



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Amendment 6 to the Asian Harmonization Working Party House Rules

Authoring Group: AHWP SECRETARIAT

Date: 14 November 2019

1. Purpose

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

2. Background

2.1. The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F002:2017 resolved in 22nd AHWP Meeting and announced on 8 Dec 2017.

2.2. This amendment of House Rules mainly to revise “member economy” to “regulatory authority and/or industry of a country or region”, to better clarify that AHWP members are the representatives from the regulatory authority and industry of their respective country or region, not referring to the country or region itself.

2.3. The amendments will follow the below general principles:-

2.3.1. AHWP & AHWPTC Terms of Reference can override the AHWP House Rules when there is any discrepancy;

2.3.2. Under the same conditions, it is preferred to make the minimum amendments to the current House Rules possible.

3. Proposed Amendments to the AHWP House Rules

3.1. The following under the current Clause 3B on Nominations and Elections of the AHWP Chair/Vice-chairs:-

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.

Is proposed to be replaced by:-

Every nomination shall be supported by at least five Primary AHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

3.2. The following under the current Clause 5B on Nominations and Elections of the AHWPTC Chair/Co-chairs:-

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.

Is proposed to be replaced by:-

Every nomination shall be supported by at least five Primary AHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

3.3. The current Clause 8A on Applications for Joining AHWP:-

The Regulatory Authority of any countries/economies interested in joining AHWP shall send the application form to the Secretariat.

Is proposed to be replaced by:-

The Regulatory Authority of any country or region interested in joining AHWP shall send the application form to the Secretariat.

3.4. The current Clause 9A on Appointments of AHWP and AHWPTC Representatives:-

Member economies shall appoint their AHWP and AHWPTC Representatives and inform the Secretariat accordingly.

Is proposed to be replaced by:-

Member Regulatory Authority and member Industry of a country or region shall appoint their AHWP and AHWPTC Representatives and inform the Secretariat accordingly.

3.5. The current Clause 9B on Appointments of AHWP and AHWPTC Representatives:-

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.

Is proposed to be replaced by:-

The AHWP and AHWPTC Representatives of a member Regulatory Authority or member industry of a country or region may be changed at any time via a notification to the Secretariat and the Chair accordingly. Such notification shall be provided by the AHWP Primary Representative from the member Regulatory Authority of the respective country or region.

3.6. The current Clause 9C on Appointments of AHWP and AHWPTC Representatives:-

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.

Is proposed to be replaced by:-

Any disputes on representations should be referred to the Secretariat. The Secretariat shall seek comments from the Representatives from member Regulatory Authority of the respective country or region before making recommendations to the AHWP Chair for the final decision.

3.7. The current Clause 17A on Advisor to AHWPTC:-

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.

Is proposed to be replaced by:-

AHWPTC shall appoint expert(s) from AHWP member Regulatory Authorities or member Industries of countries or regions, or other international or 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.

3.8. The current Clause 19C on AHWPTC WGs and STG Membership:-

Members of non-AHWP member economies can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.

Is proposed to be replaced by:-

Any person who is not from the member regulatory authority or member industry of a country or region can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.

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