Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Update from TC WG01

Daphne Yeh

AHWP TC WG01 Co-Chair

13th AHWP Meeting

NEW DELHI, INDIA, 5-6 November 2008

Agenda

Monday, 3 Nov 2008, 11:00-13:00

- **Part I**

  Update on WG01 CSDT status - in Malaysia, Philippines, Singapore, Thailand (Report prepared by Alfred Kwek, presented by Daphne Yeh)

- **Part II**

  Latest Development in GHTF IVD related documents and Progress Report of WG01a IVDD Subgroup (Report prepared and presented by Jeffery Chern)

Agenda

Monday, 3 Nov 2008, 11:00-13:00

- **Part III**

  Update on GHTF SG1 development (Meeting in Buenos Aries and Ottawa; Report prepared and presented by Daphne Yeh)

- **Part IV**
  - Discussion on future work items
  - Collect inputs from all

Part I: Summary on CSDT Status

MALAYSIA

- **Observations**

  Multinational companies be more capable of making a more complete submission. They may have more experience in using STED format for making submissions in GHTF countries.

- **Feedback from industry**
  - Industry is of the opinion that they should also be allowed to use STED
  - Suggested that products that have been evaluated in accordance with STED should be given faster market clearance.
  - There was also concern about further amendment to the current version of CSDT.

Part I: Summary on CSDT Status

MALAYSIA

- **Regulators' experience**
  - Good learning experience to evaluate the CSDT submissions.
  - As CSDT is not prescriptive, problems faced by the regulators was the absence of a common understanding of what were required .
  - Different interpretation did not just occur between regulators and the companies, but also among fellow regulators.

- **Recommendations**
  - A clear framework of what constitute and what are required from each element of CSDT.
  - A guidance document on how to implement CSDT.
  - More dialogues to get better understanding and clarify certain requirements.

Part I: Summary on CSDT Status

PHILIPPINES

- Total Number of CSDT Submission 5
  - Class 1 0
  - Class 2 1
  - Class 3 3
  - Class 4 1

- Multinational companies can easily comply with the CSDT requirements for Pilot Study because they are involved in the ACCSQ-MDPWG meeting

Part I: Summary on CSDT Status

PHILIPPINES

- The distributor/importer submitted only the registration of medical device under Class 2;
- No local manufacturer was able to submit an application using the CSDT requirements; and
- The preparation time to gather all the needed documents was very short.

Part I: Summary on CSDT Status

SINGAPORE

- From April 2002 - 31 Mar 2007: More than 250 device dealers have successfully submitted more than 4000 devices to HSA under VPRS.
- From Nov 1st 2008: Sections of Part VI Licences and Part VII Registration of Health Products will be activated to allow HSA to start accepting applications for establishment licences and product registrations.
- From May 1st 2010: All product registration and listing on the register will be effective.

Part I: Summary on CSDT Status

SINGAPORE

- Presently, Singapore has published a guidance document to clarify in greater details the technical requirements contained in AHWP CSDT.
- When adopted and finalized, Singapore proposes that AHWP CSDT be termed a “requirement” document, instead of it being known as a “guidance” document.
- From May 15, 2010, with the full implementation of Phase 3, unregistered devices cannot be supplied in Singapore.

Part I: Summary on CSDT Status

THAILAND

- Hold seminar on the following.
  - Overview/Discussion of Global Medical Device Regulatory Models (USA, EU, Canada & Singapore);
  - Risk-based Classification of Medical Devices;
  - Essential Principles for Safety & Performance of Medical Devices;
  - Role of Standards in the Assessment of Medical Devices;
  - Clinical Evidence;
  - Labelling; Quality Management System for Medical Device Manufacturers; Principles of Conformity Assessment for Medical Devices;

Part I: Summary on CSDT Status

THAILAND

- Hold seminar on the following.
  - Post-Market Requirements;
  - Introduction to the AHWP Common Submission Dossier Template (CSDT)
  - Comparison between the AHWP CSDT and GHTF STED documents;
  - Industry Comments on the AHWP CSDT and GHTF STED documents;
  - How to Prepare Device Submissions in the CSDT format (A generic example of a good submission for a class III device was explained in details, complete with documents).

Part II: Latest Development in GHTF IVD related documents and Progress Report of WG01a IVDD Subgroup

THAILAND

- Hold seminar on the following.
  - Post-Market Requirements;
  - Introduction to the AHWP Common Submission Dossier Template (CSDT)
  - Comparison between the AHWP CSDT and GHTF STED documents;
  - Industry Comments on the AHWP CSDT and GHTF STED documents;
  - How to Prepare Device Submissions in the CSDT format (A generic example of a good submission for a class III device was explained in details, complete with documents).

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Attendees List (Blue: Apologies)

- Chair: Ginette Michaud
- Vice-Chair: Benny Ons
- Secretary: Alan Kent
- USA/Canada: Mark Melkerson , USFDA; Marlene Valenti, AdvaMed USA; Nancy Shadeed, Health Canada; Brenda Murphy, MEDEC Canada
- Europe: Elke Lehmann, European CA; Peter Linders, COCIR/EMIG; John Brennan, European Commission; Carl Wallroth, EUROM VI/EMIG
- Japan/Australasia: Mike Flood, TGA, Australia; Cliff Spong, MIAA, Australia, Hiroshi Yaginuma, MHLW, Japan; Atsuchi Tamura, PMDA Japan, Naoki Morooka, JFMDA Japan; Tomomichi Nakazaki, JFMDA Japan
- AHWP: Alfred Kwek , Health Sciences Authority, Singapore; Daphne Yeh, Industry representative Chinese Taipei

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Observers from the South America and Caribbean Countries

- Tim Missios, Boston Scientific (missiost@bsci.com)
- Mercedes Boveri , Boston Scientific Argentina (boverim@bsci.com)
- Lilian Orofino, Boston Scientific Brazil (orofinol@bsci.com)
- Adriana Belza, Johnson & Johnson MD & D (abelza@medur.jnj.com)
- Sandra Dalberto, Johnson & Johnson Brazil (sdalbert@medbr.jnj.com)
- Monica Duarte, ANVISA Brazil (monica.figueiredo@anvisa.gov.br)
- Francielli Melo, ANVISA Brazil (francielli.melo@anvisa.gov.br)
- Marcio Varani, ANVISA Brazil (marcio.varani@anvisa.gov.br)
- Rogelio Lopez, ANMAT Argentina (lopezr@anmat.gov.ar)

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Observers from the South America and Caribbean Countries

- Emilce Vicentin, ANMAT Argentina (evicenti@anmat.gov.ar)
- Leandro Cian, ANMAT Argentina (lcian@anmat.gov.ar)
- Marta Ines Kaufman, ANMAT Argentina (mkaufman@anmat.gov.ar)
- Augustin Iglesias Diez, ANMAT Argentina (aiglesiasdiez@gmail.com)
- Humberto Olarte Cupas, MINSA Panama (holarte@minsa.gob.pa)
- Alejandro Martinez, MINSA Panama (amartinez@minsa.gob.pa)
- Mirtha Quiel, Ministerio de Salud Panamá (mquiel@minsa.gob.pa)
- Dulce Maria Martinez, CCEEM Cuba (dulce@cceem.sld.cu)

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Final Documents (endorsed by GHTF Steering Committee)

- SG/N044:2008 of February 21st, 2008: Role of Standards in the Assessment of Medical Devices
- SG/N011:2008 of February 21st, 2008: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- SG/N045:2008 of February 19th, 2008: Principles of Classification of In Vitro Diagnostic Medical Devices
- SG/N046:2008 of February 26th, 2008: Principles of Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices (discussion continues)

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Proposed Documents

- SG1/N055R6 of 26th February, 2008 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer has been endorsed by the Steering Committee as a Proposed Document and is on the GHTF website for public comment. Comments will be accepted until early December.
- SG1/N065R05 of 26th February, 2008: Registration of Manufacturers and other Parties and Listing of Medical Devices will be discussed later in this meeting. Comments on the document have been received, consolidated and circulated to SG1. These will be discussed later in this meeting.

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Documents Under Revision

- Comments received for consideration when SG1 revises its guidance entitled *Essential Principles of Safety and Performance of Medical Devices* later in this meeting. A list of consolidated comments has been circulated. These will be discussed later in this meeting.
- Comments received for consideration when SG1 revises its guidance entitled *Information Document Concerning the Definition of the Term "Medical Device",* at a future meeting, have been circulated.
- Comments received for consideration when SG1 revises its guidance entitled *Labelling for Medical Devices,* at a future meeting, have been circulated.

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

New SG1 Document Work Items

- GHTF SG1 has proposed two new work items and noticed to AHWP TC WG01;
  - Change management
  - Technical Documentation for Medical Devices
- AHWP TC WG01 has replied to GHTF SG1 the support of these new work items.
- WG01 suggested to separate guidance of “Change Management" for IVD and non-IVD products (or dedicating a specific section to IVD).

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Purpose of GHTF Study Group 1 modified on GHTF website

Previous:… Pre-Market…

Modified: Purpose of Study Group

- SG1 has been charged with supporting convergence of medical device regulatory systems through the development of harmonized guidelines on elements of a global regulatory model. These elements include definitions of key terms such as 'medical device' and 'manufacturer'; essential principles of safety, performance, and labelling; principles of classification and conformity assessment; and recommendations for summary technical documentation.
- In developing these guidelines, SG1 collaborates with other GHTF Study Groups in creating a global regulatory framework. It has additionally welcomed the contribution to its work of regulators and industry in other parts of the World.

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Milestones for the future (Latin America):

- Need for industry participation in the Latin America working party.
- Seek industry and regulator participation in all GHTF SGs.
- Seek ways to make AHWP WG6 work (training group) available to Latin America.
- Reinforce PAHO Resolution on Medical Devices to develop regulations, promote Latin American & Caribbean participation in GHTF & promote use of GHTF guidance.
- Speed up the translation process of the GHTF documents.
- Improve document control e.g. version control between published documents versions and the translated documents.

Part III: Update on GHTF SG1 Development, 8-11 July, 2008, Buenos Aires

Future Meetings

- 14-17 October 2008, Ottawa, Canada

  For a SG1 and Joint Study Group meeting (Done, Meeting Report not yet published)

- January 20-23, 2009, Sydney, Australia

  For a SG1 Meeting

- Mid May 2009, Toronto, Canada

  May 10-15 GHTF Conference

Part IV: Discussion on future work items

- Keep close link with GHTF SG1 Development
- A work item entitled "Adopting the Principles and Elements of Conformity Assessment for Medical Devices" and implementation phases and timelines for WG01's work items. WG01 requested Member Economies to:-
  - Reach consensus on adopting the principles of conformity as a fundamental;
  - Adopt the proposed elements of conformity assessment for MD; and
  - Have the commitment to share experience regulating medical devices
- Compare CSDT and STED, Come out with Guidance of submitting STED plus CSDT variations.


AHWP

Part IV: Discussion on future work items

Proposed Workflow to Finalize Guidance Documents for WG01

(1)
- Circulate GHTF documents to WG, in accordance to terms and conditions imposed by copyright owner
- Solicit feedback on technical issues contained within documents from WG OR
- Initiate AHWP document drafting for issues faced by AHWP member economies.

(2)
Gap analysis on
- adoption or
- identification of foreseeable difficulties faced by AHWP

(3)
Public consultation, if necessary

(4)
Feedback or modification, if necessary
- For GHTF documents: feedback to SG1
- For AHWP documents: Review and revise documents

(5)
- Submission to Technical Committee for discussion on AHWP TC position
- Finalization of AHWP TC position

(6)
Submission to AHWP Main Meeting for endorsement

Thank you for your attention!