



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: Working Group Technical Document Endorsement
Mechanism

Authoring Group: AHWP SECRETARIAT

Date: 27 September 2016

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 Amendments 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. Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- 2.3. To facilitate the acceleration of process for WG technical document endorsement.
- 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 current clause on Asian Harmonization Working Party Technical Committee (AHWPTC; or the "Technical Committee") in AHWP TOR:-

Clause 2.1 AHWPTC is the executive arm of the Working Party. It performs the following roles and responsibilities to support the Working Party:

- *Execute the Working Party's decisions and resolutions;*
- *Make recommendations to the AHWP Chair for decisions;*
- *Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;*
- *Provide expert opinions and advices;*
- *Develop technical documents and policy papers;*
- *Plan and organize meetings, training, seminars, workshops and experience sharing sessions;*
- *Work with related organizations and participate in their activities; and*
- *Report on the progress of its activities to the AHWP Meetings.*

is proposed to be replaced by:-

Clause 2.1 AHWPTC is the executive arm of the Working Party. It performs the following roles and responsibilities to support the Working Party:

- *Execute the Working Party's decisions and resolutions;*
- *Make recommendations to the AHWP Chair for decisions;*
- *Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;*
- *Provide expert opinions and advices;*
- *Develop and submit policy papers for resolutions;*
- *Develop and submit technical documents and white papers for endorsements;*
- *Plan and organize meetings, training, seminars, workshops and experience sharing sessions;*
- *Work with related organizations and participate in their activities; and*
- *Report on the progress of its activities to the AHWP Meetings.*

- 3.2. The below new clause 3.2C and 3.2D are proposed to be added in AHWP TOR after the current clause 3.2B. Resolutions & Decisions to be updated accordingly:-

Clause 3.2 Resolutions, Endorsements & Decision

- C. *AHWPTC Representatives may initiate resolutions of AHWPTC technical documents and white papers for discussions and endorsements through electronic means and/or at AHWPTC Meetings by AHWPTC Representatives.*
- D. *A simple majority is needed for any endorsements of AHWPTC technical documents and white papers through electronic means by AHWPTC Representatives.*

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