



## **FINAL DOCUMENT**

Title: The Asian Harmonization Working Party House Rules

Author: AHWP Secretariat

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**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; and
  - (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 AHWPTC 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 AHWPTC Chair/Co-chairs**

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

- D. If the Issues for Discussion are of urgent nature, the Chair may initiate a voting that will be passed by a simple majority.

**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.

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