



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Amendment 1 to the Asian Harmonization Working Party House Rules

Authoring Group: AHWP SECRETARIAT

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1. Purpose

This document proposes to make amendment to the Asian Harmonization Working Party House Rules (hereafter as "AHWP House Rules") as detailed in section 3 below under "Proposed Amendment to the AHWP House Rules".

2. Background

- 2.1 The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/001 resolved in the 15th AHWP Meeting and announced on 30 November 2010.
- 2.2 There are some conflicts between the current AHWP House Rules and the current Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference (hereafter as "TOR").
- 2.3 The amendments will follow the following general principles:-
- TOR can override AHWP House Rules when there is any discrepancy;
 - Under the same conditions, it is preferred to make the minimum amendments to the current TOR and House Rules possible.

3. Proposed Amendments to the AHWP House Rules

- 3.1. The current clause 3.A Nominations and Elections of the AHWP Chair/Vice-chairs in AHWP House Rules:-

Clause 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.

is proposed to be replaced by:-

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

A. AHWP Primary 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. AHWP Primary Representatives from the Industry could be nominated as the candidates in the AHWP Vice-chair (Industry) election.

- 3.2. The current clause 9.B Appointments of AHWP and AHWPTC Representatives in AHWP House Rules:-

Clause 9 Appointments of AHWP and AHWPTC Representatives

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

is proposed to be replaced by:-

Clause 9 Appointments of AHWP and AHWPTC Representatives

- B. Member economies may also change their AHWP and AHWPTC Representatives by informing the Secretariat and the Chair accordingly. AHWP Primary Representative from the Regulatory Authority shall update AHWP Secretariat on any changes of the AHWP and AHWPTC Representatives from Industry of his/her member economy.*

3.3. The below new clause 17 Advisor to AHWPTC is proposed to be added in the AHWP House Rules:-

Clause 17 Advisor to AHWPTC

- A. AHWPTC shall appoint expert(s) from AHWP member economies and other international and regional organizations as advisor(s) on a need basis, for the purpose of seeking his/her/their technical/professional advice towards meeting the goals of AHWP.*
- B. Chairs and Co-chairs of AHWPTC, WGs and STGs shall propose the criteria for Advisor to AHWPTC. The proposed criteria as well as any changes of the criteria shall be updated to AHWP Secretariat.*
- C. Chairs and Co-chairs of AHWPTC, WGs and STGs shall nominate expert(s) to AHWP Secretariat. Secretariat shall review the suitability of the nominated expert(s) and submit the recommendations to AHWPTC Chair. Nominated experts who satisfy the criteria shall be considered being appointed to the AHWPTC Advisory Panel. AHWPTC Chair shall submit the name of candidate(s) and advice to AHWP Chair for final confirmation. With the confirmation of AHWP Chair, AHWPTC Chair shall appoint the confirmed candidate(s) to AHWPTC Advisory Panel as Advisor(s) to AHWPTC. The number of Advisors in the panel shall not exceed ten (10).*
- D. The AHWPTC Advisory Panel is independent to WGs and STGs, but shall be available to all WGs and STGs. The scope of expertise shall meet the needs of AHWPTC, WGs and STGs.*
- E. The term of office of Advisor(s) to AHWPTC commences from the date of appointment. All Advisors to AHWPTC, regardless of when they are appointed during the term of a given AHWPTC Chair, shall retire altogether at the same time with that AHWPTC Chair. The reappointment of Advisor(s) to AHWPTC shall be made by the new AHWPTC Chair.*
- F. Appointment to the AHWPTC Advisory Panel is on a voluntary basis. All AHWPTC Advisory Panel members shall receive no compensation from AHWP, AHWPTC and AHWP Administration Services Ltd.*
- G. Apart from this panel of Advisors, WGs and STGs Chairs and Co-chairs may nominate individual experts as advisor(s) to their corresponding WGs or STGs on a need basis. With the final confirmation of AHWPTC Chair, the WG or STG Chair shall appoint the individual experts, with a maximum number of two (2), to his/her WG or STG. Advisor(s) to WGs and STGs will not be appointed to the Advisory Panel to AHWPTC.*
- H. The term of office of Advisor(s) to WGs and STGs commences from the date of appointment. All Advisors to WGs and STGs, regardless of when they are appointed during the term of a given WG or STG Chair, shall retire altogether at the same time with that WG or STG Chair. The reappointment of Advisor(s) to WGs and STGs shall be made by the new WG and STG Chairs.*
- I. Advisor(s) to AHWPTC as well as Advisor(s) to WGs and STGs shall be updated to AHWP Secretariat for record.*

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