



FINAL DOCUMENT

Title: Amendment 6 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 nomenclature "member economy" in AHWP Terms of Reference (TOR) was adopted by referencing to the Asia-Pacific Economic Cooperation (APEC), which is a regional economic forum established in 1989 to leverage the growing interdependence of the Asia-Pacific; with aim to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration. [More info on APEC: apec.org].
- 2.2. China Food and Drug Administration (CFDA), has initiated the revision of AHWP TOR by revising the nomenclature "member economy" into "member country or region", by referencing to the International Council for Harmonisation (ICH), which has better similarity with AHWP in terms of member composition and mission.
- 2.3. ICH, since its inception in 1990, brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration; with mission to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner; through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. [More info of ICH: www.ich.org].
- 2.4. This amendment of TOR is mainly to revise "member economy" to "member country or region" by referencing to ICH, which has better similarity with AHWP in terms of member composition and mission, instead of APEC.
- 2.5. 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 TOP and House Rules possible.
- 2.6. The following roles and responsibilities will remain unchanged after nomenclature revision:
 - a) Voting rights;
 - b) Responsibilities;
 - c) Participation;
 - d) Name of member.

3. **Proposed Amendments to the AHWP TOR**

- 3.1. The current Clause 1.3:-

Clause 1.3 Goals

- *To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and beyond.*

is proposed to be replaced by:-

- *To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.*

3.2. The current Clause 1.3:-

Clause 1.3 Goals

- *To work in collaboration with related international organizations such as IMDRF, WHO, ISO, IEC.*

is proposed to be replaced by:-

- *To work in collaboration with related international organizations such as International Medical Device Regulators Forum (IMDRF), WHO, ISO, IEC.*

3.3. The current Clause 1.4:-

Clause 1.4 Membership

- A. *The Working Party is a group of experts from Medical Device Regulatory Authorities (“Regulatory Authorities”) and the medical device industry including government agencies not Medical Device Regulatory Authorities (“Industry”). Membership is open to those representatives from the Asian and other regions that support the above stated goals. Any economies interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.*

is proposed to be replaced by:-

- A. *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”). Membership is open to those representatives from the Asian and other continents that support the above stated goals. Any countries and/or regions interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.*

3.4. The current Clause 1.4:-

Clause 1.4 Membership

- B. *Upon joining, each member economy 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 economy such that they could represent the views of both the Regulatory Authority and Industry of their economies.*

is proposed to be replaced by:-

- B. *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.*

3.5. The current Clause 1.4:-

Clause 1.4 Membership

C. *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. 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 economy, before subscribing to AHWP Secretariat.*

is proposed to be replaced by:-

C. *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.*

3.6. The current Clause 1.5:-

Clause 1.5 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.

is proposed to be replaced by:-

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 countries or regions.

3.7. The current Clause 1.7:-

Clause 1.7 Decisions and Resolutions

The Working Party shall operate on a consensus basis. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at AHWP Meetings. Though member economies should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on member economies such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

is proposed to be replaced by:-

The Working Party shall operate on a consensus basis. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at AHWP Meetings. 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.

3.8. The current Clause 1.8:-

Clause 1.8 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.

is proposed to be replaced by:-

The Working Party shall work closely with other international organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.

3.9. The current Clause 1.10:-

Clause 1.10 Language

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

3.10. The current Clause 1.11:-

Clause 1.11 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 economies.

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 member countries or regions.

3.11. The current Clause 2.2:-

Clause 2.2 AHWPTC Membership

A. *Each member economy should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the Regulatory Authority and one each from the Industry. The Representatives shall be knowledgeable experts in medical device regulatory services and be able to represent the views of the Regulatory Authority and Industry of their economy.*

is proposed to be replaced by:-

A. *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. The Representatives shall be knowledgeable experts in medical device regulatory services and be able to represent the views of the Regulatory Authority and Industry of their country or region.*

3.12. The current Clause 2.2:-

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. 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 economy, before subscribing to AHWP Secretariat.*

is proposed to be replaced by:-

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 country or region. The Primary and Secondary AHWPTC Representatives from the Industry should be nominated by the industry representatives of their own country or region. 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.*

3.13. The current Clause 3.1:-

Clause 3.1 Representation

The Regulatory Authorities are government bodies responsible for the regulation of medical devices. The Industry includes all business and services related to the manufacturing, supply, distribution, usage, procurement, maintenance, testing, conformity assessment and supporting services related to medical devices. Government, semi-government and non-government bodies not directly responsible for the regulation of medical devices are regarded as part of the Industry for the purpose of the Working Party.

is proposed to be replaced by:-

The Regulatory Authorities are agencies responsible for the regulation of medical devices in the countries or regions. The Industry includes all business and services related to the manufacturing, supply, distribution, usage, procurement, maintenance, testing, conformity assessment and supporting services related to medical devices. Government, semi-government and non-government bodies not directly responsible for the regulation of medical devices are regarded as part of the Industry for the purpose of the Working Party.

3.14. The current Clause 4.5:-

Clause 4.5 Change of Office Bearers and Representatives

When there are changes to office bearers, the Primary AHWP Representative of the corresponding member economy shall nominate replacements to fill the vacancies arise. If the member economy 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 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.

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