



# Resolution and Endorsement

24<sup>th</sup> AHWP Annual Meeting

11 - 14 Nov 2019 | Muscat | Oman

**Ir Bryan SO**

**Executive Secretary General, AHWP**

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*The Chinese University of Hong Kong*

# Resolution and Endorsement



## Resolutions

- AHWP Secretariat: “Amendment 7 to Terms of Reference”
- AHWP Secretariat: “Amendment 6 to House Rules”

## Endorsement of White Paper

- AHWP, APACMed, Deloitte: “White paper on Competency Framework for Medical Technology Regulators”

## Endorsement of Guidance Documents from WG

- WG1,2,3: “Categorisation of Changes to a Registered Medical Device”
- WG1,2,3: “Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)”
- WG9: “Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system”

## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



## Background

- The current TOR is specified under the Final Document AHWP/SECRETARIAT/F001:2017 resolved in 22<sup>nd</sup> AHWP Meeting and announced on 8 Dec 2017.
- The current nomenclature “member country or region” in AHWP Terms of Reference (TOR) was revised from “member economy” and was adopted in 2017.
- This amendment of TOR is mainly **to revise “member country or region” to “regulatory authority and/or industry of a country or region”**, to better clarify that **AHWP members are the representatives from the regulatory authority and industry** of their respective country or region, not referring to the country or region itself.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 1.3 on Goals:-**

To promote capacity building in member economies and to foster strategic membership expansion.

**Is proposed to be replaced by:-**

To promote capacity building in members and to foster strategic membership expansion.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 1.4A Membership**: -

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”).

**Is proposed to be replaced by:-**

AHWP is a non-profit organization which consists of regulatory authorities and industry. Its members come from the Medical Device Regulatory Authorities (“Regulatory Authorities”) and the medical device industry including government agencies which are not Medical Device Regulatory Authorities (“Industry”) of a country or region (Region includes, for example, a Special Administrative Region of one country).

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 1.4A on Membership**:-

Any countries and/or regions interested in joining the Working Party may be admitted subject to a majority support from existing members.

**Is proposed to be replaced by:-**

Any regulatory authority and industry of a country and/or region interested in joining the Working Party may be admitted subject to a majority support from existing members.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The current **Clause 1.4B on Membership**:-

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.

**Is proposed to be replaced by:-**

Upon joining, each 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 country or region such that they could represent the views of both the Regulatory Authority and Industry of their respected countries or regions.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The current **Clause 1.4C on Membership**:-

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.

**Is proposed to be replaced by:-**

The Primary and Secondary AHWP Representatives from the Regulatory Authority of a 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 country or region, before subscribing to AHWP Secretariat.



# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 1.5 on Leadership**:-

The AHWP Chair and Vice-chairs will normally rotate among member countries or regions.

**Is proposed to be replaced by:-**

The AHWP Chair and Vice-chairs will normally rotate among members.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 1.7 on Decisions and Resolutions**:-

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.

**Is proposed to be replaced by:-**

Though members should adopt as far as possible the decisions and resolutions so passed, such decisions and resolutions are not binding on members such that they may elect alternatives and decide their own implementation plans taking account of their local situations.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The current **Clause 1.10 on 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.

**Is proposed to be replaced by:-**

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

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The current **Clause 1.11 on AHWP Meetings:-**

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.

**Is proposed to be replaced by:-**

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 members.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 2.2A on AHWPTC Membership**:-

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.

**Is proposed to be replaced by:-**

Each country or region should nominate two Primary AHWPTC Representatives and two Secondary AHWPTC Representatives, with one each from the member Regulatory Authority and one each from the member Industry.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The following under the current **Clause 2.2B on AHWPTC Membership**:-

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.

**Is proposed to be replaced by:-**

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 country or region, before subscribing to AHWP Secretariat.

# Amendment 7 to AHWP & AHWPTC TOR PROPOSED FINAL Document



The current **Clause 4.5 on 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.

**Is proposed to be replaced by:-**

When there are changes to office bearers, the Primary AHWP Representative of the corresponding country or region shall nominate replacements to fill any vacancies arise. If the Primary AHWP Representative of the 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.

# Amendment 7 to 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
- ✓ Posted on AHWP Website towards Endorsement

**For Endorsement**

**Yes / No?**



# Resolution and Endorsement



## Resolutions

- AHWP Secretariat: “Amendment 7 to Terms of Reference”
- AHWP Secretariat: “Amendment 6 to House Rules”

## Endorsement of White Paper

- AHWP, APACMed, Deloitte: “White paper on Competency Framework for Medical Technology Regulators”

## Endorsement of Guidance Documents from WG

- WG1,2,3: “Categorisation of Changes to a Registered Medical Device”
- WG1,2,3: “Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)”
- WG9: “Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system”

## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



## Background

This amendment of House Rules mainly to **revise “member economy” to “regulatory authority and/or industry of a country or region”**, to better **clarify that AHWP members are the representatives from the regulatory authority and industry of their respective country or region**, not referring to the country or region itself.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The following under the current **Clause 3B on Nominations and Elections of the AHWP Chair/Vice-chairs:-**

Every nomination shall be supported by at least five Primary AHWP Representatives from other member economies with their signatures duly signed on the nomination form.

**Is proposed to be replaced by:-**

Every nomination shall be supported by at least five Primary AHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The following under the current **Clause 5B on Nominations and Elections of the AHWPTC Chair/Co-chairs:-**

Every nomination shall be supported by at least five Primary AHWP Representatives from other member economies with their signatures duly signed on the nomination form.

**Is proposed to be replaced by:-**

Every nomination shall be supported by at least five Primary AHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The current **Clause 8A on Applications for Joining AHWP:-**

The Regulatory Authority of any countries/economies interested in joining AHWP shall send the application form to the Secretariat.

**Is proposed to be replaced by:-**

The Regulatory Authority of any country or region interested in joining AHWP shall send the application form to the Secretariat.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The current **Clause 9A on Appointments of AHWP and AHWPTC Representatives:-**

Member economies shall appoint their AHWP and AHWPTC Representatives and inform the Secretariat accordingly.

**Is proposed to be replaced by:-**

Member Regulatory Authority and member Industry of a country or region shall appoint their AHWP and AHWPTC Representatives and inform the Secretariat accordingly.

# Amendment 6 to AHWP House Rules

## PROPOSED FINAL Document



The current **Clause 9B on Appointments of AHWP and AHWPTC Representatives:-**

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.

**Is proposed to be replaced by:-**

The AHWP and AHWPTC Representatives of a member Regulatory Authority or member industry of a country or region may be changed at any time via a notification to the Secretariat and the Chair accordingly. Such notification shall be provided by the AHWP Primary Representative from the member Regulatory Authority of the respective country or region.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The current **Clause 9C on Appointments of AHWP and AHWPTC Representatives:-**

Any disputes on representations should be referred to the Secretariat. The Secretariat shall seek comments from the Representatives from Regulatory Authority of that member economy before making recommendations to the AHWP Chair for the final decision.

**Is proposed to be replaced by:-**

Any disputes on representations should be referred to the Secretariat. The Secretariat shall seek comments from the Representatives from member Regulatory Authority of the respective country or region before making recommendations to the AHWP Chair for the final decision.



# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The current **Clause 17A on Advisor to AHWPTC:-**

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.

**Is proposed to be replaced by:-**

AHWPTC shall appoint expert(s) from AHWP member Regulatory Authorities or member Industries of countries or regions, or other international or 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.

# Amendment 6 to AHWP House Rules PROPOSED FINAL Document



The current **Clause 19C on AHWPTC WGs and STG Membership**:-

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.

**Is proposed to be replaced by:-**

Any person who is not from the member regulatory authority or member industry of a country or region 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.

# Amendment 6 to AHWP House Rules 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
- ✓ Posted on AHWP Website towards Endorsement

**For Endorsement**

**Yes / No?**

# Resolution and Endorsement



## Resolutions

- AHWP Secretariat: “Amendment 7 to Terms of Reference”
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## Endorsement of White Paper

- AHWP, APACMed, Deloitte: “White paper on Competency Framework for Medical Technology Regulators”

## Endorsement of Guidance Documents from WG

- WG1,2,3: “Categorisation of Changes to a Registered Medical Device”
- WG1,2,3: “Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)”
- WG9: “Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system”

## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# Competency Framework for Medical Technology Regulators

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## WHITE PAPER



- ✓ Prepared by AHWP Capacity Building Program, APACMed, Deloitte
- ✓ 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

**For Endorsement**

**Yes / No?**

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## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# Categorisation of Changes to a Registered Medical Device

## GUIDANCE DOCUMENT



- ✓ Prepared by WG1, WG2 & WG3
- ✓ 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

**For Endorsement**

**Yes / No?**

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## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency



# Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)

## GUIDANCE DOCUMENT



- ✓ Prepared by WG1, WG2 & WG3
- ✓ 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

**For Endorsement**

**Yes / No?**

# Resolution and Endorsement



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## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system

## GUIDANCE DOCUMENT



- ✓ Prepared by WG9
- ✓ 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

**For Endorsement**

**Yes / No?**

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## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# AHWP New Member Application

## Kyrgyz Republic



- ✓ AHWP Member Application was received from Ministry of Health, Kyrgyz Republic
- ✓ Official letter for application
- ✓ Application Form with Nominated Representatives:
  - ✓ AHWP Primary (Regulatory Authority) –  
Dr. Gulmira Shakirova, General Director, Department of Drug, Provision and Medical Equipment
  - ✓ AHWP Secondary (Regulatory Authority) –  
Mrs. Ainura Abalieva, Head of Registration, Medical Devices Department
  - ✓ AHWPTC Primary (Regulatory Authority) -  
Mrs. Ainura Abalieva, Head of Registration, Medical Devices Department
  - ✓ AHWPTC Secondary (Regulatory Authority) –  
Ms. Aikerim Sharypova, Specialist of Registration, Medical Devices Department

**For Endorsement**

**Yes / No?**

# Resolution and Endorsement



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## Endorsement of New Member

- Kyrgyz Republic

## Endorsement of New Liaison Member

- GMDN Agency

# AHWP New Liaison Member Application GMDN Agency



- ✓ AHWP Liaison Member Application was received from GMDN Agency
- ✓ Supported by AHWP Chair and Leadership
- ✓ GMDN Agency Representative:
  - Mark Wasmuth, CEO

**For Endorsement**

**Yes / No?**

# Thank you

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