FINAL DOCUMENT

Global Harmonization Task Force

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

Authoring Group: Study Group 2

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Introduction

This document was developed by Study Group 2 of the GHTF, to provide guidance, procedures and forms for the exchange of reports concerning the safety of medical devices between National Competent Authorities (NCA) and other participants of the GHTF National Competent Authority Report (NCAR) exchange program.

1. Scope

This document provides guidance on:

- the criteria to be used for deciding when to exchange information with other national competent authorities and other NCAR participants
- the procedures to follow when exchanging information
- the forms to use for exchanging the information

Countries participating in the exchange of GHTF NCARs are encouraged to use this guidance. Requirements for participating in the GHTF National Competent Authority Report exchange program are contained in a supplementary document N38. SG 2 document N8 provides general guidance on the public release of information.

2. References

The latest revisions of

GHTF SG2 N8, Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices
GHTF SG2 N38, Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program

3. Definitions

NCAR Secretariat

The organisation which receives NCARs from reporting NCAs and distributes them to other NCAR participants in accordance with this guidance and GHTF SG2 N38 is known as the Secretariat.

Active exchange

"Active Exchange" is a pro-active exchange of information involving direct notification to nominated contact addresses. This is achieved via e-mail currently. Active exchange is the method of choice for high risk issues.

Passive exchange:

"Passive Exchange" is the exchange of information via the use of a database, website or other means for exchange participants to view at their discretion.

Field Safety Corrective Action

A field safety corrective 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 is advised to 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 labeling 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. IVDS manufacturer advises revised quality control procedure -use of third party controls or more frequent calibration).

Confidential Information:

Information that due to its nature may be prejudicial to one or more persons, or that may be deemed as such by regional confidentiality acts and regulations, and that, for this reason, has been marked by the information provider as being confidential or not for general release.

Public Information

For the purposes of this document, public information is regarded to be non-confidential. This information may not necessarily be widely or easily available. For example, information contained in recall notifications, safety alerts, hazard alerts, product notifications and other product advisories is considered to be public information

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

Serious Public Health Threat or Concern

Any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

Safeguard Action

This describes the action taken by an EU Member State to withdraw, prohibit or otherwise restrict a device from the market or from being put into service, in accordance with EU Community Law on medical devices. (e.g. Article 8 of the Medical Device Directive 93/42/EEC).

4. Reporting Guidance

E-mail is the active exchange method used currently for exchanging information on high-risk issues. Figure 1 (Appendix A) describes the process and the appropriate route for information exchange.

The criteria given below should be considered to determine whether an NCAR should be sent.

- Seriousness
- Unexpectedness of the incident/event
- Population Vulnerable (pediatric/elderly)
- Preventability (can useful recommendations be made?)
- Public Concern / Outrage (ex: lead aprons containing radioactive material)
- Benefit/Risk - State of the art? Alternatives?
- Lack of Scientific Data (especially long term effects)
- Repeated device problems that re-surface (ex: heating pads, O.R. fires)
- Written notifications by the NCA to the public (hospitals, physicians, etc.)
- Will active exchange help protect public health or have the manufacturer's actions been sufficient?

An NCAR should only be sent if the issue is considered to be serious. For example, an unexpected but non-serious event is unlikely to be exchanged.

Each NCAR participant has the right to choose NOT to exchange data actively through NCAR Secretariat, if it believes the data has already been made public or to simply close the file if they believe the exchange criteria are not met.

a) If the investigation is complete:

If the investigation is complete, and a decision has been made by the NCA or manufacturer that action is required, and the issue fulfils the reporting criteria then a report should be sent in a normal manner.

Such reports should normally be considered "Public Information". Competent Authorities should involve the manufacturer in the investigation of incidents and resolution of issues or actions and consult with the manufacturer before sending out notices to other NCAR participants.

In the case that part of the information is considered to be confidential then this should be clearly identified in the report.

b) If the investigation is not complete:

If the investigation is not complete but a decision has been made to take action or action is likely, the public health threat or concern must be assessed and if high, a report should be sent. Such reports are normally considered to be "Confidential Information" and may contain requests for feedback from the participating NCA.

If such reports are exchanged, questions to the manufacturer from other NCAs should be directed to the lead NCA whenever possible.

c) If no action required.

If the investigation is complete and no action is required, then the report should not be exchanged actively. Passive exchange should then be considered, but it should only be used where a link between the device and adverse event concerned has been established.

5. National Competent Authority Report (NCAR)

The National Competent Authority Report (NCAR) form below should be used for active exchange. Guidance on its completion is contained in Section 7.

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**:**		20. CAB/Notified Body no.:
12. Nomenclature id:	13. No.:	
14. Trade Name and Model:		21a. Device approval status:
15. Software version:		
16. Serial no.:	17. Lot/batch no.:	21b. Risk Class:
18. Manufacturer: Country: Full Address: Contact: Tel: Fax: E-mail:	19. Authorized rep: Country: Full Address: Contact: Tel: Fax: E-mail:	7. 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 GHTF-NCAR distributed by this NCA was (>>>>>>>>>>>>>>)

6. Instructions for Filling in National Competent Authority Report

The form should be completed in English

The NCAR participant filling in and sending the NCAR will be 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 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 NCARs. An appropriate time frame for receiving manufacturers 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, 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.
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.
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 (e.g. GMDN, MHW, NKKN, UMDNS, Product Code, Preferred Name Code, etc.) used, but note that GMDN is expected.
13 - Number or code to identify the device based on the nomenclature system identified in (12).
14 - Trade name / Brand name AND Model number
15-17 Self explanatory
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.

24 c 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 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, EC and EFTA 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 be listed.
26b - Where numbers are not sequential participants should include the number of the last report issued to all NCAR participants.

7. Report Exchange Method

1) Send the completed NCAR form to the NCAR Secretariat by email.
2) A note indicating receipt of the NCAR form will be returned to the sender.
3) The National Competent Authority Reporting Form should be used.
4) Comments may be added to the report to maintain its confidentiality or to prevent public disclosure. For example, “Still under investigation, do not disclose through access to information”, or “Do not release to public”. Also, where possible and helpful, include electronically any background information such as a “Dear Doctor” letter or company letter.
5) In order to minimize the risk of confusion, The NCAR Secretariat, on behalf of GHTF, will tentatively review the form for completeness, the correct sequential references and track the reports. Content is not edited. The form will then be forwarded by e-mail to countries participating in the exchange (see note).
6) In rare circumstances, such as when there are time critical issues of significant public health threat or concern, NCA’s may send reports directly to countries participating in the exchange. 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.
7) The issuing NCAR participant is the originator of the report unless the report says otherwise.
8) Countries can contact the source country of the report for more information if they wish. This should be the first point of contact for incidents “still under investigation”.

Appendices

Appendix A: Competent Authority Reporting Flowchart

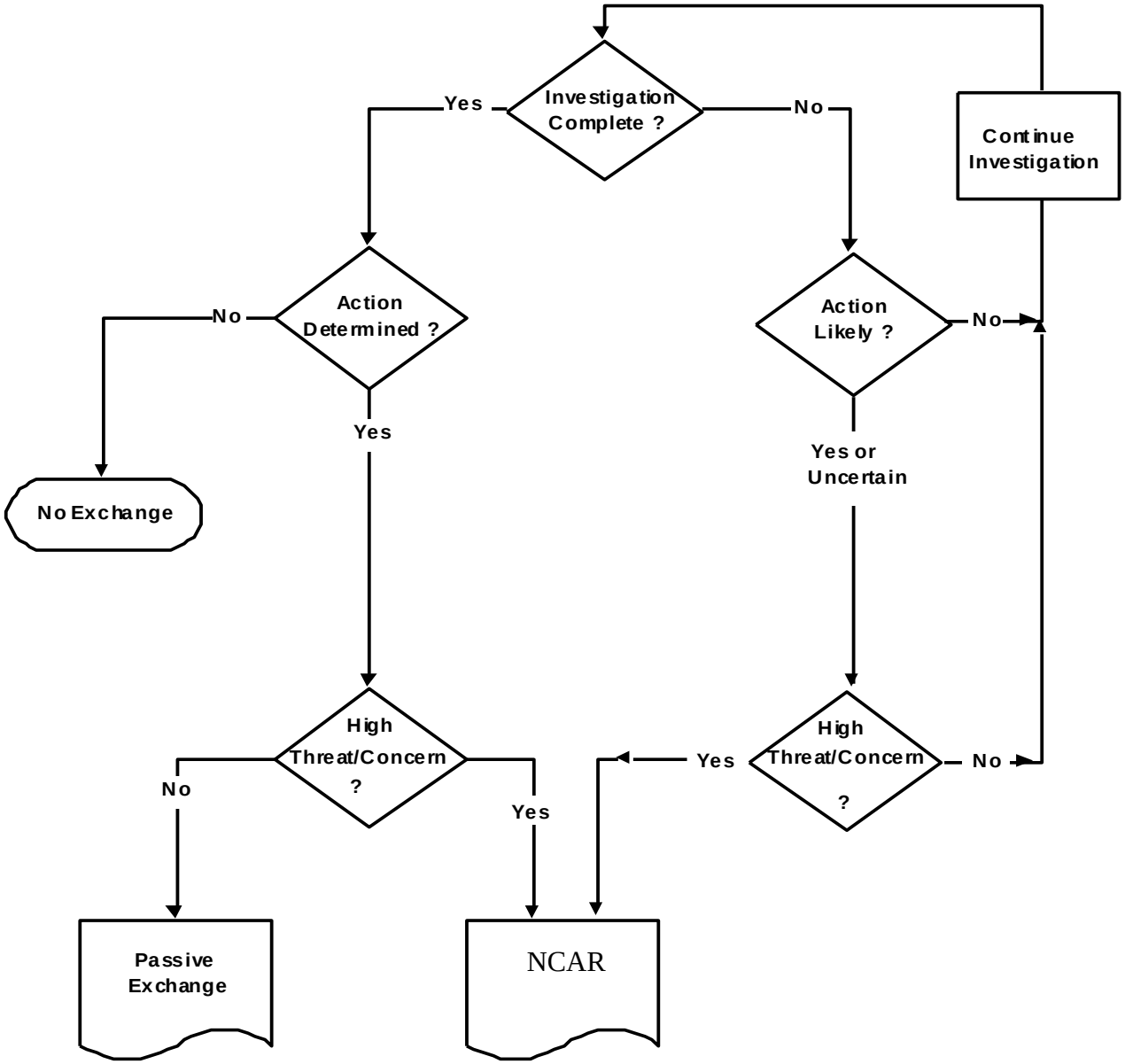

Figure 1 - Competent Authority Reporting Flowchart

Note: Please refer to section 4 of this document for guidance on using this chart.