NOTES FROM THE SG 1 MEETING OF 23 – 25 March 1999 IN BRUSSELS

Present:

Europe
Maurice Freeman (Chairman) – CEN/European Commission
Alan Kent (Secretary) – MDA/European Competent Authority
Karen Howes – European Commission (part of the time)
Johann Rader – TUV PS, Munich
Zeger Vercouteren – EUCOMED/EMIG (day 1 only)
Ian Campell – Sulzer Medical/EMIG
Vicki Dedrick – IAPM/EMIG
Carl Wallroth – EUROM VI/EMIG

North America
Kimber Richter – FDA, USA
Tim Ulatowski – FDA, USA
Michael Gropp – HIMA/Guidant (days 2 & 3)
Fred Halverson – HIMA/Medtronic (day 1 & 2)
Fred Lepner – Medical Devices Bureau, Health Canada

Asia/Australasia
Masato Yoshida – JFMDA/Asahi Medical Co
Tomiko Tawaragi – MHW, Japan
Graham Maynard – TGA, Australia
Johan Brinch – MIAA, Australia

1. Review & Acceptance of Meeting Report for 8 – 10 December in London

The report of the meeting was agreed with minor changes, and a number of matters arising were discussed.

- A HIMA representative raised the issue that manufacturers sometimes had problems where regulations required them to provide details of the materials they incorporated into their device but their supplier was not prepared to release them. This should be discussed in more depth at a later meeting.

2. Purpose of the GHTF and SG1

The meeting started with a wide-ranging discussion of the purpose of SG1 and its remit. The meeting reminded itself of the objective of the Global Harmonisation Task Force (GHTF) which is:

To encourage convergence at the global level in the evolution of regulatory systems for Medical Devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable. This is achieved by

identifying and developing areas of international co-operation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices

The purpose of SG1 was mandated by the GHTF and is:

To examine medical device regulatory systems in use in the major trading regions/countries, and to:

- *identify features of those systems which have a common basis but different application;*
- *identify features peculiar to individual systems, which may present obstacles to uniform regulation;*
- *to make proposals to the Task Force for harmonisation activities relating to these features;*
- *to suggest priorities.*

- **SG1 members reaffirmed that** the Study Group would:

- recommend the least burdensome level of premarket regulatory controls for medical devices, that ensured the appropriate level of safety of patients, the public and device users;

- identify common features of the requirements that exist currently in the countries represented by the GHTF, as well as the differences, and encourage Regulatory Authorities to reduce those differences when circumstances allow:

- encourage countries that are introducing new regulations to take account of the work of the GHTF and its Study Groups.

- **It was agreed that** SG1 could spend more time during future meetings discussing draft regulations from countries not represented on SG1. Manufacturers agreed to circulate documents describing such regulations.

3. Review current status of SG1 document on "Essential Principles of Safety & Performance of Medical Devices" (GHTF.SG1.N020R3 of 8 December 1998)

The Chairman read the note that described the status of this document as it appeared on the GHTF Web Site.

The meeting discussed comments from the Belgium CA, EUCOMED and Australia and agreed some changes.

- **It was agreed that,** with these modifications, the document should be presented to the GHTF plenary, through Bob Eccleston, as a final proposed document (GHTF.SG1.N020R4 dated 23 March 1999).

4. Review draft working proposal on "Role of Standards in the Assessment of Medical Devices" (GHTF.SG1.N012R7)

The meeting considered comments from Belgium and from attendees and modified the document accordingly. The document was revised to GHTF.SG1.N012R8 and dated 23 March 1999.

- **It was agreed that** further consideration would be postponed until the June meeting when further comments should be available.

5. Review of the draft document "Recommendation on Medical Devices Classification" (GHTF.SG1.N015R4)

- **It was agreed that** consideration of the comments from the Belgium CA would be postponed until the June meeting. The document was not changed.

6. Review of the draft document: "Labelling Recommendation for Medical Devices" (GHTF.SG1.N09R3)

The FDA had been asked at the previous meeting to propose a new introductory section. They had done so and their proposal was discussed and agreed with some modifications.

A revised version, including some editorial changes made by the secretary (GHTF.SG1.N09R3 of 24 March), is now ready for public comment and will be added to the various web sites.

7. New Work Proposal – Definition of Medical Device terms

- **It was agreed that** definitions were important and that if the GHTF was to consider the similarities and differences between definitions, those that are overarching, such as "medical devices" and "manufacturer", would be the responsibility of SG1. This would be a subject for discussion at the GHTF Plenary in June 1999.

- **It was agreed that** to enable SG1 to fulfil its purpose, it should explore the common elements and differences of the different definitions of "medical device". For this reason, the definitions from Europe, USA (two versions), Japan and Australia were compared.

- **It was agreed that** SG1 would prepare a document before the June meeting which identifies the common features of these various definitions.

- **It was agreed that** SGs2 and 4 be asked what definition they use for "manufacturer".

- **It was agreed that** SG1 members bring their definitions of "manufacturer" to the June meeting.

8. Review "Technical Requirements for Hip Implants" (GHTF.SG1.N022 of 31/12/99)

A new version of this document was tabled. The document contains performance and safety requirements followed by guidance on how the requirements can be met. The authors intend that, subject to the agreement of SG1, a manufacturer uses this document as a basis for actual submissions to different countries and this will identify critical regional differences.

The Chairman believed that the intentions of this document had been widely misunderstood by those outside of SG1.

- After considerable discussion it was agreed that the document should not be pursued further as an SG1 work item at present. There was nothing to stop it being used by a manufacturer/s for its own purpose.

9. Review "Summary Technical File for Premarket Conformity Assessment of Medical Devices" (GHTF.SG1.N011R7)

To provide focus to the discussion of this document, one member of SG1 posed some questions that needed to be addressed.

- How does the Summary Technical File fit into the pre-market and post-market procedures?

- The output of the work of SG3 is the input to SG1. Are these consistent?

- Is it intended that manufacturers of all risk classes of device use it?

In response, the document was modified to some extend by adding a section describing the purpose of the document, other comments will be considered during the June meeting.

The design and launch of a pilot project to test the flexibility of using the proposal was discussed. There would need to be manufacturers willing to participate in the project but is there any benefit for them (e.g. an expedited review)? The Manufacturers Associations will need to ask their members (preferably those with experience) to volunteer.

10. Discussion of the need for the document "Clinical Evaluation Guidance" (GHTF.SG1.N018R2)

SG1 members agreed that existing guidance needs to be improved but noted that other international groups are working in this area. The extent of any overlap and the scope of their proposed work items is not known precisely.

- **It was agreed that** before the next meeting a series of international meeting swill take place on the subject of clinical investigation and evaluation. Feedback from these will be discussed in June.

- **It was agreed that** by the next meeting, the existing documents will be reviewed and compared.

11. Discussion of the Concept of a Medical Devices Regulatory System and its Component Parts

- **It was agreed that** an overaching document describing common features may be useful but discussion will be postponed to June.

12. Date of Next Meetings

- SG1 is to meet as a group in Washington on Monday 28 June p.m.; and various Asian-Pacific and South American Regulators on Wednesday 30th and Thursday 1 July. The Plenary is on Tuesday 29th

- 13/14/15 October 1999 in Tokyo, Japan. Hotel and other arrangements will be confirmed shortly.