REPORT OF THE 15th MEETING OF THE ASIAN HARMONIZATION WORKING PARTY (AHWP)

Al Falsaliah Hotel

Riyadh, Kingdom of Saudi Arabia

30 Nov - 1 Dec 2010

INTRODUCTION

(1) The 15th Meeting of the Asian Harmonization Working Party (AHWP) was held on 30 Nov and 1 Dec 2010 at Al Falsaliah Hotel, Riyadh, Kingdom of Saudi Arabia. The Meeting was chaired by the AHWP Chair, Mr WANG Baoting, Director-General of Medical Devices Supervision, State Food and Drug Administration, People's Republic of China, and also Ms Joanna KOH, Chair of AHWPTC, Ms Daphenne YEH and Mr Ali AL DALAAN, Co-Chair of AHWPTC.

WELCOME ADDRESS BY THE CHAIR

(2) The Chair welcomed and thanked all participants for attending the 15th AHWP Meeting. He then extended his thanks and gratitude to Saudi Food and Drug Authority (Saudi FDA) for hosting this Meeting. He also thanked the members of the Organizing Committee and the AHWP Secretariat for all the arrangements of this Meeting. He then welcomed Pakistan and Yemen, the new AHWP member economies for attending this Meeting.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

(3) The Agenda of the Meeting is as in **ANNEX (3)**, which was adopted with applause.

AGENDA ITEM 2: ADMISSION OF NEW AHWP MEMBERS

(4) The Meeting confirmed the admission of Pakistan and Yemen as AHWP member economies.

AGENDA ITEM 3: ROLL CALL

(5) Over 350 participants attended the 15th AHWP Meeting.

AGENDA ITEM 4: CONFIRMATION OF THE 14th AHWP MEETING MINUTES

(6) The meeting confirmed the report of the 14th AHWP Meeting, held in Hong Kong SAR, China on 6-7 November 2009, without any amendments.

AGENDA ITEM 5: 2009/10 – REPORT OF SECRETARIAT (HONG KONG BRANCH)

(7) Mr Mark LAU, Deputy Secretary General, presented the composition and role of the secretariat, the work done in the year 2009/10 which included the Secretariat Meetings in Beijing and Shanghai, updates on AHWP membership, new training and SADS on-line platforms in AHWP Website, etc. Mark also presented the future work plan, including the formation of legal entity of the AHWP Administration Services Ltd in Hong Kong. AHWP Administration Service Limited will be the permanent secretariat of AHWP, and also serve as legal entity for AHWP for finance management. Mark also answered the queries on joining the legal entity as raised by the floor. All members were invited to join the mentioned legal entity as founding members, where the application form was available in the AHWP website, with application deadline by Dec 15, 2010. The report was agreed and confirmed with applause.

AGENDA ITEM 6: 2009/10 – FINANCIAL STATEMENT AND 2010/11 BUDGET

(8) Mr Bryan SO, the AHWP Secretariat, presented the financial statement of 2009/10, with a surplus of around USD80,000 as of 31/10/2010. The budget for 2010/11 was presented with income at around USD120,000 and expenditure of USD78,000. The financial statement of 2009/10 and budget of 2010/11 was agreed and confirmed with applause.

The financial statement is appended as **ANNEX (8).**

AGENDA ITEM 7: REPORT BY AHWPTC CHAIR

(9) Ms Joanne KOH, the Chair of AHWP Technical Committee (TC), presented work done by different workgroups. Announcement of formation of a communication forum of Conformity Assessment Bodies (CAB) and 3rd party assessment bodies was made. A CAB Working Party was formed in Hong Kong and is managed by Mr. Jack WONG. Several decisions regarding Terms of Reference (TOR) were made, include:

1. AHWP TC should have written procedures and criteria to ensure that participants from non-AHWP member economies can only be observers or advisers to the WG. Nomination should come from AHWP member economies
2. There will be no restrictions on Consultants joining as members of WG. Membership shall be based on the merits of the individual.
3. Each member is restricted to a maximum of 2 WG memberships.
4. Minimum attendance at WG meetings is required. Proposed criteria is:
   i. Minimum of 1 TC meeting attendance; and
   ii. Minimum of 1 Teleconference attendance within 12 months effective 2011
5. If the above criteria are not met, WG chair and co-chair can make the decision on the

membership based on member's contribution in other aspects.

The report by TC is appended as **ANNEX (9).**

AGENDA ITEM 8: REPORT BY WORKING GROUPS

(10) WG1 – PRE-MARKET SUBMISSION & CSTD

Ms Daphenne YEH, presented the work of WG1, including the completion of the comparison of GHTF's Summary of Technical Documentation (STED) and AHWP's Common Submission Dossier Template (CSDT), with future work towards the harmonization of STED and CSDT. The next steps of WG1 include:

1. Recommendations on Labeling Requirements
2. Definition of Manufacturer, Authorization Representatives and etc.
3. Survey on the adoption of STED or CSDT
4. Aim to adopt CSDT or STED in AHWP member economies for dossier submission during next TC meeting in 2011

The report by WG1 is appended as **ANNEX (10).**

(11) WG1A – PRE-MARKET SUBMISSION IVD

Mr Essam AL MOHANDIS, Chair of WG1A, presented the work of WG1A, including the collaboration with Global Harmonization Task Force (GHTF) on In-vitro Diagnostic (IVD) devices reporting. AHWP-WG1A has been cooperating with GHTF-SG1A to review or draft the following documents:

1. SG1-N45: 2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
2. SG1-N46: 2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
3. SG1(PD)/N063 "Summary of Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices"
4. "Clinical Evidence for IVD medical devices–Key Definitions and Concepts" (Draft)
5. "Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation"(Draft)

The report by WG1A is appended as **ANNEX (11).**

(12) WG2 – POST-MARKET SURVEILLANCE & VIGILANCE

Mr Mark LAU, Chair of WG2, and Ms TANAKASEMSUB Chadaporn (Miang), Co-chair of WG2, presented the work of WG2, with harmonization of Adverse Event (AE) report, with the ultimate objective of merging National Competent Authority Reporting (NCAR) and Safety Alert Dissemination System (SADS). Also the SADS on-line report system was also prepared on AHWP website, and all members were invited to try on the on-line system and feedback. Training Material Folder under AHWP website has been posted already. Drafted Adverse Event Report Form and Drafted FSCA Report Form are open for comments. The next steps of WG2 include:

1. Create the folder under AHWP WG2 and upload all the trainings' Materials and Video to the folder. All these materials had been consented for uploading by the trainers.
2. Proposed structure of the trainings
   - Basic training:
     i. SG2 guidance documents
     ii. Manufacturers Trend Reporting of Adverse Events
     iii. Guidance of How to handle information concerning Vigilance Reporting related to Medical Devices
     iv. FSCA
   - Advance program
3. Mark Bruley (ECRI)'s AE investigation program
4. Plan to arrange videotaping for the whole training.
5. After AHWP meeting, plan to provide DVDs to the regulators and industries group for each economy.
6. Long term - Propose WG6 to take care all these materials distribution.

The report by WG2 is appended as **ANNEX (12).**

(13) WG3 – QUALITY MANAGEMENT SYSTEM

Mr. Ali AL DALAAN, Chair of WG3, and Ronald GOON, Co-chair of WG3, presented the work of WG3. Worked with GHTF SG3, WG3 actively developed N17 (Guidance on the control of product and services obtained from suppliers) and N18 (Guidance on corrective action and preventive action). Reviewed by WG3 and AHWP member economies, N17 did not raise any issues that required modification of the document for use by AHWP. As such,

WG3 recommended that documents be adopted by AHWP with no changes. WG3 initiated survey on the QMS requirements in AHWP member economies and analyzed data from responses received to date. Development of N19 (Criteria for characterizing the significance of QMS deficiencies) with GHTF SG3 was also initiated. The next steps of WG3 include:

1. Complete QMS survey by obtaining responses from remaining AHWP member economies and analyzing data;
2. Complete development of N19 with GHTF SG3;
3. Review comments and feedback from AHWP on N18 and evaluate for adoption by AHWP;
4. Work with GHTF SG3 and ISO TC210 to evaluate need for revision of ISO 13485 and, if applicable, to work on follow-up activities.

The report by WG3 is appended as **ANNEX (13).**

(14) WG4 – QUALITY SYSTEM AUDIT

Abdullah AL RASHEED of WG4, has prepared the survey for developing the guidance document in Audit.

The report by WG4 is appended as **ANNEX (14).**

(15) WG5 – CLINICAL EVIDANCE REQUIREMENTS

Ms TRAN Quan, Co-chair of WG5, presented the works done for WG05, with works include:

1. Comparative study of Clinical Trials Regulations & related guidance on Clinical Safety/Performance in AHWP member economies:
   – Review Clinical Trials Regulations and its developments in China, India, Korea, Singapore, Chinese Taipei and Thailand;
2. Training Initiatives:
   i. Workshop at 10th AHWP TC meeting, Singapore, May 2010
   – Painting the Clinical Picture: Clinical Evaluation & Clinical Evidence by Mr. Greg LE BLANCE, Vice Chair GHTF SG5;
   ii. Workshop at 15th AHWP annual meeting, Saudi Arabia, Nov 2010
   – ISO14155 by Ms. Danielle GIROUD, Convenor TC 194 WG4;
3. Review GHTF SG5 Document & make recommendations to AHWP member economies on the feasibilities of adoption:
   – Completed studying and reviewing 5 GHTF SG5 documents (include 1

in draft)

4. Set up Advisory Expert Panels of GHTF SG5 members
   – 6 members include Chair & Vice Chair; 2 Japan PMDA officers; 2 Industry experts (EU & Australia)

The next steps of WG5 include:

1. Leveraging on the Advisory Panel of SG5 experts for training & advice on GHTF SG5 documents review & adoption
   - March / April 2011 – Review of Clinical Evidence, Key Definitions & Concepts (SG5/N1R8: 2007) & Clinical Evaluation (SG5/N2R8: 2007)
   - May/June 2011 – Face to face working session (SG5-WG5)
     - Review AHWP guidance document on adoption of GHTF SG5 GN
     - Discuss at least one GHTF GN on feasibility of adoption in AHWP member economies
   - June-Sept 2011 – Seek preliminary input from member economies on draft GN
   - Oct 2011 – Follow up to finalize recommendations for AHWP Annual meeting

2. Comparative study of Clinical Trials Regulations & related guidance on Clinical Safety/Performance in AHWP member economies
   - Deep dive into member economies regulations
   - Update survey with new questions

3. Training Initiatives
   - Organize experts to speak on GCP and Declaration of Helsinki at AHWP conferences
   - Invite Regulators from Member Economies to discuss Clinical Trial Regulations development & directions

4. Greater collaborations with other international organizations / Work Groups
   - E.g. APEC Harmonization Center & Harmonization By Doing (USFDA & MHLW, Japan)

The report by WG5 is appended as **ANNEX (15).**

(16) WG6 – CAPACITY BUILDING & REGULATORY TRAINING

Jack Wong, Co-chair of WG6, presented the development of Regulatory Training certificate course together with AHWP and GHTF. A new chair of WG6, Mr Sanjay Kumar in Singapore

HSA, was appointed. The objectives of WG6 was confirmed, which is to arrange regulatory training to Regulators and Industry. Setting up an On-line Training Platform was confirmed. Training syllabuses about Introduction of GHTF and AHWP and Introduction of member economies regulatory system were also confirmed. The next steps of WG6 include:

1. First Quarter of 2011: Identify on-line platform;
2. Second Quarter of 2011: Training content is ready;
3. End of 2011: Program Launch.

(17) STG (LE) – LEGAL ENTITY

Mr Mark LAU reported the work of Special Task Group (Legal Entity) [STG (LE)] where the M&A was finalized, and the recruitment of the founding members for the AHWP Administration Services Ltd in Hong Kong was ready. The terms of reference have been endorsed and available.

The report by STG (LE) is appended as **ANNEX (17).**

(18) STG (N) – NOMENCLATURE

Lindsay TAO, Co-chair of STG (N), reported the work of STG (Nomenclature) [STG (N)], where two representatives from AHWP has joined the GMDN board of trustees, who are Singapore and China. Lindsay also reported the new STG (N) Chair, Mr YANG Lianchun of China SFDA.

The report by STG (N) is appended as **ANNEX (18).**

AGENDA ITEM 9: RESOLUTION 1 – ADOPTION OF THE PROPOSED AHWP HOUSE RULES

(19) Mr Mark LAU presented the background of the resolution regarding the AHWP house rules draft, which was circulated to all members earlier through AHWP web posting. With no other comments, it was agreed and confirmed with applause the pass of resolution for the adoption of the proposed AHWP house rules.

AGENDA ITEM 10: RESOLUTION 2 – ADOPTION OF THE PROPOSED AMENDMENT 1 TO THE AHWP TERMS OF REFERENCE

(20) Mr Mark LAU presented the background of the proposed amendments to add one more Vice-chair of AHWP to the organization structure. Therefore, there would be one Vice-chair from regulatory and one Vice-chair from non-regulatory. The resolution was passed.

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a) WG02 will take up the task of Adverse Event (AE) reporting and AE investigation;
b) WG01 will take up the task of Guidance on regulation and classification of combination products and Guidance on Risk classification of medical devices;
c) WG06 will take up the task of training for elimination of Mercury in all medical devices.
d) The next TC meeting will be held in April / May of 2011, the host is to be confirmed by 1st Jan 2011.

The AHWP Chair Mr WANG Baoting thanked all the participants and the 1st day meeting finished at 15:52.

The 2nd day meeting started at 08:35. Mr WANG Baoting delivered welcome noted.

WORKSHOP

(21) We had guest speakers for the following topics:

1. Speaker 1: Mr. Chris JEPSON (Global Manager- Medical Device Certification, SGS)
   Topic: Conformity Assessment
2. Speaker 2: Mr. Gert BOS (BSI)
   Topic: Notified Body Harmonization Effort in Europe
3. Speaker 3: Mr. Michael FLOOD (ex-TGA)
   Topic: Practicing GHTF Recommendations in Regulatory Systems
4. Speaker 4: Mr. Vincent LAM (TUV SUD)
   Topic: Good Distribution Practice
5. Speaker 5: Mr. Michael CHENG (Sympatico)
   Topic: Shared responsibility in medical device regulations

COLLABORATION

(22) We had guest speakers for the following topics:

1. Collaboration between AHWP and WHO (Speaker: Ms Adriana VELAZQUEZ)
2. Collaboration between AHWP and APEC (Speaker: Mr Jeffrey GREN)
3. Collaboration between AHWP and LSIF (Speaker: Ms Lindsay TAO)
4. Collaboration between AHWP and GHTF (Speaker: Mr Jean-Yves CARENTZ)

UPTATE BY GHTF STUDY GROUPS

(23) We had guest speakers for the following topics:

1. SG1 (Speaker: Mr Kentaro AZUMA)
2. SG2 (Speaker: Ms Isabelle DEMADE)
3. SG3 (Speaker: Dr Dirk WETZEL)
4. SG4 (Speaker: Mr Ronald GOON)
5. SG5 (Speaker: Mr Greg LE BLANC)

PANEL DISCUSSION

(24) Panel Discussion: The Possibility of AHWP Joining GHTF Steering Committee (by TC Chair, TC Co-chairs, member economies, guests from GHTF Steering Committee)

Mr WANG Baoting invited AHWP TC Chair and Co-chairs to give comment:

1. Joanna found the working relationship with GHTF is important. It will take some time for AHWP to get prepared and be the regional member of GHTF
2. Daphne found GHTF is group of countries while AHWP is group of member economies. It is pre-mature for AHWP to join GHTF
3. Ali found GHTF is helpful to AHWP

Mr WANG Baoting thanked all comments from AHWP TC Chair and Co-chairs and appreciated the invitation from GHTF. GHTF provided lots of support in past few years. AHWP also actively participated in GHTF SGs' activities. We often invite GHTF experts to share SG updates. The presentations in this AHWP meeting were also in great quality. We really appreciate the support from GHTF.

Mr WANG Baoting described AHWP is a mix of government and industry from member economies, and serves as a platform for communication and discussion. AHWP member economies have great variety of economy status and regulatory system. After numbers of discussion, AHWP had no consensus to join GHTF regional member yet. Mr WANG encouraged member economies to continue to discuss this issue and get more feedbacks. AHWP will still continue to work closely with GHTF, WHO and APEC etc., which will help harmonization overall.

4. Pakistan encouraged more interaction with GHTF
5. Korea mentioned many key tasks need to be resolved in AHWP e.g. nomenclature

Mr WANG Baoting thanked all the comments and will work hard to get the nomenclature resolution and planned to attend the WHO meeting in 2011.

If we cannot resolve the GMDN issue in 2011, Mr WANG suggested we should consider creating our own system, e.g. AMDN.

NEXT AHWP MEETING

(25) The Host of the 16th AHWP Meeting is confirmed:

- After discussion with TC and member economies, Indonesia was considering to host our next AHWP meeting
- Indonesia will get approval from Indonesia government
- Mr WANG Baoting also wrote a letter to Ministry of Health of Indonesia and we hoped we can have meeting in Indonesia
- Dr Bahdar HAMID mentioned he would try his best to support

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Kuwait informed us that they have applied to be member of AHWP.

CLOSING REMARKS

(26) The AHWP Chair Mr WANG Baoting presented the meeting Closing Remarks. Mr Ali, Co-Chair of AHWPTC, thanked all the support of Saudi FDA team, AHWP TC and Secretariat team to make the meeting successful. The Chair concluded the Meeting by thanking all participants for their contributions and wishing them a safe journey to home. The meeting was adjourned at 16:45 on 1st December 2010.

ACKNOWLEDGEMENT

(27) The participants from Yemen, Malaysia, Thailand, South Africa, Philippines, Pakistan, South Korea, Singapore, China, Saudi Arabia, Jordon, Indonesia, India, Hong Kong, Chinese Taipei, Peru, Chile, Japan, Egypt, Germany, UK, USA, Australia and etc., as well as the observers expressed their appreciation to the Saudi FDA for the warm hospitality and the excellent arrangements made for this Meeting.

Report Prepared by:
Mr Bryan SO
AHWP Secretariat