ASIAN HARMONIZATION WORKING PARTY
Working towards medical device harmonization in Asia

REPORT OF THE 10th MEETING OF THE ASIAN HARMONISATION WORKING PARTY (AHWP)

Genting Highlands, Malaysia

24th – 25th November 2005

INTRODUCTION

1) The 10th Meeting of the Asian Harmonisation Working Party (AHWP) was held on 24th – 25th November 2005 at Genting International Convention Centre (GICC), Genting Highlands, Malaysia. The Meeting was chaired by Datuk Dr M S Pillay and co-chaired by Dr Davey Han. The objectives of this Meeting were;

i) to review and set policy directions for AHWP in terms of its objectives and goals;

ii) to discuss and to determine work programme covering functional strategic plans, activities, expected output, timeframe, responsible Member Economies or Technical Committee (TC) and financial resources.

WELCOME ADDRESS BY THE CHAIR

2) Datuk Dr M S Pillay, the Chair of AHWP welcomed all participants to Malaysia and to the 10th of AHWP. He informed the objectives of this Meeting and encouraged all members to work hard so that AHWP can be a major global player in regulation of medical devices. He pointed out that Member Economies in the Asian region represent a diverse group with different regulatory status and with the largest population in the world. In view of this, harmonising regulation within the region is not an easy task. Hence, making medical devices safe and effective is the responsibility of AHWP.

3) In order for AHWP to achieve its objectives faster, AHWP should adopt and implement suitable recommended decisions of GHTF and not to reinvent the wheel. In addition, with Government support and cooperation of Member Economies in the region, AHWP can realise its goals in a shorter time.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

4) The Agenda of the Meeting is as in **ANNEX 1**.

AGENDA ITEM 2: ROLL-CALL

5) Delegates from nine Member Economies attended the meeting. The list of participants appears as **ANNEX 2**.

AGENDA ITEM 3: BUSINESS ARRANGEMENT

6) The Chair briefed on the arrangement of this Meeting. The Meeting was conducted according to the Agenda as in **ANNEX 1**. In Agenda Item 9 (Meeting Deliverables), the participants were divided into two groups to discuss and review the policy directions and strategic plans for AHWP. The items discussed in Agenda 9 were consolidated on the second day of the Meeting.

AGENDA ITEM 4: DEBRIEFING OF GHTF STEERING COMMITTEE MEETING, 6th NOVEMBER 2005, LONDON

7) The Chair reported the outcome of the Global Harmonisation Task Force (GHTF) Steering Committee (SC) Meeting on 6th November 2005 in London, which he attended (The report is as in **ANNEX 3**). He was invited to present AHWP status as well as its efforts and activities towards harmonising medical devices regulatory requirements in the Asian region.

8) He informed that AHWP participation was well received by GHTF SC. GHTF acknowledged the important role AHWP plays and AHWP involvement in GHTF was upgraded to a permanent Liaison Member. As a Liaison Member, AHWP will be invited to all GHTF activities. He further informed that there are three types of membership of the GHTF, namely;

i) Founding Members;

ii) Participating Members (open to individual countries);

iii) Liaison Members – AHWP, World Health Organisation (WHO), International Standardisation Organisation (ISO), Pan-American Heath Organisation (PAHO).

9) The Chair then reported the following;

i) GHTF members agreed to support AHWP in training, information exchange and possible funding;

ii) The next major activity of GHTF will be the GHTF Conference at Lubeck, Germany on 28 – 30 June 2006. This Conference can be a forum to enhance AHWP/GHTF cooperation. The Chair of AHWP has been invited to be a prominent speaker on Asian perspective, issues and challenges. An extended Open Session has been planned for the Conference to encourage active participation of all Liaison Members. Some GHTF and APEC members announced that they would investigate possibilities to fund participation of AHWP members in the GHTF Conference. The Chair encouraged all Member Economies to attend and actively participate in the Conference. He also encouraged them to make early registrations and hotel reservations to avoid disappointment as a large turnout is expected. If the turnout of AHWP Member Economies is good, the Chair suggested that a small meeting be organised in conjunction with the Conference.

iii) In terms of support in training, GHTF Study Groups (SGs) and Founding Members offered the following training possibilities/proposals;

- The Chair of SG 4 (Prof Frankenberger) offered the possibility of a training seminar in Taipei on risk management;
- Canada proposed an electronic learning programme;
- Australia proposed annual training programme/attachment at TGA;
- FDA offered video conferencing, on-line training programmes and satellite video-conferencing;
- EU invited AHWP Member Economies to participate in the Lubeck Conference and EU training sessions.

10) With regard to the details of the above trainings, the Secretariat was requested to communicate with GHTF Secretariat and post the details on the AHWP website. The Secretariat was also requested to e-mail details of the trainings to all Member Economies. At this juncture, the Chair informed that Malaysia has taken over the secretarial functions and he expressed his heartfelt thanks to Singapore who has done an excellent job as AHWP Secretariat since its inception.

11) The Meeting noted that funds would be required to attend/participate in such trainings. With regard to this, the Chair solicited the support of the industry in this region to contribute generously to AHWP trust fund. The Secretariat was requested to write to industry associations to contribute to this fund. Besides financial support, contributions could also be in other forms, such as organising training sessions and providing expert trainers. It was suggested that some of GHTF training programmes might be organised in this region to get better participation from AHWP Member Economies. In this respect, Malaysia offered to host some of the training programmes.

AGENDA ITEM 5: AHWP AS THE LIAISON MEMBER OF GHTF – DISSCUSSION ON THE OFFERS BY GHTF TO SUPPORT AHWP IN TRAINING, INFORMATION EXCHANGE AND FUNDING

12) The Chair emphasised the importance of establishing close relationship with GHTF and hoped that the relationship could be further strengthened in the future. Close relationship with GHTF is important as it benefits both GHTF and AHWP Member Economies. In addition, there is no need for AHWP to re-invent the wheel in its harmonisation effort as what have been done by GHTF can be used and adopted by AHWP. The Chair informed that as a Liaison Member, AHWP can participate in all GHTF activities and he encouraged active participation of all Member Economies in GHTF activities. He further encouraged AHWP to play an important and active role in GHTF to ensure its views are taken into consideration and to make its presence felt.

13) Due to the wide scope of medical devices regulation, it was suggested that activities towards harmonisation within Asian region should be prioritised and undertaken step by step. Harmonisation of conformity assessment procedures is one of the most important steps to be focussed on. In this respect, it was suggested that abridged approval process should be considered for adoption. Harmonisation of conformity assessment procedures and adoption of abridge approval process can save a lot of time and resources for both manufacturers and regulators.

14) In relation to the harmonisation effort, the Meeting was informed that in ASEAN, a study on medical devices regulatory systems in ASEAN Member Economies is currently

being undertaken by the ASEAN Consultative Committee on Standards and Quality – Medical Devices Product Working Group (ACCSQ-MDPWG) prior to the actual harmonisation effort. The study is crucial as it will put the present situation into a proper perspective and it helps in planning and strategising the harmonisation. It was suggested that similar study be undertaken by AHWP with possible funding from Asia Pacific Economic Cooperation (APEC) and WHO. The outcome of this study can be used as a directory of the regulatory status within Asian region and this is useful in the harmonisation effort. The Chair will personally write to seek financial support from APEC, WHO and some of AHWP Member Economies.

15) The Chair decided that matters raised in this Agenda should be further discussed in Agenda Item 8.

AGENDA ITEM 6: AHWP PARTICIPATION IN GHTF STEERING COMMITTEE (SC) AND STUDY GROUPS (SGs)

16) As an outcome of the GHTF SC Meeting in London, GHTF has offered support and invited AHWP to participate in GHTF SC and SGs' activities and meetings. The Chair reiterated the importance of participation of AHWP in GHTF SC and all GHTF SGs, as this will provide avenues for AHWP to present its views in matters relating to global harmonisation effort.

17) The Chair then requested nominations from Member Economies to participate as AHWP focal points in GHTF SC and SGs. The nominations were as follows;

i) GHTF Steering Committee: AHWP Chair/Co-chair;

ii) SG 1 (Pre-market): Malaysia, Chinese Taipei, Hong Kong Industry Group and Thailand;

iii) SG2 (Post-market): Singapore and Philippines;

iv) SG3 (Quality System): Indonesia, China;

v) SG 4 (Auditing): Malaysia, Chinese Taipei (to be confirmed later);

vi) SG5 (Clinical Investigation): Korea.

The purposes of the establishment of GHTF SGs are attached as in **ANNEX 4.**

18) Member Economies nominated as AHWP focal points were expected to coordinate activities/meetings of the respective GHTF SGs. These include;

i) updating AHWP Member Economies with the latest activities/meetings of the respective SGs and their outcomes;

ii) translating outcomes of GHTF activities/meetings into achievable AHWP activities;

iii) representing AHWP and presenting the standpoints and perspectives of AHWP;

iv) being committed and maintaining frequent attendance at the SGs meetings.

19) The nominated Member Economies were requested to work out their own plans to participate in the SGs and report back to AHWP. Any issue on funding should be forwarded to the Chair and Co-Chair of AHWP. It was also suggested that they should collect relevant materials of the activities/meeting and forward them to the Secretariat. The Secretariat was

requested to coordinate collection and distribution of materials of the respective GHTF SGs activities/meetings. It was decided that the Secretariat should prepare preliminary draft Terms of Reference (TOR) for participation of Member Economies as focal points in GHTF SGs. The draft TOR shall be circulated to Member Economies for comments.

20) The Meeting noted that funding was a major issue and appreciated the importance of having a sustainable fund to be able to constantly participate in GHTF SGs activities/meetings and to carry out AHWP's planned activities. The issue of funding would be discussed further in Agenda Item 9 (Meeting Deliverables).

21) The Meeting further noted the significance of China and India in the global economy and their active participation is important to make the AHWP's presence felt. The Meeting was informed that representatives from the Chinese regulatory authority were unable to attend this Meeting due to the short notice. It was informed that representatives from India were also invited but they could not attend due to prior commitments.

AGENDA ITEM 7: AHWP MEETING IN KOREA

22) Member Economies were pleased to note that Korea is willing to host the next AHWP Meeting in September 2006. It was suggested that Technical Committee (TC) and Workgroup (WG) meetings should be held in conjunction with the meeting in Korea and it should be held for three days (two days pre-conference workshop and one day AHWP Meeting). It was also suggested that some of the trainings offered by GHTF should be conducted during the pre-conference workshop. The workshop should cover topics on risk management, conformity assessment procedures, STED and GMDN. The Secretariat was requested to find out the possibility to conduct the training offered by GHTF in conjunction with this Meeting. The Secretariat was also requested to work out the details of the meeting with the Korean counterpart and post the announcement and details of the meeting on the AHWP website.

23) Among the items/activities proposed to be discussed in the next Meeting in Korea were;

i) Structure of AHWP – TC, Workgroup;

ii) Funding – business model for management of funds;

iii) Pre-Conference Workshop on Conformity Assessment Procedure, STED, Risk Management (if change of venue is confirmed);

iv) Capacity building and overall training strategy;

v) Post-marketing alert system;

vi) Pre-market Common Submission Dossier Template;

vii) Updates on TC activities.

AGENDA ITEM 8: UPDATES ON AHWP TECHNICAL COMMITTEE (TC) ACTIVITIES

24) The Meeting was informed that there are two projects currently undertaken by the TC. These are the Pre-market Common Submission Dossier Template (CSDT) and the survey on pre-market requirements of the Member Economies. The latest updates on the projects

will be presented in the next AHWP Meeting in Korea. The Secretariat was requested to communicate with the Chair of AHWP TC to present the updates in Korea.

AGENDA ITEM 9: MEETING DELIVERABLES

25) The Chair presented the AHWP policy directions in terms of its objectives, TOR and activities. His presentation is in **ANNEX 5**. He highlighted the following;

i) Harmonisation effort in this most diverse region is a big challenge;

ii) Efforts have to be made to create increased understanding on the benefits of harmonisation;

iii) The importance of participation of other Member Economies such as Cambodia, Laos, Myanmar, Vietnam, India, Pakistan and other countries in this region in AHWP to maximise the benefit of the harmonisation process in Asia. The Secretariat was requested to contact all countries in the Asian region and invite them to be members of AHWP and to participate in the next AHWP Meeting in Korea;

iv) The three major issues in Asian region, namely, the lack of infrastructure, trained manpower, expertise and finance;

v) Seeking GHTF support in capacity building and training; expert advice in strengthening infrastructure and development of regulation; and financial support.

vi) At the end of his presentation, the Chair stressed that the success AHWP should be towards forging strategic regional partnership for facilitating regulatory processes; eliminating technical and economic barriers; and promoting timely access to medical devices

26) The Chair further informed that at the GHTF SC Meeting in London, GHTF decided that Global Medical Devices Nomenclature (GMDN) would be used as a common nomenclature system. Member Economies can use the latest version of GMDN and can translate it to other languages. They are allowed to sell translated versions of GMDN with no copyright implications.

27) Group discussion ensued and participants were divided into two groups to review AHWP's policy direction. They were requested to discuss and deliberate on the following items;

i) Review of AHWP objectives, aims, TOR and activities;

ii) Setting of AHWP strategic direction for the next three years;

iii) Development of work programme on functional strategy, activity, deliverables, timeframe, responsible Member Economy/TC/Workgroup;

iv) Funding;

v) Organisation structure of AHWP activities – TC and Workgroups.

28) The Chair suggested that the current TOR of AHWP (as in **ANNEX 6**) and his presentation could be used as guidance and reference for group discussion. He also suggested that the groups should prioritise areas for harmonisation and start with the most feasible area. In this respect, three main areas were suggested, namely definition, classification and a common nomenclature system. The Chair then pointed out that in the

process of harmonisation, the interest of medical devices industry in this region should be taken into consideration and to achieve this, industry representatives should work closely with the regulators.

29) The groups presented their inputs/suggestions on the second day of the Meeting. The presentations of Groups A and B are attached as **ANNEX 7** and **ANNEX 8** respectively. The Meeting agreed on the following amendments to the current objectives and aims of AHWP proposed by the two Groups;

i) Current objectives of AHWP were accepted with the inclusion of an additional objective, ie: "To encourage active participation by all Asian Economies"

ii) The aims of AHWP were amended to;
- To provide a forum for discussion and training, facilitate information exchange, initiate projects and provide platform for implementation of harmonisation among regulators and industry groups in Asia (the current aim reads: *"to provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonisation among regulators and industry groups in Asia"*)
- To establish AWHP as a formal regional grouping in GTHF (the current aim reads: *"seek to establish AHWP as a formal regional grouping under the GHTF"*)

30) The Meeting also agreed to the following changes on the AHWP's TOR;

i) To study and recommend ways to harmonise regulation in Asian region in-line with global harmonisation efforts and to work in coordination with GHTF, APEC and relevant organisations (the current TOR reads: *"To study and recommend ways to harmonise medical device regulation in the Asian region with global trends and to work in coordination with the Global Harmonisation Task Force and APEC")*

ii) To examine ……. and accepted quality system standard for manufacturing of medical devices (the current TOR reads: *"To examine …..… and accepted quality system standard for medical devices"*)

iii) To work with the GHTF on technical harmonisation efforts and seek formal representation and participation at GHTF Steering Committee and Study Groups (current TOR reads: *"Work with the GHTF on technical harmonization efforts and seek representation as observers at their study groups")*

iv) Under topic of Change to Office Bearers: **…….** nominated from the incumbent member economy. To ratify the change to office bearer, AHWP …… (the current TOR reads: *"**….** nominated from the incumbent member economy. To rectify the change to office bearer, AHWP …..…")*

v) Other items in the current TOR were accepted without changes.

vi) The revised TOR is as in **ANNEX 9**.

31) The Meeting then agreed to undertake the following strategies;

i) Comparative study on the existing medical device regulations in AHWP Member Economies;

ii) Harmonisation of definition, classification and nomenclature of medical devices within AWHP;

iii) Formalisation of a post marketing alert system;

iv) Capacity building through training;

v) Work towards a common submission dossier in alignment with ASEAN project;

vi) Funding.

A detail work programme specifying the strategies, activities, expected outcomes, timeframe and responsible Member Economies/TC/Workgroups is shown in **ANNEX 10.**

AGENDA ITEM 10: OTHER MATTERS

32) The Co-Chair encouraged local manufacturers to actively participate and contribute towards harmonisation of regulations. He further requested all Member Economies to explain the activities of AHWP and share decisions and information made at this Meeting to local industries as well as to share progress made with other Member Economies.

33) The Meeting was informed that since AHWP is going on a fund raising campaign, a structured procedure for the management of AHWP funds is required. A draft procedure will be tabled at the next meeting in Korea.

CLOSING REMARKS

34) In his closing remarks, the Chair thanked all the participants who have contributed positively towards the harmonisation process in the Asian region. The objectives of the Meeting have been met and during the two-day meeting, the TOR of AHWP has been successfully reviewed. The AHWP harmonisation effort will be reaffirmed at the next Meeting in Korea. The Chair thanked Korea for the willingness to host the next AHWP Meeting. He reiterated that finance has always been an issue and sustainable fund is required to carry out the planned activities.

35) Active participation of China and India as well as other Economies in Asia to be members of AHWP is crucial to make AHWP presence felt and to maximise the benefits of the harmonisation process to Asia. In this respect, the Chair planned to visit China and India to explain the benefits of harmonisation.

ACKNOWLEDGEMENT

36) The participants from Chinese Taipei, Hong Kong, Indonesia, Korea, Malaysia, Peoples' Republic of China, Philippines, Singapore, Thailand and the observers expressed their appreciation to the Ministry of Health of Malaysia for the warm hospitality and the excellent arrangements made for the Meeting.

37) The Chair thanked all participants for their contributions and wished them a safe journey home. He also thanked the Malaysian Government for the financial support and support in policy. Finally, he thanked the Secretariat for the job well done in organising this Meeting.

ANNEX 1

AGENDA

10th ASIAN HARMONISATION WORKING PARTY (AHWP) MEETING

OBJECTIVES

1) To review and set policy directions for AHWP in terms of its objectives and goals
2) To discuss and to determine strategic plans, activities and resources towards achieving the goals of AHWP

AGENDA

1) Registration
2) Welcome address by AHWP Chair
3) Agenda Item 1: Adoption of agenda
4) Agenda Item 2: Roll-call
5) Agenda Item 3: Business arrangement
6) Agenda Item 4: Debriefing of GHTF Steering Committee Meeting, 6 Nov 2005, London by AHWP Chair
7) Agenda Item 5: AHWP as the Liaison Body of GHTF – Discuss the offer by GHTF to support AHWP in training, information exchange and funding
8) Agenda Item 6: AHWP nominations to participate in;
   - GHTF Steering Committee
   - Study Group (SG) 1 (Pre-market)
   - SG2 (Post-market)
   - SG3 (QMS)
   - SG4 (Auditing)
   - SG5 (Clinical Investigation)
9) Agenda Item 7: AHWP Meeting in Korea, Taipei Risk Mgmt Seminar
10) Agenda Item 8: Updates on AHWP Technical Committee (TC) Activities
11) Agenda Item 9: Meeting Deliverables
   - Review of AHWP objectives, aims, TOR, activities
   - Set AHWP strategic direction (2006 – 2010)
   - Develop work programme on functional strategy, activity, deliverables, timeframe, responsible Member Economies/TC/Workgroup
   - Funding
12) Agenda Item 10: Consolidation
13) Agenda Item 11: Other matters

ASIAN HARMONIZATION WORKING PARTY
Working towards medical device harmonization in Asia

ANNEX 2

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ANNEX 3

REPORT OF GHTF STEERING COMMITTEE MEETING

7-10 November 2005

London, UK

Matters to Report

- Dr M.S. Pillay, the Chairman of AHWP was invited to present AHWP activities in Open Session, together with WHO and ISO
- AHWP status and activities and the harmonisation efforts in Asia and ASEAN was presented
- The GHTF Chair and Members of GHTF acknowledged the important role AHWP plays and will be inviting AHWP to be a permanent Liaison Member of GHTF

Matters to Report

- There are three types of membership of the GHTF Steering Committee;
  - Founding Member
  - Participating Members (open to individual countries)
  - Liaison Bodies – AHWP, WHO

Matters to Report

- GHTF Members agreed to support AHWP in training, information exchange and possible funding
- The next major activity of GHTF will be the GHTF Conference, Lubeck, Germany from 28 – 30 June 2006. this can be a forum to enhance GHTF/ AHWP cooperation.
- Chair of AHWP invited as a prominent speaker on Asian perspective, issues and challenges

Matters to Report

- Various SC members announced that they will investigate possibilities to fund participation of AHWP members in the GHTF Conference.
- Various SC members announced that they will investigate possibilities to fund participation of AHWP members in the GHTF Conference.
- Canada proposed electronic learning programme

Matters to Report

- Australia proposed annual training programme/attachment at TGA
- FDA offered training programmes, video-conferencing, on-line training programmes & satellite video-conference
- EU invited AHWP members to participate in the Lubeck Conference and EU training session

AHWP must participate actively

- A lot of what GHTF has developed can be used in AHWP
- No point in re-inventing the wheel
- We have to move faster than GHTF
- We have a lot more to do in this region
- We have established a good working relationship with GHTF
- AHWP participation was well received

THANK YOU

ANNEX 4

PURPOSES OF GHTF STUDY GROUPS

Study Group 1 has been charged with comparing operational medical device regulatory systems around the world and from that comparison, isolating the elements / principles that are suitable for harmonization and those that may present obstacles to uniform regulations. In addition, the group is also responsible for developing a standardized format for pre-market submissions and harmonized product labelling requirements.

Study Group 2 is charged with the task of reviewing current adverse event reporting, post-market surveillance and other forms of vigilance for medical devices and performing an analysis of different requirements amongst countries with developed device regulatory systems with a view to harmonizing data collection and reporting systems.

Study Group 3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization.

Study Group 4 has been charged with the task of examining quality system auditing practices (initially among the founding members of the GHTF) and developing guidance documents laying harmonized principles for the medical device auditing process.

Study Group 5 has been charged with promoting convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices. The group will concentrate on establishing harmonized definitions for commonly used terms (clinical investigation, clinical data, clinical evaluation and clinical evidence) as well as developing harmonized guidance on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. The group will work closely other GHTF study groups to review existing documents to ensure that terminology is consistent and interfaces are clear and that there is a consistent approach to broader GHTF initiatives (e.g., STED).

ASIAN HARMONIZATION WORKING PARTY

Working towards medical device harmonization in Asia

ANNEX 5

REVIEW OF AHWP's POLICY DIRECTION

10th AHWP Meeting

Genting International Convention Centre
Genting Highlands, MALAYSIA
24 – 25 November 2005

INTRODUCTION

- AHWP was established in 1998
- Non-profit organisation
- Informal regional forum comprising
  - Government regulators
  - industry representatives

  from Member Economies in Asia

INTRODUCTION

Welcome to the most diverse region ….

Diversity of regulatory requirement or no regulation

Diverse population

High proportion of population rural based

38 Currencies

High volatility
- Politically
- Economically
- Socially

Over 40 languages; over 300 dialects

Asia is not following the same evolutionary model

AHWP OBJECTIVES

- To forge a common direction for harmonization of medical devices regulation in Asia
- To encourage increased understanding on the benefits of harmonization
- To facilitate a linkage with GHTF

AIMS OF AHWP

- To provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonization among regulators and industry groups in Asia
- To establish AHWP as a formal regional grouping under GHTF

TERMS OF REFERENCE

- To study and recommend ways to harmonize regulation in the Asian region with global trends and to work in coordination with GHTF and APEC
- To examine the use of quality system requirements around the world and prospects for adopting a quality system standard based on internationally recognized and accepted quality system standard for medical devices

TERMS OF REFERENCE

- Work towards building a common regulatory consensus based on acceptance of international standards as the chief means of ensuring product safety and assurance
- Work towards a harmonized system of medical device vigilance reporting for adoption within the region and information sharing

TERMS OF REFERENCE

- Work with the GHTF on technical harmonization efforts and seek representation as observers at their Study Groups
- Facilitate the process of regional implementation of APEC initiatives for medical devices and equipment sector

CHALLENGES

PREMARKET

Definition & Coding of Medical Device/IVDD

Conformity Assessment Procedures

STED

Essential Principles of Safety & Performance

Standards

Audit, Quality System – ISO 13485?

PLACEMENT ON MARKET

Common Language

Regulatory Requirements

Regulatory Charges

POST MARKET

Surveillance System

Adverse Event Reporting Format

No Data Bank- Linkage

MAJOR ISSUES

- INFRASTRUCTURE
- MANPOWER – EXPERTISE/TRAINING
- FINANCE

FUTURE DIRECTION

- Establish an effective communication network and presence amongst participating economies through scheduled AHWP meetings, e-mails, correspondence and Internet-based access site
- Work towards enlarging the base of participating economies so as to maximize the benefit of the GHTF harmonization process to Asia

STRATEGIC PLANNING

- Organize awareness education, training and seminars for medical device regulators and industry in the area of regulatory requirements
- Define the scope and deliverables and tasks of Technical Committee
- Seek budgetary and strategic support for AHWP activities and programs

GHTF SUPPORT

- Capacity building; training and host attachment programs
- Advice and experts in development, strengthening of the existing infrastructure of Member Economies
- Assist and advice Member Economies without regulations in development and implementation of the regulations
- Financial support

CONCLUSION

The success of AHWP shall be towards forging strategic regional partnership for

- **facilitating regulatory processes**
- **eliminating technical and economic barriers,**
- **promoting timely access to medical devices**

Thank you

ASIAN HARMONIZATION WORKING PARTY

Working towards medical device harmonization in Asia

ANNEX 6

TERMS OF REFERENCE

INTRODUCTION

Asian Harmonization Working Party (AHWP) is established as a non-profit organisation. Its objectives are to forge a common direction for the harmonization of medical device regulation in Asia, encourage increased understanding on the benefits of harmonization and facilitate a linkage with the Global Harmonization Task Force (GHTF). As a regional organisation, we aim to provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonisation among regulators and industry groups in Asia; and seek to establish AHWP as a formal regional grouping under the GHTF.

Our success as a regional grouping depends on active participation from member economies in Asia working in collaboration with medical device regulatory authorities and industry organisations regionally and internationally.

TERMS OF REFERENCE

Purpose

To study and recommend ways to harmonize medical device regulation in the Asian region with global trends and to work in coordination with the Global Harmonization Task Force and APEC. The AHWP will strive to:

- Examine the use of quality system requirements around the world and prospects for adopting a quality system standard based on internationally recognized and accepted quality system standard for medical devices.
- Work toward building a common regulatory consensus based on acceptance of international standards as the chief means of ensuring product safety and assurance.
- Move toward recognition of a common audit that can be accepted throughout the Asian region.
- Work toward a harmonized system of medical device vigilance reporting for adoption within the region and information sharing.
- Work with the GHTF on technical harmonization efforts and seek representation as observers at their study groups.
- Facilitate the process of regional implementation of APEC initiatives for the medical devices and equipment sector.

Framework and Procedures

Membership

The Working Party is an informal group of experts from Medical Device Regulatory Authorities and the medical device industry. Membership is open to those representatives from within the Asian region who support and endorse the above

stated goals. Each member economy has two representatives to the Working Party - one from the Medical Device Regulatory Authority and the other from the industry. Medical Device Regulatory Authority participants must be knowledgeable experts drawn from the competent authority responsible for medical device regulation. Industry representatives must be knowledgeable of international regulatory standards for medical devices and involved in current global initiatives sponsored by the GHTF. It is expected that industry representatives will consult with other industry representatives in their member economy in developing industry views.

Members of the AHWP (both from regulatory authorities and from industry) are expected to participate as representatives of their respective economies to develop understanding of the GHTF approaches to harmonization and guidance documents. With this understanding members are to review recommendations of the AHWP Technical Committee for adoption of GHTF harmonized guidance documents and review proposed feedback to the GHTF on draft guidance documents ensuring that the results of these activities can be utilized to initiate harmonization efforts in their respective regulatory systems.

Leadership

The Chair and Co-chair persons of AHWP will be elected by way of voting by members in the Working Party to be office bearers for a period of three years. The Chairperson comes from a Medical Device Regulatory Authority and the Co-chair person is selected from the medical device industry. The Chair and Co-chair persons will normally rotate among member economies once every three years.

- The participating members may nominate appropriate persons to sit on its Technical Committees of the Working Party. Its Chair and Co-chair persons, being duly elected, are expected to rotate among member economies once every three years.
- Any nominated member of any committee that is unable to attend may appoint a proxy.

Support

Secretariat support for Working Party meetings and ongoing business of the group will be provided by industry.

Meetings

The Working Party and its Technical Committees shall meet at regular intervals to be determined by the group. However, the Working Party should meet at least once every 18 months preferably in conjunction with the GHTF and at more frequent basis for the Technical Committees. The Working Party and Technical Committee members must agree to attend meetings on a regular basis. Meeting locations may rotate based upon an agreed upon schedule.

Decisions

The Working Party and its Technical Committees shall operate on a consensus basis in keeping with the GHTF model. The group will decide appropriate procedures for arriving at a common position.

Technical Committee

The Technical Committee is established to provide a working level of regulatory professionals that understand the work of the GHTF and the GHTF Study Groups to support the AHWP in their achievement of their goals.

Major Roles for Technical Committee are:

- To plan and organize training
- To promote and recommend the implementation of the GHTF Final guidance documents into the regulatory framework of the AHWP member economies.
- To review GHTF working draft and proposed documents
- To recommend feedback to the AHWP for communication to the GHTF from an Asian perspective and
- To participate in the various GHTF Study Groups and represent AHWP member economies' interests.

Membership in the Technical Committee will consist of one primary representative from each AHWP member economy and one alternate representative. The alternate representative will serve and participate when the primary is unable to do so. A member of the technical committee may also be a member on the working party.

The Technical Committee members must be:

- Person(s), from government and/or industry, nominated to represent the respective economy.
- Able to fulfill the commitments and participate in approximately 2 meetings annually.
- A person possessing technical and regulatory expertise in the respective economy.
- Able to comprehend, speak and write in English.

The Technical Committee functions through the AHWP member economies' representatives by undertaking detailed work activities or deliberate technical issues, leading to recommendations for feedback or actions, which will be reviewed and decided upon by the AHWP.

The measure of success of the Technical Committee is tangible evidence of adoption and implementation of GHTF concepts, principles and guidance documents in the various medical device regulations of the AHWP member economies.

Change to Office Bearers

When there is a change in the office bearers in the Working Party or its Technical Committees, an agreement shall be sought from the AHWP Chair and Co-Chair and/or the Chair of the Technical Committee in the interim to replace the incumbency by a person nominated from the incumbent member economy. To rectify the change to office bearer, AHWP members shall at its next meeting soonest affirm the incumbency or select a person amongst other nominations.

Relationship to Trade Groups

The Working Party will investigate developments taking place within APEC and other trade pacts such as WTO, ASEAN, ASEM or EU to identify areas of

compatibility and possible cooperation regarding standards and harmonization activities.

Observers to AHWP and AHWP Technical Committee Meetings

In the spirit of communicating, sharing and spreading the harmonization approach widely throughout Asia, all meetings are open to interested observers, on a space available basis. All meetings will require registration and assistance in sharing the costs of the event. We will attempt to accommodate as many observers as possible. Observers must be from regulatory authorities, industry or conformity assessment bodies.

It is our belief that the message of harmonization will be better facilitated and implemented, with observers participating in the meetings.

We welcome all observers to participate in the meetings and provide the benefit of their experience as the AHWP and its Technical Committees perform their roles and responsibilities. However, observers may not be involved in decision making nor participate in consensus determinations.

ACTIVITIES

They are spearheaded by the diligent efforts of a group of committed regulatory affairs professionals in Asia Pacific. We have gained momentum from the growing interest of regulators in working towards greater harmonization of medical device regulations in Asia and in the efforts of Global Harmonization Task Force.

Future Directions

- Organise awareness education, training and seminars for medical device regulators and industry in the area of regulatory requirements (such as Essential Principles of Safety and Performance of Medical Devices; Classification Rules and risk-based management approach) and premarket review processes. One possibility is to tap the availability of GHTF SG resource persons on business trips or visits to Asia;
- Define the scope and deliverables and tasks of Technical Committee, including the conduct and frequency and venue of meetings;
- Seek budgetary and strategic support for AHWP activities and programmes;
- Establish an effective communication network and presence amongst participating Asian economies through scheduled AHWP meeting, e-mails, correspondence and Internet-based access site;
- Plan for the next AHWP Meeting;
- Work towards enlarging the base of participating economies so as to maximise the benefit of the GHTF harmonization process to Asia.

ANNEX 7

10th ASIAN HARMONIZATION WORKING PARTY (AHWP) MEETING

Group A

24th November 2005

TERMS OF REFERENCE

- To study and recommend ways to harmonize regulation in the Asian region with global trends and to work in coordination with GHTF, APEC and relevant organizations

TERMS OF REFERENCE

- Work with the GHTF on technical harmonization efforts and seek formal representation & participation at GHTF steering committee and study group

STRATEGIC PLANNING

- Organize awareness education, training and seminars for medical device regulators and industry to facilitate harmonization in Asia

GHTF SUPPORT

- Provide advice & experts in development, strengthening of the existing infrastructure of Member Economies
- Assist and advise Member Economies without regulations in development and implementation of the regulations

WORK PROGRAMME – Strategies

1. Comparative study on the existing medical device regulations in AHWP Member Countries
2. Formalization of a post marketing alert system for defective or unsafe medical devices
3. Capability building through training
4. Work towards common denominator GHTF's definition of Medical Device & classification; GMDN
5. Work towards a common submission dossier in alignment with ASEAN project

FUNDING FOR AHWP

1. Membership subscriptions
2. Excess generated from training & conferences

AHWP MEETING – KOREA 2006

1. Update from study group
2. Pre-Conference training or workshop on STED
3. ? Risk Management training
4. Venue: ? in Korea
5. Date: 3rd to 4th week of Sept 2006

ANNEX 8

Presentation on Discussion

Group B

Presented by: Daphne Yeh

AHWP Objective

- Current objectives accepted as it is
- Proposed to include:
  - To encourage active participation by all Asian economies

Aims of AHWP

- To provide a forum for discussion and training, facilitate information exchange, initiate projects and **provide platform for implementation** of harmonization among regulators and industry groups in Asia
- To establish AWHP as a formal regional grouping **in** GTHF

Terms of Reference 1

- To study and recommend ways to harmonize regulation in Asian region **in-line with global harmonization efforts**
- To examine…….and accepted quality system standard for **manufacturing of** medical devices
- 3rd and 4th items are accepted as it is

Terms of Reference 2

- Work with the GHTF on technical harmonization efforts and seek representation **in** their Study Groups
- 6th item are accepted as it is

Work Program (1)

- Strategy 1
  - Comparative study on the existing regulations in Asian member Economies
  - To review survey form from ACCSQ-MDPWG
  - To review the current result surveyed by WG001
  - To be completed by May 2006 (Before Lubeck meeting)
  - TC / WG001 will be responsible

Work Program (2)

- Strategy 2
  - Harmonization of definition, classification and nomenclature of medical devices within AWHP
  - Timeline and responsibility to be defined after comparative survey

Work program (3)

- Strategy 3
  - Common submission dossier
  - TC / WG001 will report on progress at Korea meeting

Work Program (4)

- ACTIVITY: Korea Meeting 2006
  - Thailand proposed to avoid the timing of last week of September
  - Proposed plan for meeting
    - AHWP Meeting
    - Technical Committee Meeting
    - Training Session by TGA, GHTF etc. (if budget allowed)

The issue of structure of TC

- Currently: TC only have one Chair person and two Co-Chairs
- Current terms of reference: TC membership limited to gov. rep and ind. Rep from each member economy
- Suggestions:
  - **To revise term of reference and liberate the membership of TC.**
  - **Ensure industry and regulators actively participate in the Technical Committee**
  - **Work Group may be organized under TC by SG or tasks**

The Issue of Funding

- Currently AHWP funded by activity-basis
  - **Registration fees (50% off for regulators)**
  - **Meeting, accommodation and transportation cost mostly paid by the country authority / industry**
  - **Hosting authority / industry contribute more**
- Suggestions:
  - **Still activity based**
  - **Still country authority / industry paid by themselves**
  - **APEC, or other funding sources**
  - **Proposed membership fees for industry**
  - **Minimize the cost of projects (eg. Survey by TC / WG)**

ASIAN HARMONIZATION WORKING PARTY (AHWP)

TERMS OF REFERENCE

PURPOSE

To study and recommend ways to harmonize regulation in Asian region in line with global harmonization efforts and to work in coordination with the Global Harmonization Task Force, APEC and relevant organizations. The AHWP will strive to:

- Examine the use of quality system requirements around the world and prospects for adopting a quality system standard based on internationally recognized and accepted quality system standard for manufacturing of medical devices.

- Work toward building a common regulatory consensus based on acceptance of international standards as the chief means of ensuring product safety and assurance.

- Move toward recognition of a common audit that can be accepted throughout the Asian region.

- Work toward a harmonized system of medical device vigilance reporting for adoption within the region and information sharing.

- Work with the GHTF on technical harmonization efforts and seek formal representation and participation at GHTF Steering Committee and Study Groups.

- Facilitate the process of regional implementation of APEC initiatives for the medical devices and equipment sector.

ASIAN HARMONIZATION WORKING PARTY (AHWP)

TERMS OF REFERENCE

FRAMEWORK AND PROCEDURES

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ASIAN HARMONIZATION WORKING PARTY (AHWP)

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ASIAN HARMONIZATION WORKING PARTY (AHWP)

TERMS OF REFERENCE

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ASIAN HARMONIZATION WORKING PARTY (AHWP)

TERMS OF REFERENCE

Relationship to Trade Groups

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ASIAN HARMONIZATION WORKING PARTY
Working towards medical device harmonization in Asia

ANNEX 10

AHWP WORK PROGRAMME FOR 2005 – 2007

Strategy	Activity	Expected output	Timeframe	Responsible Member Economy/TC/WG
1) Comparative study on the existing medical device regulations in AHWP Member Economies	To review survey form from ACCSQ-MDPWG i) Malaysia to send out survey form to all Member Economies ii) Member Economies to comment, endorse and return comment to Malaysia To conduct the survey i) Malaysia to send out finalised survey form ii) Member Economies to return survey form iii) Malaysia to analyse, prepare and print report	Finalised survey form Printed report ready to be sold in GHTF Conference, Lubeck, Germany	End Dec 05 By Feb 06 By May 2006	Malaysia, Member Economies
2) Harmonisation of definition, classification and nomenclature of medical devices within AWHP			To be defined after comparative survey	

Strategy	Activity	Expected output	Timeframe	Responsible Member Economy/TC/WG
3) Formalisation of a post marketing alert system	Prepare draft proposal for post-market alert system	Proposal paper to be presented in the next AHWP Meeting, Korea	By Sept 06	Singapore
4) Capacity building through training	i) Prepare draft proposal on training strategy In preparing the proposal, training plan for specific Member Economy and development of training capacity within AHWP need to be looked into.	Proposal paper on training strategy to be presented at the next AHWP Meeting, Korea.	By Sept 06	Hong Kong industry
	ii) Develop standard procedures for organising meetings/conference/ training	Draft standard procedures for organising meetings/ conference/training to be presented at the next AHWP Meeting, Korea.	By Sept 06	Secretariat, Korea, Singapore
5) Work towards a common submission dossier in alignment with ASEAN project	i) Secretariat to request progress report from TC and prepare report for decision making ii) AHWP to discuss progress report at the next AHWP Meeting in Korea	Decision on the strategy and work plan to firm up the work towards the development of common submission dossier	May 06 Sept 06	Secretariat, TC/WG01
6) Funding	i) Chair to write letter to request for AHWP funding	Letter to request for funding to companies, international organisations	Dec 05	Chair/Co-Chair

Strategy	Activity	Expected output	Timeframe	Responsible Member Economy/TC/WG
	ii) To work out structured mechanism/process for funding and prepare a proposal on AHWP funding and its management Suggestions on the sources of funding include membership fees, contributions from industry, industry associations, specific countries and meeting/ training registration fees	Proposal of mechanism/ process for AHWP funding to be presented at the next AHWP Meeting, Korea	Sept 06	