REPORT OF A JOINT MEETING OF THE AHWP and GHTF SG1 HELD ON 5/6th FEBRUARY 2007 IN KYOTO, JAPAN

Attendees

Chair - Ginette Michaud
Vice-Chair - Benny Ons
Secretary - Alan Kent

North America

Mark Melkerson – FDA, USA
Nancy Shadeed - Health Canada
Brenda Murphy – MEDEC, Canada
Michael Gropp – AdvaMed, USA

Europe

Elke Lehmann – European Commission
John Brennan – European Commission
Peter Linders – COCIR/EMIG
Carl Wallroth – EUROM VI/EMIG

Asia/Australasia

Shinichi Takae – MHLW, Japan
Naoki Morooka – JFMDA, Japan
Kiyoshi Ikeda – PMDA, Japan
Mike Flood – TGA, Australia

Asian Harmonization Working Party

Hwee Beng Wang – MoH , Malaysia
Alfred Kwek – Health Sciences Authority, Singapore
Mark Lau – DoH, Hong Kong
Henry Chiu – DoH, Hong Kong (Day 2)
Jiing Feng Chen – Office Medical Device Evaluation, Chinese Taipei
Daphne Yeh – Director Regulatory Affairs, Chinese Taipei
Jacqueline Monteiro - Singapore Manufacturers Association
Tran Quan - Singapore Manufacturers Association
Nellie Ong - Malaysian Medical Device Association
Jack Wong - BSI Product Services, Hong Kong
Albert Poon - Health Sector Services, EMSD, Hong Kong
Saleh S. Al-Tayyar - Saudi Food & Drug Authority
Hye Won Roh - Korea Food and Drug Administration
Adbul Rahman Saleh M. Al Gifari - Saudi Food & Drug Authority

Observers

Hirofumi Koide – JACRI, Japan
Masahiko Hasumi – JFMDA, Japan
Hiroshi Ishikawa – JFMDA, Japan

1 Welcome to the meeting and introduction of delegates

Ginette Michaud, Chair of SG1, welcomed the members of SG1 and the AHWP this inaugural meeting of the two groups. The meeting was held on the premises of Shimadzu Corporation in Kyoto, Japan. She thanked Naoki Morooka and his assistant, together with JFMDA, for organising and hosting the event and providing facilities for the meeting.

Hwee Beng Wang from the Malaysian MoH introduced the attendees from the AHWP and made some introductory remarks.

Members of SG1 and observers introduced themselves.

The Chair read a letter of welcome, encouragement and support from Larry Kessler, current Chair of the GHTF.

2 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed without change.

3 Introduction to AHWP

Mr Hwee Beng Wang, leading the AHWP delegates, made a presentation on the work of the AHWP.

He drew attention to the fact that a shortage of funding for the AHWP's work on the development of regulatory guidance remained a problem that slowed progress. Michael Gropp suggested a possible source of additional funding (APEC) that he could discuss with the AHWP.

In addition to the Common Submission Document Template, the AHWP is working on a classification system for medical devices and a harmonized definition of a "medical device". The subject of conformity assessment has yet to be tackled but is an subject for future work. Their goal is to adopt the majority of SG1 documents but this will be easier in countries where they have yet to introduce regulations (e.g. Singapore and Malaysia) than in jurisdictions where existing regulations are in place already (e.g. Thailand).

Governments of the 10 member countries of ASEAN, a sub-group within the AHWP, have formally agreed to adopt the GHTF documents on medical device classification and the harmonized definition of the term "medical device".

The AHWP will be considering post-market controls, such as adverse incident reporting, in the future.

The AHWP is looking at the feasibility of introducing an internet-based regulatory training programme. Michael Gropp reported that the GHTF Steering Committee's strategy includes an objective on providing guidance on training.

However, the work to support this aim is at an early stage and has yet to generate a policy outcome.

The next meeting of the AHWP will take place in China during November 2007. Members of SG1 are invited to attend.

Regulatory Status Review

Singapore is writing medical device regulations and these will follow GHTF guidance closely. Conformity assessment will be the responsibility of HSD.

Hong Kong has a voluntary system and has incorporated some GHTF guidance within it. They will use independent CABs for conformity assessment. They are conducting a regulatory impact assessment this year to decide the way forward. At present they accept marketing approval from GHTF Founding Members.

Malaysia also has the advantage of having "clean sheet of paper" at this time. This will help them introduce medical device regulations compatible with GHTF guidance when the time comes. **Thailand**, on the other hand, has existing regulations and this will be difficult to harmonize.

Saudi Arabia recently established the SFDA as a first step to controlling medical devices. This initiative has the support of senior Ministers. At present there are no local regulations for medical devices but the intention is that they will introduce some in the future. As the largest market for medical devices within the Middle East, Saudi Arabia is encouraging the formation of a Middle East group within the AHWP.

Korea separated medical device regulations from pharmaceutical affairs law in 2004 and is seeking to incorporate GHTF principles into them.

4 GHTF SG1 – Review of Accomplishments and Future Direction

Ginette Michaud, Chair of SG1, made a presentation on the structure and work of SG1.

In response, SG1 members were asked what resistance they had encountered from industry, to regulatory harmonization.

The following responses were provided:

- Industry shows a resistance to change since any changes to a regulation is seen as having the potential for delaying market access and/or product availability ("better the devil you know" effect).
- Harmonization is seen as a good thing only if convergence is towards the regulations that apply within your "home" jurisdiction but otherwise is not.
- Poor understanding as to precisely what has to be done to gain access to a particular market, caused in part by poor communication with the Regulatory Authority.

- A perceived lack of a "flat playing field" whereby some jurisdictions are believed to follow the new harmonized regulations closely whereas others are seen to be more "flexible" when it comes to their local manufacturers.
- Europe encountered a problem where many small manufacturers (e.g. dental device manufacturers and small ophthalmic companies) were included within the scope of the regulations and such companies had few staff and little understanding of what they were required to do.

The Chair asked whether the SG1 guidance document on Essential Principles was suitable for AHWP purposes.
The following answers were provided:

- **Singapore** is adopting it but first had to convince its Government that it wasn't too broad in its scope and its target audience was industry not members of the public.
- **Hong Kong** have transformed it into a checklist and adopted it.
- In some current Asia Pacific requirements the result of conformity assessment of Essential Principles is referenced but in their regulatory scheme the use of Essential Principles is not clearly defined at this stage.

SG1 was asked why devices used on animals were not included in the definition of a medical device.
Answer:

- Veterinary procedures and devices are outside the scope of the GHTF's mandate.
- Veterinary devices are not included in the medical device regulations of Founding Members.

The AHWP Technical Committee is encouraged to comment on SG1's Proposed Document on the Role of Standards (available at www.ghtf.org). Comments will be accepted until 15 March 2007.

Nancy Shadeed explained that the preparation of a STED for IVDDs is a new work item for the SG1 sub-group

John Brennan explained that in the future the EU Commission would adopt some GHTF documents as non-mandatory guidance (called Med-Devs).

5 The AHWP Common Submission Dossier Template

The history and purpose of this document was described by Alfred Kwek. Its purpose was to provide a descriptive document for use by manufacturers to submit information to Regulatory Authorities in order to obtain a marketing authorisation. Furthermore, it sought to harmonize such requirements.

The AHWP Technical Committee believed that some of the Section Headings appearing in SG1's STED were unclear to their local manufacturers and there was a need to provide an explanation.

The AHWP was asked whether the title of their document implied manufacturers would have to submit such information for all devices, whatever their Class.

- Answer:- this was not the intention and submission would be linked to device Class.

Some of the work undertaken by SG1 when it last met in Ghent was discussed. In particular, it had identified the totality of documents developed by a manufacturer during the design of a new device. The AHWP asked for a copy of this document but did not want to contribute to its development at this time.

Action: Secretary to e-mail a copy

SG1 presented a list of consolidated comments on the Common Submission Dossier Template for the consideration of the AHWP Technical Committee. These comments had come from a few SG1 members and have not been discussed by SG1 as a whole; hence they did not necessarily represent the considered view of the whole Study Group.

Other points discussed during this part of the meeting were:-

- That the AHWP should reconsider whether is wanted to prescribe the format of the documentation submitted to a RA. As an alternative, it could choose to specify the information to be made available but leave the manufacturer latitude in its precise format. It remained important that the reviewer could easily access the information he/she required.
- The implications of asking a manufacturer to provide a significant proportion of its technical documentation for retention by a RA should be considered.
- That developing an effective inter-regulator information exchange programme (see guidance from SG2) was a better source of information on medical device problems and recalls than holding a huge amount of pre-market technical information on higher risk devices. In part, because low as well as high risk devices are able to harm patients and users but also because pre-market information does not necessarily reflect actual outcomes.
- Regarding Section 3.0 Executive Summary - that more details of what is required should be added to the phrase “important safety/performance related information”, otherwise the volume of documentation could be excessive.
- Regarding Section 4.1.1 – it is recommended Certificates of Compliance or summary reports are all that is required in the first place, reserving the right to ask the manufacturer to provide “raw test data” if the situation warrants.
- Regarding Section 4.2 – care is needed in what is being asked for since the current requirement is for the manufacturer to provide routinely an enormous amount of information on each device.
- Throughout the document as a whole - it is important that a manufacturer knows precisely what it has to do to comply with the requirements of this document. The manufacturer should not be in doubt as to the applicable requirements neither should it have to interpret what the text means for a specific device.

6 Future role of AHWP during SG1 Meetings

To develop further the dialogue between the AHWP and SG1, two representatives of the AHWP are invited to attend future SG1 meetings as Participating Members. They will have equal standing to existing members and be encouraged to participate fully in SG1's deliberations.

SG1 also offers the AHWP two places on its IVDD sub-group. The representatives should have experience in the technology.

7 Contact Data Base

Alan Kent described the purpose of SG1's Contact Database and agreed to circulate the draft to AHWP attendees with a request to further populate it.

Action: Secretary

8 Future Meetings and Action Items

Meetings

The AHWP's attention is drawn to the forthcoming joint meeting of GHTF Study Groups (with the exception of SG2) in Los Angeles, USA, from May 7th to 11th, 2007. If there is an interest in AHWP representatives participating in meetings of SG3, 4 and 5 (two representatives of the AHWP will be joining SG1 already), they are asked to communicate directly with the relevant Study Group Chairs.

The AHWP's attention is drawn to the forthcoming GHTF Conference on 3rd/4th October, 2007 in Washington DC. Study Group meetings will be held at the same venue before the conference. A detailed programme will be posted on the GHTF web site, shortly.

Action Items

- **Ginette Michaud** will alert Dr Larry Kessler to AHWP's training proposal. Its should be consistent with the GHTF Training Strategy.
- **Alan Kent** will circulate a draft report of this meeting for comment. The final report will be posted on the GHTF web site.
- **Alan Kent** will circulate the two PowerPoint presentations made to the meeting.
- **Alan Kent** will circulate the spreadsheet that identifies the totality of documents developed by a manufacturer during the design of a new device.
- **Alan Kent** will circulate SG1's Contact Database to AHWP attendees with a request for help in populating it.
- **Alan Kent** will circulate a list of attendees and their contact details.