



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Amendment 7 to the Asian Harmonization Working Party (AHWP) & AHWP Technical Committee (AHWPTC) Terms of Reference (TOR)

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 AHWP TOR".

2. Background

- 2.1. The current TOR is specified under the Final Document AHWP/SECRETARIAT/F001:2017 resolved in 22nd AHWP Meeting and announced on 8 Dec 2017.
- 2.2. The current nomenclature "member country or region" in AHWP Terms of Reference (TOR) was revised from "member economy" and was adopted in 2017.
- 2.3. This amendment of TOR is mainly to revise "member country or region" 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.
- 2.4. The Amendments will follow the below general principles:-
 - 2.4.1. TOR can override the AHWP House Rules when there is any discrepancy;
 - 2.4.2. Under the same conditions, it is preferred to make the minimum amendments to the current TOR and House Rules possible.
- 2.5. The following roles and responsibilities will remain unchanged after nomenclature revision:
 - 2.5.1. Voting rights;
 - 2.5.2. Responsibilities;
 - 2.5.3. Participation;
 - 2.5.4. Name of member.

3. Proposed Amendments to the AHWP TOR

- 3.1. The following under the current Clause 1.3 on Goals:-

To promote capacity building in [member economies](#) and to foster strategic membership expansion.

Is proposed to be replaced by:-

To promote capacity building in [members](#) and to foster strategic membership expansion.

- 3.2. The following under the current Clause 1.4A Membership: -

The Working Party is a group of experts from Medical Device Regulatory Authorities ("Regulatory Authorities") and the medical device industry [including country or regional](#) (Region includes [the Special Administrative Region of one country](#)) government agencies which are not Medical Device Regulatory Authorities ("Industry").

Is proposed to be replaced by:-

AHWP is a non-profit organization which consists of regulatory authorities and industry. [Its members come from the Medical Device Regulatory Authorities](#) ("Regulatory Authorities") and the medical device industry [including government agencies](#) which are not Medical Device Regulatory Authorities ("Industry") [of a country or region](#) (Region includes, [for example, a Special Administrative Region of one country](#)).

3.3. The following under the current Clause 1.4A on Membership:-

Any countries and/or regions interested in joining the Working Party may be admitted subject to a majority support from existing members.

Is proposed to be replaced by:-

Any regulatory authority and industry of a country and/or region interested in joining the Working Party may be admitted subject to a majority support from existing members.

3.4. The current Clause 1.4B on Membership:-

Upon joining, each member country or region should nominate two Primary AHWP Representatives and two Secondary AHWP Representatives, with one each from the Regulatory Authority and one each from the Industry. Representatives from the Regulatory Authority shall be responsible persons in the development and implementation of medical device regulatory frameworks while those from the Industry shall be senior managers from the industry of the member country or region such that they could represent the views of both the Regulatory Authority and Industry of their respected countries or regions.

Is proposed to be replaced by:-

Upon joining, each country or region should nominate two Primary AHWP Representatives and two Secondary AHWP Representatives, with one each from the Regulatory Authority and one each from the Industry. Representatives from the Regulatory Authority shall be responsible persons in the development and implementation of medical device regulatory frameworks while those from the Industry shall be senior managers from the industry of the country or region such that they could represent the views of both the Regulatory Authority and Industry of their respected countries or regions.

3.5. The current Clause 1.4C on Membership:-

The Primary and Secondary AHWP Representatives from the Regulatory Authority of a member country or region 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. Unless the Secretariat is otherwise informed, 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 country or region, before subscribing to AHWP Secretariat.

Is proposed to be replaced by:-

The Primary and Secondary AHWP Representatives from the Regulatory Authority of a country or region 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. Unless the Secretariat is otherwise informed, 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 country or region, before subscribing to AHWP Secretariat.

3.6. The following under the current Clause 1.5 on Leadership:-

The AHWP Chair and Vice-chairs will normally rotate among member countries or regions.

Is proposed to be replaced by:-

The AHWP Chair and Vice-chairs will normally rotate among members.

3.7. The following under the current Clause 1.7 on Decisions and Resolutions:-

Though member countries or regions should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on member countries or regions such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

Is proposed to be replaced by:-

Though members should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on members such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

3.8. The current Clause 1.10 on Language:-

English will be used as the only language in documents and communications of the AHWP. Member countries or regions may arrange for translation and/or employ interpreters for their own use if needed.

Is proposed to be replaced by:-

English will be used as the only language in documents and communications of the AHWP. Members may arrange for translation and/or employ interpreters for their own use if needed.

3.9. The current Clause 1.11 on AHWP Meetings:-

The Working Party shall meet at regular intervals (normally once a year). The AHWP Chair may organize ad hoc meetings when needed. Meeting locations shall preferably be rotated among member countries or regions.

Is proposed to be replaced by:-

The Working Party shall meet at regular intervals (normally once a year). The AHWP Chair may organize ad hoc meetings when needed. Meeting locations shall preferably be rotated among members.

3.10. The following under the current Clause 2.2A on AHWPTC Membership:-

Each member country or region should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the Regulatory Authority and one each from the Industry.

Is proposed to be replaced by:-

Each country or region should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the member Regulatory Authority and one each from the member Industry.

3.11. The following under the current Clause 2.2B on AHWPTC Membership:-

Unless the Secretariat is otherwise informed, 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 country or region, before subscribing to AHWP Secretariat.

Is proposed to be replaced by:-

Unless the Secretariat is otherwise informed, 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 country or region, before subscribing to AHWP Secretariat.

3.12. The current Clause 4.5 on Change of Office Bearers and Representatives:-

When there are changes to office bearers, the Primary AHWP Representative of the corresponding member country or region shall nominate replacements to fill the vacancies arise. If the member country or region fails to make nominations for such replacements for any reason, the AHWP Chair may appoint acting replacements until new office bearers are elected to fill the relevant vacancies in the next AHWP Meeting.

Is proposed to be replaced by:-

When there are changes to office bearers, the Primary AHWP Representative of the corresponding country or region shall nominate replacements to fill any vacancies arise. If the Primary AHWP Representative of the country or region fails to make nominations for such replacements for any reason, the AHWP Chair may appoint acting replacements until new office bearers are elected to fill the relevant vacancies in the next AHWP Meeting.

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