



FINAL STATUS DOCUMENT

Global Harmonization Task Force

Title: Summary of Current Requirements for Where to Send Adverse Event Reports.

Authoring Group: GHTF Study Group 2

Endorsed by: The Global Harmonization Task Force

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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.

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Preface

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1 Introduction / Scope

Once a manufacturer of a medical device has made the decision that an adverse event report must be submitted, the manufacturer must decide what timeframes have to be met for reporting, the amount of detail that must be contained in the report and to which regulatory authority or authorities the adverse event report must be submitted. Guidance regarding timeframes for submission of a report and the amount of detail that must be enclosed in the report are provided in other GHTF SG2 guidance documents (see References).

Study Group 2 has made an attempt at producing unified guidance regarding who should adverse event reports must be sent to. The main alternatives discussed were:

1. Submission of reports to every regulatory authority of the countries where the device subject of the adverse event report is marketed;
2. Submission of a single report to the regulatory authority of the country in which the adverse event took place, and
3. Submission of a single report to a central global repository (database) of adverse event information.

In lieu of creating a guidance document, the SG2 created this document which provides guidance to the medical device manufacturer regarding to whom adverse events should be sent to by listing the national requirements of the five GHTF founding members, as well as the legal reference to those requirements. The reader should note that some adverse events will need to be reported to more than one regulatory authority. This is because some regulatory authorities require reports to be submitted irrespective of the geographical location of the event.

2 References

GHTF SG2 N21R8 – “Medical Device Postmarket Vigilance and Surveillance: Guidance on Adverse Event Reporting for the Manufacturer or its Authorised Representative”

GHTF SG2 N33R11 – “Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports”

GHTF SG2 N32R3.1 – “Medical Devices: Post Market Surveillance: Universal Manufacturer Report Format”

3 Definitions

None

4 Who Should Adverse Event Reports be Sent To?

Table 1 summarizes the national requirements of the five GHTF founding members regarding the reportability of an adverse event on the basis of the place where the event took place.

GHTF SG2 68R3:2005 Summary of Current Requirements for Where to Send Adverse Event Reports.
Study Group 2 – Final Status Document

USA	EUROPE	AUSTRALIA	CANADA	JAPAN
<p>“Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer: May have caused or contributed to a death or serious injury; or Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”</p> <p>[21CFR803A]</p> <p>"FDA is interested in information about any reportable event without regard to the location of the event because such information may enable FDA to assist in the protection of the public health. This rule applies equally to manufacturers and importers because both are required to register with FDA. If an importer receives information about a reportable event, a report is required regardless of the location of the event."</p> <p>[Federal Register / Vol 49, No. 180 /Friday, September 14,1984/ page 36333 / Comment #22]</p> <p>The words in 21CFR803A specifically state that the reporting rule applies to the manufacturer’s MARKETED DEVICES. “Marketed” is used interchangeably with "interstate commerce" which is a statement defined in USA Law. If the product involved in the adverse event is not “Marketed” in the USA a report need not be submitted. "Approved" or "cleared" (by the FDA) is considered to be the same as "marketed".</p>	<p>“In general, the report should be made to the Competent Authority in the country of occurrence of the incident, with the following provisions or exceptions:</p> <p>In the case of an incident involving an implant, which occurs in a Member State other than the Member State where the implant was performed, the above principle still applies. In addition, the manufacturer should copy the report to the Competent Authority of the State where the implant was performed, if known.</p> <p>Reports on incidents concerning devices in Class II or Class III and IVDs listed in Annex II or for self-testing and occurring in countries outside the EEA and which result in corrective action, should be made to the Competent Authority in the State where the Notified Body is situated and which made the attestations which led to the CE marking being attached to the device.</p> <p>Reports on incidents concerning Class I devices and IVDs neither listed in Annex II nor for self-testing and occurring outside the EEA and which result in corrective action, should be made to the Competent Authority of the Member State in which the manufacturer, or the person responsible for placing on the market, has made his notification within Article 14 of MDD or Article 10 of the IVDD respectively.”</p> <p>[MEDDEV 2.12-1 rev 4 April 2001 – Guidelines on a medical Device Vigilance System, Section 6.1]</p>	<p>Manufacturers or their authorized representatives are required to report adverse events occurring in Australia to the TGA as follows:</p> <ul style="list-style-type: none"> - within 2 days of becoming aware of an event of significant public health threat or concern; - within 10 days of becoming aware of an event that lead to serious injury or death; and - within 30 days of becoming aware of a “near event”; <p>In this context a “near event” is one that could have led but did not lead to death or serious injury.</p> <p>[Therapeutic Goods Act 1989, Section 41MP , Therapeutic Goods (Medical Devices) Regulations 2002</p> <p>Australian Medical Devices Guidelines - Guidance Document Number 11, Version 1.7]</p>	<p>“60. (1) A preliminary report shall be submitted to the Minister</p> <p>in respect of an incident that occurs in Canada</p> <p>within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or</p> <p>within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and</p> <p>in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph (2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.”</p> <p>[Canadian Medical Devices Regulations, Section 60 and 61]</p>	<p>Under the current laws and requirements in Japan, manufacturers and importers of medical devices shall submit a Fuguai(AE) report to the Japanese Government. The law states that the MHLW is able to be a contact window for submission of Fuguai Reports and delegate the report reviewing function to the PMDA (Pharmaceutical and Medical DeviceAgency; one of the independent administration legal entity) . No other entity ,organization or body can receive a Fuguai report directly in Japan. Foreign organizations can’t receive Fuguai reports either.</p> <p>Article 64-5-2 of the Japanese Enforcement Regulations specifically states that events that occurred in a foreign country and were caused by a medical device that is of the same “shape form structure indications for use etc” as one that is approved for use in Japan, then those events are reportable to the Japanese Authority.</p> <p>[Phamaceutical affairs law (translated by Jiho Inc. 2001)Article 77-4-2</p> <p>Enforcement Regulations (translated by Jiho 2001, Inc. 2001)Article 64-5-2]</p>