

AHWP & AHWPTC

Terms of Reference

Summary of Proposed Amendment 2

17th AHWP Annual Meeting
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Chinese Taipei

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Content

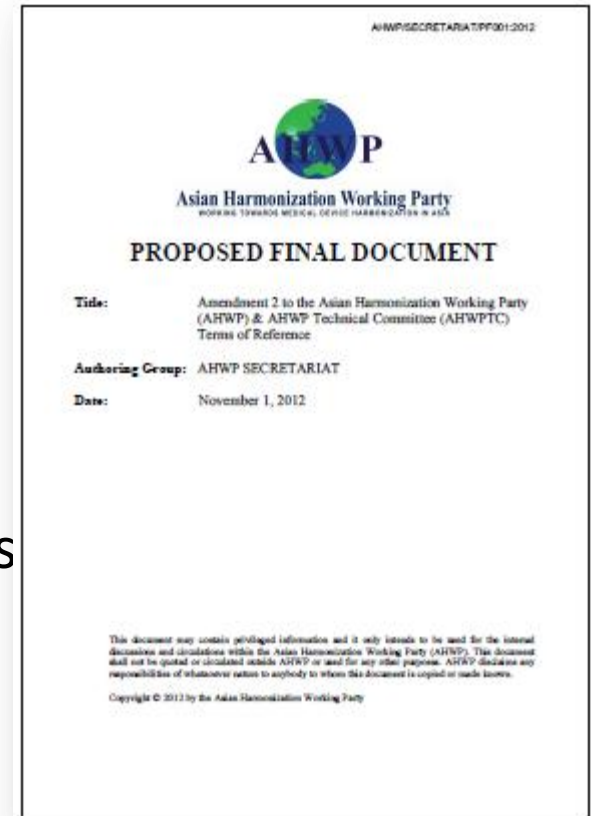
- Background
- Overview
- Amendment 2 to AHWP & AHWPTC Terms of Reference

Background

- Purpose
 - This document proposes to make amendment to the AHWP & AHWPTC Terms of Reference (hereafter as “TOR”).
- Background
 - AHWP & AHWPTC Terms of Reference (Amendment 1), which became the current TOR, is specified under the Final Document AHWP/STG(LE)/001A resolved in the 15th AHWP Meeting and announced on 30 November 2010.
 - There are some ambiguous areas within the current TOR, some conflicts within TOR, and some conflicts between TOR and the current AHWP House Rules (AHWP/SECRETARIAT/001).
 - 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 TOR and House Rules possible.

Overview

- Raised at AHWP Singapore Secretariat Meeting, 28 Feb 2012
- Discussed & commented at Secretariat Riyadh Meeting, 18-19 Sep 2012
- Post on AHWP website, Call for Comments
- For resolution, 17th AHWP Taipei Meeting



For resolution

Overview

AHWP Terms of Reference (30/11/2010)

- 1 Asian Harmonization Working Party (AHWP; or the “Working Party”)
 - 1.1 Goals
 - 1.2 **Membership**
 - 1.3 **Leadership**
 - 1.4 Decisions and Resolutions
 - 1.5 **Relationship with Other Parties**
 - 1.6 Observers to Meetings
 - 1.7 Language
 - 1.8 AHWP Meetings
- 2 Asian Harmonization Working Party Technical Committee (AHWPTC; or the “Technical Committee”)
 - 2.1 (General)
 - 2.2 **AHWPTC Membership**
 - 2.3 **AHWPTC Leadership**
 - 2.4 Working Groups (WGs) and Special Task Groups (STGs)
 - 2.5 AHWPTC Meetings
- 3 Terms of Representation, Resolutions & Decisions
 - 3.1 Representation
 - 3.2 Resolutions & Decisions
- 4 Voting, Nomination, Election, Terms of Service, Change of Office Bearers /Representatives and Representation in the Absence of Representatives
 - 4.1 **Voting**
 - 4.2 Nomination
 - 4.3 Election
 - 4.4 Terms of Office
 - 4.5 Change of Office Bearers and Representatives
 - 4.6 **Representation in the absence of the Representatives**

Last updated on
30/11/2010

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

- First of all, all the clauses in TOR are numbered for ease of reference.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

1.2 Membership

The Primary ~~and Secondary~~ AHWP Representatives from the Regulatory Authority of a member economy shall be nominated by the medical device regulatory authority of the corresponding government. ~~He/she could in turn nominate the Secondary AHWP Representative for his/her economy.~~ All organizations from the Industry ~~should~~ shall nominate ~~a representative~~ the Primary and Secondary Representatives to subscribe to the AHWP Secretariat ~~for serving as the contact person.~~ Unless the Secretariat is otherwise informed, the nominated AHWP Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy, before subscribing to AHWP Secretariat.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

1.3 Leadership

One AHWP Chair and two AHWP Vice-chairs shall be elected from Primary AHWP Representatives at the AHWP Annual Meeting through voting by all **presented** Primary AHWP Representatives for a term of office until the next election. The AHWP Chair and one AHWP Vice-chair shall come from Regulatory Authorities while one AHWP Vice-chair shall come from the Industry. The AHWP Chair and Vice-chairs will normally rotate among member economies. ~~In the absence of the AHWP Chair and/or AHWP Vice-chairs at a given AHWP Meeting, they or the organizations that they are representing may nominate suitable persons as acting AHWP Chair and/or AHWP Vice-chairs for the purpose of the said meeting.~~

Remarks:

- a) No proxy for voting
- b) Chairs shall join the meeting

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

1.5 Relationship with Other Parties

The Working Party shall work closely with ~~GHTF, APEC, WTO, WHO, ASEAN, ASEM, LAHWP~~ and other international and regional organizations to identify areas of compatibility and cooperation towards harmonization of medical device regulations.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

2.2 AHWPTC Membership

- C The Primary AHWP Representative from the Regulatory Authority ~~could~~ shall nominate both the Primary and Secondary AHWPTC Representatives for the Regulatory Authority of his/her economy. The Primary and Secondary AHWPTC Representatives from the Industry should be ~~elected~~ nominated by the industry representatives of their own economy. Unless the Secretariat is otherwise informed, the nominated AHWPTC Primary and Secondary Representatives from the Industry shall be endorsed by the AHWP Primary Representative from the Regulatory Authority of the same member economy, before subscribing to AHWP Secretariat.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

2.3 AHWPTC Leadership

One AHWPTC Chair and two AHWPTC Co-chairs shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives [at the AHWPTC Meeting that is held in conjunction with the AHWP Annual Meeting](#). The AHWPTC Chair and one AHWPTC Co-chair shall come from the Regulatory Authorities while one AHWPTC Co-chair shall come from the Industry. In the absence of the AHWPTC Chair at a given AHWPTC Meeting, the AHWPTC Co-chair from the Regulatory Authority shall assume the duties of the AHWPTC Chair. In the absence of both the AHWPTC Chair and Co-chair from the Regulatory Authority, the AHWPTC Co-chair from the Industry shall assume the duties of the AHWPTC Chair.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

Original Text

The original text:-

Voting

Each **Primary AHWP Representative** and **Primary AHWPTC Representative** shall have one vote at the AHWP Meeting and AHWPTC Meeting **respectively**.

is proposed to be replaced by:-

4.1 Voting

Each **Primary AHWP Representative** shall have one vote at the AHWP Meeting.
Each **Primary AHWPTC Representative** shall have one vote at AHWPTC Meeting.

AHWP & AHWPTC TOR

(Areas recommended amendments in [red] , proposed amendments in [blue])

4.6 Representation in the absence of the Representatives

Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence. In case that both the Primary and Secondary AHWPTC Representatives are absent, the corresponding Primary AHWP Representative could take up all the roles and responsibilities as well as voting rights at the AHWPTC Meetings. Similarly, Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent. However, representatives from the Regulatory Authority shall not represent representatives from the Industry. Similarly, representatives from the Industry shall not represent representatives from the Regulatory Authority.

Remarks:

- a) No cross-representing between Regulatory Authority and Industry

- Thank You –

Yes / No ?