PROPOSED FINAL DOCUMENT

Title: Amendment 8 to the Global Harmonization Working Party House Rules

Authoring Group: GHWP SECRETARIAT

Date: 7th February 2023

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1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) House Rules (hereafter as "GHWP House Rules") as detailed in section 3 below under "Proposed Amendments to the GHWP House Rules".

2. Background

2.1. The current GHWP House Rules is specified under the Final Document AHWP/SECRETARIAT/F002:2021 resolved in 25th AHWP Meeting and announced on 1st Dec 2021.

2.2. This amendment of House Rules mainly incorporates the provisions on GHWP Strategic Advisory Board (SAB), its formation, term of office, roles and responsibilities in GHWP.

2.3. The amendments will follow the below general principles: -
    2.3.1. GHWP & GHWPTC Terms of Reference can override the GHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the GHWP House Rules

3.1. The following new provision to be added under the new Clause 20 "Strategic Advisory Board to GHWP Chair" under GHWP House Rules: -

A. GHWP Chair shall appoint expert(s) from GHWP member Regulatory Authorities of countries or regions with robust medical device regulatory systems, or other international or regional organizations as Member(s) of the Strategic Advisory Board (SAB) on a need basis, for the purpose of seeking his/her/their advice towards meeting the goals of GHWP.

B. The role of SAB Member(s) is to bring their knowledge and experience to support the goals of GHWP in high-level planning and steering on the development of GHWP, and the promotion of GHWP's mission, vision, and goals. This is accomplished via such activities as providing objective advice and recommendation, insights and intelligence for the strategic positioning and development of GHWP. SAB Member(s) operate and provide input under the direction of the GHWP Chair.

C. The role of SAB, as mentioned above, should be differentiated from GHWPTC Advisory Panel, which offers technical/professional advice towards meeting the goals of GHWP.

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D. Expert(s) who are qualified to join SAB as Member(s) should be familiar with the operations and management of GHWP and GHWPTC, support GHWP's mission, vision, and goals, with senior management experience in medical device regulatory authority, and with active participations in past events and annual meetings of GHWP. GHWP Chair shall propose any new admission criteria for SAB, including the participation of expert(s) from industry to SAB meetings on need basis. The proposed criteria and any changes of the criteria shall be updated to GHWP Secretariat.

E. GHWP Chair and Vice-chairs, GHWPTC Chairs and Co-chairs shall nominate expert(s) to join the SAB. Secretariat shall review the suitability of the nominated expert(s) and submit the recommendations to GHWP Chair for final confirmation and appointment. The number of members in the SAB shall not exceed ten (10), and preferably from different continents.

F. The SAB is independent to GHWP Leadership and GHWPTC Leadership, and shall be available to GHWP Chair.

G. The term of office of the SAB Member(s) commences from the date of appointment. All SAB Members, regardless of when they are appointed during the term of a given GHWP Chair, shall retire altogether at the same time with that GHWP Chair. The reappointment of SAB Member(s) shall be made by the new GHWP Chair.

H. Appointment to the SAB is on a voluntary basis. All SAB Member(s) shall receive no compensation from GHWP, GHWPTC and GHWP Administration Services Ltd.

I. SAB Member(s) will not be appointed to the Advisory Panel to GHWPTC and will not be appointed as Advisor(s) to WGs and STGs

J. Any changes on SAB membership shall be updated to GHWP Secretariat for record.

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