ASIAN HARMONIZATION WORKING PARTY

Summary of discussion 26 Feb 2013

- AHWP strategic framework elements
  - Need for continued education & capacity building
  - Identification & training of future leaders

- AHWP member economies current status
  - More granularity & qualification in regards to status summary for different member economies

- SWOT analysis
  - Challenges presented mirror those faced by GHTF & other harmonization forums
  - Potential issue of lack of industrial commitment for harmonisation
  - Opportunity for AHWP to develop a guideline that member economy can adopt
  - Active participation and commitment to develop guidelines.
  - Different requirements may be explored for lower risk v.s. higher risk MDs

- Discussion on the rule of Consultants in AHWP
  - Consideration for Liaisons to include persons apart from regulator and industry background. (e.g. academic associations, standardisation bodies, patient groups)
  - To define roles and objectives of observers or liasion participation

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Summary of discussion 26 Feb 2013

Working Group	Summary of Plan
WG1	• Review revised GHTF definitions in guidance & their impact on AHWP • Software standards review & Draft of preliminary guidance document for internal circulation for comments
WG1a	• Development of AHWP guidances on IVD medical devices • Training for AHWP member economies (Roadmap)
WG2	• Set up & promote use of electronic AE reporting forms across MEs • Developing AE reporting requirements & timelines for all stakeholders • Develop guidance document for MD disposal - in context of complaints • Formal training of SG2/WG2 guidance document
WG3	• Review QMS guidance documents • New guidance document (QMS - local industry, distributor and importer)

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Summary of discussion 26 Feb 2013

Working Group	Summary of Plan
WG4	• Finalising guidance documents • Training of AHWP guidance documents for MEs • Development for auditing guidance for importers & distributors • Survey development and distribution among member economies
WG5	• Build consensus within WG to continue framing guidance document based on GHTF SG5, ISO 14155 and ICH GCP – survey to be re-issued • Providing inputs to ISO 14155 team on the latest ISO 14155 version for their upcoming meeting in Apr 2013 • Comparative study of regulations & related guidance on clinical trial requirements • Partnering with other TC work groups' initiatives to provide expertise & input relating to clinical safety/performance • Training on GCP, GHTF SG5 GN and latest version of ISO 14155 and Clinical investigation evaluation
WG6	• Prioritise needs of different WGs • Explore available training materials that caters for WG needs • Map training requirements with other organisations • Establish and implement basic online system for different WGs

Closed Meeting For TC Leaders

1. **How WG Membership should be determined in the future/selection criteria**

1.1 Voting among the four options:-

A. Person moving from member economy to non-member economy

B. Person moving from one company to another within member economies (WG1, WG1a, WG2, WG3, WG4, WG5, WG6)

C. Person moving from MD industry to another industry

D. Appointing a proxy/ representative who is not based in member economy

1.2 Conclusion - Proposed change to TOR to Secretariat :

A WG member must be based in AHWP member economy

2. **Frequency of TC meetings**

2.1 Continue to have 1 TC leaders (close) meeting plus 1 TC (open) meeting back to back with AHWP main meeting in 2014

2.2 Location of TC Leaders 2014 will tentatively be either in India or Hong Kong

2.3 TC leaders meeting would only allow the attendance of TC Advisors and WG Chair & Co-Chair

2.4 In case of apology, WG Chair and Co-Chair can send representative, while TC Advisors cannot send representative (who is invited in personal capacity)

Closed Meeting For TC Leaders

3. AHWP RAPS 1st Joint Conference

3.1 Suggestions from WG on training topics should be feedback to Secretariat by 31 Mar 2013

4. Updates of Current Regulatory Status of Member Economies

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification	Nomenclature	Essential Principles
1	Abu Dhabi					
2	Brunei	No	No	No	No	No
3	Cambodia	Yes	Yes	Yes, GHTF	No	No
4	Chile	Yes	Yes	Yes	No	Yes
5	China	Yes	No	Yes	No	No
6	Chinese Taipei	Yes	Yes	3 risk-class, & GHTF guidelines	TMDN	Yes for Class III only
7	Hong Kong	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, AMDN	Yes, GHTF
8	India	No, moving towards GHTF	National definition & moving towards GHTF	No	No	No, moving towards GHTF
9	Indonesia	Yes, GHTF	Yes, GHTF	Yes	No	Yes, GHTF

Updates received by 27 Feb 2013

Updates by 2011

ASIAN HARMONIZATION WORKING PARTY

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification	Nomenclature	Essential Principles
10	Jordan					
11	Korea	Yes, national definition based on GHTF	No	Yes	Yes	Yes, KFDA Medical Device Act requirements are equivalent to EPs; include the contents of EPs
12	Laos	Yes	No	Yes	No	No
13	Malaysia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS	Yes, GHTF
14	Myanmar					
15	Pakistan					
16	Philippines	Yes	Yes	Yes	No	No

Updates received by 27 Feb 2013

Updates by 2011

Current Regulatory Status of Member Economies (as at 2012)

S/N	Member Economy	Medical Device Definition	Manufacturer Definition	Classification	Nomenclature	Essential Principles
17	Saudi Arabia	Yes, GHTF	Yes, GHTF	Yes, GHTF	Yes, UMDNS & GMDN	Yes
18	Singapore	Yes, GHTF	Yes	Yes, GHTF	Yes	Yes, GHTF
19	South Africa	Yes	Yes	No	Yes, UMDNS	No
16	Thailand	Yes, GHTF	No, but definition of ***manufacture*** in the MD Act	Presently No, but being in the procedure of reclassification	Yes, UMDNS& GMDN	Yes
21	State of Kuwait	Yes	No	No	No	Yes
22	Vietnam					
23	Yemen	YES	Yes	No	No	Yes

Updates received by 27 Feb 2013

Updates by 2011

Closed Meeting For TC Leaders

4. TC roles and responsibility

AHWPTC as the executive arm of the Working Party should perform the following roles and responsibilities to support the Working Party:

1) Execute the Working Party's decisions and resolutions

   1.1 WG leaders should report and present their recommendations to TC leaders for final endorsement after their posting of DRAFT/DRAFT PROPOSED document on AHWP website for "call for comment" from all AHWP members

2) Make recommendations to the AHWP Chair for decisions;
3) Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;
4) Provide expert opinions and advice;
5) Develop technical documents and policy papers;

Closed Meeting For TC Leaders

6) Plan and organize meetings, training, seminars, workshops and experience sharing sessions;
7) Work with related organizations and participate in their activities; and
8) Report on the progress of its activities to the AHWP Meetings.
9) To revisit the goals and directions of the TC for in line with AHWP's objectives (and the Strategic Framework) in the light of the formation of the TC Advisory Panel – in the areas of :-
10) The work plan of each Work Group
11) To strengthen the TC procedures so as to facilitate TC's overall objectives.
12) Strengths & Weaknesses identified in last meeting

ASIAN HARMONIZATION WORKING PARTY

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5. What we would hope Advisors' role to encompass

5.1 To offer advice on work items which are assigned to AHWP by other international /regional org

Sharing from TC Advisors

Recommendations

1. Strategy

a) Identification of elements of a comprehensive regulatory system needed to be addressed in the **AHWP regulatory model** (ARM) for IVD and MD

b) Identification (through gap analysis) of **building blocks** that needed for the purpose in the regional context to develop the ARM (considering the differences among member economies)

2. Three levels of documents which will lead to AHWP's Best Practices

a) Focusing more on the creation of AHWP unique documents in addition to the adoption of GHTF/IMDRF* ones [Level 1]

b) Interpretive documents on existing documents – lead to capacity building [Level 2]

c) Collaborative decisions on **borderline issues** – by making AHWP's decision and setting of position on standards (e.g. determine borderline definition/inclusion of certain product as MD) [Level 3]

* GHTF documents can be regarded as level 1 or 2 doc

regulatory model can be regarded as level 0

Sharing from TC Advisors

Recommendations

3. Process

a) Need more governance and oversight to **verify work items** fit in the approved ARM

b) Address recruitment, qualified, balanced, consistent **participation on work group**

c) Industrial participation is not limited to multi-national corporations (MNC) especially if topics are directly related to local environment

d) Need to **clarify the meaning of adoption or implementation** for AHWP

4. Structure and International alignment

a) Consider a more flexible working structure not like GHTF

b) Roles of TC advisors

c) Determine the AHWP liaison activities

d) Consider to form a focus group (special task group - STG) on standards

Quick Feedback from TC Leaders on recommendations

1. Agreed on setting priority work on sharing of "How to set up regulatory framework" for AHWP members.
2. AHWP makes recommendation on technical aspect instead of having the power to request jurisdiction to change their regulations to fit the endorsed AHWP GN
3. AHWP play book (how to set goal, plan resources, implement strategy, etc) can be useful to help members who are preparing their MD regulation within AHWP ME
4. Acknowledged and appreciated the recommendations from TC advisors and will determine action & follow up items