

AHWP New Membership Type

AHWP Secretariat Meeting
6-7 May 2013
Kuala Lumpur, Malaysia

Bryan SO
AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Content

- Background
- Existing Type of AHWP Membership
 - Regulatory Authority
 - Industry
- Proposed Type of Membership
 - Liaison Member

To support the Framework Element on AHWP's Global Partnership

AHWP should proactively approach international organizations, global leaders and experts, to identify important topics and to establish mechanisms for effective interaction and networking. This could include, but not be limited to:

- a process of receiving from and providing feedback to these organizations;
- membership and representation at these organizations;
- joint strategic planning and roadmap development (especially in the areas of common interest and benefit) including joint conferences and activities, etc.

All these partnerships would further enhance the extent of regulatory harmonization within the AHWP member economies.

Background (Cont.)

- Last presented at AHWP TC Leaders Meeting on 26-27 Feb 2013, Bangkok, Thailand

1.2 Membership (A)

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.

1.2 Membership (B)

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.**

1.2 Membership (C)

The Primary and Secondary AHWP Representatives from the Regulatory Authority of a member economy shall be nominated by the medical device regulatory authority of the corresponding government. All organizations from the Industry shall nominate the Primary and Secondary Representatives to subscribe to the AHWP Secretariat. Unless the Secretariat is otherwise informed, the nominated **AHWP Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy**, before subscribing to AHWP Secretariat.

2.2 AHWPTC Membership

The Primary AHWP Representative from the Regulatory Authority shall 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 nominated by the industry representatives of their own economy. Unless the Secretariat is otherwise informed, the nominated AHWPTC Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy, before subscribing to AHWP Secretariat.

1.5 Relationship with Other Parties

The Working Party shall work closely with other international and regional organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.



(Proposed) AHWP Liaison Membership

Background

AHWP pursues to maintain working relationships with other international and regional entities that have a mutual interest in medical device regulatory activities that are directly related to the common goals of nurturing global convergence, leveraging resources and making available safe and effective medical devices globally.



(Proposed) AHWP Liaison Membership

Action

A new clause to be added to the **House Rules** of AHWP to allow the recruitment of Liaison Member(s) to AHWP.

•*(Remarks: Example of potential liaison members: DITTA, AHC, WHO, etc.)*

AHWP House Rules

(proposed amendments in blue)

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. **If the application comes from any organization rather than the government Regulatory Authority, a letter from the corresponding government Regulatory Authority nominating such organization as representative for discussion on joining of member economy is required. Such organization shall appoint its representative and inform the Secretariat accordingly.**
- 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.

D. AHWP Liaison Membership

AHWP House Rules

(proposed amendments in blue)

8. Applications for Joining AHWP

D. AHWP Liaison Membership

- 1) The Liaison Membership is open to the regional and international organizations who wish to join AHWP and with their goals in-line with the work of AHWP towards harmonization of medical device regulations.
- 2) Any organization interested in joining AHWP as a Liaison Member shall send their request to AHWP with attention to AHWP Chair and cc AHWP Secretariat at secretariat@ahwp.info.
- 3) AHWP shall evaluate and determine the suitability of the applying organization for joining AHWP as a Liaison Member.
- 4) AHWP Chair shall have the rights to reject any AHWP Liaison Membership application.
- 5) Once the Liaison Membership application is confirmed, an official letter of confirmation from the AHWP Chair will be send via AHWP Secretariat to the new Liaison Member.

AHWP House Rules

(proposed amendments in blue)

8. Applications for Joining AHWP

D. AHWP Liaison Membership

- 6) The confirmed Liaison Member shall nominate a representative and subscribe to AHWP Secretariat as the contact person.
- 7) Liaison Member of AHWP shall have higher priority to co-organizing activities with AHWP.
- 8) The representative from Liaison Member can be an observer; however, shall not have voting rights in AHWP meetings.
- 9) The full list of Liaison Members of AHWP as well as the contacts of the corresponding representatives shall be kept by the AHWP Secretariat for record.
- 10) The list of Liaison Members of AHWP shall also be available at AHWP website.

Discussion Q&A