



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED FINAL DOCUMENT

Title: **Amendment 2 to the Asian Harmonization Working Party House Rules**

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Date: **29 November 2013**

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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 Global Partnership, AHWP should, and has already been proactively approaching international organizations, leaders and experts on medical device regulations to identify important topics and to establish mechanisms for effective interaction and networking.
- 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.D Applications for Joining AHWP is proposed to be added in AHWP House Rules:-

Clause 8 Applications for Joining AHWP

D. AHWP Liaison Membership

- a) The Liaison Membership is open to the regional and international organizations who wish to join AHWP and with their goals in-line with the work of AHWP towards harmonization of medical device regulations.
- b) Any organization interested in joining AHWP as a Liaison Member shall send their request to AHWP with attention to AHWP Chair and cc AHWP Secretariat at secretariat@ahwp.info.
- c) AHWP shall evaluate and determine the suitability of the applying organization for joining AHWP as a Liaison Member.
- d) AHWP Chair shall have the rights to reject any AHWP Liaison Membership application.

- e) Once the Liaison Membership application is confirmed, an official letter of confirmation from the AHWP Chair will be send via AHWP Secretariat to the new Liaison Member.
- f) The confirmed Liaison Member shall nominate a representative and subscribe to AHWP Secretariat as the contact person.
- g) Liaison Member of AHWP shall have higher priority to co-organize activities with AHWP.
- h) The representative from Liaison Member can be an observer; however, shall not have voting rights in AHWP meetings.
- i) The full list of Liaison Members of AHWP as well as the contacts of the corresponding representatives shall be kept by the AHWP Secretariat for record.
- j) The list of Liaison Members of AHWP shall also be available at AHWP website.

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