Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

BLUE PAPER

Secretariat of AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

Preface

Since its establishment in 1996, Asian Harmonization Working Party (AHWP) has always been adhering to the principle of democracy, magnanimity and openness. With its member economies closely working with each other to harmonize the medical device regulations in Asia, AHWP has made great contributions to the healthy development of Asian medical device industry. In order to thoroughly display AHWP's history and achievements, the Secretariat of AHWP compiled this "AHWP Blue Paper" for your reference. Due to some historical reasons, it is really hard to collect all relevant data at the early stage. Thanks for your understanding.

The Secretariat of AHWP
October 2011

Contents

PART 1

Introduction and Overview of AHWP

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA

Initiation and Establishment of AHWP

With the globalization of medical device industry, related harmonization of regulations on medical devices in Asian economies are increasingly important. In order to harmonize the medical device regulations in Asia, the governments and industries of Asian economies set up Asian Harmonization Working Party (AHWP) in 1996-1997. As a regional and non-profit organization, AHWP is designed to boost the harmonization of medical device regulations in Asia, encourage better understanding on the benefits of such harmonization, provide a platform for member economies to discuss and train medical device regulations, and facilitate the information exchange among regulators and industrial groups in Asia. Joining hands with Global Harmonization Task Force (GHTF), APEC and other related international organizations, AHWP aims to promote the harmonization of medical device regulations.

Responsibilities and Tasks of AHWP

1. Understand the worldwide application of quality system requirements as well as the operation of internationally accepted quality system standards for medical devices;
2. Mainly rely on international standards to guarantee the product safety and make efforts to reach a consensus on regulations;
3. Seek to establish an examination & approval procedure for product access acceptable to Asian areas;
4. Seek to set up the adverse event reporting system and information sharing mechanism for regional use;
5. Work with GHTF for technical harmonization;
6. Promote the implementation of APEC's proposals on medical device and equipment industry.

Terms
of Reference

Goals

To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

Membership

The Working Party is a group of experts from Medical Device Regulatory Authorities ("Regulatory Authorities") and the medical device industry including government agencies not Medical Device Regulatory Authorities ("Industry"). Membership is open to those representatives from the Asian and other regions that support the above stated goals. Any economies interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.

Upon joining, each member economy should nominate two Primary AHWP Representatives and two Secondary AHWP Representatives, with one each from the Regulatory Authority and one each from the Industry. Representatives from the Regulatory Authority shall be responsible persons in the development and implementation of medical device regulatory frameworks while those from the Industry shall be senior managers from the industry of the member economy such that they could represent the views of both the Regulatory Authority and Industry of their economies.

The Primary AHWP Representative from the Regulatory Authority of a member economy shall be nominated by the medical device regulatory authority of the corresponding government. He/she could in turn nominate the Secondary AHWP Representative for his/her economy. All organizations from the Industry should nominate a representative to subscribe to the AHWP Secretariat for serving as the contact person.

Leadership

One AHWP Chair and two AHWP Vice-chairs shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all Primary AHWP Representatives for a term of office until the next election. The AHWP Chair and one AHWP Vice-chair shall come from Regulatory Authorities while one AHWP Vice-chair shall come from the Industry. The AHWP Chair and Vice-chairs will normally rotate among member economies. In the absence of the AHWP Chair and/or AHWP Vice-chairs at a given AHWP Meeting, they or the organizations that they are representing may nominate suitable persons as acting AHWP Chair and/or AHWP Vice-chairs for the purpose of the said meeting.

Decisions and Resolutions

The Working Party shall operate on a consensus basis. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at AHWP Meetings. Though member economies should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on member economies such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

Relationship with Other Parties

The Working Party shall work closely with GHTF, APEC, WTO, WHO, ASEAN, ASEM, LAHWP and other international organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.

Observers to Meetings

It is our belief that the message of harmonization will be better spread and promoted with observers from different corners of the world participating in the meetings. All AHWP Meetings are open to interested parties to join as observers on a space availability basis.

Language

English will be used as the only language in documents and communications of the AHWP. Member economies may arrange for translation and/or employ interpreters for their own use if needed.

AHWP Meetings

The Working Party shall meet at regular intervals (normally once a year). The AHWP Chair may organize ad hoc meetings when needed. Meeting locations shall preferably be rotated among member economies.

Asian Harmonization Working Party Technical Committee (AHWP TC)

AHWPTC is the executive arm of the Working Party. It performs the following roles and responsibilities to support the Working Party:

- Execute the Working Party's decisions and resolutions;
- Make recommendations to the AHWP Chair for decisions;
- Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;
- Provide expert opinions and advices;
- Develop technical documents and policy papers;
- Plan and organize meetings, training, seminars, workshops and experience sharing sessions;
- Work with related organizations and participate in their activities; and
- Report on the progress of its activities to the AHWP Meetings.



AHWP TC Membership

Each member economy should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the Regulatory Authority and one each from the Industry. The Representatives shall be knowledgeable experts in medical device regulatory services and be able to represent the views of the Regulatory Authority and Industry of their economy.

The Primary AHWP Representative from the Regulatory Authority could nominate both the Primary and Secondary AHWPTC Representatives for the Regulatory Authority of his/her economy. The Primary and Secondary AHWPTC Representatives from the Industry should be elected by the industry representatives of their own economy.

AHWP TC Leadership

One AHWPTC Chair and two AHWPTC Co-chairs shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives. The AHWPTC Chair and one AHWPTC Co-chair shall come from the Regulatory Authorities while one AHWPTC Co-chair shall come from the Industry. In the absence of the AHWPTC Chair at a given AHWPTC Meeting, the AHWPTC Co-chair from the Regulatory Authority shall assume the duties of the AHWPTC Chair. In the absence of both the AHWPTC Chair and Co-chair from the Regulatory Authority, the AHWPTC Co-chair from the Industry shall assume the duties of the AHWPTC Chair.

Working Groups (WGs) and Special Task Groups (STGs)

With the consent of the AHWP Chair, the AHWPTC Chair may create Working Groups and Special Task Groups for carrying out specific tasks and duties of the Technical Committee. Each Group shall have one Chair from the Regulatory Authority and one Co-chair from the Industry.

The AHWPTC Chair may appoint Acting Chairs and Co-chairs to take charge of the newly formed Groups until the next AHWP Meeting in which the Chairs and Co-chairs of the newly formed Groups are elected.

AHWP TC Meetings

The AHWPTC Chair may organize AHWPTC Meetings as and when needed. At least one of the AHWPTC Meetings shall be held in conjunction with the AHWP Annual Meeting in which the AHWPTC Chair shall report on the developments and achievements of the Technical Committee.

Terms of Representation, Resolutions & Decisions

- Representation

The Regulatory Authorities are government bodies responsible for the regulation of medical devices. The Industry includes all business and services related to the manufacturing, supply, distribution, usage, procurement, maintenance, testing, conformity assessment and supporting services related to medical devices. Government, semi-government and non-government bodies not directly responsible for the regulation of medical devices are regarded as part of the Industry for the purpose of the Working Party.

- Resolutions & Decisions

AHWP and AHWPTC Representatives may initiate resolutions and recommendations for discussions and voting at the AHWP Meetings and AHWPTC Meetings respectively. Requests shall be made to the AHWP Secretariat and copied to the AHWP Chair and AHWPTC Chair at least one week before the relevant Meeting. Any proposed amendments to the resolutions shall be made to the AHWP Secretariat and copied to the AHWP Chair and AHWPTC Chair at least one day before the relevant meeting.

A simple majority is needed for passing any resolutions and recommendations at the AHWP Meetings and AHWPTC Meetings respectively.

Voting, Nomination, Election, Terms of Service, Change of Office Bearers /Representatives and Representation in the Absence of Representatives

- Voting

Each Primary AHWP Representative and Primary AHWPTC Representative shall have one vote at the AHWP Meeting and AHWPTC Meeting respectively.

- Nomination

Primary AHWP Representatives may propose nominations for election as office bearers in the AHWP, AHWPTC, WGs and STGs.

- Election

Nominees with the highest number of votes shall be elected as office bearers.

- Terms of Office

The terms of office of all AHWP and AHWPTC office bearers will be around three years commencing from the date of appointment until the next election. All office bearers in the AHWP, AHWPTC, WGs and STGs, regardless of when they are elected into the office during the term of a given AHWP Chair, shall retire altogether at the same time with that AHWP Chair. The current AHWP Chair is responsible for organizing the next election of new office bearers in an AHWP Meeting in about three years'time after his/her election.

- Change of Office Bearers and Representatives

When there are changes to office bearers, the Primary AHWP Representative of the corresponding member economy shall nominate replacements to fill the vacancies arise. If the member economy fails to make nominations for such replacements for any reason, the AHWP Chair may appoint acting replacements until new office bearers are elected to fill the relevant vacancies in the next AHWP Meeting.

- Representation in the absence of the Representatives

Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence. In case that both the Primary and Secondary AHWPTC Representatives are absent, the corresponding Primary AHWP Representative could take up all the roles and responsibilities as well as voting rights at the AHWPTC Meetings. Similarly, Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent.

House Rules

1. Applications of the AHWP House Rules

A. The AHWP House Rules are guidelines to supplement the Terms of Reference of the AHWP and AHWPTC for promoting the AHWP activities. The House Rules shall be followed by all members as far as applicable.

B. Should there be any conflicts between the House Rules and the Terms of Reference, the latter shall prevail.

2. Requirements of the AHWP Chair /Vice-chairs

A. The AHWP Chair/Vice-chairs shall be strong supporters of the Goals of AHWP and could take the lead to promote these Goals to all related parties.

B. The AHWP Chair/Vice-chairs shall fulfill the following requirements:

(a) The AHWP Chair and one of the AHWP Vice-chair shall come from Regulatory Authorities while the other AHWP Vice-chair shall come from the Industry;

(b) The Chair and Vice-chair from Regulatory Authorities shall come from the senior management with decision making power while the Vice-chair from the Industry shall come from the senior management of a reputable organization with good knowledge of the Industry;

(c) They shall have sufficient support and resources in planning, organizing and participating in meetings and teleconferences within AHWP as well as with other international organizations;

(d) They shall have been actively participating in AHWP activities and are familiar with the AHWP operations;

(e) They shall have good networks with other Regulatory Authorities and the Industry;

(f) They shall be committed to promote the Goals of AHWP.

3. Nominations and Elections of the AHWP Chair/Vice-chairs

A. AHWP Representatives from Regulatory Authorities could be nominated by Primary AHWP Representatives as the candidates in the AHWP Chair election and AHWP Vice-chair (Regulatory Authority) election while AHWP Representatives from the Industry could be nominated as the candidates in the AHWP Vice-chair (Industry) election.

B. Candidates shall submit their nomination forms to the Secretariat before the commencement of each election as declared by the chair of the meeting. Every nomination shall be supported by at least five Primary AHWP Representatives from other member economies with their signatures duly signed on the nomination form.

C. Every Primary AHWP Representative shall support only one nomination in each election. He/she may vote for another candidate in the election.

D. In the AHWP Chair election, every Primary AHWP Representative shall vote for one candidate. The candidate with the highest number of votes will be elected the AHWP Chair. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.

E. Upon the completion of the AHWP Chair election, the AHWP Vice-chair (Regulatory Authority) election will be conducted in the same way as the AHWP Chair election.

F. Upon the completion of the AHWP Vice-chair (Regulatory Authority) election, the AHWP Vice-chair (Industry) election will be conducted in the same way as the AHWP Chair election.

4. Requirements of the AHWP TC Chair /Co-chairs

A. The AHWPTC Chair/Co-chairs shall be strong supporters of the Goals of AHWP and shall possess experience and expertise in medical device regulatory services.

B. The AHWPTC Chair/Co-chairs shall fulfill the following requirements:

(a) The AHWPTC Chair and one of the AHWPTC Co-chair shall come from Regulatory Authorities while the other AHWPTC Co-chair shall come from the Industry;

(b) They shall have sufficient support and resources in planning, organizing and participating in meetings and teleconferences within AHWPTC as well as with other international organizations;

(c) They shall have been actively participating in AHWPTC activities and are familiar with the AHWPTC operations;

(d) They shall have good networks with other Regulatory Authorities and the Industry; and

(e) They shall be committed to execute the policies and decisions of AHWP and provide professional support to achieve the Goals of AHWP.

5. Nominations and Elections of the AHWP TC Chair/Co-chairs

A. AHWP TC Representatives from Regulatory Authorities could be nominated by Primary AHWP Representatives as the candidates in the AHWP TC Chair election and AHWP TC Co-chair (Regulatory Authority) election while AHWP TC Representatives from the Industry could be nominated as the candidates in the AHWP TC Co-chair (Industry) election.

B. Candidates shall submit their nomination forms to the Secretariat before the commencement of the election as declared by the chair of the meeting. Every nomination shall be supported by at least five Primary AHWP Representatives from other member economies with their signatures duly signed on the nomination form.

C. Every Primary AHWP Representative shall support only one nomination. He/she may vote for another candidate in the election.

D. In the AHWPTC Chair election, every Primary AHWP Representative shall vote for one candidate. The candidate with the highest number of votes will be elected the AHWPTC Chair. The chair of the meeting can cast an extra vote when there is more than one candidate having the highest number of votes.

E. Upon the completion of the AHWPTC Chair election, the AHWPTC Co-chair (Regulatory Authority) election will be conducted in the same way as the AHWPTC Chair election.

F. Upon the completion of the AHWPTC Co-chair (Regulatory Authority) election, the AHWPTC Co-chair (Industry) election will be conducted in the same way as the AHWPTC Chair election.

6. Roles and Responsibilities of the Secretariat

A. The Secretariat is a team including the Secretary-General, Deputy Secretary-General and other team members providing secretariat support to the AHWP including the organization of meetings and activities, implementation of resolutions and decisions, management of website, preparation of meeting agendas and minutes, keeping of documents and records, management of funds, updating of contact emails and promotion of activities. Its email address is secretariat@ahwp.info .

B. The Secretary-General is the person in charge of the Secretariat. He/she shall assist the AHWP Chair to overlook the performance of the Secretariat Team.

C. The Deputy Secretary-General is the person in charge of the day-to-day operations of the Secretariat. He/she shall provide assistance to the AHWP Chair and Secretary-General to manage the AHWP and promote its activities.

7. Appointment of the Secretariat Team

A. The AHWP Chair may appoint office bearers of the Secretariat including one Secretary-General and several Deputy Secretary-Generals responsible for different duties. The Secretary-General takes charge of the Secretariat and supervises the Deputy Secretary-Generals.

B. The AHWP Chair shall appoint the President of the AHWP Administration Services Ltd duly elected in the general meeting of the company the Deputy Secretary-General responsible for the day-to-day operations of the company. The AHWP Chair may recommend the Secretary-General or one person to join the company as Director.

8. Applications for Joining AHWP

A. The Regulatory Authority of any countries/ economies interested in joining AHWP shall send the application form to the Secretariat.

B. The Secretariat shall inform the AHWP Chair upon the confirmation of the application.

C. The applicants will be invited to attend the next AHWP Meeting where voting on their applications will take place.

9. Appointments of AHWP and AHWPTC Representatives

A. Member economies shall appoint their AHWP and AHWPTC Representatives and inform the Secretariat accordingly.

B. Member economies may also change their AHWP and AHWPTC Representatives by informing the Secretariat and the Chair accordingly.

C. Any disputes on representations should be referred to the Secretariat. The Secretariat shall seek comments from the Representatives from Regulatory Authority of that member economy before making recommendations to the AHWP Chair for the final decision.

10. Upkeep of Members and Representatives Records

A. The Secretariat shall keep the most up-to-date records of members, representatives, office bearers, working group members and special task group members.

B. The records kept by the Secretariat shall be the only official records.

C. Members, representatives, office bearers, working group members and special task group members shall ensure that their contact email addresses being kept by the Secretariat are correct.

D. Chairs of Technical Committee, Working Groups and Special Task Groups shall inform Secretariat of any changes in memberships under their charge.

11. Hosting AHWP and AHWPTC Meetings

A. Members intend to host any AHWP and/or AHWPTC Meetings shall plan ahead before making applications. They shall inform the AHWP Chair, AHWPTC Chair and Secretariat of their intention as early as possible. If there is more than one applicant, the decision shall be made in the AHWP Meeting through voting by Primary AHWP Representatives and the one with the highest number of votes will be selected. The chair of the meeting can cast an extra vote when there is more than one applicant having the highest number of votes. AHWP Meetings are normally held on yearly basis while the AHWPTC Meetings are held on need basis.

B. In the planning of a Meeting, the host member shall ensure that the event will be self-financed while sponsorships may be sought if needed. There shall be a contingency plan for the settlement of deficits that may arise.

C. The host member shall prepare a financial statement for posting on the AHWP website after the completion of the event. The surplus should be contributed to the AHWP Reserve.

12. Management of the AHWP Account and Reserve

A. The Secretary-General is responsible to supervise the AHWP account including that of the AHWP Administration Services Ltd. The Secretariat shall prepare annual financial statements and post them on the website.

B. The Secretariat shall prepare financial budgets for approval in the AHWP Meetings on annual basis. The ceiling of the overall budget shall not be exceeded unless the supplementary budget is approved as stated in paragraph C below.

C. If any budgets are needed without the approval in an AHWP Meeting or a supplementary budget is needed, an ad hoc Budget Committee shall be formed to vet and approve the request. The request shall be made to the Secretariat who shall seek the consent from the Chair to set up the Budget Committee. The Committee shall be chaired by the AHWP Chair or his/her delegate. All the AHWP and AHWPTC Representatives interested shall be invited through the Secretariat to join as Committee Members.

D. Annual operational surplus shall be pooled into the AHWP Reserve for supporting AHWP activities.

13. Management of the AHWP Website

A. The Secretariat is responsible to develop, operate and maintain the website.

B. The Secretary-General and/or the Deputy Secretary-General shall have the authority to decide whether any specific document/information should be posted or not. If there are any disputes, the Secretary-General shall consult the Chair for the final decision.

C. Logos of sponsors may be put on AHWP website whilst the money from the sponsorship shall be credited to the AHWP account.



14. Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat

A. Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions.

B. Documents shall be labeled "DRAFT" when they are prepared for discussion within their group members.

C. Documents shall be labeled "PROPOSED" if they are prepared for the discussion in the AHWP and/or AHWPTC Meetings.

D. Documents prepared for resolutions and/or approvals shall be labeled "PROPOSED FINAL".

E. Documents accepted, approved and/or prepared for already passed resolutions shall be labeled "FINAL".

F. "FINAL" documents should be forwarded to the Secretariat and posted on the website unless considered inappropriate.

15. Proposing Issues For Discussion in AHWP Meetings

A. Important policies and/or ways forward that may affect many members shall be brought up for approval as Issues For Discussion in AHWP Meetings. Resolutions shall be initiated for disputable issues.

B. Chairs of committees, working groups, special task groups, the Secretariat, AHWP Representatives and AHWPTC Representatives could initiate Issues For Discussion that shall reach the Secretariat at least one week before the AHWP Meeting. The Secretariat shall add them to the meeting agendas and post the related documents, if any, on the website.

C. Consensus views shall be sought in the AHWP Meeting to agree on the policies and/or ways forward regarding the Issues for Discussion. If no consensus could be reached, the Chair may appoint the AHWPTC, the Secretariat or any AHWP/ AHWPTC Representative to form a committee, working group or special task group to study the issues and make recommendations for resolving in the AHWP Meetings

16. Proposing Resolutions in AHWP Meetings

A. Resolutions shall be initiated for disputable issues after discussions so as to seek majority views from all AHWP members. Resolutions are only AHWP policies and/or recommendations that shall not be binding on members.

B. Chairs of committees, working groups, special task groups, the Secretariat, AHWP Representatives and AHWPTC Representatives could propose resolutions that shall reach the Secretariat at least one week before the AHWP Meeting. The Secretariat shall post the proposed resolutions and related documents, if any, on the website and add them to the meeting agendas.

C. All proposed resolutions shall be discussed and voted in the AHWP Meeting. A simple majority is needed to pass the resolution.

D. If the matter is under the purview of AHWPTC, the resolution shall be resolved in the AHWPTC Meeting before passing it to the AHWP Meeting for discussion and voting.

Historical Development of AHWP

Initial Stage in 1996-1997

AHWP was initiated by Asian member economies in 1996-7997 and gradually improved its organizational structure and working mechanism.

AHWP Meeting in 1998

In 1998, AHWP meeting was held in conjunction with GHTF meeting in Sydney, Australia. After the meeting, member economies of AHWP began to concentrate on promoting the regulation guidelines proposed by GHTF.

AHWP Meeting in 1999

In June 1999, AHWP convened its annual meeting in Bethesda, Maryland, US, electing Dr. Clarence Tan from the Health Services Authority (Singapore) as the interim chairman of AHWP, establishing and adopting AHWP Statutes of for the first time.

AHWP Meeting in 2000

In September 2000, the annual meeting of AHWP was held in Ottawa, Canada. Dr. Clarence Tan was elected to be the first Chairman of AHWP for a term of three years. It officially set up the framework of member economies and working mechanism, and appointed the representatives of member economies (a regulator and an industry representative designated by the regulator). AHWP also set up its Technical Committee and elected its leadership in the meeting.

On September 6-7, 2001, the first conference of AHWP Technical Committee was held in Kuala Lumpur, Malaysia.

1st Leadership of AHWP (September 2000-June 2005)		
Chairman	Singapore	Dr Clarence Tan
Vice Chairman	Hong Kong, China	Mr Ed Woo
1st TC Leadership (September 2000-May 2005)		
Chairman	Taibei, China	Mr Albert Li
Vice Chairwoman	Malaysia	Ms Eishah Abdul Rahman
Vice Chairman	Boston Scientific, Singapore	Mr Jack Moore

2nd Leadership of AHWP (June 2005-November 2008)		
Chairman	Malaysia	Dr R P Pillay
Vice Chairman	Siemens, China	Han Dehui
2nd TC Leadership (June 2005-November 2008)		
Chairman	Hong Kong, China	Mr. Albert POON
Vice Chairman	Singapore	Mr. Alfred KWEK
Vice Chairwoman	Taibei (Philips Company)	Ms. Daphne YEH

10th AHWP Meeting in 2005, Bangkok

The 10th Annual Meeting of AHWP was held in Bangkok on June 13-17, 2005, where the second leadership of AHWP was elected. Dr. Pillay from Malaysian Ministry of Health was elected Chairman of AHWP for a term of three years, and the Secretariat of AHWP was set up in Malaysia.

13th AHWP Meeting in 2008

The 13th Annual Meeting of AHWP was held on November 3-6, 2008 in New Delhi, India, where the third leadership of AHWP was elected. At the meeting, Wang Baoting, Director of the Department of Medical Devices Supervision of China State Food and Drug Administration (SFDA), was elected chairman of AHWP for a term of three years.

14th AHWP Meeting in 2009

The 14th Annual Meeting of AHWP was held on November 4-7, 2009, in Hong Kong, China. Some 350 representatives from 27 countries and regions participated in the meeting.

15th AHWP Meeting in 2010

The 15th Annual Meeting of AHWP was held from November 27 to December 1, 2010, in Riyadh, Saudi Arabia.

16th AHWP Meeting in 2011

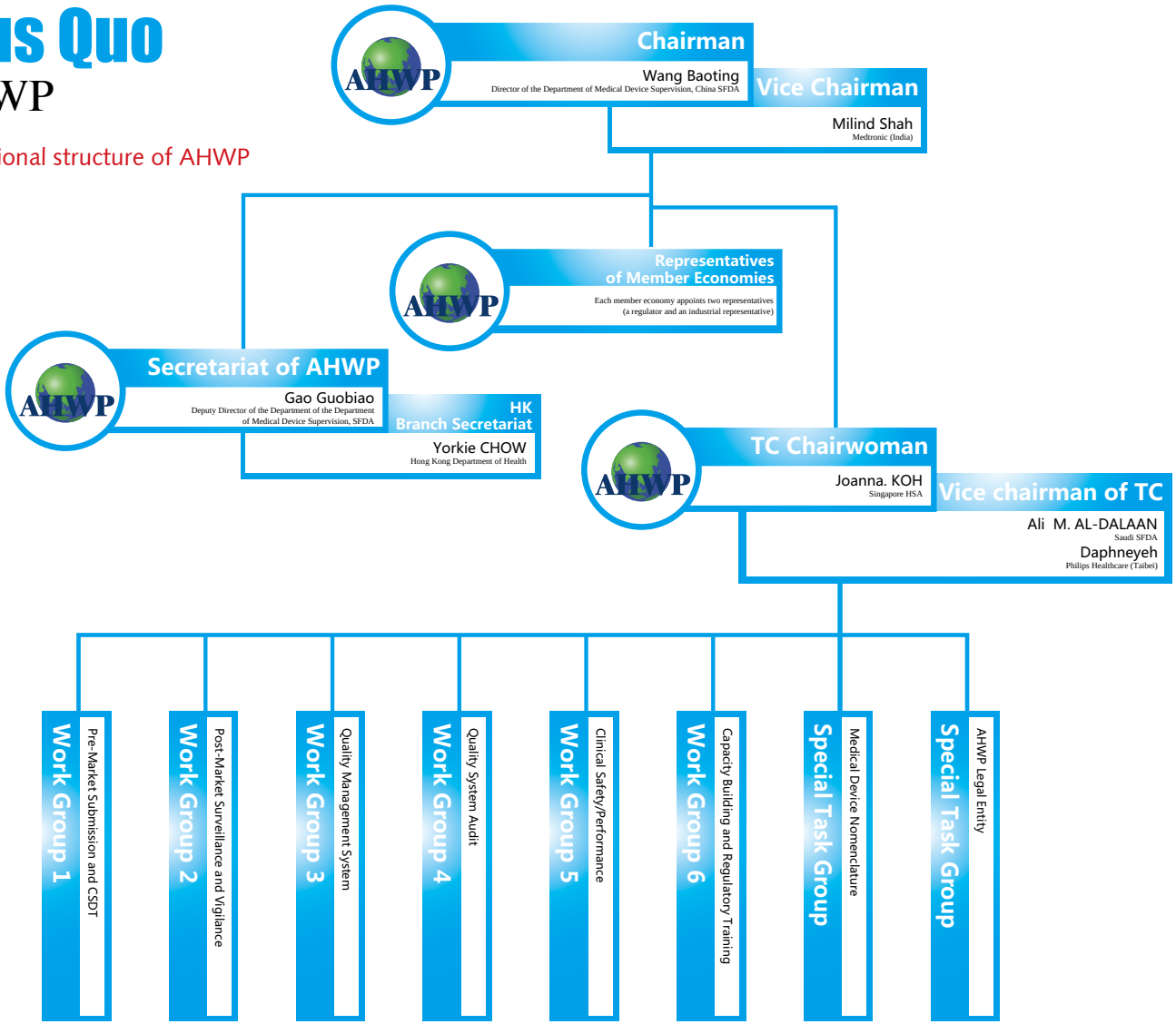
The 16th Annual Meeting of AHWP was held on November 8-12, 2011, in Bali, Indonesia.

AHWP TC Meeting

1. The 1st AHWP TC meeting was held in Kuala Lumpur, Malaysia on September 6-7, 2011;
2. The 2nd AHWP TC meeting was held in Bangkok, Thailand on December 12-13, 2002;
3. The 3rd AHWP TC meeting was held in Taibei, China on April 29-30, 2004;
4. The 4th AHWP TC meeting was held in Bangkok, Thailand on June 13-14, 2005;
5. The 5th AHWP TC meeting was held in Seoul, South Korean on September 15, 2006;
6. The 6th AHWP TC meeting was held in Hong Kong, China on April 26-27, 2007;
7. The 7th AHWP TC meeting was held in Chengdu, China on October 24, 2007;
8. The 8th AHWP TC meeting was held in New Delhi, India on November 3, 2008;
9. The 9th AHWP TC meeting was held in Hong Kong, China on December 4, 2009;
10. The 10th AHWP TC meeting was held in Singapore on May 11-12;
11. The 11th AHWP TC meeting was held in Taibei, China on September 7, 2010;
12. The 12th AHWP TC meeting was held in Riyadh, Saudi Arabia on November 27, 2010;
13. The 13th AHWP TC meeting was held in Seoul, South Korea on May 6-7, 2011.

Status Quo
of AHWP

1. Organizational structure of AHWP



2. Present Leadership of AHWP and Representatives of Member Economies

AHWP Chair	Mr Wang Baoting	State Food and Drug Authority, People's Republic of China
AHWP Vice-Chair (Industry)	Mr Milind Shah	Managing Director, India Medtronic Pvt. Limited, India

Governmental Representative	Industrial Representatives
Abu Dhabi Dr. Mohammed ABUELKHAIR Director of the Section of Drug and Medical Product Supervision, Department of Health Administration	TBD
Brunei Dr. Sablee ASPAR Senior Biomedical Engineer of Ministry of Health	TBD
Cambodia Ms. Kuy Heang Department of Food and Drug Administration, Cambodia Ministry of Health	TBD
Chile Regina PEZOA Instituto de Salud Publica (ISP)	Giovanna BENITEZ Johnson & Johnson (Chile)
Taibei, China Li-Ling LIU, Director Department of Medical Device and Cosmetics, Taibei SFDA, China	Daphne YEH Taibei Philips, China
Hong Kong, China Dr. Teresa LI Medical Device Control Office of Hong Kong Department of Health	Mr Jack WONG
India Dr. S Eswara REDDY Ministry of Health and Family Welfare	TBD
Indonesia Dr. T Bahdar J HAMID Administration of Drug and Medical Devices, Ministry of Health, Indonesia	Fiametta SACRA Johnson & Johnson (Indonesia)
Jordan Dr. Anan Abu HASSAN Jordan Food and Drug Administration	Dr. Mohammed Saleem Jordan SIPS
Saudi Arabia Dr. Saleh S AL-TAYYAR SFDA	Mr. Fahad Faisal Almoammar Saudi Arabia

South Korea Yang Rae RHO KFDA	Eun-Hee CHO Abbott (South Korea)
Laos Bounxou Keohavong Food and Drug Administration, Ministry of Health	TBD
Malaysia Dr. Myint SEIN Department of Medical Devices, Ministry of Health, Malaysia	Tony LOW Malaysia BSI
Myanmar Dr. Myint SEIN Deputy Director General of Myanmar Pharmaceutical Factory	TBD
Pakistan Mr. Sheikh Ansar AHMAD Drug Administration of Ministry of Health	Sardar N H ALAMGIR Johnson & Johnson (Pakistan)
China Wang Baoting SFDA	Han Dehui Siemens (China)
Philippine Director, Maria Cecilia MATIENZO Department of Non-Radioactive Medical Device Supervision, Administration of Medical Devices and Technologies	TBD
Singapore Ms. Joanna KOH Health Science Authority	TBD
South Africa Dr. TOIT Deputy Director of Radiation Control and Medical Device Administration, Department of Health, South Africa	Tanya Vogt COO of South Africa Association for Medical Devices Industry
Thailand Ms. Yuwadee PATANAWONG Director of the Department of Medical Device Control, TFDA	Ms. Mallika LATAVALYA NA AYUDHAYA Thailand Association for Medical Devices and Technologies
Vietnam Mr. NGUYEN Minh Tuan Deputy Director of the Department of Medical Device and Construction, Ministry of Health	Mr. NGO Hung Cuong Johnson & Johnson (Vietnam)
Yemen Mr. Safwan Ali Al Aoudi Ministry of Health	TBD

3. AHWP TC and Leadership of Work Groups

AHWP TC: Chairman, Vice Chairmen

Chairwoman	Ms Joanna KOH Singapore HAS	Regulator
Vice Chairman	Mr Ali M. AL-DALAAN Saudi Arabia SFDA	Regulator
Vice Chairwoman	Ms Daphne YEH Taibei Philips Healthcare, China	Non-regulator

AHWP's Work Groups: Chairmen, Vice Chairmen

Work Group 1 (WG1)-Pre-market Approval

Chairwoman	Ms Huifen BAI Singapore HAS	Regulator
Vice Chairwoman	Ms Daphne YEH Taibei Philips Healthcare, China	Non-regulator

Work Group 2 (WG2) –Post-market Supervision System

Chairman	Mr Yorkie CHOW Hong Kong Department of Health	Regulator
Vice Chairwoman	Ms Chadaporn TANAKASEMSUB (Miang) Zimmer	Non-regulator

Group 3 (WG3) –Quality Control System

Chairman	Mr Ali M AL-DALAAN Saudi Arabia	Regulator
Vice Chairman	Mr. Ronald GOON Johnson & Johnson (Singapore)	Non-regulator

Work Group 4 (WG4) –Quality Control System Assessment

Chairman	Mr Moloy MITRA Indian Ministry of Health and Family Welfare	Regulator
Vice Chairman	Eun Hee CHO Abbott (South Korea)	Non-regulator

Work Group 5 (WG5) – Clinical Trials and Investigation

Chairwoman	Gao Jie China SFDA	Regulator
Vice Chairwoman	Ms Quan TRAN GE Healthcare (Singapore)	Non-regulator

Work Group 6 (WG6) –Capability Building and Regulation Training

Chairman	Mr Yiting CAI Singapore HAS	Regulator
Vice Chairman	Mr Jack Won Johnson & Johnson Healthcare (Singapore)	Non-regulator

Special Task Group (STG–Nomenclature) - Nomenclature of Medical Devices

Chairman	Yang Lianchun China SFDA	Regulator
Vice Chairman	Chen Li Johnson & Johnson Healthcare (China)	Non-regulator

Special Task Group (STG - Legal Entity) – AHWP Legal Entity

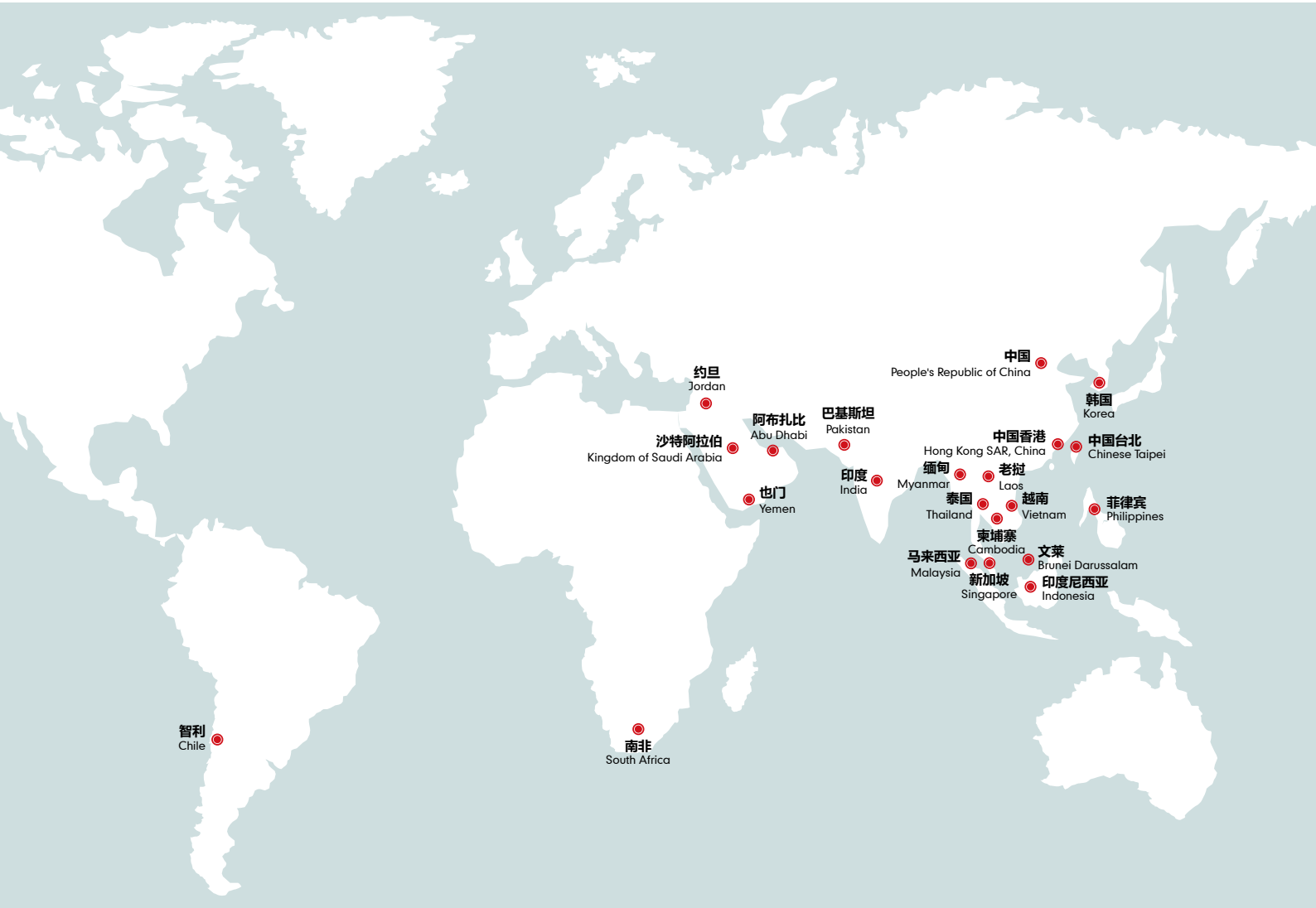
Chairwoman	Ms Althea LAU Hong Kong Department of Health	Regulator
Vice Chairman	Mr. Jack Wong Johnson & Johnson (Singapore)	Non-regulator

4. Structure of the Secretariat

Secretary General	Gao Guobiao	China SFDA
Executive Vice Secretary General	Zhu Xuejun	China National Medical Equipment Co. Ltd
Assistants	Jack Wong	Johnson & Johnson, (Singapore)
	Byran Su	Hong Kong Productivity Council
Vice Secretary General	Du Huiqin	China SFDA
	Wang Xiangyu	China SFDA
	Zhou Xulin	The Medical Device Control Office of Hong Kong Department of Health
SecretarySecretary	Peng Da	China SFDA

5. Member Economies of AHWP

AHWP has a total of 22 member economies now.



Asian Harmonization Working Party Blue Paper

PART 2

Activities of AHWP from 2009 to 2011

Activities
of AHWP Secretariat

1. Preparation for the Secretariat's Establishment

In the 13th Annual Meeting of AHWP held in India in November 2008, China took over the presidency of AHWP. Then in December 2008, the AHWP Secretariat was established, Mr. Gao Guobiao from SFDA was appointed the Secretary General, Mr. Zhu Xuejun from CAMDI was designated the Executive Vice Secretary General. Ms. Du Huiqin, Mr. Wang Xiangyu from SFDA and Mark Lau from Hong Kong's Department of Health held the posts of Vice Secretary General. Both the operational system and mechanism were set down at the meeting. The AHWP Secretariat was inaugurated in China Association for Medical Devices Industry (CAMDI) and a branch of the Secretariat was established in Hong Kong, mainly responsible for tasks such as the website maintenance.

2. Three-year (2009-2011) Working Plan Workshop

On December 20, 2008, AHWP held its 2009-2011 working plan conference in Shenzhen, China, which was presided by Mr. Wang Baoting, Chair of AHWP, Mr. Gao Guobiao, Secretary-general of the Secretariat and Mr. Alfred, Chair of TC. The conference was also attended by TC Vice Chairmen of TC, Chairs and vice Chairs of working groups, the staff responsible to prepare for the Secretariat's establishment, and representatives from CAMDI and related enterprises.

The main contents of the conference included: firstly, passed the appointments of AHWP Secretariat. secondly, reviewed and passed the "2009-2011 Working Plan of AHWP", which included publishing E-journals of AHWP, annual collection and comparative study of member economies' regulation systems, statute revision and approval and cooperation with GHTF, APEC and other international organizations; thirdly, reviewed and passed the "2009-2011 Working Objectives of AHWP", which included setting up the principles to classify and name medical devices, harmonizing the requirements for registration documents and establishing the info sharing platform of adverse events and recalls of medical devices; fourthly, reviewed and passed the Main Tasks of AHWP in 2009, such as comparative study of member economies' regulation systems, convening the 14th Annual Meeting, publishing E-journals, participating the conference of GHTF and training programs from APEC on regulation harmonization; fifthly, heard and discussed TC chair and each working group's detailed working plans and objectives in the upcoming three years.

3. Handover of the AHWP's Secretariat

In line with the working plan, Mr. Gao Guobiao, the newly appointed Secretary General of the Secretariat and other three officials from the Secretariat visited in succession Singapore Health Sciences Authority, Malaysian Ministry of Health, Hong Kong's Department of Health to hand over the Secretariat's work, which included handing over documents of the last Secretariat, discussing the transfers of AHWP's website and funds, as well as talking over the nomenclature systems and UDI of medical devices and the preparation of taking part in GHTF conference.

The visit helped to complete the handover of the AHWP Secretariat, understand the operational situation and mechanism of the Secretariat, sort through various regulations of AHWP, and also boost the exchange between the Secretariat and member economies.

Structure and Operational Mechanism of the AHWP Secretariat

1. Structure of the Secretariat

The Secretariat of AHWP is the standing body to assist the AHWP Chair to perform his duty.

- The Secretariat’s tasks include:

(1) Assist to organize various meetings of AHWP;

(2) Supervise the Technical Committee of AHWP and various working groups;

(3) Take charge of the communication and cooperation between AHWP and other international organizations;

(4) Manage the website of AHWP;

(5) Distribute a variety of publications of AHWP;

(6) Carry out routine management over the corporate body of AHWP;

(7) Complete other tasks assigned by man AHWP Chair.

- Structure of the Secretariat

The Secretariat consists of representatives from SFDA, Hong Kong’s Department of Health, CAMDI and related enterprises. For convenience sake, the Secretariat sets up a branch in Hong Kong, China.

Components & Mechanisms 组成和机制

2. Working System and Requirements of the AHWP Secretariat

- Regular Meeting System

The Secretariat of AHWP convenes its plenary meeting semiannually and the meeting of Vice Secretary Generals once a quarter. These meeting are presided over by the Secretary General.

- Work Requirements for the Secretariat's Members

(1) Before conducting outside contact on behalf of the Secretariat, its members should firstly be ratified by the Secretary General or even the Chairman in the case of momentous affairs. After the activities, they should report to the Secretary General;

(2) The Secretariat's members are forbidden to carry out unwarranted external activities;

(3) The Secretariat's workflow is "members-Vice Secretary General-Secretary -Chair."

3. The Branch Secretariat of AHWP in Hong Kong

For convenience sake, the Secretariat particularly sets up a branch in Hong Kong, which accepts the command of the Secretariat.

- Main Responsibilities of the Branch Secretariat in Hong Kong

Facilitate the internal connection of member economies and TC work groups;

Maintain the contact between AHWP and GHTF, APEC, WHO and other international organizations;

Manage the website of AHWP;

Manage the funds of AHWP;

Accept sponsorship from enterprises or organizations.

Activities
of the AHWP Secretariat

1. Plenary Meeting of the Secretariat in June 2009, Jinan

The 1st Plenary Meeting of the AHWP Secretariat was held in Jinan, Shandong province on June 25-26, 2009.

The meeting summarized the AHWP Secretariat's work in the first half year of 2009, examined and adopted the Secretariat's operational system, heard to Hong Kong's Ministry of Health to report the preparation of 2009 Annual Meeting of AHWP, and mapped out the Secretariat's work plan in the second half year of 2009.

The plenary meeting enhanced the communication of the Secretariat's members, especially between them and the branch Secretariat in Hong Kong, standardized the Secretariat's operational mechanism, and subdivided the Secretariat's work, therefore laying solid foundation for the smooth implementation of subsequent activities of AHWP.

2. Plenary Meeting of the Secretariat in September 2009, Zhuhai

The 2nd Plenary Meeting of the AHWP Secretariat in 2009, also the Preparatory Meeting of the 14th AHWP Annual Meeting, was convened on September 1-2 in Zhuhai City.

During the meeting, Hong Kong branch Secretariat introduced the preparation progress of the 14th AHWP Annual Meeting, including collection of member economies' regulations, preparation of meeting documents and souvenirs, etc. Other issues, such as the revision of AHWP Statute, the setup of legal entity, the nomenclature system of Asian medical devices, the replacement of TC Chair and the host city of the 15th AHWP Meeting, were reviewed at the meeting as well. Finally the meeting fixed the later part of October as the time for the Secretariat to inspect the preparation work of Hong Kong meeting.

3. Plenary Meeting of the Secretariat in January 2010, Beijing

On January 7-8, 2010, the Secretariat held its 3rd Plenary Meeting in Beijing. The meeting summed up the Secretariat's main work in 2009; reviewed the summary report of the 14th AHWP Annual Meeting delivered by Hong Kong branch Secretariat; discussed the Secretariat's working plan in 2010 and the preparation work of 2010 Annual Meeting in Saudi Arabia.

4. Plenary Meeting of the Secretariat in July 2010, Shanghai

The 4th Plenary Meeting of the Secretariat was held in Shanghai on July 22-23, 2010, and attended by Mr. Wang Baoting, AHWP Chair, and all the Secretariat's members. Dr. Saleh, Deputy Director of the State Food and Drug Administration of Saudi Arabia, and Ms. Joanna, TC chair, were invited to participate in the meeting as well.

The meeting mainly discussed the organizational work arrangement of 2010 Annual Meeting in Riyadh, Saudi Arabia, and Mr. Saleh, Deputy Director of the State Food and Drug Administration of Saudi Arabia, introduced the meeting's preparation progress. In addition, Ms. Joanna, Chair of AHWP's Technical Committee, summarized the 10th TC Meeting in Singapore held in May and introduced the preparation of Taibei TC Meeting in September. Meanwhile, the AHWP Secretariat talked about the website, E-journals, funds of AHWP and issues related to those new member economies which were expected to enter AHWP in 2010.

5. Plenary Meeting of the Secretariat in March, 2011, Beijing

The 5th Plenary Meeting of the Secretariat was held in Beijing on March 10-11, 2011.

The meeting summed up the Secretariat's work in 2010. The website of AHWP, maintained by Hong Kong Productivity Council, had developed along the right lines in 2010, acquiring steady sponsorship and sufficient operational funds. The website covered in time all meetings of AHWP and the progress those work groups made. The website of AHWP had grown to be a vital medium to distribute the global development of AHWP.

6. Plenary Meeting of the Secretariat in September 2011, Beijing

On September 20-21, 2011, the Secretariat held the 6th Plenary Meeting in Beijing, which was also the last such meeting in this Secretariat's term. This meeting summarized the main tasks of Secretariat in 2011, heard the preparations on 16th annual meeting reported by Indonesian Ministry of Health and discussed the election of new term of AHWP.

Activities
of AHWP Technical Committees

Work Group 1 (WG01) – Pre-Market Submission and CSDT

- Introduction

AHWP WG01 is focused on premarket requirements for medical device. According to Dec 2008, AHWP planning meeting in Shenzhen, following WG01 plan was set:

(1) Prepare comparison of GHTF STED and AHWP CSDT

(2) Prepare and finalize guidance on AHWP CSDT

(3) Implement pilot trial on AHWP CSDT in AHWP member economies

(4) Study GHTF's Definition of Manufacturer (importer, authorized representatives) and issues related to product registration and import due to different definitions

(5) Come out with proposal related to Definition of Manufacturer

From 2009 – 2011, under the leadership of HAS officers, Elaine TAN, Marianne YAP and Hui Fen BAI as WG1 Chair and Daphne YEH as WGI Co-chair, WG01 achieved the following results:

- Topic-wise:

(1) Completed the comparison of CSDT and STED jointly with GHTF SG01 and published on AHWP website (posting tbd with AHWP secretariat).

(2) Completed the guidance document of CSDT for ASEAN (posting tbd with AHWP Secretariat).

(3) Continuous updated on the implementation status of CSDT in Singapore for members' reference, position WG01 as a platform to understand CSDT requirements Introduced GHTF SG01 guidance document to members in timely manner

(4) Come out with proposal on Definition of Manufacturer with focus on good practice sharing in resolving product approval and importing issue (by Nov 2011).

(5) Come out with proposal related to medical device classification (by Nov 2011)

(6) Come out with proposal on combination products (by Nov 2011)

(7) Come out with proposal on medical device labeling with focus on localization issue (by Nov 2011)

(8) Grouping of medical device in registration and change manager will be 2012 target.

- Structure-wise:

(1) Monthly t-con to connect WG01 members and maintain member list

(2) Set up of five subgroups to facilitate progresses

(3) Enhance the participation in GHTF SG01 meeting from 2 rep. to 4 rep. from 2010

(4) Held GHTF SG01 meeting in Beijing and held SG01 Training for Chinese audience in June 2011

Open WG01 participation to non AHWP members and accept as WG01 full member by level of contribution

Potential Topics for 2012, moving forward:

(1) Grouping of Medical Device in registration

(2) Change Management

(3) Regulated Product Submissions (e-submission format)

Work Group 2 (WG02) – Post-Market Surveillance and Vigilance

- Objectives

(1) Examine the requirements for the reporting and dissemination of medical device safety alerts;

2. Recommend an harmonized approach in the following areas:
   - Sharing of medical device safety alerts;
   - Defining the roles and responsibilities of regulatory authorities, manufacturers and their representatives in the reporting and dissemination of medical device safety alerts.

Work towards a harmonized regional Safety Alert Dissemination System with a view to link with the GHTF National Competent Authority Report (NCAR) Exchange Program;

- Key Achievements

(1) Completed the postmarket surveillance survey in 2008

(2) Implemented SADS (Safety Alert Dissemination System) since 2008.

In November 2011, we asked all the AHWP TC members to re-apply the SADs members. As a result, 15 AHWP countries economy members as follows have been joined SADS.

- Health Authority, Abu Dhabi
- State Food and Drug Administration, China
- Department of Health, Hong Kong
- Ministry of Health, Indonesia
- Jordan Food & Drug Administration, Jordan
- Medical Device Bureau, Ministry of Health, Malaysia
- Ministry of Health, Pakistan
- Bureau of Health Device & Technology, Department of Health, Philippines
- Saudi Food and Drug Authority, Saudi Arabia
- Health Sciences Authority, Singapore
- Ministry of Health, South Africa
- Medical Device Control Division, Food and Drug Administration, Thailand
- Ministry of Health, Yemen
- Chile
- Chinese Taipei

Saudi Arabia FDA (SFDA) has reviewed all the safety alert of GHTF founder members website and disseminated to all relevant organizations in Saudi Arabia therefore we asked SFDA to extend the list to all the SADS members. Currently WG02 successfully disseminate these safety alerts information in weekly basis.

(1) Coordinate with GHTF SG02 for AHWP economics members to apply NCAR membership. So far there are 4 economy members are official NCAR members (Hong Kong, Saudi Arabia, Thailand and Chinese Taipei)

(2) Actively participated GHTF SG02 meetings. There are 2 representatives from WG02 (regulators and industry), Essam M. AL-MOHANDIS, SFDA, Saudi Arabia and Miang TANAKASEMSUB (AHWP TC WG02 co-chair)

(3) Harmonized AR from across AHWP economy members
   - Proposed AE Form for AHWP approval
   - Post the electronic AR Form on the AHWP website

(4) Harmonized FSCA from across AHWP economy members
   - Proposed FSCA Form for AHWP approval
   - Post the electronic FSCA Form on the AHWP website

(5) 6 officials SADs training to all the regulators

- Proposed Projects

(1) On-going items
   - Maintenance of SADS
   - Develop Safety Alert Assessment Guideline for Regulatory Authorities

(2) New Items
   - Develop PMS training tools

Work Group 3 (WG03) –Quality Management System

- Achievement：

  (1) Adapted N17 (Guidance on the control of product and services obtained from suppliers) as joint work with GHTF SG03.

  (2) Established N18 (Guidance on corrective action and preventive action) as joint work with GHTF SG03

  (3) Circulate N18 to be reviewed by AHWP member economies and industry to adapt AHWH CAPA

  (4) Participate in development of N19 with GHTF SG03

- Next Steps

  (1) Complete QMS survey by obtaining responses from remaining AHWP member economies and analyzing data.

  (2) Complete development of N19 with GHTF SG03

  (3) Review comments and feedback from AHWP on B18 and evaluate for adoption by AHWP

  (4) Work with GHTF SG03 and ISO TC210 to evaluate need for revision of ISO 13485 and, if application, to work on the follow-up activities

Work Group 4 (WG04) –Quality System Audit

- Introduction

WG04 was firstly formed for AHWP in 2009 and the working item was developed studying ISO 13485 to understand quality management requirements for auditing. And then identified the demands of AHWP member economies for auditing through the survey.

- Achievement

Guidance for auditing, training for auditors, standardized report format was identified as a top priority in 2010. According to the survey result, WG04 decided to review GHTF SG04 guidance which satisfies all demands of AHWP member economies in 2011. The goal for WG04 is to propose to member economies to adopt GHTF guidance documents in Bali Meeting sharing the key highlights of each guidance with AHWP member economies. In 2012 onwards, the work items will be having an official AHWP guidance and the training for the member economies for guidance will be required.

Work Group 5 (WG05) – Clinical Safety/ Performance

- Background:

WG5 was first formed in Nov 2008 to mirror GHTF SG5 in addressing medical device issues pertaining to Clinical Safety & Performance with the elected Chair: Director Gao Jie, SFDA China & Co-Chair: Tran Quan, GE Healthcare. The wor group has progressed on track according to the work plan 2009-2011.

- Work Items:

(1) Establish WG5 representation at GHTF SG5 & participate in the development of SG5 guidance documents

(2) Comparative study of Clinical Trials regulations & related guidances on Clinical Safety/Performance in AHWP member economies

(3) Review SG5 & other relevant guidance documents and make recommendations to AHWP member economies on the feasibility of adoption

(4) Training to promote Good Clinical Practice, Declaration of Helsinki & ISO 14155 governing clinical investigations

(5) Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/ performance eg. WG01 regarding CSDT's section on clinical evidence

- Accomplishments

(1) WG5 setup: 19 members consisting of regulators/ industry, covering 6 member economies (China, Singapore, India, Korea, Malaysia, Chinese Taipei).

(2) Co-Chair established membership & participation in SG5 initiatives to effectively disseminate SG5 information & guidance documents amongst WG5 & AHWP member economies & feedback to SG5 initiatives/guidance documents

(3) Advisory Expert Panel of 6 GHTF SG5 members formed mid 2010 for greater support on training & advice on GHTF SG5 documents review & adoption

- Chair (MHRA, UK) & Vice Chair (Industry, Canada); 2 Japan, PMDA officers; 2 Industry experts (EU & Australia)

(4) Comparative study of Clinical Trials regulations in AHWP member economies with 2 surveys conducted.

- Phase I completed in 2009 - 10 member economies responded on Clinical Trials regulations implementation in China, Hong Kong, Singapore, Saudi Arabia, South Africa, Korea, Chinese Taipei, Malaysia, Thailand & Philippines respectively.
- Phase II Follow up to be completed by Oct 2011 – In depth review of adoption of GHTF guidance documents: 1) Clinical Evidence – Key Definitions and Concepts GHTF SG5/N1R8: 2007; 2) Clinical Evaluation GHTF SG5/N2R8:2007
- Taking into considerations of clinical trials regulation development of member economies to make recommendations to AHWP member economies on the feasibilities of adoption – by Nov 2011

(5) Completed studying and reviewing the 5 GHTF SG5 documents within WG5.

- AE reporting during clinical investigation (GHTF SG2-SG5)

- Post-market Clinical Follow-up Studies (GHTF/SG5/N4:2010)
- Clinical Investigations (GHTF/SG5/N3:2010)
- Clinical Evidence - Key Definitions & Concepts (SG5/N1R8:2007)
- Clinical Evaluation (SG5/N2R8:2007)

- Training completed:
  - Training at 14th AHWP meeting, HK, Nov 2009: Medical Device Regulations in Japan with focus on Clinical Trials regulations (Speaker: Mr Azuma Kentaro, MHLW, Japan)
  - Training at 10th AHWP TC meeting, Singapore, May 2010: Painting the Clinical Picture - Clinical Evaluation & Clinical Evidence (Speaker: Mr. Greg LeBlanc, Vice Chair GHTF SG5)
  - Training at APEC Harmonization Centre Workshop for Medical Device, Korea, Nov 2010: Co-Chair moderated on Clinical Investigation Policies in major countries; Co-ordinated speakers from SG5 experts: a) Overview of GHTF/SG1 activities & GHTF/SG 5 key definitions – Atsushi Tamura, PMDA, Japan; b) Focus on Clinical Evaluation GHTF SG5/N2R8:2007 – Greg LeBlanc, Cook, Inc.; c) Requirements and suggestions for Clinical Trial Investigations – Herbert Lerner (USFDA); d) Post Market Clinical Follow up Studies GHTF SG5 N4:2010 – Madoka Murakami, PMDA, Japan
  - Training at 15th AHWP annual meeting, Saudi Arabia, Nov 2010: a) ISO14155 (Speaker: Ms. Danielle Giroud, Convenor TC 194 WG4); b) Reflection on clinical trials regulation development – A WG5 member perspective (Speaker: Prof Mi Xian Qiang); c) Clinical Trials Regulatory development in India (Speaker: Sumati Randeo)

- Future Opportunities
  - Partner with other TC work groups' initiatives to provide expertise & input relating to clinical safety/performance
  - Partner with GHTF SG5 Advisory Expert Panel to provide guidance for clinical trials regulations development in emerging countries
  - Training modules on regulatory aspects of clinical safety/performance through e-learning platform

Work Group 6 (WG06) – Capacity Building and Regulatory Training

- Achievements

  (1) Training syllabus was agreed in AHWP TC and AHWP meetings before

  (2) Training will be online as agreed

  (3) Partners were identified. WG06 will work with APEC and HKU for future trainings

  (4) A page of country requirement websites link with disclaimer was done in AHWP website already http://www.ahwp.info/index.php?q=node/35

- Next Steps

  (1) AHWP to explore and leverage on APEC AHC framework for regulatory convergence for training

  (2) Additional Topics to include – combination products, clinical evaluation and training to qualify a member to be a key contributor in a work group (e.g. SADS)

  (3) WG06 Chair and co-chair to draft strategic training roadmap for consideration during Bali meeting

  (4) Each WG may continue to conduct training. TC will endorse and approve the training direction, justification for type of training and trainer.

Special Task Group (STG – Nomenclature) – Medical Device Nomenclature

- Introduction

Medical device nomenclature system facilitates the management and regulation by standardizing terms that enable communication despite linguistic and other barriers. There is several medical device nomenclature systems used by different economies and group of professionals. AHWP recognized the importance of a regional/ global single nomenclature in effective and efficient medical device. In addressing the need of harmonization as well as the issues facing some economies on using of different nomenclature system, STG working group on nomenclature was established in 2008. STG works jointly with GHTF on resolving nomenclature issues. STG nomenclature later expanded its scope to cover UDI as both topics are close related to each other.

- Achievement

(1) Resolution passed on requirements of medical device nomenclature in Nov 2009, consensus achieved on criteria for a medical device nomenclature among AHWP members

(2) GHTF proposed new governance structure in the end of 2009 , AHWP was invited to participate new GMDN governance structure (1 Board of Trustee, 5 Policy Advisory Group); AHWP requested additional seats at board of trustee in 2010 to increase AHWP voice at GMDN, it was accepted.

(3) Finalize nomination of AHWP representatives to GMDN in 2011

- Board of Trustee: SingaporeHSA and Chinese SFDA
- Policy advisory group: China, Korea, India, Singapore, Saudi Arabia

(4) AHWP representative active participate GMDN reform in order to meet AHWP criteria

(5) Establish linkage and work with WHO on medical device nomenclature issue

(6) Work with GMDN on providing free access to AHWP regulators to GMDN

(7) Joint GHTF efforts in develop GHTF guidance on UDI

- Next Steps

(1) Moving toward a single global nomenclature system in the spirit of global harmonization.

(2) Working at GMDN on resolving fees / national license of GMDN

(3) Working with GMDN and each AHWP economy, ensure regulators' free access to GMDN and also get appropriate training on GMDN

(4) Continuous working with WHO on single medical device nomenclature

(5) Finish GHTF UDI document and promote the adoption in AHWP




Special Task Group (STG – Legal Entity) – AHWP Legal Entity

- Introduction

During various Asian Harmonization Working Party Technical Committee (AHWP TC) session held between June 2005 and 2008, several workgroups (WG) and special task group (STG) were formed to manage and deal with AHWP activities aiming at establishing harmonized requirements, procedures and standards for medical devices.

The issue to establish a legal entity was first brought up in early 2008 when WG06 was coordinating with the US Northeastern University to organize a regulatory training course for AHWP regulatory authorities and industries on different regulatory models and requirements with a view of training up competent regulatory staffs as well as working towards harmonization. According to the plan, some revenues would be generated from the training course for promoting AHWP activities. However, AHWP was not a legal entity and encountered difficulties in signing the contract with the University and opening a bank account for managing the money.

Furthermore, there was also a need to manage the website, organize sponsorship, arrange meetings and perform the day-to-day secretariat duties such as updating membership records and preparing meeting minutes. Therefore, the suggestion to form a legal entity was raised.

With the support of AHWPTC members, the TC Chair formed the STG tasked at establishing a legal entity for AHWP. In the 13th Meeting of AHWP at AHWP at New Delhi, India, The STG(LE) was officially established. Though the training course collaborated with the US Northeastern University did not work out eventually, the establishment of a legal entity for AHWP is still considered desirable for the long-term developments of the AHWP.

- Achievement

(1) The Memorandum and Articles of Association (M&A) document for the AHWP Legal Entity as a non-profit sharing company in Hong Kong was developed. The M&A document was finalized and uploaded to AHWP website in June 2010

(2) The existing AHWP Terms of Reference (ToR) has been reviewed and made available on the AHWP website

(3) Setting up AHWP Administration Service Limited (AHWP ASL) has been completed. AHWP ASL will be situated in Hong Kong with 5 Directors and 13 founding members in the Board so far :

Board of Directors

- President: Mr Ali Mohsin ZALDALAAN
- Treasurer: Mr Benjamin, Wai KitCHAN
- Vice-Treasurer: MrRicky, Chi Ming HO
- Director: MsHui-ChuanYEH
- Director: Mr LungWONG

Founding Members

(I) Regulator Members

- Mrs Joanna KOH, Health Science Authority, Singapore
- Ms Li-Ling LIU, Division of Medical Devices and Cosmetics, FDA Chinese Taipei
- Ms. AnaaSalch Abu HASSAN, Jordan Food & Drug Administration, Jordan
- Mr. Zamane Bin Abdul RAHMAN, Ministry of Health, Medical Device Bureau, Malaysia

(II) Industry Members

- Dr. Kulwant S SAINI, Johnson & Johnson Ltd, India
- Ms. Fiametta S. SOENARDI, PT GatrajasaMedika PRATAMA, Indonesia
- Mr. Tony LOW, Medical Device Conformity Assessment Services, Malaysia
- Ms. MallikaLatavalya Na AYUDHAYA, Thai Medical Device Technology Industry Association, Thailand

(III) Associate Members

- Mr. Mohd Amin Bin YAAKOB, Ministry of Health, Medical Devices Bureau, Malaysia
- Dr. Mohd AZMAN, Prinitis Resources SDN, BHD, Malaysia
- Ms. Annie ENG, MEDCERT Services, Malaysia
- Ms Suzette Caravana TOMANENG, QUE Standards SDN BHD, Malaysia
- Mr. Siew Leong, (Eric) CHIN, 3M Asia Pacific Pte Ltd, Singapore

- Next Steps

(1) To open a bank account for the revenue and any donated funds by Nov 2011

(2) To notify the AHWP Secretariat Team regarding the completion of all Legal Entity STG tasks, and to hand-over for the Secretariat Team to assign the secretariat support service from a competence organization, e.g. Hong Kong Productivity Council, through AHWP ASL under agreement terms.

Activities and Events
of AHWP (2009-2011)

1. 14th AHWP Annual Meeting in November 2009, Hong Kong

The 14th AHWP Annual Meeting was held on November 4-7, 2009 in Hong Kong Convention and Exhibition Center. More than 350 guests from 27 countries and regions attended the meeting, including representatives from member economies' government supervision departments and industry representatives, international organizations like GHTF and APEC, main medical device manufactures from the Europe, US and China. 20 member economies of AHWP all sent their delegates to the meeting, setting a record of the number of participating member economies.

The meeting reviewed the 2009-2011 Working Plan and Objectives of AHWP, compared the regulation systems of member economies, heard the reports from AHWP Technical Committee and various work groups, discussed the requirements for nomenclature system of medical devices, heard the reports about the latest progress of Philippine and Saudi Arabian medical device regulations and examined the revised AHWP Statutes and the bill of establishing the legal entity of AHWP. Besides, the meeting studied the initiative to enhance AHWP and APEC's cooperation in medical device regulation training programs and put forward proposals on cooperation. During the meeting, the expert seminar was arranged to identify the challenges faced by AHWP and probe its development direction.

The meeting approved "the AHWP Statutes (Revised Edition)", "Bill on Establishing the Legal Entity", and "Basic Requirements for the nomenclature System of Medical Devices". Moreover, GHTF representatives were invited to give theirs reports about the work progress of GHTF and various work groups. The meeting unanimously agreed that the next AHWP annual meeting would be held in Saudi Arabia.

During the meeting, the organizer, Hong Kong Department of Health, invited GHTF experts of medical device regulations to deliver speeches on the GHTF's researches, especially involved in aspects of the supervision of medical devices before and after marketing, clinical trials and quality systems.

2. 15th AHWP Annual Meeting in November 2010, Riyadh of Saudi Arabia

The 15th AHWP Annual Meeting was convened from November 27 to December 1 in Riyadh, Saudi Arabia.

At the AHWP Technical Committee Meeting, member economies adopted the proposal of appointing Mr. Yang Lianchun from China SFDA the Chair of Special Task Group(STG-Nomenclature). During the meeting, all work groups reported their work and achievements in 2010.

What's more, the meeting arranged a series of regulation trainings, such as the introduction of ISO 14155 and India's Clinical Trial Regulations, ECRI adverse events investigation, the introduction of European regulations on medical devices and qualified distributors as well as European regulators' harmonization effort, the suggestions on implementation of GHTF in the regulation system, and the responsibility sharing principle in the medical device regulation system. The meeting also invited Dr. Pillay from WHO to give a briefing on the status quo of replacing mercury-based medical devices, and Mr. Eamonn Hoxey from ISO to report any work progress the working group of ISOTC210 had made.

With Pakistan and Yemen entering AHWP during this meeting, the number of AHWP member economies was increased to 22. Some member economies, including Chile, Saudi Arabia, Taibei (China), India, Pakistan, Singapore, Hong Kong (China), Indonesia and Thailand, introduced their medical device regulation development. The AHWP Secretariat gave its 2011 Work Report, which included the Secretariat's two plenary meetings in 2010, the current use of AHWP funds, and summary of TC meetings in Singapore and Taibei. It also introduced the operation of AHWP website and the progress of establishing the AHWP legal entity.

The meeting adopted two resolutions, namely the revised AHWP Statutes and the Statutes of AHWP Legal Entity, discussed the cooperation between AHWP and WHO, APEC, LSIF and GHTF, and also invited the representative of GHTF to introduce the status quo of GHTF as well as the working progress of all work groups.

The meeting unanimously agreed that the 16th AHWP Annual Meeting was held in Indonesia.

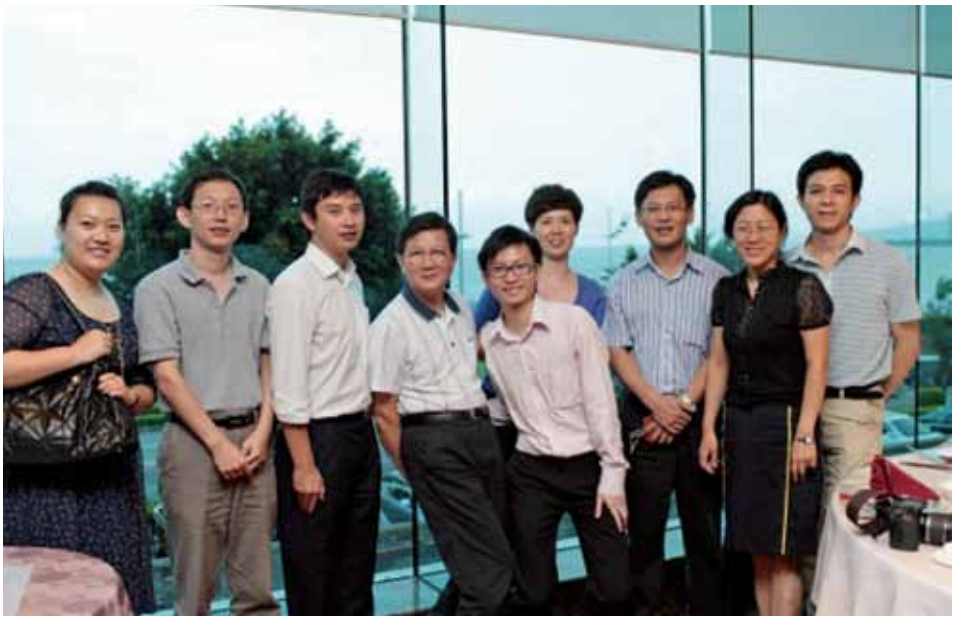

AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICES HARMONIZATION IN ASIA
亚洲医疗器械法规协调组织蓝皮书

Main
Progresses

With joint efforts of all member economies, AHWP smoothly pushed forward all its working plans, enrolled more and more member economies and played a vital role in Asian and even global medical device regulation harmonization.

1. New member economies in 2009 - 2011

In 2009 - 2011, AHWP enrolled 5 member economies including Jordan, Abu Dhabi Emirate of UAE, Chile, Pakistan and Yemen, with its number of members up to 22 and continuous expansion of influence.



2. AHWP website

The website obtained a new domain name and was managed by the branch Secretariat in Hong Kong. Presently, the website has its steady sponsors and sufficient operational funds. It is able to cover all the events of AHWP in time and has become an important medium to display the development of AHWP.

3. AHWP E-Journal

After the elaborate preparation in 2009, AHWP finally unveiled its E-journal in March 2010 through the Secretariat's Outside Contact Data Base. The AHWP Chair wrote an inaugural editorial for the journal, and Jack Wong from the branch Secretariat in Hong Kong, was obliged to run it.

4. Financial Procedure of AHWP Fund

Subsequent to the 14th Annual Meeting in Hong Kong, AHWP reconstructed its Fund. With the authorization of AHWP Chairman, AHWP Fund was employed during 2010-2011 to support many representatives to participate in the annual meetings of AHWP and invite some industrial celebrities to deliver speeches.

5. Ever-increasing International Influence Power of AHWP

AHWP had long been devoted to strengthening its cooperation with GHTF, WHO, APEC and other international organizations, further driving up its fame throughout the world. As a noticeable power, AHWP has played an important role in the global medical device regulation harmonization.

6. Establishment of AHWP Legal Entity to boost the development of AHWP

The work of establishing legal entity and permanent secretariat was steadily pushed forward as expected. The branch Secretariat in Hong Kong drafted the procedures to establish the legal entity, brought forward the staffing plan and openly enrolled shareholders and initiators at the 15th AHWP Annual Meeting.

7. Communication with TC and work groups is strengthened to offer excellent service.

8. The AHWP Secretariat further coordinated and supported the organizers to ensure that the 14th Hong Kong Annual Meeting in 2009, the 15th Riyadh Annual Meeting in 2010 and the 16th Bali Annual Meeting in 2011 were held smoothly.

9. The AHWP Secretariat has excellently functioned as a bridge among its member economies. It took one year to conduct a comparative study of the medical device regulations in its member economies, then compile and distribute the study results to the representatives of all member economies, thereby promoting the members to understand and exchange with each other. Still, the Secretariat consulted some member economies' representatives over several hot issues such as the naming and coding of medical devices, and also reached an agreement at the plenary meeting, which greatly accelerated the work progress of AHWP.

10. Collaboration with other international organizations.

As the outside contact arm of AHWP, the AHWP Secretariat has attached much importance to promoting AHWP. Through persistent efforts, it enabled AHWP to come into cooperation with WHO, APEC, LSIF, GHTF and other international organizations. In 2009, we successfully organized some member economies of AHWP to take part in the GHTF annual meeting and the APEC-sponsored medical device regulation training program in Australia, as well as 2010 APEC medical device regulation training program in Taibei and 2011 LSIF medical device regulation training program in Seoul. During those meetings, we insisted on inviting representatives of GHTF to introduce the status quo of GHTF and the progress its work groups had made.

Besides, the Secretariat has closely coordinated with GHTF, the Executive Committee of GMDN and other organizations on issues such as the nomenclature systems and UDI of medical devices, sparing no efforts to reach an agreement with them and promote the global harmonization of medical device regulations.

Asian Harmonization Working Party Blue Paper

PART 3

Collaborations with Other International Organizations

AHWP
and GHTF

A representative from WG2 industry Miang Tanakasemsub joined the first SG02 meeting in Washington DC in 2007. The regulators are joined SG2 officially, Essam M.Al-Mohandis SFDA, Saudi Arabia joined the first meeting in Brussels in 2009.

SG02 member acknowledge the need of AHWP to set up our own Safety Alert dissemination program as a learning program for NCAR therefore SG02 allows us to use the same reporting form. So far, there are 15 AHWP countries economy members as follows have been join SADS.

- Saudi Food and Drug Authority
- Department of Health, Hong Kong
- Medical Device Bureau, Ministry of Health, Malaysia
- Bureau of Health Device & Technology, Department of Health, Philippines
- Health Sciences Authority, Singapore
- Medical Device Control Division, Food and Drug Administration, Thailand
- Ministry of Health, Indonesia
- Health Authority, Abu Dhabi
- State Food and Drug Administration, China
- Jordan Food & drug Administration, Jordan
- Chinese Taipei
- Ministry of Health, South Africa
- Ministry of Health, Yemen
- Ministry of Health, Pakistan
- Chile

Saudi Arabia FDA has reviewed all the safety alert of GHTF founder members website and disseminated to all relevant organizations in Saudi Arabia therefore we asked SFDA to extend the list to all the SADS members. Currently WG02 successfully disseminate these safety alerts information in weekly basis.

SG02 offered the help with the Harmonized AE form across AHWP economy members. They reviewed our template and offered the HTML platform for AHWP consideration. We currently completed draft AE report form and call for AHWP approval.

SG02 acknowledge that we are harmonizing FSCA form across AHWP economy members. This project will perfectly support the new FSCA guideline that will be finalized by Q2 next year.

SG02 and WG02 are co-monitoring the SG02 documentation implementation status and prepare the annual report for AHWP website publication.

12 NCAR trainings have been conducted since 2007 when we started our collaboration.

SG02 created the SG02 documentation trainers pool and qualified both Miang and Essam to be GHTF SG02 training that reside in AHWP economy members.

There are 4 economy members have been granted as NCAR members. (Hong Kong, Saudi Arabia, Thailand and Chinese Taipei).

AHWP
and APEC

APEC workshop on on clinical evidence for premarket conformity assessment. It was held in Nov, 2010 in Seoul, Speakers from US FDA, Japan PMDA, GHTF experts, regulator and industry represeantive from APEC economies, over 200 regulators and industry represeantives from 12 APEC econmnies particiated the workshop.

The objective is to promote the understanding and implementation of GHTF guidance on clinical evidence in supporting premarket conformity asessment. There were about 200 participants from 12 APEC economies particiated the workshop.

Understanding the infrastructure needed in supporting clinical trial which is designed and conducted ethically and scientifically when it is required for premarket conformity assessment, building confidence on clinical data generated in other jurisdictions.

The topics covered are:

- Difference clincial evidence between device and drug
- Overview of GHTF global model and SG5 definition
- Focus on clincial evaluation and case studies
- Requirements and suggestions on clincial investigations
- Post market clincial follow up studies
- Clincial trial policies and regulation in key APEC countries
- Clinical Trial Design in Medical Device Clinical Trial to meet Regulatory Requirements on Premarket Conformity Assessment
- Medical Device GCP

It was held in July 2011 in conjuction with AHWP TC meeting in Seoul. Over 200 regulators and industry represeantives from 11 APEC economies particiated the workshop.

The objective of the workshop is to promote the understanding of GHTF guidance and share experience and lessons learned of the implementation.

The key topics covered are:

- GHTF global model
- QSM/GMP system and audit
- Essential principles, use of Essential Principles in Defining Safety and Effectiveness Requirements, checklist and case studies
- Review of medical device applications using STED
- Comparison of STED and CSDT
- Adverse Event Reporting
- Implemenation GHTF in Japan, Canada, and Singapore
- GMDN and UDI
- Utilization of GMDN in combination with GHTF risk-base classification rule

AHWP and WHO

AHWP attended WHO Informal Stakeholders' Consultations on Nomenclature for Medical Devices on 23-24 March 2011 at WHO Headquarter in Geneva.

Approximately thirty participants attended, including representatives from governments/regulators (Australia, China, Ghana, Denmark, EU, Germany, Hong Kong, Mexico, Tanzania and the United States), WHO's regional offices and industry.

Information was shared with participants. Including:

1. WHO recommended naming systems in health care
    a. International non-proprietary names for medicines
    b. International classification of diseases
    c. International classification for patient safety
2. Naming systems for health technologies
    a. GMDN
    b. UMDNS
    c. ISO standards
    d. SNOMED
3. Regulatory needs for medical device nomenclature
    a. Australia – Therapeutic Goods Administration
    b. European Commission
    c. Asian Harmonization Working Party
    d. Industry perspective – Janet Trunzo as GMDN Industry Rep.
4. Nomenclature needs for management purposes
    a. Ghana – clinical engineering department, Ministry of Health
    b. Mexico – Lists of medical devices for health care facilities, procurement or reimbursement and reference in clinical practice guideline
    c. Current situation in the Eastern Mediterranean countries
5. Future developments of nomenclature
    a. Global Harmonization Task Force
    b. U.S. Food and Drug Administration
    c. European Union

Mr. Wang Baoting, AHWP Chair made a speech. He said that AHWP noted the importance of the nomenclature issue from a patient safety, regulatory, procurement and management process. The AHWP established a committee to review the issue of naming of medical devices and concluded that the naming system should support government regulation and manufacturer registration. Whatever naming system to be adopted should be done so with caution, and

with focus on patient safety. AHWP is committed to working with the WHO and the development of a unified naming system through consensus.

Participants also discuss future action plan:

The following proposals/commitments were made for the following six month period which will move the discussion forward:

- Two naming agencies (ECRI and GMDN Agency) return to their Boards / Trustees with a view to making available information to facilitate a mapping exercise, and to a move towards convergence in the future. Each agency will report back.
- WHO will clarify the road map, raise the issue with the Classification Network to determine opportunities, discuss with patient stakeholders, discuss traditional medicine with interested parties, raise it with the IHTSDO stakeholders, discuss the UDI database with the FDA, discuss their respective databases with ECRI and GMDN with a view to creating a possible model, and evaluate the utility of a high level tabular list for medical devices.
- ECRI suggests working with WHO to see what mapping can be done with ICD-11, and to work with IHTSDO on a similar issue.
- WHO will provide information to Member States on both systems and review possibilities to provide free access.
- IHTSDO will engage with the GMDN agency, create a SNOMED CT mode, develop high level terms within a year, and work with the GHTF and regulators on this process.
- The EU will report to Member States, including on the process for the implementation of the EU/UDI, and request feedback.
- WHO will identify focal points (national regulatory agencies and HTM) within countries and promote the principles of nomenclature use for medical devices (for regulators and health technology managers).
- FDA will report back on advances with UDI.

Asian Harmonization Working Party Blue Paper

第四部分

The Future of AHWP

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As we have witnessed, after 15 years of development, AHWP has grown to be an international regulation harmonization organization with 22 member economies, spanning Asia, Africa and South America. It is the important communication channel of medical device supervision departments of Asian countries, the important institution for governmental departments and manufacturing enterprises to harmonize the regulations of different countries as well as the important platform to enhance Asian and even global medical device regulation harmonization.

The democratic, comprehensive and open characteristics have brought unlimited energy for AHWP, making it attract many developing countries and also gradually expand its global influence.

The globalization of medical device trade and the common demand for safe and effective medical devices have pressed for such an exchange platform for us to communicate and learn from with each other. AHWP has played a vital role in this aspect.

In the future, we hope to turn AHWP into an important platform for global medical device regulation harmonization:

1. The platform for member economies to communicate on the medical device regulations;
2. The platform for medical device regulation training;
3. The platform for enhancing the developing countries' supervision on medical devices;
4. The test platform for harmonizing the medical device regulations globally;
5. The platform for promoting international cooperation in the field of medical device regulations.

AHWP Technical Committee will continue to carry out some important researches:

(1) Popularize the use of CSDT and STED guidelines among member economies for preparation of medical device registration documents;

(2) Promote the adoption of STED from IVD;

(3) Set up the uniform after-sale supervision system--SADS (Safety Alert Dissemination System);

(4) Promote QMS requirements defined by GHTF in the member economies;

(5) Promote the establishment and improvement of approval authorities according to the status quo of member economies;

(6) Harmonize the clinical trial regulations of member economies;

(7) Set up an Online Regulation Training Center of AHWP;

(8) Promote the construction and improvement of AHWP organization and secure the capital and personnel for AHWP's future development;

(9) Harmonize the adoption of uniform nomenclature systems and UDI of medical devices.

Moreover, AHWP will continue to strengthen its cooperation with GHTF, APEC, WHO and other organizations, and jointly promote the global harmonization of medical device regulations, to benefit the people of all countries.

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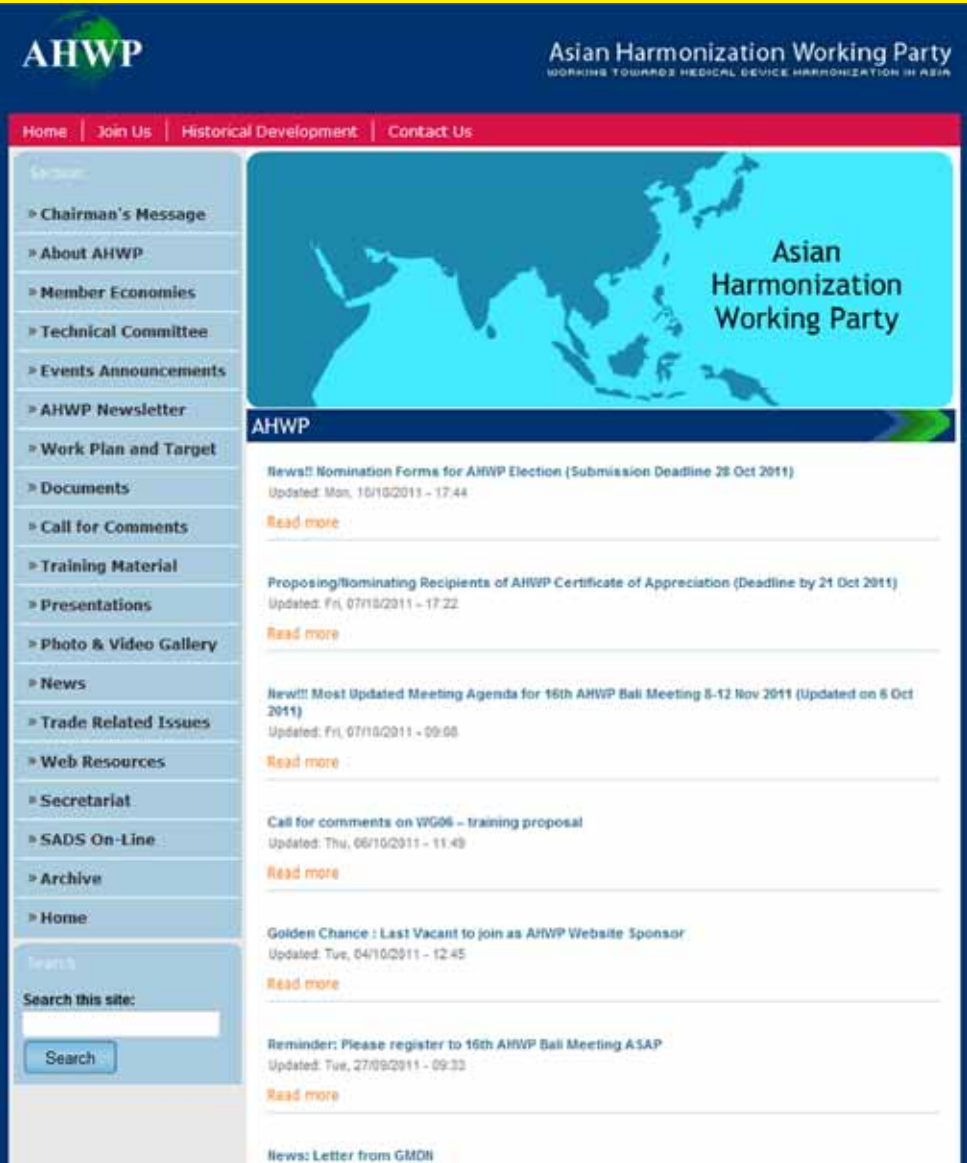
www.ahwp.info

Official Website of AHWP



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