



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL

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

Authoring Group: GHWP [Secretariat](#)

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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. [The proposed](#) amendments of TOR and House Rules [in this document](#) 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 updating the corresponding GHWP Terms of Reference and House Rules as well as the GHWP organizational structure onto GHWP website.](#)

2.6. 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. **The size of the Management Committee and its composition are subject to changes based on reviews and according to the development needs of GHWP, with any such changes needed to be thoroughly discussed before voting and endorsement at GHWP meetings.**
- (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.
- (C) **GHWP Management Committee has no decision-making power. GHWP Leadership that consists of GHWP Chair and two GHWP Vice-chairs shall make decisions for the planning and operations of GHWP, and the GHWPTC Leadership that consists of GHWP TC Chair and two GHWPTC Co-chairs shall make decisions for the planning and operations of GHWPTC with the consensus of GHWP Leadership. Decisions and resolutions on key issues and controversial matters should be made only after thorough discussions before voting at GHWP Meetings.**

Rules of Composition:

- (D) The Standing Members and Rotating Members within the Management Committee should **in principle be** represented by GHWP member countries/regions **from** different continents **and areas**, that include Asia, the Middle East, Africa, **Central and South America, Caribbean, etc., as well as**

GHWP member countries/regions which represent different regulatory development stages.

- (E) GHWP Leadership, GHWPTC Leadership and Executive Secretary General, shall be the necessary members of the Management Committee, even if there are representatives from the same member countries/regions in the Management Committee.
- (F) Representatives of the **Standing Members** shall be appointed by the medical device regulatory **authorities** of the corresponding **GHWP 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 is no term limit for all **Standing Members**. In the event of a vacancy in **Standing Member(s)**, GHWP Chair could arrange the Executive Secretary General to initiate the nomination and election/endorsement process on a need basis to fill the vacancy in accordance with the requirements for **Standing Members**. Every three years there will a review on the performance of the **Standing Members** by the Management Committee, to ensure the existing **Standing Members** continue to fulfil the requirements.
- (G) **Standing Members** are elected or endorsed in accordance with the requirements as stated in the House Rules.
- (H) **Rotating Members** are elected in accordance with the requirements as stated in the House Rules. 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. In the event of a vacancy in **Rotating Member(s)**, GHWP Chair could arrange the Executive Secretary General to initiate the nomination and election process on a need basis to fill the vacancy in accordance with the requirements for **Rotating Members** in GHWP TOR and House Rules.

Principles of Establishment:

- (I) 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 **roles and responsibilities**.
- (J) **Adhering** to the principle of voluntary **participation**, **GHWP member countries/regions** are encouraged to actively participate in the Management

Committee, to make further contributions to the GHWP and its sustainable development.

- (K) **Adhering** to the **principles** of openness and transparency, the Management Committee is formed based on the endorsement by GHWP members. The formation of the Management Committee also **complies with** the GHWP Terms of Reference and House Rules, **adhering** to the principles of fairness and impartiality.
- (L) 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 on “Nomination and Election of the **Standing Members and Rotating Members** in Management Committee” shall be added after Clause 5 of the current House Rules, with the following provisions:

Standing Members

- (A) **The election/endorsement of Standing Members shall be arranged by GHWP Chair at GHWP annual meetings, after the availability of the arrangement for nomination, election/endorsement of Standing Members in the Management Committee in GHWP TOR and House Rules. A maximum of seven Standing Members shall be appointed.**
- (B) **A Standing Member should fulfill the following requirements:**
 - i) **Standing Members should be familiar with the operations and management of GHWP and GHWPTC, and should be strong supporters of GHWP’s mission, vision, and goals.**
 - ii) **Conversion and implementation of 2025 at least three GHWP guidance documents in the corresponding country/region.**
 - iii) **Assignment of at least one representative to physically participate in every GHWP Technical Committee Leaders Meeting (except those held online) in the past ten years by the time of nomination or election/endorsement.**
 - iv) **Assignment of at least one representative to physically participate in every GHWP Annual Meeting (except those held online) in the past ten years by the time of nomination or election/endorsement.**

- v) Having sufficient capacity to host GHWP Annual Meeting(s) and GHWP Technical Committee Leaders Meeting(s) in different years.
- (C) Nomination shall be opened to all eligible member countries/regions which fulfil the requirements of a Standing Member in the Management Committee, with the arrangement on nomination and election as follows:
- i) Candidates shall submit their nomination forms to the Secretariat before the commencement of each election as declared by the Chair of the Meeting.
 - ii) Every nomination shall be supported by at least five Primary GHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.
 - iii) Every Primary GHWP Representative shall support only two nominations in the election of Standing Member of the Management Committee. He/she may vote for another candidate in the election.
 - iv) Endorsement of Standing Member shall be carried out through resolutions, where simply majority is needed to pass the resolutions when the number of candidates matches or smaller than the available vacancies.
 - v) If there are more eligible candidates than the available vacancies of Standing Member in the Management Committee, election shall be taken place during the coming GHWP annual meeting, where candidates with the highest and/or higher numbers of votes shall be given the higher priority to fill up the vacancies as Standing Member in the Management Committee, until all the vacancies are filled.
 - vi) In case of same number of votes for more than one candidate, Chair of the Meeting can cast an extra vote.

Rotating Members

- (D) The election/endorsement of Rotating Members shall be arranged by GHWP Chair at GHWP annual meetings, after the availability of the arrangement for nomination, election/endorsement of Rotating Members in the Management Committee in GHWP TOR and House Rules. Two Rotating Members shall be elected from regulatory authorities and two Rotating Members from the industry.
- (E) A Rotating Member should meet the following requirements:

- i) Rotating Members should be familiar with the operations and management of GHWP and GHWPTC, and should be strong supporters of GHWP's mission, vision, and goals.
 - ii) A Rotating Member (Industry) should be a primary industry representative or a secondary industry representative of GHWP or GHWPTC.
 - iii) In principle, the Rotating Members (Regulatory Authority) should be elected from different countries/regions, and different from the countries/regions of the Standing Members, whose representatives should be civil servants at the directorate level responsible for the regulations of medical devices.
 - iv) The Rotating Members (Industry) should be senior executive officers of the medical device companies or medical device industry associations.
 - v) A Rotating Member (Industry) should have organized or sponsored at least one GHWP Annual Meeting or GHWP Technical Committee Leaders Meeting.
- (F) Nomination shall be opened to all eligible member countries/regions which fulfil the requirements of a Rotating Member in the Management Committee, with the arrangement on nomination and election as follows:
- i. Candidates shall submit their nomination forms to the Secretariat before the commencement of each election as declared by the Chair of the Meeting.
 - ii. Every nomination shall be supported by at least five Primary GHWP Representatives from other countries or regions with their signatures duly signed on the nomination form.
 - iii. Every Primary GHWP Representative shall support only two nominations in the election of Rotating Member of the Management Committee. He/she may vote for another candidate in the election.
 - iv. Endorsement of Rotating Member shall be carried out through resolutions, where simply majority is needed to pass the resolutions when the number of candidates matches or smaller than the available vacancies.
 - v. If there are more eligible candidates than the available vacancies of Rotating Member in the Management Committee, election shall be

taken place during the coming GHWP annual meeting, where candidates with the highest and/or higher numbers of votes shall be given the higher priority to fill up the vacancies as Rotating Member in the Management Committee, until all the vacancies are filled.

vi. In case of same number of votes for more than one candidate, Chair of the Meeting can cast an extra vote.

- (G) There is no term limit for **Standing Members** in the Management Committee. If there is a **vacancy** for Standing Member, a new Standing Member may be elected from the existing Rotating Member (Regulatory Authority) by the Management Committee, where **that new Standing Member should also satisfy the requirements of a Standing Member**.
- (H) 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).
- (I) 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.

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