

Updates on Amendment to AHWPTC Term of Reference/ House Rules

Mechanism for WG Documents Endorsement

AHWP TC Pre-Meeting
24 Nov 2016, Cebu, Philippines

Dr. Jeong-Rim LEE
Secretary General & TC Co-chair



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Resolution towards Endorsement

AHWP Terms of Reference (TOR)

- 1) AHWP Vision & Mission, Goals
- 2) Official Observer
- 3) Working Group Technical Document Endorsement Mechanism

AHWP House Rules

- 1) Working Group Technical Document Endorsement Mechanism

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

Background

- The current AHWP Terms of Reference (TOR) is specified under the Final Document AHWP/SECRETARIAT/F001:2012 resolved in the 17th AHWP Meeting and announced on 20 November 2012.
- Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- To facilitate the acceleration of process for WG technical document endorsement.

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

Proposed Text

Clause 2.1

AHWPTC is the executive arm of the Working Party. It performs the following roles and responsibilities to support the Working Party:

- Execute the Working Party’s decisions and resolutions;*
- Make recommendations to the AHWP Chair for decisions;*
- Submit resolutions to the AHWP Meetings for decisions of key issues related to the policy, direction, organization, structure and operation of the Working Party;*
- Provide expert opinions and advices;*
- Develop **and submit** policy papers **for resolutions**;*
- **Develop and submit technical documents and white papers for endorsements**;*
- Plan and organize meetings, training, seminars, workshops and experience sharing sessions;*
- Work with related organizations and participate in their activities; and*
- Report on the progress of its activities to the AHWP Meetings.*

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

Newly Proposed Text

Clause 3.2 Resolutions, Endorsements & Decision

*C. AHWPTC Representatives may initiate resolutions of **AHWPTC technical documents and white papers** for discussions and **endorsements through electronic means** and/or at AHWPTC Meetings by AHWPTC Representatives.*

*D. A simple majority is needed for any **endorsements** of AHWPTC technical documents and white papers through **electronic means** by **AHWPTC Representatives**.*

Amendment to AHWP TOR – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

- Prepared by Secretariat
- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Towards Endorsement on 25 Nov 2016

Amendment to AHWP House Rules – WG Technical Document Endorsement Mechanism

FINAL DOCUMENT

Background

- The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F001:2014 resolved in the 19th AHWP Meeting and announced on 21 November 2014.
- Currently, WG technical documents (guidance documents, reference documents) and white papers, are under resolutions towards endorsement during TC Meetings, which are held annually in recent years.
- To facilitate the acceleration of process for WG technical document endorsement.

Amendment to AHWP House Rules – WG Technical Document Endorsement Mechanism

Proposed Text

Clause 14

Preparation of Documents for Committees, Working Groups, Special Task Groups and Secretariat

- A. *Chairs of committees, working groups, special task groups and the Secretariat could initiate the preparation of documents for discussions, approvals and resolutions/**endorsements**.*
- D. *Documents prepared for resolutions/**endorsements** and/or approvals shall be labeled “PROPOSED FINAL”.*
- E. *Documents accepted, approved, and/or prepared for already passed resolutions/**endorsements** shall be labeled “FINAL”.*

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FINAL DOCUMENT

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- ✓ Discussed in AHWP Secretariat Meeting in Apr 2016 and TC Leaders Meeting, Apr 2016
- ✓ Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- ✓ Posted on AHWP Website and completed Calls for Comments
- ✓ Posted on AHWP Website towards Endorsement

Towards Endorsement on 25 Nov 2016

Thank You

AHWP Secretariat Contact:
Mr. Bryan SO / Ms. Carol LIU
secretariat@ahwp.info