



Highlights of the minutes of GHTF-SG2 compiled by Carl Wallroth during the meeting in Canberra, Australia on 18 and 19 February 1998.

Chair: Larry Kessler, FDA, USA

Acting Secretary: Carl Wallroth, Dräger, Germany, EUROM VI

Host: Mike Flood, TGA

Other participants:

Kasuhisa Hasebe, MOH, Japan

Masaaki Naito, JFMDA

Pierre Landry, Health Canada

Ian Campbell, IAPM, Switzerland

John Michalicek, Med Dev Br., Prague

Jacob Nordan, Board of Health, Norway

Ken Kopesky, HIMA, USA

Axel Godeck, TGA

Arthur Brandwood, TGA

Kelwant Dillon, TGA

Martin Van Lith, TGA

Yvonne Aggett, TGA

Jim Collins, Dräger, Germany

Glenn Street, TGA

Masato Yoshida, JFMDA

Werner Schönbuhler, COCIR, Germany

Martin Bayreuther, COCIR, Germany

Kevin Murray, MEDEC, Canada

Trevor Nisbet, MOH, New Zealand

Derek Fitzgerald, MOH, New Zealand

Robert Virefléau, EC

Jeffrey Dutton, TGA

Rich Farb, USA, ISO TC 210 WG3

Denise Sofoulis, TGA

Alan Kent, MDA, UK

Joanna Bartholomeus, TGA

Linda Punyer, TGA

Absent/Regrets:

Deb Blum, FDA, USA

Kim Dix, Health Canada

John Worroll, MDA, UK

Gisela Ininger, EU/BfArM

Tom Gross, FDA, USA

Jean-Claude Bonnace, COCIR, France

Roland Gerard, IAPM/EUCOMED

Ben Khosravi, NEMA, USA

Emil Tschöpe, EU/BfArM

Vivian Coates, ECRI, USA

Executive Summary

GHTF-SG2 was commissioned by GHTF plenary to submit the following guidelines for public comment:

- Comparison of adverse event reporting systems in USA, Europe, Canada, Australia and Japan (N6)
- Minimum data set for manufacturer reporting to competent authorities (N7)
- Global medical devices vigilance report, guidance and form (N8 and N9)
- Adverse event reporting rules and decision tree for manufacturers (N21)

Documents are scheduled for worldwide dissemination by 1 March, for comments by 1 June 1998.

Document Details and Dissemination

There is an expectation that NCAs will review current postmarket systems and consider an approach to adopt regulations and laws as needed, and attempt to come into conformance with SG2 recommendations. Some modifications to the above mentioned documents may occur during the Canberra meeting, and would be reflected in an updated document "R" number. Any revisions would be completed prior to submitting the document to the first 90 day comment period.

Reference to “GHTF-SG2” will be replaced by reference to “GHTF” during the second 90 day endorsement period.

Documents to be placed on “web” by: FDA in USA, MDA in UK, TGA via bulletin for Australia and New Zealand, JFMDA/MHW for Japan, EMIG (i.e., 7 European Federations), HIMA in USA, and MEDEC/MDB in Canada.

Updated documents to be sent to SG2 members by 1 March 1998 (done). Paper copies to be made available by members for local dissemination. LGK to communicate with SG1, SG3 and SG4 Chairs for coordinated efforts, including, if possible, uniformity of layout of front page.

Precis (GHTF-SG2 N12 R__)

Document not formally presented to GHTF as not yet ready at that time. Document reviewed on line-by-line basis, with revisions made (which has been faxed to SG2 members). Definitions of terms was recommended. Please see amended document for further details.

Document amendments include:

I & II - unchanged

III Structure of harmonized vigilance system

A. Authority of international system - unchanged

B. Process of harmonization - unchanged

C. Information sharing - minor revisions

D. Considerations for future information system - add: a coordinating body composed of NCAs should give consideration, confidentiality and linguistic features

IV Manufacturer reporting to NCA - replace “rule” with “guidance”

V Timeframe for manufacturer reporting- unchanged

VI Basic elements of reporting by manufacturers- minor revisions

VII Communication of vigilance reports among NCAs - minor revisions

VIII Considerations for User Facilities (UF) and Health Professional (HP) reporting - many cultural differences make harmonization difficult. UF should report to mfr and NCAs simultaneously. UF and HP reporting is viewed as starting point for most AE systems, and crucial to the overall process of protecting the public health.

IX Postmarket surveillance - minor revisions

X Communication - minor revisions

Adverse Event (AE) Rules Guidelines (GHTF-SG2 N21 R__)

This document takes into consideration the following:

- Evaluation of incidents
- Manufacturer’s decision tree
- Use error considerations
- Minimum data set
- Definition of “serious injury”

NB: FDA definition of labeling *includes* promotional materials, however ISO 13485 *excludes* promotional materials.

Definitions within documents may need additional clarification.

New clarifications/revisions:

- addition of “or representative” added to all texts referencing “manufacturer”.
- document amended to include definitions from FDA and MEDDEV for “serious injury”

- was device *being* used? Or was situation discovered during scientific/technical evaluation?
 - use of device other than intended by mfr, because of the clinical situation facing clinician, and clinician judges device to have potential benefit that outweighs risk.
 - concept of exemptions re-introduced
 - decision tree amended to be in accordance with detailed guidance. (There was some concern expressed at a recent European medical experts meeting on, 9 & 10 Feb 1998, about the usefulness of the SG2 decision tree. It is felt that the tree needs to be trialed to determine usefulness.)
 - Block 5 of decision tree: "no" answer goes to Block 10
- Please review revised document for full details.

New Subgroup : Identification of well-characterized AEs

Members drafted by Chair: Rich Farb, Mike Flood, Kim Dix, Alan Kent, Ken Kopesky, Ian Campbell, Kazuhisa Hasebe, and Deb Blum (group leader). Subgroup to convene via email and teleconferencing.

Translation of documents into actual regulations - deferred

Vigilance reports and vigilance sharing

Document N20 disseminated by Kim Dix, prior to Canberra meeting. Concern of how to prevent "echo reporting". Database may help this concern. In interim, Lead NCA is recommended. Reporting also recommended to be linked to minimum data set. Further discussion deferred.

Thanks

Chair thanked Host TGA and Mike Flood for excellent facilities and hospitality. Carl was thanked for taking a group picture, and Rich was thanked for his computer support and humorous graphics. As an absent member of this meeting, I especially thank Carl for his notes. (Please send me the Toronto notes so I may get started on them, as well.)

Next SG2 Meetings

3-5 June 1998 in Toronto, Canada

23-25 September 1998 in Zurich, Switzerland, at Sulzer site

11-15 January 1999 tentatively set at Maurico, Puerto Rico, at Baxter site

It was not noted if previous minutes had been approved. In the interest of time and formality, the minutes to the Tokyo meeting will be considered final as disseminated, unless amendments are received in writing. Corrections or revisions will be duly noted and forwarded to members via next meeting in review of "old business".

Since these highlights are taken from notes, I apologize, in advance, for any misspellings of names. In addition, I would appreciate any corrections or clarifications be submitted as soon as possible. Please fax me at 301-594-2965 or em at DYB@CDRH.FDA.GOV

Highlights prepared by Deb Blum on 7 March 1998. Reviewed by LGK prior to distribution.