PROPOSED DOCUMENT

Global Harmonization Task Force

Title: Review of Current Requirements on Postmarket Surveillance

Authoring Group: Study Group 2

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GHTF Chairman

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 to regulatory authorities 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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Introduction

All regulatory systems recognize that adverse event reporting alone cannot capture all risks related to the use of medical devices. Diagnostic devices where false positive and false negative are expected, long term implantable devices and devices for home use are examples of cases where the evaluation of the performance from adverse event reports alone is difficult or even impossible.

For this reason, various programs for the systematic collection of data on the performance of devices during the postmarketing phase exist in different countries. At the moment current requirements, definitions and understanding of Post-Market Surveillance (PMS) activities are not harmonised. The identification of these programs is required in order to determine, in a second step, whether harmonisation of some of their aspects may benefit regulatory authorities and industry.

1.0 Scope

This document provides an overview of the current regulatory requirements for Postmarket Surveillance in the 5 founding members of GHTF. As such it is meant to be a status document, representing a brief overview only and does not represent the full scope and nature of the regulations.

A general description of PMS is given for each founding member. PMS activities are then divided into Surveillance activities carried out by the authorities and those carried out by the manufacturers.

2.0 References

None

3.0 Definitions

None

4.0 Current requirements

AU	*CA*	*US*	*JP*	*EU*
4.1 General Descriptions of Post-Market Surveillance				
"Medical device post-market surveillance" means those activities carried out (by either the regulator or the manufacturer) to gain information about the quality, safety or performance of medical devices which have been placed in the market. In contrast to Vigilance, Post Market Surveillance measures are usually proactive.	The proactive collection of information on medical devices could be considered as post-market surveillance.	Broadly speaking, “surveillance” encompasses all post-approval product monitoring activities and is distinct from enforcement. Specifically, the term “Postmarket Surveillance” refers to Section 522 of the Federal Food, Drug, and Cosmetic Act, which defines FDA’s authority to order manufacturers to conduct studies of certain high risk marketed products.	Post Market Surveillance includes surveillance activities carried out after the products have been approved by MHLW. Surveillance is understood as an active investigation or survey with the specific purpose of confirming or better defining the safety or efficacy of a medical device.	There are no explicit definitions in the European directives. However, "surveillance" is used to indicate active collection of information on medical devices. The wording "Market Surveillance" is used to indicate the tasks carried out by the authorities, while "Postmarket Surveillance" refers to activities carried out by the manufacturers.

AU	CA	US	JP	EU
4.2 Market surveillance activities carried out by authorities				
TGA Surveillance activities include (but are not restricted to): • laboratory testing; • market surveys of technical documentation for evidence of conformity; and • audits of manufacturer facilities. The TGA considers the review of clinical and technical information (technical and clinical file audit) to constitute "Postmarket Monitoring" As for vigilance, the regulatory tools available to the TGA include: • requiring the manufacturer or their authorized representative to	Planned testing of devices on the market: In the past, Health Canada has tested devices against standards to see if they meet those standards. For example, condoms and medical examination gloves were tested. When non-compliant products were found, recalls and other appropriate actions were requested. Proactive review of websites: Health Canada has participated in the US FDA / US Federal Trade Commission "Surf Day". This is organized to search out fraudulent claims for drugs and devices (such as 'cures cancer'). This is not an on-going activity. Health Canada has just	Regulatory "surveillance" activities include, but are not limited to: • Review of mandatory and voluntary adverse event reports; • Review of required postmarket studies (522); • Review of product - associated clinical trials that were required as a condition of market approval; • Review of product claims, labeling, and literature used for promotion and advertising; • Inspection of manufacturer procedures for product complaint handling • Developing safety alerts, public health notifications and other	The term "surveillance" is normally not used to designate the activity of the competent authority but rather for the activity of manufacturers and importers. The authority can audit and inspect manufacturing sites and any other office. If needed, the authority can order manufacturers and importers to recall, to stop distribution, or to carry out any other action for ensuring the safety of patients and medical staffs. In addition to that, there are the reevaluation schema and the reexamination schema for reviewing the contents of approval. Under the reexamination scheme the efficacy and	Medical Device Directives (90/385/EEC; 93/42/EEC; 98/79/EC): Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose. Guide to the Implementation of Directives Based on New Approach and Global Approach, "Blue Guide": Market surveillance authorities should have the necessary resources and powers to conduct their

AU	CA	US	JP	EU
provide information (samples, test results, documentation) relating to quality safety and performance of the product upon request as a standard condition of approval; • the authority to seize product and inspect premises; • the authority to cancel/suspend the marketing approval of the product; and • the authority to mandate a recall of the product.	instituted an inspection programme for medical device importers, distributors and Class I device manufacturers that compliments the 3rd party audits of manufacturers of Class II, III and IV to assess conformance with ISO Quality System requirements (ISO 13485).	publications about suspected device problems and distributing them to the public. • Ensuring public access to information taken and reported to the Agency.	safety of a new device on the basis of results of investigations conducted by manufactures for a period of four or seven years after the approval are reviewed. The period is fixed on the approval. Reevaluation is the system to confirm the efficacy, safety and quality after the approval. MHLW can assign the devices to be reevaluated on the gazette.	surveillance activities. This is to monitor products placed on the market and, in cases of non-compliance, to take appropriate action to enforce conformity. [...] To be able to monitor products placed on the market, surveillance authorities shall have the power, competence and resources: • to regularly visit commercial, industrial and storage premises; • to regularly visit, if appropriate, work places and other premises where products are put into service; • to organise random and spot checks; • to take samples of products, and to subject them to examination and testing; and • to require all necessary information. Competent national

AU	CA	US	JP	EU
				authorities must take action to enforce conformity, when they discover that a product is not in compliance with the provisions of the applicable directives. The corrective action depends on the degree of non-compliance and, thus, must be in accordance with the principle of proportionality.

4.3 Market surveillance activities carried out by manufacturers				
The TGA may impose certain specific conditions on approval - e.g. that postmaket studies be conducted, particular tracking requirements, etc. ISO 13485, which is cited in Australian legislation, includes requirements for manufacturers or their representatives to undertake postmarket surveillance activities to gather experience about product performance and safety. Such activities may include: • market surveys; • product trials; • clinical studies; and • research & development towards improvement.	In the Medical Devices regulations [Section 36 (2)], there is a provision for Health Canada to issue a medical device license with conditions. 36. (2) The Minister may set out in a medical device license terms and conditions respecting (a) the tests to be performed on a device to ensure that it continues to meet the safety and effectiveness requirements; and (b) the requirement to submit the results and protocols of any tests performed. The Medical Devices Bureau would make decisions on which devices	"Postmarket Surveillance" is defined in Title 21 of the Food Drug and Cosmetic Act: Sec 522, and 21USC360l, [360] (a). FDA may by require a device manufacturer to conduct postmarket surveillance of any class II or class III device that meets any of the following criteria: 1) the failure of the device would be reasonably likely to have serious adverse health consequence; 2) the device is intended to be implanted in the human body for more than one year; or 3) the device is to be used outside a user facility to support or sustain life	Surveillance is mainly classified in two. 1. The surveillance that is enforced prior to approval of the device. In many cases, the post market surveillance plan is an obligatory condition for approval. This is enforced when the safety, efficacy and the quality of the device could not be sufficiently demonstrated at the time of submission for final approval. This type of surveillance is arranged in the approval section because the PMS plan is considered to be a part of the process of approval. 2. The surveillance performed after the marketing of the product because of adverse events or other reasons. The main objective of this type of surveillance is to re-assess	Medical Device Directives (90/385/EEC; 93/42/EEC; 98/79/EC) (Similar wording also in ISO EN 13485): The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action. The requirements of the PMS should be in direct proportion to the risk associated with the device. In addition the available scientific knowledge (e.g. long term effects), market experience with similar products, and manufacturer experience with the product or technology should be considered (from NB-

	to require this extra information.	Manufacturers must simultaneously comply with FDA medical device reporting (MDR) requirements, even during concurrent 522 data collection.	the safety of the product. This kind of surveillance is managed in conjunction between the approval section and vigilance section. This kind of surveillance is hardly ever done because the manufacturer in most cases prefer to stop the distribution of the product rather than be submitted to the surveillance procedure.	MED/2.12/Rec1, a guidance document on Post-marketing Surveillance systems published by the European Coordination of Notified Bodies Medical Devices). Manufacturers determine the extent of the PMS that is required for their products. This and its functioning are checked by the NB. Notified Bodies may request at the time of the conformity assessment, that further studies to better define the safety and performance of the device be carried out after placing the device on the European market. The Clinical Evaluation Task Force (CETF) of the European Commission is drafting a guidance document (MEDDEV) describing when a post-market clinical follow-up may be required.