAD). These devices are used in very ill patients who depend on these devices for survival. If the LVAD is stopped or slowed because of thrombosis the patient requires immediate treatment such as thrombolytics or surgical intervention to avoid patient death. The root cause is not identified.

The NCA requests information and assistance if other jurisdictions have encountered this issue and have any additional information that might be useful in determining a root cause.

(b) Several reports have been received of embolus, which has led to or could lead to the death of the patient during an operation, for devices delivering fibrin to seal the gut during surgery. It is unclear whether the device or the drug is responsible for the observed event. The competent authority circulates the NCAR and requests information from other competent authorities regarding any reported adverse events associated with fibrin and embolus.

(c) An NCA notes a series of field actions that have been conducted by a manufacturer. The field actions all relate to one specific device that is used both in the High Dependency Unit setting and palliative care settings. The large number of field actions and the manner in which the manufacturer has managed the identified issues raises questions about the manufacturer's quality management system. The competent authority

seeks information from other authorities relating to their experience with the manufacturer and the product.

(d) An NCA restricts the importation of a medical device(s) due to concerns about device safety that could result in a serious public health threat.

4.2 Participation

Participation in the NCAR Exchange Program will be limited to the IMDRF Management Committee (MC) Regulators from Australia, Brazil, Canada, China, Europe, Japan, Russia and the United States of America.

IMDRF MC Regulators who to date have not been involved in the GHTF NCAR Exchange Program shall inform the Management Committee of their wish to join the IMDRF NCAR Exchange. Applicants will be required to review implementation materials on the key elements of the exchange, the definitions and confidentiality before joining the Exchange Program.

Note:
non-IMDRF MC regulators that are currently involved in the existing GHFT Exchange will not be eligible for participation in the IMDRF NCAR Exchange.

4.3 Confidentiality

National Competent Authority Reports (NCARs) identified as "Confidential" by the author of the NCAR may only be shared with NCAR exchange program members with whom the NCA who authors the NCAR has confidentiality arrangements. NCARs identified as "Non Confidential" by the author of the NCAR may be shared with all NCAR exchange program members.

The recipients of NCARs may use the information in the report to assist in their assessment of the risk issue. The form is not a releasable document. None of the information in the NCAR may be released without the explicit authorization of the authoring NCA. However specific information in the form may be deemed appropriate for release by the authoring NCA, in which case it would be clearly noted by the latter.

The NCAR Secretariat having a pivotal role in ensuring/maintaining the quality and consistency of the circulated NCARs will need to have confidentiality arrangements will all participants to the Exchange Program.

4.4 Implementation Materials

It is necessary to ensure that all participants have a full understanding of the key features of the Exchange. Implementation materials will be developed and posted on the IMDRF website.

5. National Competent Authority Report (NCAR) FORM

5.1 Exchange format

The NCAR form in Annex 1 should be used for the exchange reports.

Note: other regional exchange networks may exist in addition to the IMDRF NCAR exchange program and these forms should not be substituted.

5.2 Instructions for completing the NCAR Form

The form should be completed in English.

The point of contact identified in Field 4 of the NCAR form, acting for the NCA identified in Field 3, is considered to be the author of the report. The author is responsible for:

- ensuring that the NCAR is issued in accordance with the criteria described in Section 4;
- the accuracy, completeness and relevance of the content; and
- the scope of its distribution.

NCARs should 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 involves a specific manufacturer's device, then the manufacturer or authorized representative may be consulted regarding the NCARs content and distribution of the device 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, particularly the technical content, of the NCAR. An appropriate timeframe for receiving manufacturer's comments should be communicated.

Field:

1 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 new NCAR should be given a unique NCAR number. If an NCAR relates to a previously exchanged NCAR ensure that the "Amended" box has been checked.

2 Check the box associated with the purpose of the exchange.

3 Indicate if the NCAR will be circulated exclusively to the NCAs with whom the authoring NCA has confidentiality arrangements or to all Exchange Program members.

4-5	Identify person and organization sending the NCAR. This should be the single point of contact, previously identified to the NCAR Secretariat.
6-8	Telephone, Fax and e-mail of person in (4) above.
9	Add the date this NCAR has been circulated
10	Kind of device or generic descriptor
11	Identify the nomenclature system used (e.g. Global Medical Device Nomenclature [GMDN], etc.).
12	Number or code to identify the device based on the nomenclature system identified in (10).
13	IMDRF Medical speciality Area, are listed in the Annex 2.
14	Trade name / Brand name AND Model number
15	List the marketed trade name(s) in other countries, if different.
16	Enter information related to the UDI #.
17-19	If there are many lot/batch numbers or serial numbers (i.e., more than 3 or 4), a detailed list should be appended to the bottom of the report.
20	Manufacturer of device - full address, including country, fax, phone numbers and e-mail.
21	Identify the natural or legal entity in reporting country who is responsible for placing the subject device on the market where the incidents occurred, full address, including country, fax, phone numbers and e-mail.
22	Indicate name or code number of Conformity Assessment Body / Notified Body involved, if applicable.
23	Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (SECTION 4-1 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. Identify any investigation taken by the manufacturer and also whether there has been any regulatory, legal or company-initiated action taken in advance of sending out the report. Indicate if the investigation of the report is complete or not. Check either the 'Yes' or 'No' boxes to indicate whether there are any attachments associated with this report.
24	Indicate a date for which the sending NCA would like to receive responses from recipients of the NCAR.
25	List questions under the heading 'Questions'. Number the questions for ease in replying.
26	Add any information that is relevant and will assist the receiver of the information to undertake action or to be able to answer the questions appropriately.

27 Provide the name of the NCA, the name of the person that the sending NCA can contact if they need to clarify any responses, a telephone and/or fax number and an email address for the contact person.

28 This section is used by the sending NCA to inform other NCAR members of the outcome of enquires related to a 'Request for Information' under the heading Purpose of the Exchange' (Section 2 above).

Sending NCAs should provide feedback on their request for information using the summary template provided in Annex 3.

6. Report Exchange Method

6.1 Exchange mechanism and process

The NCARs exchange will be supported by the existing email exchange system. At a later stage, the feasibility of a more secure cost effective exchange system may be explored.

The National Competent Authority Report – the Exchange Form (annex 1) should be used.

NCARs identified as "Confidential" by the authoring NCA will be circulated by the authoring NCA to participants of the NCAR Exchange in accordance with the confidentiality rules referred under section 4.3. A copy will be sent to the NCAR secretariat for recording purposes. The correct sequential references will be confirmed by the NCAR secretariat after circulation has taken place.

NCARs identified as "Non-Confidential" by the authoring NCA will be circulated by the NCAR Secretariat to all participants of the Exchange Program. The Secretariat will confirm the correct sequential references and attachments have been provided prior to circulating the NCAR. Content will not be edited.

When the NCAR concerns a request for information, responses to queries will be communicated directly to the contact name detailed on the requesting NCAR. Summaries of investigation outcomes will be collated by the original requester and distributed to the recipients of the original NCAR using the form detailed in annex 3. A copy will be sent to the NCAR secretariat.

When a receiving NCA needs more information on a particular NCAR, the NCA may contact the source country of the NCAR for more information. The receiving NCA may only contact the concerned manufacturer or its representative if the authoring NCA has agreed to it.

If a receiving NCA considers that it is important that they take national action, the NCA will contact the authoring NCA to seek permission to contact the manufacturer and to ensure no confidential data is unduly released and the timing of such action will not compromise the on-going risk assessment.

When an NCAR concerns a critical issue of significant public health threat and one NCA enforces measures on the affected manufacturer, the measure(s) should be communicated via the Secretariat to all participants of the Exchange Program.

6.2 Timelines for submitting reports

Submission of reports will be dependent on the issue identified. Where assistance is requested Exchange Participants are expected to respond by the identified deadline.

ANNEX 1: NATIONAL COMPETENT AUTHORITY REPORT EXCHANGE FORM

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. All information contained in this form is considered confidential unless specifically indicated otherwise in section 3 or in the background section of the annex.

1. CA Report Number: <CA reference number>

☐ New
☐ Amended

2. PURPOSE of the EXCHANGE:

☐ **Share Information**
- ☐ Events leading or highly likely to lead to unanticipated serious public health threat.
- ☐ Observations from national trend analysis
- ☐ Share Information as outlined in Section 4.1.3

☐ Request Information
☐ Summary of query findings

3. Confidentiality/DISTRIBUTION CHANNEL

☐ Yes/**Restricted.** (The authoring NCA may share only with NCAR exchange program members with whom the NCA has confidentiality arrangements).

☐ No/ **All** NCAR exchange program members.

DETAILS OF INITIATING NCA			
4. Authoring NCA:	<name of CA>		
5. Contact Person:	<name of contact person>	**6. Telephone:**	<telephone number>
7. E-mail:	<email address>	**8. Fax:**	<fax number>
9. Circulated:	<date circulated - dd/mm/yyyy>		

DEVICE DETAILS	
10. Generic name / kind of device:	
11. Nomenclature Type:	**12. No / Code:**
13. IMDRF Medical Speciality Area: **(list detailed in Annex 2)**	
14. Trade Name and Model:	

15. Device also marketed as (trade name), if known:	
16. If Applicable, UDI #:	**17. Software version (If Applicable):**
18. Serial number(s):	**19. Lot / batch number(s):**

Regulated Parties		
20. Manufacturer: **Country:** **Full Address:** **Contact:** **Telephone:** **Email:**	**21. Entity legally representing the manufacturer:** **Country:** **Full Address:** **Contact:** **Telephone:** **Email:**	**22. IIf Applicable, CAB / Notified Body #:**

BACKGROUND INFORMATION AND REASON FOR THIS REPORT

23. <background of query / notification of lead CA>

Is the Investigation of the report Complete : ☐ Yes ☐ No

Attachments : ☐ Yes ☐ No

(… include info re manufacturer/assembly location)

QUESTIONS AND RESPONSES (If Applicable)		
24. Deadline For Response: <date of deadline for response - dd/mm/yyyy>		
Question	**Answer**	**Rational / Remarks**
25.		

ADDITIONAL RATIONALE AND REMARKS
26.

DETAILS OF RESPONDING NCA			
27. Responding NCA:	<name of CA>		
Contact Person:	<name of contact person>	**Telephone:**	<telephone number>
E-mail:	<email address>	**Fax:**	<fax number>

FINAL SUMMARY / COMMENTS
28.

ANNEX 2: IMDRF Medical Speciality Areas
in relation to field 12 of the NCAR Form of Annex 1.

1- Anaesthesia

2- Cardiovascular

3- Chemistry

4- Dental

5- Ear, nose and throat

6- Gastroenterology/urology

7- General and plastic

8- General hospital

9- Haematology

10- Immunology

11- Microbiology

12- Neurology

13- Obstetrics and gynaecology

14- Ophthalmology

15- Orthopaedics

16- Pathology

17- Physical medicine

18- Radiology

19- Clinical toxicology

20- Paediatrics

ANNEX 3: REQUEST FOR INFORMATION. SUMMARY TEMPLATE in relation to field 27 of the NCAR Form of Annex 1.

SUMMARY FORM			
COUNTRIES	**QUESTIONS**	**ANSWERS**	**ADDITIONAL COMMENTS**