



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Summary Report from TC WG01

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13th AHWP Meeting

NEW DELHI, INDIA, 5-6 November 2008

Discussion on Future Work Items



- 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, (e.g. Come out with Guidance of submitting STED plus CSDT variations.)
- The definition of manufacturer

Discussion on Future Work Items



- UDI (Unique Device Identifier)
- Format of Certificate
- Questionnaire for economy (Experience study on CSDT)
- Special Import process
- Counterfeit MD / IVD (could be special task)
- Mutual recognition of pre-market approval
- Best practice sharing among economies (reference to the presentations made in the “Update from Economy on Harmonization)
- Reference to GHTF SG1’s projects and select AHWP focused topics

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)

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.

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.

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).

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.

Update on GHTF SG1

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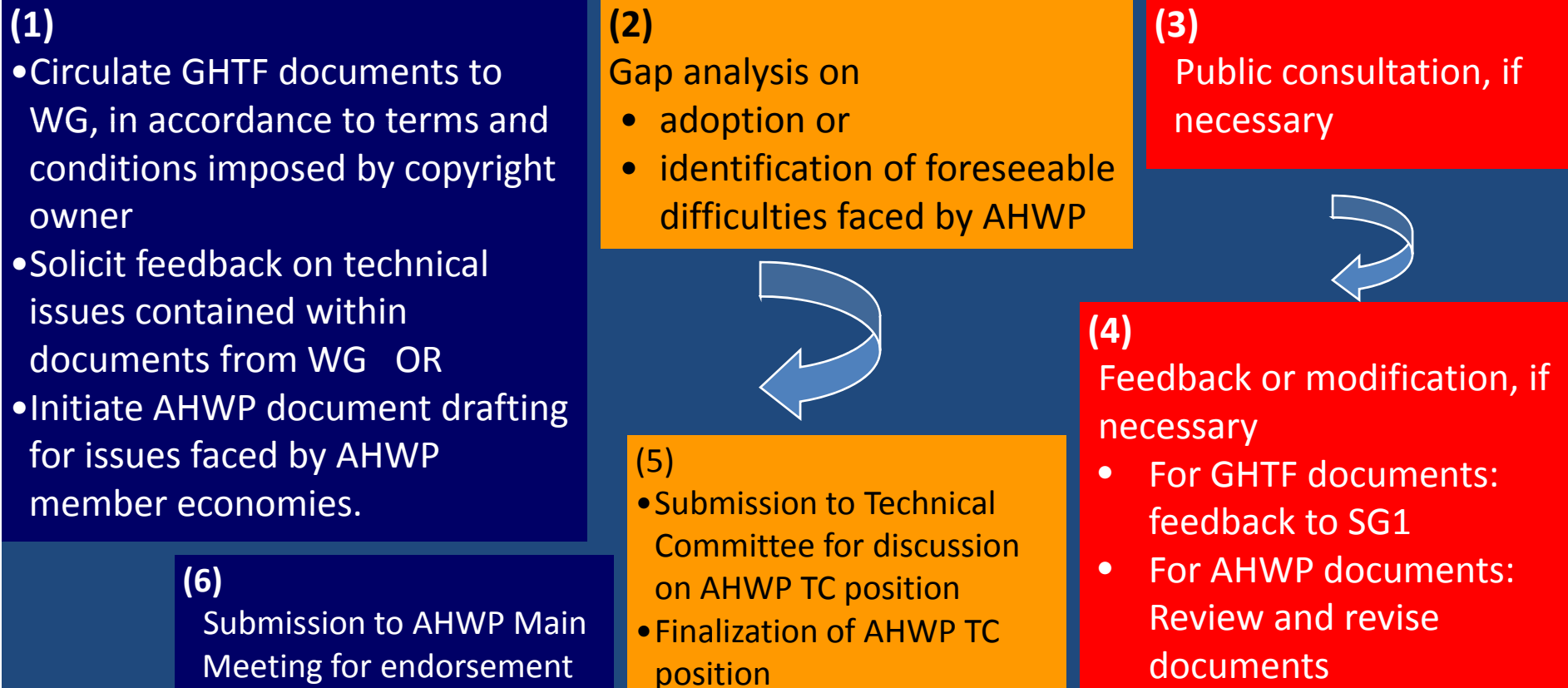
Milestones for the future (Latin America):

- 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 IV: Discussion on future work items



Proposed Workflow to Finalize Guidance Documents for WG01





Thank you for your attention!

