SUMMARY REPORT OF THE SG1 MEETING HELD ON 18/19th FEBRUARY 2004 IN CANBERRA

Attendees

Europe
Maurice Freeman - Chairman
Alan Kent – Secretary
Elke Lehmann – BfArM, Germany
Benny Ons – EDMA/EMIG
Petra Kaars-Wiele - EDMA/EMIG, Abbott (invited expert on IVDDs)
Peter Linders – COCIR/EMIG
Carl Wallroth – EUROM VI/EMIG

North America
Ginette Michaud – FDA, Office of IVD Evaluation & Safety, USA
Dan Schultz – FDA, Office of Device Evaluation, USA
Nancy Shadeed - Medical Devices Bureau, Health Canada (Chair of IVDD sub-group)
Brenda Murphy – SciCan/MEDEC, Canada
Fred Halverson – AdvaMed, USA
Michael Gropp – AdvaMed, USA

Asia/Australasia
Kiyohito Nakai – MHLW, Japan
Naoki Morooka – JFMDA/JIRA, Shimadzu Corp.
Michiko Masaka – JFMDA, Japan
Masato Yoshida – JFMDA, Japan
Yoko Ikeda – JACR, Japan (invited expert on IVDDs)
Shelley Tang – TGA, Australia
Mike Flood – TGA, Australia
Johan Brinch - MIAA, Australia

Apologies

Johann Rader - TUV PS, European Conformity Assessment Body
Koji Ikeda – MHLW, Japan
Masaaki Naito – JFMDA, Japan
Tsuneo Ohaku – JACR, Abbott, Japan (invited expert on IVDDs)
Maria Carballo – Device Evaluation Division, Medical Devices Bureau, Health Canada

Observers

Karen Howes – EDMA
Hideo Oya – JAIMA, Japan (invited expert on IVDDs)
Ronda Balham – FDA, International Affairs
George Azoury – MIAA, Australia

1 Welcome to the meeting and introduction of delegates

The Chairman welcomed attendees to the meeting and thanked TGA for offering their facilities at Canberra for the meeting.

Apologies were reported as shown above.

2 Review of the notes of the meeting held in London from 9 to 10th September 2003 (SG1/N053 of 26th March 2003)

The meeting report was accepted without change.

3 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was modified to include a discussion of experiences with the STED (see Item 11 below) and a report by Carl Wallroth on a recent meeting of ISO TC 210 (see Item 5 below).

4 To note the latest version of *Status of Active GHTF Study Group Work Programme SG1/N034R16 of 9th February 2004*

A new revision SG1/N034R16 was circulated prior to the meeting. There were no comments upon it.

5 Discussion on documents submitted to Steering Committee for publication on the GHTF web and update of other Steering Committee matters.

a) The Chairman reported on the progress of SG1 draft documents submitted to the GHTF Steering Committee.

The following are posted to the GHTF website as Proposed Documents on 16 December 2003 with a comment period through to 16 March 2004.

- SG1/N011R17 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices
- SG1/N015R22 Principles of Medical Devices Classification (meeting reference T4)
- SG1/N029R13 Information Document Concerning the Definition of the Term "Medical Device"
- SG1/N041R6 Essential Principles of Safety and Performance of Medical Devices (including In Vitro Diagnostic Devices)
- SG1/N044R4 Role of Standards in the Assessment of Medical Devices (including In Vitro Diagnostic Devices)

Chairman's Note: Since the meeting the comment period has been extended to 15th May 2004 to allow for delay in receiving response from FDA circulation (see 5b)

b) It was reported that the FDA have only recently (11th February 2004) published within the Federal Register a notice announcing the availability

of the GHTF documents. Under FDA procedures, this triggers a mandatory period of 3 months during which the public may make comments on the referenced documents.

The meeting noted and welcomed the FDA's continuing support of GHTF matters.

c) During discussion it was noted that there was no formal mechanism for informing industry and regulators that new/revised documents had been posted on the GHTF website. The current method relied on Study Group participants to cascade such information to those they represent.

d) The Steering Committee had expressed some concern with SG1 posting Working Drafts on the website as a step towards arriving at a Proposed Document. The Chairman pointed out that this had been a beneficial procedure during the development of some SG1 documents.

e) It was noted that Japan has passed the chairmanship of the GHTF to Europe for a period of 3 years.

f) It was noted that the FDA has taken responsibility for maintaining the GHTF website on a permanent basis.

g) It was noted that the next meeting of the GHTF Steering Committee is at the end of June, 2004.

h) A representative of US industry suggested the Classification Document should include a section describing how an earlier classification decision may be changed. AdvaMed were likely to submit a comment along these lines.

i) A representative of European industry suggested reported on a recent meeting of **ISO TC 210** where 2 resolutions were agreed that affect GHTF. One concerns a link between standards and the Essential Principles document. The second is to update and extend Technical Report 16142. There was also a resolution welcoming the participation of Regulatory Authorities in the drafting of medical devices standards.

j) It was suggested ISO TC 210 should address the problem of transition periods when technical standards are superseded. This varies between the standards bodies and is complicated.

k) At the last meeting of the Steering Committee there was discussion on clinical evaluation. A small ad-hoc working group, chaired by Michael Gropp, is considering whether GHTF needs to undertake work on this subject. The first meeting of the sub-group is taking place mid-March. Kimber Richter will attend for the FDA.

6 Summary by In Vitro Diagnostic devices sub-group of discussions at meeting held on 16th & 17th February 2004.

The chairperson of the sub-group described progress made during the meeting.

The main topic under development was a Classification document for IVDDs.

A table showing apparently different classification decisions in different jurisdictions was discussed.

A comparison of international IVD regulations, prepared by TGA, was circulated.

7 "Pre-market Conformity Assessment for Medical Devices" - discuss revised documents SG1/N040R9 of 29 September 2003 and new comments received

Comments have been received on SG1/N040R9 from the FDA, from Japan MHLW and from Japanese industry.

The comments were discussed in turn and the document revised accordingly.

An ad-hoc sub-group of SG1 will suggest guidance on the use of the STED for conformity assessment. The sub-group's recommendations will be presented to SG1 at a future meeting.

US industry suggested the document should include guidance on how the conformity assessment process and review should be carried out. He will suggest a possible text.

8 "Labelling for Medical Devices (including IVD's)" SG1/N043R5 of 9 September 2003.

The document currently posted on the GHTF website is SG1/N043R3 of 21 November 2001 rather than the most recent version. The document was subject to minor revision and the issue number raised to SG1/N043R6 of 19 February 2004. This revised document will be submitted to the Steering Committee as a Proposed Document.

9 Proposed new work item on The Format and Content of Registration and Listing Information for Medical Devices

A rationale for SG1 undertaking this work was circulated. However, it was not felt to be entirely satisfactory and will be rewritten.

10 Proposed new work item for the definition of "Manufacturer".

After the last meeting, a document was circulated that described the definitions of "manufacturer" used in the US, Europe, Canada, Australia and, separately the changes occurring in Japan under the Amendment of the Pharmaceutical Affairs Law. The Chairman and Secretary will consider this information and draft a preliminary definition for consideration at the next SG1 meeting.

11 Review of progress on Pilot Study using the Summary Technical Documentation for demonstrating conformity with the Essential Principles of Safety and Performance of Medical Devices (STED) - SG1/N011R16 of December 18th 2000

No formal comments have been received on the STED but some shortcomings have been referred to during this meeting.

The Japanese pilot will be extended to March 2005. To date approximately 10 applications have been received.

The FDA has one 510(k) in the STED format with approximately two others in the pipeline.

The STED is being used to some extent in Asia and South America.

During the meeting issues were raised concerning the difficulty of providing guidance on the amount and type of documentation required for devices of different risk class. It was agreed that this subject should be revisited during consideration of comments on the STED, rather than within this document.

12 Emerging Regulations in other countries

- Hong Kong is in the process of drafting new regulations.
- Malaysia is starting to work in the same area.

China is becoming more involved in the Asian Harmonization Working Party. They are interested in observing the work of SG1 and will be invited to observe the next meeting.

13 Global Medical Devices Nomenclature – (GMDN) Progress report.

The latest version was issued at the beginning of the year on CD ROM.

The database is being transferred into a new format that will be easier to access and use. A permanent Secretariat for maintenance of the GMDN will be appointed within the next 2 to 3 months.

14 Document Priorities and Timetable

SG1 has prepared three final documents:

- SG1/N020 *Essential Principles of Safety and Performance of Medical Devices* (30 June 1999)
- SG1/N009 *Labelling for Medical Devices* (18 November 1999)
- SG1/N012 *Role of Standards in the Assessment of Medical Devices* (18 November 1999)

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	PRIORITY	TARGET FOR COMPLETION
Principles of Medical Devices Classification	SG1/N015	Proposed Document - comments awaited.	1	2004 / Q4
Principles of Conformity Assessment for Medical Devices	SG1/N040	Revised Working Draft to incorporate comments from SG1 membership.	1	2005 / Q1
Pilot testing of *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance(STED)*	SG1/N011	Pilot starting 2002 Q1 in some regions and finishing 2005	1	2005 / Q1
Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance(STED)	SG1/N011	Proposed Document - comments awaited.	2	2004 / Q4
Information Document Concerning the Definition of the Term "Medical Device"	SG1/N029	Proposed Document - comments awaited.	2	2004 / Q3
Labelling for Medical Devices - Revision of SG1/N009	SG1/N043	Latest draft being submitted to the Steering Committee as a Proposed Document.	3	2005 / Q1
Essential Principles for Safety and Performance of Medical Devices – Revision of SG1/N020	SG1/N041	. Proposed Document - comments awaited.	3	2004 / Q3
Role of Standards in the Assessment of Medical Devices - Revision of SG1/N012	SG1/N044	Proposed Document - comments awaited.	3	2004 / Q4
Classification of In Vitro Diagnostic Devices	SG1/N045	Working Draft to be circulated to SG1 shortly	4	2005 / Q1
Premarket Conformity Assessment for In Vitro Diagnostic Devices	SG1/N046	Sub-group preparing first draft	4	2004 / Q3

15 Date and place of next meeting

SG1 will meet on the 5th & 6th October in Europe with an IVD sub-group meeting on the 4th and 7th.