WORKING DRAFT DOCUMENT

Global Harmonization Task Force

Title: PMS Harmonization Chart

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 to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

1.0 Scope and introduction

GHTF SG2 N16R5 (the SG2 Charge and Mission Statement) identified a number of tasks for SG2. The study group was to "define requirements for a common medical device vigilance system and provide an international protocol to define and facilitate the transmission of vigilance information on a global basis. " This has been the focus of SG2 for a number of years and a number of approved documents have been produced.

Another task identified in the Charge and Mission statement was to "…define recommendations and guidelines of post-market surveillance". This document represents the outcome of discussions on Post Market Surveillance (PMS) within SG2. The first step was to identify post-market surveillance activities and related regulations (summarized in SG2-N47) and then determine if there was a potential for harmonization of those activities in some way. This document reviews all post-market surveillance areas with a view to harmonization

2.0 References

GHTF SG2 N47: Review of Current Requirements on Postmarket Surveillance
GHTF SG2 N16R5: SG2 Charge and Mission Statement

3.0 Definitions

none

4.0 Harmonisation Chart

Table 1 summarizes the current position of SG2 on the potential for harmonization regarding PMS activities and, where relevant, names of the organizations that in the opinion of the group would be best suited to cover the topic.

Post Market Surveillance Activity	Short Description	Comments	Harmonisation Useful?	In what areas?	Recommendation on how to progress
Laboratory Testing	Testing of product for compliance with standards		no		Sharing of corrective action taken covered by NCAR (SG2-N20). Standards against which tests are done developed by ISO
Market Surveys on Information	Market Surveys of Technical and clinical documentation	In the US & JP this is a pre-market activity - In CA and AU this is done as a follow up to an issue with specific types of devices.	no		Results of surveys may be shared using NCARs.
Audits of Manufacturer Facilities	Inspect manufacturer processes and procedures for production and complaints handling	only periodic audits in JP	yes	auditing reports and techniques	addressed by SG4
Technical File Reviews	Review of Clinical and Technical Information for a specific product		no		Standards for technical files are addressed by SG1. Result of review may be shared using an NCAR
Review of Product Claims/Labeling	Labeling includes labels, IFU, promotional materials, websites		no		

Post Market Surveillance Activity	Short Description	Comments	Harmonisation Useful?	In what areas?	Recommendation on how to progress
Condition of Approval Studies, PMS Studies, re-evaluation re-examination schemes	Review of product - associated clinical trials	AU has the authority to impose conditions including request studies but studies are not normally requested. In EU, at the request of a Notified Body	yes	Common format for submitting report	Could be addressed by SG5
Recalls	Order, Monitor, and Classify product recalls, and disseminate written communications to appropriate recipients	This may be an enforcement activity not part of PMS. CA cannot order a recall. EU does not classify recalls	yes	what to report in a recall, information given to affected users	N57 will address this.
Enforcement	Prohibit distribution of violative products via regulatory processes such as injunction, product seizure, import detention, etc.	This may be an enforcement activity not part of PMS	no		Enforcement per se does not need to be harmonised. Safety related measures taken are addressed shared by NCAR.
Vigilance/AE Monitoring	Evaluate and investigate reported device problems and complaints		yes		Addressed by SG2-N54
Public Access to Information	Provide public access to information taken and reported to the Agency		no		Related to legislation normally out of control of NCAs
Standards Activities	Participate in global and international programs towards standardization and harmonization		no		Other groups are responsible.
Other Post-Market feedback	Information on device performance in post-market phase.		yes	What is the minimum requirement for a “systematic review of experience gained …” (ISO 13485)	This is related to QS. Could be addressed by SG3

5.0 Conclusion

The SG2 review of areas of post-market surveillance where there is a potential value in harmonization resulted in the identification of a number of areas where harmonization is recommended.

However there is only one area where SG2 feels it is within their mandate to pursue harmonization. That is in the category of recalls including what to report in a recall and what information should be given to users.

This topic is currently being developed based on an approved work item by the GHTF Steering Committee and is covered by document SG2-N57.