

AHWP

Terms of Reference & House Rules

Summary of Proposed Amendments

AHWP Secretariat Meeting
18 Sep – 19 Sep 2012
Riyadh, Kingdom of Saudi Arabia

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Background

- Purpose
 - To manage the ambiguous areas of AHWP TOR and House Rules
 - To eliminate conflicting clauses within and between AHWP TOR and House Rules
- General Principles
 - Once confirmed, AHWP TOR can override the House Rules when there is any discrepancies
 - Minimum amendment efforts to be needed

Overview

AHWP Terms of Reference (18/12/2009)

- 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
18/12/2009

Overview

AHWP House Rules (11/10/2011)	
1	Applications of the AHWP House Rules
2	Requirements of the AHWP Chair/Vice-chairs
3	Nominations and Elections of the AHWP Chair/Vice-chairs
4	Requirements of the AHWPTC Chair/Co-chairs
5	Nominations and Elections of the AHWPTC Chair/Co-chairs
6	Roles and Responsibilities of the Secretariat
7	Appointment of the Secretariat Team
8	Applications for Joining AHWP
9	Appointments of AHWP and AHWPTC Representatives
10	Upkeep of Members and Representatives Records
11	Hosting AHWP and AHWPTC Meetings
12	Management of the AHWP Account and Reserve
13	Management of the AHWP Website
14	Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat
15	Proposing Issues For Discussion in AHWP Meetings
16	Proposing Resolutions in AHWP Meetings

Last updated on
11/10/2011

AHWP TOR

(suggested amendments in [red], elaborations in [blue])

1.2 Membership

- 1.2.1 The Working Party is a group of experts from Medical Device Regulatory Authorities (“**Regulatory Authorities**”) and the medical device industry including government agencies not Medical Device Regulatory Authorities (“**Industry**”). Membership is open to those representatives from the Asian and other regions that support the above stated goals. Any economies interested in joining the Working Party may be admitted subject to a majority support from existing members. The full list of members will be kept by the AHWP Secretariat.

Discussions:

- a) Liaison partnership is suggested to be included in TOR clause 1.5 “Relationship with Other Parties”, on an invitation basis.

AHWP TOR

(suggested amendments in [red] , elaborations in [blue])

1.2 Membership

- 1.2.3 The Primary ~~and Secondary~~ AHWP Representative[s] 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 nominate ~~a representative~~ [the Primary and Secondary Representatives for each country of economy] to subscribe to the AHWP Secretariat ~~for serving as the contact person.~~ [The functions are more than contact persons.]

Ambiguous Descriptions and Discussions on:

- a)Suggested to adjust the nomination of Primary & Secondary Representatives from regulatory authority & industry

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

1.3 Leadership

- 1.3.1 One AHWP Chair and two AHWP Vice-chairs shall be elected **from Primary AHWP Representatives** **at** the AHWP Annual Meeting through voting **by all 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.

Confliction with **House Rules** & Discussions:

a) **House Rules** clause 3 – “Nominations and Elections of the AHWP Chair/Vice-chairs”: Chairs shall be elected **from both Primary and Secondary AHWP Representatives**.

b) The Chairs election results will be fully decided by voting. If not rotated does it mean **abnormal**?

AHWP House Rules

(Suggested amendments in [red] In text elaborations in [blue])

3 Nominations and Elections of the AHWP Chair/Vice-chairs

- 3.A **AHWP Representatives** from Regulatory Authorities could be nominated **by** Primary AHWP Representatives as the candidates in the AHWP Chair election and AHWP Vice-chair (Regulatory Authority) election while AHWP Representatives from the Industry could be nominated as the candidates in the AHWP Vice-chair (Industry) election.

Confliction with TOR:

- a) TOR clause 1.3.1 – “(AHWP) Leadership”: AHWP Chairs shall be elected **from** Primary AHWP Representatives.

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

1.5 Relationship with Other Parties

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

Added Contents for Discussions:

a)IMDRF may be updated as a primary collaborating organization?

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

1.5 Relationship with Other Parties

- 1.5.2 Liaison partnership is open to those representatives from international organizations towards harmonization of medical device regulations on an invitation basis. Any representative interested in joining the Working Party may be admitted by confirming the invitation from AHWP Chairs and AHWPTC Chairs. The full list of liaison partners will be kept by the AHWP Secretariat.

Added Contents for Discussions:

- a) New clause 1.5.2 was proposed for discussions

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

2.2 AHWPTC Membership

- 2.2.2 The Primary AHWP Representative from the Regulatory Authority could 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 by the industry representatives of their own economy.

For your reference:

a) Both Primary & Secondary AHWPTC representatives will be nominated **by AHWP Primary representative** of his/her economy.

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

2.3 AHWPTC Leadership

- 2.3.1 One AHWPTC Chair and two AHWPTC Co-chairs shall be elected **by** the AHWP Primary Representatives **among** the AHWPTC Representatives [at the AHWPTC Meeting In line with 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.

Ambiguous descriptions & Discussions:

- a) AHWPTC meeting is currently held twice/year. Should the TC Chairs be elected at the TC Meeting which is in line with AHWP Annual Meeting?

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

4 Voting, Nomination, Election, Terms of Service, Change of Office Bearers /Representatives and Representation in the Absence of Representatives

4.1 Voting

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

Any Discussions on:

- a) Each Primary AHWPTC Representatives have one vote, for resolutions ONLY. AHWP Chairs, TC Chairs and WG Chairs are elected by Primary AHWP Representatives.

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

2.4 Working Groups (WGs) and Special Task Groups (STGs)

2.4.1 With the consent of the AHWP Chair, the AHWPTC Chair may create Working Groups and Special Task Groups for carrying out specific tasks and duties of the Technical Committee. Each Group shall have one Chair from the Regulatory Authority and one Co-chair from the Industry.

The AHWPTC Chair may appoint Acting Chairs and Co-chairs to take charge of the newly formed Groups until the next AHWP Meeting in which the Chairs and Co-chairs of the newly formed Groups are elected.

Ambiguous Descriptions & Discussions:

a) WG & STG Chair and Co-chair are nominated by Primary AHWP Representatives, however from ??? and elected at ??? meeting?

Detailed descriptions are not included neither in TOR nor in House Rules.

AHWP TOR

(Suggested amendments in [red] In text elaborations in [blue])

4.2 Nomination

- 4.2.1 Primary AHWP Representatives may propose nominations for election as office bearers in the AHWP, AHWPTC, WGs and STGs.

Ambiguous Descriptions & Discussions:

a)WG & STG Chair and Co-chair are nominated by Primary AHWP Representatives, however from ??? and at ??? meeting?

Detailed descriptions are not included neither in AHWP TOR nor in House Rules.

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