



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Amendment 2 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference

Authoring Group: AHWP SECRETARIAT

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1. Purpose

This document proposes to make amendment to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (hereafter as "TOR") as detailed in section 3 below under "Proposed Amendment to the TOR".

2. Background

- 2.1 Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference (Amendment 1), which became the current TOR, is specified under the Final Document AHWP/STG(LE)/001A resolved in the 15th AHWP Meeting and announced on 30 November 2010.
- 2.2 There are some ambiguous areas within the current TOR, some conflicts within TOR, and some conflicts between TOR and the current Asian Harmonization Working Party House Rules (AHWP/SECRETARIAT/001).
- 2.3 The amendments will follow the below general principles:-
- TOR can override the 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 TOR

- 3.1. All the clauses in the TOR are numbered for ease of reference.
- 3.2. The current clause on Membership in TOR:-

Membership

The Primary AHWP Representative from the Regulatory Authority of a member economy shall be nominated by the medical device regulatory authority of the corresponding government. He/she could in turn nominate the Secondary AHWP Representative for his/her economy. All organizations from the Industry should nominate a representative to subscribe to the AHWP Secretariat for serving as the contact person.

is proposed to be replaced by:-

Clause 1.2 Membership

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. 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.

3.3. The current clause on Leadership in TOR:-

Leadership

One AHWP Chair and two AHWP Vice-chairs shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all Primary AHWP Representatives for a term of office until the next election. The AHWP Chair and one AHWP Vice-chair shall come from Regulatory Authorities while one AHWP Vice-chair shall come from the Industry. The AHWP Chair and Vice-chairs will normally rotate among member economies. In the absence of the AHWP Chair and/or AHWP Vice-chairs at a given AHWP Meeting, they or the organizations that they are representing may nominate suitable persons as acting AHWP Chair and/or AHWP Vice-chairs for the purpose of the said meeting.

is proposed to be replaced by:-

Clause 1.3 Leadership

One AHWP Chair and two AHWP Vice-chairs shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all presented Primary AHWP Representatives for a term of office until the next election. The AHWP Chair and one AHWP Vice-chair shall come from Regulatory Authorities while one AHWP Vice-chair shall come from the Industry. The AHWP Chair and Vice-chairs will normally rotate among member economies.

3.4. The current clause on Relationship with Other Parties in TOR:-

Relationship with Other Parties

The Working Party shall work closely with GHTF, APEC, WTO, WHO, ASEAN, ASEM, LAHWP and other international organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.

is proposed to be replaced by:-

Clause 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.

3.5. The current clause on AHWPTC Membership in TOR:-

AHWPTC Membership

The Primary AHWP Representative from the Regulatory Authority could 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 elected by the industry representatives of their own economy.

is proposed to be replaced by:-

Clause 2.2 AHWPTC Membership

B. 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. 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.

3.6. The current clause on AHWPTC Leadership:-

AWHPTC Leadership

One AHWPTC Chair and two AHWPTC Co-chairs shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives. The AHWPTC Chair and one AHWPTC Co-chair shall come from the Regulatory Authorities while one AHWPTC Co-chair shall come from the Industry. In the absence of the AHWPTC Chair at a given AHWPTC Meeting, the AHWPTC Co-chair from the Regulatory Authority shall assume the duties of the AHWPTC Chair. In the absence of both the AHWPTC Chair and Co-chair from the Regulatory Authority, the AHWPTC Co-chair from the Industry shall assume the duties of the AHWPTC Chair.

is proposed to be replaced by:-

Clause 2.3 AHWPTC Leadership

One AHWPTC Chair and two AHWPTC Co-chairs shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives at the AHWPTC Meeting that is held in conjunction with the AHWP Annual Meeting. The AHWPTC Chair and one AHWPTC Co-chair shall come from the Regulatory Authorities while one AHWPTC Co-chair shall come from the Industry. In the absence of the AHWPTC Chair at a given AHWPTC Meeting, the AHWPTC Co-chair from the Regulatory Authority shall assume the duties of the AHWPTC Chair. In the absence of both the AHWPTC Chair and Co-chair from the Regulatory Authority, the AHWPTC Co-chair from the Industry shall assume the duties of the AHWPTC Chair.

3.7. The current clause on Voting in TOR:-

Voting

Each Primary AHWP Representative and Primary AHWPTC Representative shall have one vote at the AHWP Meeting and AHWPTC Meeting respectively.

is proposed to be replaced by:-

Clause 4.1 Voting

Each Primary AHWP Representative shall have one vote at the AHWP Meeting. Each Primary AHWPTC Representative shall have one vote at AHWPTC Meeting.

3.8. The current clause on Representation in the absence of the Representatives in TOR:-

Representation in the absence of the Representatives

Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence. In case that both the Primary and Secondary AHWPTC Representatives are absent, the corresponding Primary AHWP Representative could take up all the roles and responsibilities as well as voting rights at the AHWPTC Meetings. Similarly, Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent.

is proposed to be replaced by:-

Clause 4.6 Representation in the absence of the Representatives

Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC

Representatives in their absence. In case that both the Primary and Secondary AHWPTC Representatives are absent, the corresponding Primary AHWP Representative could take up all the roles and responsibilities as well as voting rights at the AHWPTC Meetings. Similarly, Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent. However, representatives from the Regulatory Authority shall not represent representatives from the Industry. Similarly, representatives from the Industry shall not represent representatives from the Regulatory Authority.

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