

Global Harmonization Working Party (GHWP) Procedure for Strategic Advisory Board Establishment and Operation

1.Introduction

To further implement the GHWP Strategic Framework towards 2026 and effectively leverage the role of Strategic Advisory Board (SAB) as think tank, this procedural document is prepared in accordance with the House Rules 20-Strategic Advisory Board to GHWP Chair.

2.Purpose

GHWP Chair shall appoint expert(s) as Member(s) of SAB on a need basis, for the purpose of seeking his/her/their advice towards meeting the goals of GHWP.

3.Orientation

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

B. SAB Member(s) operate and provide input under the direction of the GHWP Chair.

C. The SAB is not responsible for the administrative affairs of GHWP and liaisons with GHWP Chair through the GHWP Chair Secretariat.

D. GHWP Chair appoints one SAB member to act as liaison. The liaison member conveys the work arrangement from GHWP Chair to SAB Member(s) on his/her own or through the Executive Secretariat. The liaison member is also responsible for compiling strategic recommendations from SAB Member(s) and feeding them back to the GHWP Chair Secretariat.

E. All SAB Member(s) shall receive no compensation from GHWP, GHWPTC and GHWP Administration Services Ltd.

4.Responsibility

A. 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.

B. This is accomplished via such activities as providing objective advice and recommendation, insights and intelligence for the strategic positioning and development of GHWP.

C. SAB Member(s) attend GHWP related meetings, including GHWP Annual Meeting, GHWP TC Meeting, GHWP Leadership Brainstorming Meeting, SAB Roundtable Meeting and other meetings that GHWP Chair invites SAB Member(s) to attend.

5.Criteria

A. Expert(s) from GHWP member Regulatory Authorities of

countries or regions with robust medical device regulatory systems, or other international or regional organizations on a need basis.

B. Expert(s) who are 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.

C. Expert(s) with senior management experience in medical device regulatory authority, and with active participations in past events and annual meetings of GHWP.

D. Based on the above criteria, previous GHWP Leadership, GHWP TC Leadership, in-service medical device department level personnel from mature medical device regulatory countries, senior leaders of international medical device organizations, and vice presidents or regional heads of large multinational medical device groups are eligible for the range of priority nominations.

GHWP Chair shall propose any new admission criteria for SAB.

The proposed criteria and any changes of the criteria shall be updated to GHWP Secretariat.

6. Establishment Procedure

6.1 Nomination

A. In principle, GHWP Executive Secretariat shall initiate

nomination for SAB Member(s) with the consent of GHWP Chair within three months after the election of the new GHWP Chair.

B. GHWP Chair and Vice-chairs, GHWPTC Chairs and Co-chairs shall nominate expert(s) to join the SAB.

C. The Executive Secretariat may provide candidates who are included in the range of priority nominations in the light of previous participation in GHWP work.

D. The nomination period for SAB Member(s) is within one month.

E. The nominator(s) shall provide the Executive Secretariat with the application forms and resumes of the nominated expert(s) prior to the expiry of the nomination period.

6.2 Review

A. The Executive Secretariat shall review the suitability of the nominated expert(s) and submit the recommendations to GHWP Chair within two weeks after the nomination period.

B. The number of members in the SAB shall not exceed ten (10), and preferably from different continents.

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

6.3 Appointment

- A. GHWP Chair shall convene a meeting of GHWP Leadership to confirm and appoint SAB Member(s) within one month after the nomination period.
- B. The term of the SAB Member(s) commences from the date of appointment.
- C. The Executive Secretariat post the list of SAB Member(s) on the GHWP website.
- D. 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.
- E. The reappointment of SAB Member(s) shall be made by the new GHWP Chair.

6.4 Performance

- A. SAB Member(s) shall perform their duties as listed in Responsibility listed in this document from the date of appointment.
- B. The absence of SAB Member(s) from two consecutive meetings or their voluntary withdrawal shall be recorded by the Executive Secretariat, their appointment shall be cancelled with the consent of GHWP Chair, and be updated on the GHWP website.
- C. In the event of a vacancy in SAB Member(s), GHWP Chair

could arrange for the Executive Secretariat to initiate the nomination process on a need basis to fill the vacancy in accordance with the above requirements.

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

7. Operation Procedure

7.1 Proposal of topics

A. After a comprehensive consideration of the international medical device regulatory situation, GHWP Chair shall agree with GHWP Leadership on the topics requiring strategic services from SAB members and specify arrangements for topics and work in GHWP Annual Meeting or GHWP TC Meeting.

B. SAB Member(s) can propose issues to be considered by GHWP Leadership through the liaison member, and the liaison member will summarize the feedback to GHWP Chair Secretariat who will submit it to GHWP Chair.

C. The scope of the topics will focus on, not limited to, the revision of GHWP constitution, the draft of new GHWP strategic framework, the action plan or projects under GHWP strategic framework, the direction of cooperation with other international organizations, and other major issues of GHWP.

7.2 Research of topics

A. SAB Member(s) shall complete material related to the topics as arranged by GHWP Chair.

B. The content of material should be consistent with GHWP's mission, vision and goals, and specifically include necessity analysis, key comments, implementation steps, expected outcomes, and cost-benefit analysis.

C. SAB Member(s) shall submit the material to the liaison member no later than one month prior to Roundtable Meeting.

D. The liaison member shall summarize the documents and submit to the Executive Secretariat.

7.3 Roundtable Meeting

A. The Executive Secretariat shall determine the dates of the Roundtable Meeting after seeking the advice of GHWP Chair, which shall generally be held by video conference in the third quarter of the year, or as a side event at the GHWP TC meeting.

B. The Roundtable Meeting will be hosted by GHWP Chair with the participation of GHWP Leadership, GHWP TC Leadership, SAB Member(s), the Secretary General of GHWP Chair Secretariat and the Secretary General of the Executive Secretariat.

C. The Roundtable Meeting will conduct research and discussion on specific topics.

D. The Executive Secretariat shall complete the minutes of the

Roundtable Meeting, which be submitted to GHWP Chair for approval and disseminated to the meeting participants.

7.4 Annual Meeting

A. SAB Member(s) will be awarded with a letter of appointment by GHWP Chair at the first GHWP Annual Meeting following their appointment.

B. SAB Member(s) could attend GHWP Leadership close-door meetings or participate in panel discussions on relevant topics according to the agenda of GHWP Annual Meeting.