GHTF

FINAL DOCUMENT

Title: Global Medical Devices Competent Authority Report

Authoring Group: SG 2

Endorsed by: Global Harmonization Task Force

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Taisuke Hojo, GHTF Chair

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.

Preface

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GLOBAL MEDICAL DEVICES COMPETENT AUTHORITY REPORT
Form N9R11

A link to a WORD version of this form that can be downloaded and filled in can be found at:

http://www.ghtf.org/sg2/inventorysg2/N9R11_NCA-Report-Form.doc

GLOBAL MEDICAL DEVICES COMPETENT AUTHORITY REPORT

Form N9R11

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

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: b. Risk Class:
15. Software version:		
16. Serial no.:	17. Lot/batch no.:	
18. Manufacturer: Country: Full Address: Contact: Tel: Fax: E-mail:	19. Authorized rep (if different from 18): Country: Full Address: Contact: Tel: Fax: E-mail:	22. Action taken: [ ] None [ ] Recall [ ] Safeguard Clause [ ] 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. NCA of _____ is willing to take the lead and co-ordinate the investigation

25a. Recommendation to receivers of this report:

25b. Device known to be in the market in:
25c. Device also marketed as (trade name):

Report Distribution

26. This report is being distributed to the NCAR Secretariat for further distribution to NCAR participants.
This report is also being distributed to:
[ ] EEA states, EC, ESA, and EFTA
[ ] The following targeted NCAs:
[ ] The manufacturer / authorized rep.:

Instructions for Filling in Form N9

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

The NCA filling in and sending the form will be responsible for the quality of the content as well as the appropriateness of sending such a message and certain rules for distribution. SG2 N20 (National Competent Authority Reporting Criteria) provides guidance on which issues should be selected for exchange between competent authorities. 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 is for NCAs and should not be passed directly on to patients, users, third person or the public unless the document is deemed to be public.

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 EEA States must exchange reports with each other per current European Guidelines, and shall also send the report to the NCAR Secretariat for further distribution to all other NCAR participants.

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 know 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 at E-mail: MDV@hc-sc.gc.ca.

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 (N20), which incorporates a two letter code of the issuing country to fill in this item. For example: CA-2001-10-19-004 is a report from Canada sent 19 October, 2001 and is the 4th report for 2001.

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.

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 - If different than 18, 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 or FDA Approval number or licence number b.)Risk Class. Device class 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 the Safeguard Clause.

23a - Provide a description of what has happened, including consequences to patients or users. With reference to the criteria for reporting (N20), 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.
24b - Enter NCA name if willing to take the lead on co-ordination of the investigation.
25a - Recommendations to receivers of this report
25b - List countries known to have received the device
25c - List the marketed trade name(s) in other countries, if different.
26 - Indicate to whom the report has been sent. This will help minimize duplicate reporting. The manufacturer, or authorized representative, should always be consulted before sending a report and be provided with a copy.