

AHWP

House Rules

Summary of Proposed Amendment 1

17th AHWP Annual Meeting
2–6 Nov 2012
Chinese Taipei

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AHWP Secretariat



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Content

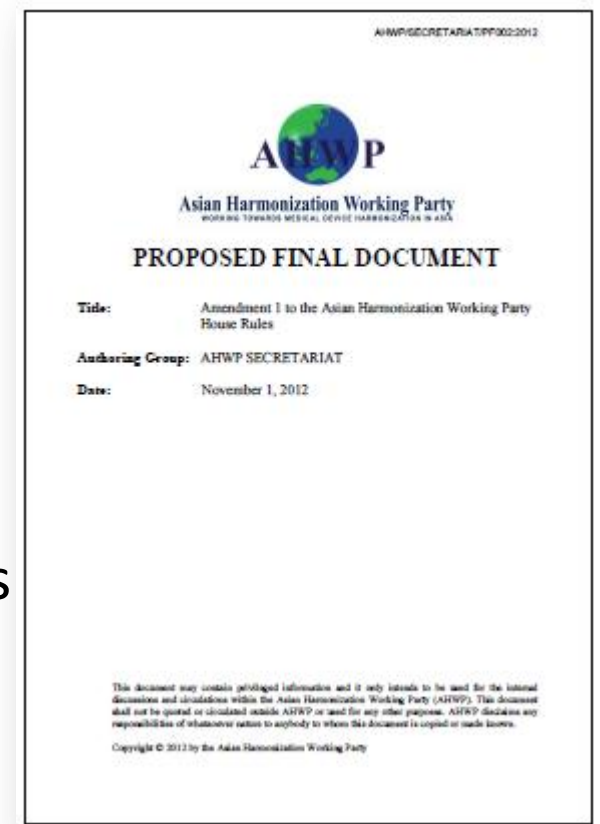
- Background
- Overview
- Amendment 1 to AHWP House Rules

Background

- Purpose
 - This document proposes to make amendment to the AHWP House Rules.
- Background
 - The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/001 resolved in the 15th AHWP Meeting and announced on 30 November 2010.
 - There are some conflictions between the current AHWP House Rules and the current Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference (hereafter as “TOR”).
 - 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 House Rules (30/11/2010)

- 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

17

Last updated on
30/11/2010

AHWP House Rules

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

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

- A AHWP Primary 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 Primary Representatives from the Industry could be nominated as the candidates in the AHWP Vice-chair (Industry) election.

Remarks:

- a) AHWP Vice-chair candidates shall be Primary Representatives.

AHWP House Rules

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

9 Appointments of AHWP and AHWPTC Representatives

- B Member economies may also change their AHWP and AHWPTC Representatives by informing the Secretariat and the Chair accordingly. **AHWP Primary Representative from the Regulatory Authority shall update AHWP Secretariat on any changes of the AHWP and AHWPTC Representatives from Industry of his/her member economy.**

Remarks:

a) AHWP Primary Regulatory Rep

Changes of
AHWP and TC
Primary & Secondary
Industry Reps.

Secretariat
(Record)

Website
(Public)

AHWP House Rules

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

Newly Proposed Text

17 Advisor to AHWPTC

- A AHWPTC shall appoint expert(s) from AHWP member economies and other international and regional organizations as advisor(s) on a need basis, for the purpose of seeking his/her/their technical/professional advice towards meeting the goals of AHWP.
- B Chairs and Co-chairs of AHWPTC, WGs and STGs shall propose the criteria for Advisor to AHWPTC. The proposed criteria as well as any changes of the criteria shall be updated to AHWP Secretariat.
- C Chairs and Co-chairs of AHWPTC, WGs and STGs shall nominate expert(s) to AHWP Secretariat. Secretariat shall review the suitability of the nominated expert(s) and submit the recommendations to AHWPTC Chair. Nominated experts who satisfy the criteria shall be considered being appointed to the AHWPTC Advisory Panel. AHWPTC Chair shall submit the name of candidate(s) and advice to AHWP Chair for final confirmation. With the confirmation of AHWP Chair, AHWPTC Chair shall appoint the confirmed candidate(s) to AHWPTC Advisory Panel as Advisor(s) to AHWPTC. The number of Advisors in the panel shall not exceed ten (10).

To be continued...

AHWP House Rules

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

Newly Proposed Text

17 Advisor to AHWPTC

- A AHWPTC shall [red] regional organ[red] technical/professional advice towards [red] meeting the goals of AHWP. [red] and other international and [red] purpose of seeking his/her/their
- B Chairs and Co- [red] the criteri [red] C. The proposed [red] all be upda [red] t.
- C Chairs and Co-chairs of AHWPTC, WG [red] and STGs shall nominate expert(s) to AHWPTC Secretariat. [red] and submit the [red] recommendations to AHWPTC Chair. [red] nominated experts who satisfy the criteria shall be [red] considered bei [red] AHWPTC Chair shall submit the name [red] of candidate(s) [red] n. With the confirmation of AHWPTC Chair, AHWPTC [red] to AHWPTC Advisory Panel as [red] Advisor(s) to AHWPTC. The number of [red] Advisors in the panel shall not exceed ten (10).

Confirmed by:
AHWP Chair

Appoint

Advised by:
TC Chair

Advisors to TC

Criteria

Reviewed & Recommended by:
Secretariat

Proposed by:
Chairs/Co-chairs of TC, WGs, and STG

To be continued...

AHWP House Rules

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

Newly Proposed Text (Cont.)

17 Advisor to AHWPTC

- D The AHWPTC Advisory Panel is independent to WGs and STGs, but shall be available to all WGs and STGs. The scope of expertise shall meet the needs of AHWPTC, WGs and STGs.
- E The term of office of Advisor(s) to AHWPTC commences from the date of appointment. All Advisors to AHWPTC, regardless of when they are appointed during the term of a given AHWPTC Chair, shall retire altogether at the same time with that AHWPTC Chair. The reappointment of Advisor(s) to AHWPTC shall be made by the new AHWPTC Chair.
- F Appointment to the AHWPTC Advisory Panel is on a voluntary basis. All AHWPTC Advisory Panel members shall receive no compensation from AHWP, AHWPTC and AHWP Administration Services Ltd.

To be continued...

AHWP House Rules

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

Newly Proposed Text (Cont.)

17 Advisor to AHWPTC

- G Apart from this panel of Advisors, WGs and STGs Chairs and Co-chairs may nominate individual experts as advisor(s) to their corresponding WGs or STGs on a need basis. With the final confirmation of AHWPTC Chair, the WG or STG Chair shall appoint the individual experts, with a maximum number of two (2), to his/her WG or STG. Advisor(s) to WGs and STGs will not be appointed to the Advisory Panel to AHWPTC.
- H The term of office of Advisor(s) to WGs and STGs commences from the date of appointment. All Advisors to WGs and STGs, regardless of when they are appointed during the term of a given WG or STG Chair, shall retire altogether at the same time with that WG or STG Chair. The reappointment of Advisor(s) to WGs and STGs shall be made by the new WG and STG Chairs.
- I Advisor(s) to AHWPTC as well as Advisor(s) to WGs and STGs shall be updated to AHWP Secretariat for record.

AHWP House Rules

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

Newly Proposed Text (Cont.)

17 Advisor to AHWPTC

G Apart from this panel of Advisors, WGs and STGs Chairs and Co-chairs may nominate individual experts as advisor(s) to their corresponding WGs or STGs on a need basis. With the final confirmation of AHWPTC Chair, the WG or STG Chair shall appoint the individual experts, with a maximum number of [red] to [red] per WG or STG. [red] Advisors to WGs will not be appointed to the [red] Secretariat for [red] WGs.

H The term of office of Advisor(s) to WGs and STGs commences from the date of appointment. All Advisors to WGs and STGs, regardless of when they are appointed during the term of a given WG or STG Chair, shall retire altogether at the same time with that WG or STG Chair. The reappointment of Advisor(s) to WGs and STGs shall be made by the new WG and STG Chairs.

I Advisor(s) to AHWPTC shall be appointed by the AHWPTC Secretariat for [red] WGs and STGs.

Confirmed by:
TC Chair

Appoint

Proposed by:
Chairs/Co-chairs of WGs and STG

Advisors to WG
and/or STG

- Thank You –

Yes / No ?