



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

**PROPOSED FINAL DOCUMENT**

**Title:**            **Amendment 3 to the Asian Harmonization Working Party House Rules**

**Author:**        **AHWP SECRETARIAT**

**Date:**           **29 November 2013**

This document may contain privileged information and it only intends to be used for the internal discussions and circulations within the Asian Harmonization Working Party (AHWP). This document shall not be quoted or circulated outside AHWP or used for any other purposes. AHWP disclaims any responsibilities of whatsoever nature to anybody to whom this document is copied or made known.

**1. Purpose**

This document proposes to make amendment to the Asian Harmonization Working Party House Rules (hereafter as “AHWP House Rules”) as detailed in section 3 below under “Proposed Amendment to the AHWP House Rules”.

**2. Background**

- 2.1 The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F002:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.
- 2.2 Since 2012, the Asian Harmonization Working Party (AHWP) leadership has initiated the document entitled “AHWP Strategic Framework Towards 2020 – The Foreseeable Harmonization Horizon” (hereafter the “Strategic Framework”).
- 2.3 To support the Strategic Framework element on AHWP membership expansion, AHWP should welcome non-AHWP economic members who show interests in participating. At the mean time, current AHWP member economies who has experiences and knowledge on medical device regulation should be invited to take leadership roles at AHWP, AHWP Technical Committee (TC) and Working Groups.
- 2.4 The amendments to AHWP House Rules in section 3 of this document are prepared to facilitate the aforementioned purposes, by interaction and networking.
- 2.5 AHWP Terms of Reference can override AHWP House Rules when there is any discrepancy;

**3 Proposed Amendment to the AHWP House Rules**

- 3.1 The below new clause 8.E Applications for Joining AHWP is proposed to be added in AHWP House Rules:-

***Clause 8 Applications for Joining AHWP***

*E. The AHWPTC Working Group membership shall be open to individuals whose work is based in AHWP member economies in the field of medical device. Individuals based in non-AHWP member economies in the field of medical device who wish to join Working Group Membership can be accepted as Working Group Advisor(s), subject to the final decision of corresponding Working Group Chair and Co-chair. Working Group Chair and Co-chair shall have the rights to nominate, accept and reject the Advisor(s) to his/her Working Group. The number of Advisor(s) to each Working Group shall not exceed two (2).*

-----End-----