Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: AHWP Vision & Mission

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. Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference (Amendment 2), which became the current TOR, is under the Final Document AHWP/SECRETARIAT/F001:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.

2.2. Since the AHWP Secretariat Meeting in Seoul on 25 February 2016, Asian Harmonization Working Party (AHWP) leaders has initiated the issue of setting Vision and Mission.

2.3. To visualize the strategic plan of AHWP, it is fundamental and important to set the Vision and Mission to clarify the plan of AHWP as the roadmap for success.

2.4. 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.

3. Proposed Amendments to the AHWP TOR

3.1. The below new clause Vision is proposed to be added as:-

Clause 1.1 Vision
To Achieve International Harmonization of Medical Device Regulations through Collaborative Efforts of Regulators and the Industry in Asia and Beyond.

3.2. The below new clause Mission is proposed to be added as:-

Clause 1.2 Mission
To Strategically Accelerate Medical Device Regulatory Convergence through Promotion of an Efficient and Effective Regulatory Model for Medical Devices.

3.3. The current Clause 1.1:-

Clause 1.1 Goals
To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

is proposed to be replaced by:-

Clause 1.3 Goals
- To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and beyond.
- To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.
- To promote capacity building in member economies and to foster strategic membership expansion.
- To work in collaboration with related international organizations such as IMDRF, WHO, ISO, IEC.

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