



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

**PROPOSED FINAL DOCUMENT**

**Title:** Official Observer

**Authoring Group:** AHWP SECRETARIAT

**Date:** 10 November 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 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 17<sup>th</sup> AHWP Meeting and announced on 20 November 2012.
- 2.2. To set up a role of Official Observer of AHWP, for close collaborating partnership with international organizations and other regulatory authorities, which have constraints to join AHWP liaison membership.
- 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 TOP and House Rules possible.

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

- 3.1. The below new clause 1.4 Official Observers is proposed to be added in AHWP TOR between the current clause 1.3 Leadership and 1.4 Decisions and Resolutions, with numbering of clauses under Clause 1. Asian Harmonization Working Party (AHWP; or the "Working Party") to be updated accordingly:-

***Clause 1.4 Official Observers***

*The AHWP leadership may designate Official Observers on the basis of expected contribution and value. Official Observers must be approved by the unanimous consent of the voting members present in AHWP annual meetings. Official Observers do not participate in the decision making process.*

----- End -----