



Global Harmonization Working Party
Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Amendment 10 to GHWP TOR and House Rules on GHWP Management Committee

Authoring Group: GHWP Strategic Advisory Board

Date: 9th September 2024

1. Purpose

This document proposes to make amendment to the Global Harmonization Working Party (GHWP) Terms of Reference and House Rules (hereafter as “GHWP TOR and House Rules”) on the establishment of the GHWP Management Committee, as detailed in section 3 below under “Proposed Amendments to the GHWP TOR and House Rules”.

The objective of establishing the GHWP Management Committee is to further strengthen the cohesion, identification and participation of GHWP members, to accelerate the realization of Global Harmonization Working Party Strategic Initiatives e.g. GHWP Strategic Framework towards 2026.

2. Background

2.1. The current GHWP TOR is specified under the Final Document GHWP/SECRETARIAT/F001:2021 resolved in the 25th GHWP Meeting and announced on 1st Dec 2021, and the current GHWP House Rules is specified under the Final Document GHWP/SECRETARIAT/F001:2023 resolved in 26th GHWP Meeting and announced on 16th Feb 2023.

2.2. This amendments of TOR and House Rules mainly incorporate the provisions on the establishment of the GHWP Management Committee.

2.3. The revision of the TOR mainly includes the duties, composition and principles of the GHWP Management Committee (MC), as detailed in section 3.1 of this document.

2.4. The revision of the House Rules mainly includes the qualification requirements, rights and obligations of the members of the Management Committee, as detailed in section 3.2 of this document.

2.5. After the consideration and approval of the proposed amendments at the GHWP Annual Meeting, the GHWP Secretariat will be responsible for the drafting of the procedure documents of the Management Committee, such as the selection process, and the revision of the organizational structure of the GHWP accordingly.

2.6. For more details on the background and rationales for the proposed amendments, as well as the steps following the endorsement of this document, please refer to the document titled “Explanation of compilation”.

2.7. The amendments will follow the general principles, therefore GHWP & GHWPTC Terms of Reference can override the GHWP House Rules when there is any discrepancy.

3. Proposed Amendments to the GHWP TOR and House Rules

3.1 A new Clause “1.6 Management Committee” shall be added to the TOR after Clause 1.5, including the following provisions:

Management Committee:

- (A) GHWP Management Committee consists of GHWP Chair and two GHWP Vice-chairs, GHWP TC Chair and two GHWP TC Co-chairs, Executive Secretary General, and a maximum of seven Standing Members and a maximum of four Rotating Members who are the representatives of the GHWP member countries/regions.
- (B) The duties of the Management Committee include the implementation of the decisions endorsed in GHWP Annual Meetings, formulation of the development strategy of the GHWP, recommendation on the schedule of the annual meetings, preparation of the proposals when necessary, discussion on the annual work plan, review on the implementation of annual work plan, confirmation on the accession and withdrawal of member country/region, facilitation on the exchange and cooperations with other international organizations, and the review on any needs for internal restructuring in GHWP.

Rules of Composition:

- (C) The Standing Members and Rotating Members within the Management Committee, which should be represented by different member countries/regions in principles, to represent the interests of GHWP member countries/regions in different continents, as far possible, that include Asia, the Middle East, Africa and South America.
- (D) Representatives of the Standing Member Countries/Regions shall be appointed by the medical device regulatory authorities of the corresponding member countries/regions. They shall be in principle the civil servants at the directorate level who are responsible for the regulations of medical devices. There can be two representatives from the same member country/region in the Management Committee if the GHWP Chair is also from one of the Standing Member Countries/Regions. There is no term limit for all Standing Member Countries/Regions.
- (E) Rotating Members are elected in accordance with certain conditions and procedures. There are two Rotating Members from regulatory authorities and two Rotating Members from the industry in the Management Committee.

The term of office for a Rotating Member is 3 years, who are also eligible for re-election to serve for more than one term.

Principles of Establishment:

- (F) The establishment and composition of the GHWP Management Committee is based on the development needs of GHWP and its members. It also adheres to the principle of consistency of responsibilities and powers.
- (G) Adhere to the principle of voluntary participations in GHWP, member countries/regions are encouraged to actively participate in the Management Committee, to make further contributions to the GHWP and its sustainable development.
- (H) Adhere to the principle of openness and transparency, the Management Committee is formed based on the endorsement by GHWP members. The formation of the Management Committee is also comply to the GHWP Terms of Reference and House Rules, adhere to the principles of fairness and impartiality.
- (I) The existing rights and interests of GHWP members, as according to the GHWP Terms of Reference and House Rules, shall remain unchanged after the formation of the GHWP Management Committee.

3.2 A new Clause “6. Nomination and Election of the Management Committee” shall be added after Clause 5 of the current House Rules, with the following provisions:

- (A) The 29th GHWP Annual Meeting in 2025 should determine the list of Standing Member Countries/Regions in the Management Committee, with a maximum of seven Standing Member Countries/Regions to be appointed. A Standing Member Country/Region should fulfill the following requirements:
 - i) Conversion and implementation of at least one GHWP guideline in the corresponding country/region.
 - ii) Assignment of at least one representative to participate in every GHWP Technical Committee Leaders Meeting (except those held online) since 2014.
 - iii) Assignment of at least one representative to participate in every GHWP Annual Meeting (except those held online) since 2014.
- (B) The election of Rotating Members should be carried out at the 29th GHWP Annual Meeting in 2025. Two Rotating Members should be elected from regulatory authorities and two Rotating Members from the industry. A Rotating Member should meet the following requirements:

- i) In principle, the Rotating Members (Regulatory Authority) should be elected from different countries/regions, whose representatives should be civil servants at the directorate level responsible for the regulations of medical devices.
 - ii) The Rotating Members (Industry) should be senior executive officers of the medical device companies or medical device industry associations.
 - iii) A Rotating Member (Industry) should have organized or sponsored at least one GHWP annual meeting or technical committee leaders meeting.
- (C) There is no term limit for Standing Member Countries/Regions in the Management Committee. If there is a vacant of Standing Member, a new Standing Member may be elected from the existing Rotating Member (Regulatory Authority) by the Management Committee.
- (D) If there is no GHWP member country/region to serve as the host in any of the GHWP Annual Meeting(s) or Technical Committee Leaders Meeting(s), the Standing Members (Regulatory Authority) should take turns to host the Meeting(s).
- (E) Members of the Management Committee shall actively participate in the development of the GHWP guidance documents, that include the offering of feedback on the proposed guidance documents, coordination and promotion on the implementation of the GHWP guidance documents in their corresponding countries/regions.
- (F) SAB Member(s) can attend the GHWP Management Committee Meetings and to provide advice towards meeting the goals of GHWP.

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