

# Summary of Proposed Updates in AHWP House Rules

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

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Bryan SO  
AHWP Secretariat



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

## To support the Framework Element on AHWP Membership Expansion

- Welcome any non-AHWP economic members who shows interest in participating
- Invite current AHWP economic member who has experience and knowledge on medical device regulation to take leadership role at various levels (AHWP, AHWP TC, working groups) at AHWP
- Secretariat office offer consistent support to member economies

## 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.

# Overview

## AHWP House Rules (20/11/2012)

	Applications of the AHWP House Rules
2	Requirements of the AHWP Chair/Vice-chairs
3	Nominations and Elections of the AHWP Chair/Vice-chairs
4	Requirements of the AHWPTC Chair/Co-chairs
5	Nominations and Elections of the AHWPTC Chair/Co-chairs
6	Roles and Responsibilities of the Secretariat
7	Appointment of the Secretariat Team
8	Applications for Joining AHWP
9	Appointments of AHWP and AHWPTC Representatives
10	Upkeep of Members and Representatives Records
11	Hosting AHWP and AHWPTC Meetings
12	Management of the AHWP Account and Reserve
13	Management of the AHWP Website
14	Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat
15	Proposing Issues For Discussion in AHWP Meetings
16	Proposing Resolutions in AHWP Meetings
17	Advisor to AHWPTC

Last updated on  
20/11/2012

# 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.

## 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](mailto: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.

## 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.

# Obligation of AHWP Annual Meeting Host

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(ANNEX\_11)



**Asian Harmonization Working Party**  
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- To support the preparation for AHWP and AHWPTC meetings
- To support the meeting host to have a better understanding of the obligation
- To support the meeting host to have a better understanding of the financial arrangement

## 11. Hosting AHWP and AHWPTC Meetings

- 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.

## GUIDANCE for Member Economy hosting the Meetings of AHWP or its Technical Committees

4. **The Meetings of AHWP and/or its Technical Committee and the various programmes for the event will be entirely self-funding. AHWP will provide a seed fund to manage cashflow.** Each delegate shall pay his share of the cost for attending the event. Cost of any pre- and post-event local tours arranged outside the event's programme shall be borne by individual delegate.
  
5. Member Economy's host organization and the local industry association will undertake to manage the following services and support:  
Pre-Event:
  - ii) Act on behalf of AHWP, through the local host Secretariat, on meeting venue contract and agreement subject to final approval from AHWP Organizing Committee. **AHWP will be solely responsible for the payment of the rental fees to the selected venue for rental of conference facility and equipment as well as tea breaks, lunches and a social dinner.** If required, the local host Secretariat will negotiate for a waiver of all necessary deposits.

## GUIDANCE for Member Economy hosting the **Annual Meetings of AHWP or its Technical Committees**

4. The Meetings of AHWP and/or its Technical Committee and the various programmes for the event will be entirely self-funding. AHWP will provide a seed fund to manage cashflow [on a request basis]. [AHWP and AHWP Administration Services Limited (ASL), through the AHWP Secretariat, will review the seed fund request, meeting budget, meeting sponsorship income status and ASL financial status by the moment the request is received, and decide the seed fund amount] Each delegate shall pay his share of the cost for attending the event. Cost of any pre- and post-event local tours arranged outside the event's programme shall be borne by individual delegate.

## GUIDANCE for Member Economy hosting the **Annual Meetings of AHWP or its Technical Committees**

5. Member Economy's host organization and the local industry association will undertake to manage the following services and support:

Pre-Event:

- ii) Act on behalf of AHWP, through the local host Secretariat, on meeting venue contract and agreement subject to final approval from AHWP Organizing Committee. ~~AHWP will be solely responsible for the payment of the rental fees to the selected venue for rental of conference facility and equipment as well as tea breaks, lunches and a social dinner.~~ If required, the local host Secretariat will negotiate for a waiver of all necessary deposits.

## GUIDANCE for Member Economy hosting the **Annual Meetings of AHWP or its Technical Committees**

5. Member Economy's host organization and the local industry association will undertake to manage the following services and support:

Pre-Event:

- vi) Meeting registration fees could be collected by the local host to better facilitate the cashflow. Sponsorships, if any, from local industries will be collected by the local host. Sponsorships, if any, from multinational companies will be directly collected by AHWP ASL through the Secretariat.

## GUIDANCE for Member Economy hosting the **Annual Meetings of AHWP or its Technical Committees**

5. Member Economy's host organization and the local industry association will undertake to manage the following services and support:

Post-Event:

- x) The meeting total income will include registration income, sponsorships received by local host and sponsorships received by AHWP ASL. The meeting total expenses will include meeting direct expenses generated in the local host side and the direct expenses generated in AHWP ASL side. The meeting surplus will be based on total income and total expenses. The meeting local host shall prepare an contingency plan in case for any deficiency.

# Review of ASL M&A

- Background
  - There are some ambiguous areas and conflicts within the Memorandum and Articles of Association (M&A) of AHWP ASL, regarding to membership and voting.



# AHWP ASL M&A

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## Members

2. The Members of the Company shall consist of:

- 1) Regulator Members;
- 2) Industry Members; and
- 3) Associate Members.

Regulator Members and Industry Members are collectively referred to as the “**Voting Members**”.

“**Company**” means AHWP ADMINISTRATION SERVICES LIMITED.

# AHWP ASL M&A

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## Members

3. Individuals from member economies of the Asian Harmonization Working Party that support the missions, goals and objects of the Company as set out in the Memorandum of Association are eligible to apply for membership as Regulator Member, Industry Member or Associate Member as appropriate.

## Members

- 4. Regulatory Members
  - 5. Industry Members
  - 6. Associate Members
- } Voting Members

### Summary:

a) Regulatory member and industry member are from AHWP member economies

b) Each AHWP member economy can have:-

- maximally 1 Regulator Member and
- maximally 1 Industry Member.

c) Regulatory Members and Industry Members are voting members

# AHWP ASL M&A

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## Members

### 6. Associate Member

- (2) The number of Associate Members from any economy (**whether or not it is an economy of the Asian Harmonization Working Party**) shall not exceed one hundred (100).
- (3) Associate Members shall have right to attend but no right to vote at general meetings.

*Associate members could be from any economy.*

**is conflicting with**

*Individuals from AHWP member economies are eligible to apply for ASL membership.*

# AHWP ASL M&A

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## BOARD OF DIRECTORS

37. The **Directors** of the Board shall be a **member** of the Company and shall be elected at the annual general meetings when their respective terms of appointment expire.

Discussion:

The Directors could be elected from an associate member.

However, associate members have no right to vote at a general meeting.

Proposed amendment:

Any associate member, once elected as a Director of the Board, shall have the right to vote at a general meeting.

# Discussion

## Q&A