



## **Final DOCUMENT**

Title: Asian Harmonization Working Party (AHWP) & Asian Harmonization Working Party Technical Committee (AHWPTC) Terms of Reference (Amendment 1)

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**Asian Harmonization Working Party (AHWP; or the “Working Party”)****Goals**

To study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, APEC and other related international organizations aiming at establishing harmonized requirements, procedures and standards.

**Membership**

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.

Upon joining, each member economy 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 economy such that they could represent the views of both the Regulatory Authority and Industry of their economies.

The Primary AHWP Representative 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 to subscribe to the AHWP Secretariat for serving as the contact person.

**Leadership**

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.

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

### **Relationship with Other Parties**

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

### **Observers to Meetings**

It is our belief that the message of harmonization will be better spread and promoted with observers from different corners of the world participating in the meetings. All AHWP Meetings are open to interested parties to join as observers on a space availability basis.

### **Language**

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

### **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 economies.

### **Asian Harmonization Working Party Technical Committee (AHWPTC; or the “Technical Committee”)**

#### **AHWPTC Roles and Responsibilities**

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 technical documents and policy papers;
- 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.

### **AHWPTC Membership**

Each member economy 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 economy.

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.

### **AHWPTC Leadership**

One AHWPTC Chair and two AHWPTC Co-chairs shall be elected by the AHWP Primary Representatives among the AHWPTC Representatives. 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.

### **Working Groups (WGs) and Special Task Groups (STGs)**

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.

### **AHWPTC Meetings**

The AHWPTC Chair may organize AHWPTC Meetings as and when needed. At least one of the AHWPTC Meetings shall be held in conjunction with the AHWP Annual Meeting in which the AHWPTC Chair shall report on the developments and achievements of the Technical Committee.

## **Terms of Representation, Resolutions & Decisions**

### **Representation**

The Regulatory Authorities are government bodies responsible for the regulation of medical devices. 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.

### **Resolutions & Decisions**

AHWP and AHWPTC Representatives may initiate resolutions and recommendations for discussions and voting at the AHWP Meetings and AHWPTC Meetings respectively. Requests shall be made to the AHWP Secretariat and copied to the AHWP Chair and AHWPTC Chair at least one week before the relevant Meeting. Any proposed amendments to the resolutions shall be made to the AHWP Secretariat and copied to the AHWP Chair and AHWPTC Chair at least one day before the relevant meeting.

A simple majority is needed for passing any resolutions and recommendations at the AHWP Meetings and AHWPTC Meetings respectively.

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

#### **Voting**

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

#### **Nomination**

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

#### **Election**

Nominees with the highest number of votes shall be elected as office bearers.

#### **Terms of Office**

The terms of office of all AHWP and AHWPTC office bearers will be around three years commencing from the date of appointment until the next election. All office bearers in the AHWP, AHWPTC, WGs and STGs, regardless of when they are elected into the office during the term of a given AHWP Chair, shall retire altogether at the same time with that AHWP Chair. The current AHWP Chair is responsible for organizing the next election of new office bearers in an AHWP Meeting in about three years' time after his/her election.

#### **Change of Office Bearers and Representatives**

When there are changes to office bearers, the Primary AHWP Representative of the corresponding member economy shall nominate replacements to fill the vacancies arise. If the member economy 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.

**Representation in the absence of the Representatives**

Secondary AHWP and AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights of the corresponding Primary AHWP and AHWPTC Representatives in their absence. In case that both the Primary and Secondary AHWPTC Representatives are absent, the corresponding Primary AHWP Representative could take up all the roles and responsibilities as well as voting rights at the AHWPTC Meetings. Similarly, Primary AHWPTC Representatives could take up all the roles and responsibilities as well as voting rights at AHWP Meetings if the corresponding Primary and Secondary AHWP Representatives are both absent.

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