Resolutions towards Endorsement

22nd AHWP Meeting
4-8 Dec 2017, New Delhi, India

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Resolution towards Endorsement

1) Special Task Group (STG) (UDI & Nomenclature) changing to WG9 (U&I)

Terms of Reference (TOR) & House Rules

1) Amendment 6 to the AHWP & AHWPTC TOR
2) Amendment 5 to AHWP House Rules

WG Documents

1) Handbook for Approval of Patient-matched Medical Devices Using 3D Printers
2) Regulation and Treatment of e-IFU and e-Label of Medical Devices - Review of International Practice
3) Guidance for Additional Considerations to Support Conformity Assessment of Companion In vitro Diagnostic Medical Devices
4) Clinical Investigation
5) Post Market Clinical Follow-Up Studies

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Amendment 6 to the AHWP & AHWPTC TOR
PROPOSED FINAL DOCUMENT

Background

- **The current nomenclature "member economy" in AHWP Terms of Reference (TOR) was adopted by referencing to the Asia-Pacific Economic Cooperation (APEC)**, which is a regional economic forum established in 1989 to leverage the growing interdependence of the Asia-Pacific; with aim to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative and secure growth and by accelerating regional economic integration. [More info of APEC : apec.org]

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Amendment 6 to the AHWP & AHWPTC TOR
PROPOSED FINAL DOCUMENT

Proposer & Rationale

- China Food and Drug Administration (CFDA), has initiated the revision of AHWP TOR by **revising the nomenclature "member economy" into "member country or region"** , by referencing to the International Council for Harmonisation **(ICH), which has better similarity with AHWP in terms of member composition and mission.**

- ICH, since its inception in 1990, brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration; with mission to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner; through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side. [More info of ICH: www.ich.org]

Amendment 6 to the AHWP & AHWPTC TOR
PROPOSED FINAL DOCUMENT

Proposed Amendment

- To revise “member economy” to “member country or region” by **referencing to ICH, which has better similarity with AHWP in terms of member composition and mission, instead of APEC.**

Roles and Responsibilities after nomenclature revision

- **Voting rights unchanged**
- **Responsibilities unchanged**
- **Participation unchanged**
- **Name of member unchanged**

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Amendment 6 to the AHWP & AHWPTC TOR

Proposed Text

Clause 1.3 *Goals*

A. To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and ***other continents****.*

B. To work in collaboration with related international organizations such as ***International Medical Device Regulators Forum*** *(IMDRF), WHO, ISO, IEC.*

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Amendment 6 to the AHWP & AHWPTC TOR

Proposed Text

Clause 1.4 *Membership*

A. The Working Party is a group of experts from Medical Device Regulatory Authorities ("Regulatory Authorities") and the medical device industry including ***country or regional (Region includes the Special Administrative Region of one country) government agencies which are*** *not Medical Device Regulatory Authorities ("Industry"). Membership is open to those representatives from the Asian and other continents that support the above stated goals. Any* ***country or region*** *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.*

B. Upon joining, each ***member country or region*** *should nominate two Primary AHWP Representatives and two Secondary AHWP Representatives, with one each from the Regulatory Authority and one each from the Industry. Representatives from the Regulatory Authority shall be responsible persons in the development and implementation of medical device regulatory frameworks while those from the Industry shall be senior managers from the industry of the* ***member country or region*** *such that they could represent the views of both the Regulatory Authority and Industry of their respected countries or regions.*

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Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 1.4 *Membership*

C. The Primary and Secondary AHWP Representatives from the Regulatory Authority of a ***member country or region*** *shall be nominated by the medical device regulatory authority of the corresponding government. All organizations from the Industry shall nominate the Primary and Secondary Representatives to subscribe to the AHWP Secretariat. 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 country or region****, before subscribing to AHWP Secretariat.*

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Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 1.5 *Leadership*

A. 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 ***countries or regions****.*

Clause 1.7 *Decisions and Resolutions*

The Working Party shall operate on a consensus basis. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at AHWP Meetings. Though ***member countries or regions*** *should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on* ***member countries or regions*** *such that they may elect alternatives and decide their own implementation plans taking account of their local situations.*

Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 1.8 *Relationship with Other Parties*

The Working Party shall work closely with other ***international organizations*** *to identify areas of compatibility and cooperation towards harmonization of medical device regulations.*

Clause 1.10 *Language*

English will be used as the only language in documents and communications of the AHWP. ***Member countries or regions*** *may arrange for translation and/or employ interpreters for their own use if needed.*

Clause 1.11 *Language*

The Working Party shall meet at regular intervals (normally once a year). The AHWP Chair may organize ad hoc meetings when needed. Meeting locations shall preferably be rotated among ***member countries or regions.***

Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 2.2 *AHWPTC Membership*

*A. Each **member country or region** should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the Regulatory Authority and one each from the Industry. The Representatives shall be knowledgeable experts in medical device regulatory services and be able to represent the views of the Regulatory Authority and Industry of their country or region.*

*B. 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 country or region**, before subscribing to AHWP Secretariat.*

Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 3.1 *Representation*

The Regulatory Authorities are ***agencies*** *responsible for the regulation of medical devices* ***in the countries or regions****. The Industry includes all business and services related to the manufacturing, supply, distribution, usage, procurement, maintenance, testing, conformity assessment and supporting services related to medical devices. Government, semi-government and non-government bodies not directly responsible for the regulation of medical devices are regarded as part of the Industry for the purpose of the Working Party.*

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Amendment to the AHWP & AHWPTC TOR

Proposed Text

Clause 4.5 *Change of Office Bearers and Representatives*

When there are changes to office bearers, the Primary AHWP Representative of the corresponding ***member country or region*** *shall nominate replacements to fill the vacancies arise. If the* ***member country or region*** *fails to make nominations for such replacements for any reason, the AHWP Chair may appoint acting replacements until new office bearers are elected to fill the relevant vacancies in the next AHWP Meeting.*

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Amendment to the AHWP & AHWPTC TOR

PROPOSED FINAL DOCUMENT

- Prepared by Secretariat
- Reviewed and commented by AHWP & TC & WG Leaders and TC Advisors
- Posted on AHWP Website and completed Calls for Comments
- Further discussed at TC Pre-meeting, Dec 2017
- Posted on AHWP Website towards Endorsement

For Endorsement **Yes / No?**

Resolution towards Endorsement

1) Special Task Group (STG) (UDI & Nomenclature) changing to WG9 (U&I)

Terms of Reference (TOR) & House Rules

1) Amendment 6 to the AHWP & AHWPTC TOR
2) Amendment 5 to AHWP House Rules

WG Documents

1) Handbook for Approval of Patient-matched Medical Devices Using 3D Printers
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5) Post Market Clinical Follow-Up Studies

Amendment 5 to the AHWP House Rules
PROPOSED FINAL DOCUMENT

Background

- The current AHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F003:2016 resolved in the 21st AHWP Meeting and announced on 26 November 2016.

- To better clarify the roles and responsibilities of leaders of AHWPTC, WGs, Capacity Building programme, and TC Advisor;

- To better clarify the eligibility for participating WG activities

- AHWP & AHWPTC Terms of Reference can override AHWP House Rules when there is any discrepancy

Amendment to the AHWP House Rules

Proposed Text

Clause 18 *Roles and Responsibilities of Technical Committee*

A. Role and Responsibility of AHWPTC Chair

i. The AHWPTC Chair shall conduct the decision-making on the overall WG work plan.

ii. The AHWPTC Chair shall designate a TC secretary who can dedicate his/her time and effort for AHWPTC, especially for WI and Guidance document management.

iii. The AHWPTC Chair shall conduct the final approval on WG members, WG advisors, Capacity Building trainers/leaders.

iv. The AHWPTC Chair shall designate TC advisors.

v. The AHWPTC Chair shall assign tasks to TC advisors.

vi. The AHWPTC Chair shall make the overall confirmation of TC workshop program and In-country training.

vii. The AHWPTC Chair shall sign communication letter with international partners, e.g. IMDRF, ISO, etc., for technical related subjects.

viii. The AHWPTC Chair shall conduct the overall approval on AHWPTC and WG member's nomination for representing AHWP in international organization, e.g. ISO, IMDRF, etc.

ix. The AHWPTC Chair shall make the overall confirmation of speaker on behalf of AHWP or AHWPTC.

Amendment to the AHWP House Rules

Proposed Text

Clause 18 *Roles and Responsibilities of Technical Committee*

B. Role and Responsibility of AHWPTC Co-chair (Regulatory Authority)

i. The AHWPTC Co-chair shall conduct the overall coordination of program of AHWPTC workshop.

ii. The AHWPTC Co-chair shall be the contact person for important international organizations, e.g. IMDRF, WHO, APEC, PAHO, etc.

iii. The AHWPTC Co-chair shall take over AHWPTC Chair's responsibilities in case of absence.

iv. The AHWPTC Co-chair shall recommend AHWPTC WG member's nomination for representing AHWP in international organizations.

v. The AHWPTC Co-chair shall recommend speaker on behalf of AHWP or AHWPTC.

Amendment to the AHWP House Rules

Proposed Text

Clause 18 *Roles and Responsibilities of Technical Committee*

C. Role and Responsibility of AHWPTC Co-chair (Industry)

i. The AHWPTC Co-chair shall be the contact person for Industry Liaison Members, i.e. APACMed, DITTA and GSI.

ii. The AHWPTC Co-chair shall conduct the overall coordination of Joint-workshop program of AHWPTC workshop with Liaison Members.

iii. The AHWPTC Co-chair shall recommend AHWPTC WG member nomination for representing AHWP in international organizations.

iv. The AHWPTC Co-chair shall recommend speaker on behalf of AHWP or AHWPTC.

Amendment to the AHWP House Rules

Proposed Text

Clause 18 *Roles and Responsibilities of Technical Committee*

D. Role and Responsibility of WG Chairs and Co-chairs

i. The WG Chairs and Co-chairs shall conduct the management of WG members and updates.

ii. The WG Chairs and Co-chairs shall designate member with the confirmation by AHWPTC Chair.

iii. The WG Chairs and Co-chairs shall make progress report to AHWPTC Chair every 3 months.

iv. The WG Chairs and Co-chairs shall set up prior or post side-meeting to AHWP Meeting to avoid any influences on AHWP main meetings.

E. Additional Role and Responsibility of AHWPTC Advisors

i. The AHWPTC Advisors shall designate a leader of AHWPTC Advisors.

ii. The AHWPTC Advisors shall report assignment to AHWPTC Chair.

Amendment to the AHWP House Rules

Proposed Text

Clause 19 *AHWPTC WGs and STG Membership*

A. *Only members of AHWP member economies can be accepted as WGs or STG members.*

B. *In case of absence of WG chair, AHWPTC Chair can assign one of the WGs or STG regulatory members with the most expertise along with AHWPTC Co-chairs agreement.*

C. *Members of non-AHWP member economies can participate in WGs or STG as an observer or can become a WG advisor on a case-by-case basis with an approval of TC Chair.*

D. *All WGs and STG members need to be confirmed by TC Chair.*

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Handbook for Approval of Patient-matched Medical Devices Using 3D Printers

GUIDANCE DOCUMENT

- Prepared by WG 1 – Pre-market: General MD
- Discussed in AHWP TC Leaders Meeting, Mar 2017
- Reviewed and commented by AHWP TC Leaders
- Posted on AHWP Website and completed Calls for Comments
- Posted on AHWP Website towards Endorsement

For Endorsement **Yes / No?**

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Regulation and treatment of e-IFU and e-Label of Medical Devices - Review of International Practice

White Paper

- Prepared by WG 1 – Pre-market: General MD
- Discussed in AHWP TC Leaders Meeting, Mar 2017
- Reviewed and commented by AHWP TC Leaders
- Posted on AHWP Website and completed Calls for Comments
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Guidance for Additional Considerations to support Conformity Assessment of Companion In vitro Diagnostic Medical Devices

GUIDANCE DOCUMENT

- Prepared by WG 2 – Pre-market: IVDD
- Discussed in AHWP TC Leaders Meeting, Mar 2017
- Reviewed and commented by AHWP TC Leaders
- Posted on AHWP Website and completed Calls for Comments
- Posted on AHWP Website towards Endorsement

For Endorsement **Yes / No?**

Resolution towards Endorsement

AHWP New Member Economy Application

1) Republic of Kenya

AHWP Terms of Reference (TOR)

1) Amendment 6 to the AHWP TOR

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Clinical Investigation

GUIDANCE DOCUMENT

- Prepared by WG 5 – Clinical Evidence for Performance and Safety
- Discussed in AHWP TC Leaders Meeting, Mar 2017
- Reviewed and commented by AHWP TC Leaders
- Posted on AHWP Website and completed Calls for Comments
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Thank You