

Terms of Reference for the Technical Advisory Group on Market Access for Vaccines (TAG-MVAC)

In 2018, World Health Organization (WHO) launched the Market Information for Access to Vaccines (MI4A) initiative, to contribute to the achievement of Strategic Development Goal 3.8 (Universal Health Coverage target) by enhancing access to safe, effective, quality, and affordable vaccines for all.

Over time WHO has increased its contributions to broader efforts to increase access to medicines and vaccines, an important topic highlighted by the World Health Assembly in 2019 with the endorsement of a Roadmap for Access to medicines and vaccines¹ and the adoption of a new resolution on improving the transparency of markets for medicines, vaccines and other health products². Through key initiatives such as MI4A, WHO respond to specific requests from Member States and the WHO Strategic Advisory Group of Experts on Immunization (SAGE) to address vaccine market information gaps and improve equitable access to vaccines. MI4A is part of the WHO Global Public Health Goods.

WHO's overall objectives are to:

- Enhance the understanding of global vaccine demand, supply and pricing dynamics and identify access risks e.g. lack of affordability and shortages;
- Convene all relevant global health partners to contribute to the development of policies, strategies, and actions to address identified access risks and opportunities;
- Strengthen national and regional capacity for improved access to vaccines supply.

To carry out its objectives, every year WHO collects information on vaccines purchased by countries (including products, volumes purchased and related price) and vaccines produced (including information on production available for commercialization and on pipeline products). This information as well as publicly available information on vaccine markets, partners resources and any programmatic or access considerations, is leveraged to develop market studies which aim to understand access dynamics and spotlight opportunities, risks and corrective action by WHO in collaboration with partners.

The Technical Advisory Group on Market Access for Vaccines (the "TAG-MVAC") will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, the AG shall have the following functions:

¹ https://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/

² http://apps.who.int/gb/e/e_wha72.html#resolutions

- Provide an independent recommendation on technical and/or strategic aspects of key global vaccine market topics
- Deliver recommendations on proposed areas for action by WHO to enhance global access to vaccines resulting from market analyses and as proposed by the WHO Secretariat;
- Advise WHO on data sources, data quality, methodologies and overall market assessments with a key focus on supply demand balance, pricing dynamics, supply sustainability, regional supply security and other relevant aspects related to global vaccine market access³.

II. Composition

1. The TAG-MVAC shall have up to 15 members⁴, who shall serve in their personal capacities to represent the broad range of disciplines relevant to the following areas:
 - global vaccine supply, demand, and market landscape dynamics across key regions and immunization areas
 - vaccine manufacturing
 - global immunization and/or infectious disease epidemiology;
 - global vaccine market access and/or procurement

In the selection of the TAG -MVAC members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of the TAG-MVAC, including the Chairperson, shall be selected and appointed by WHO⁵ following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the TAG-MVAC;
 - to liaise with the WHO Secretariat between meetings.

In appointing a Chairperson, consideration shall be given to gender and geographical representation.

3. Members of the TAG-MVAC shall be appointed to serve for a period of 2 years and shall be eligible for reappointment ⁶. A Chairperson is eligible for reappointment as a member of the TAG-MVAC but is only permitted to serve as Chairperson for one term. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or as otherwise specified in these terms of reference or letters of appointment. Where a member's appointment is terminated, WHO may decide to appoint a replacement member.
4. TAG-MVAC members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government

³ This can be done building upon the standard methodology endorsed by IVIRAC in March 2019

https://cdn.who.int/media/docs/default-source/immunization/ivir-ac/meeting_report_ivir_ac_march2019.pdf?sfvrsn=d38ae23f_8

⁴ Members serve as full participants and partake in the deliberations and the adoption of the recommendations of the meeting in which they are involved.

or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

5. Following a determination that a proposed member's participation in the TAG-MVAC would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the TAG-MVAC. Their appointment to the TAG MVAC is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, TAG- MVAC members have an ongoing obligation to inform the WHO of any interests real or perceived that may give raise to a real, potential or apparent conflict of interest.
6. As contemplated in paragraph II.4 above, WHO may, from time to time, request TAG-MVAC members to complete a new declaration of interest form. This may be before a TAG-MVAC meeting or any other TAG-MVAC-related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG-MVAC member's participation in the TAG-MVAC activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.
7. Where a TAG-MVAC member is invited by WHO to travel to an in-person TAG-MVAC meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter'). WHO shall not authorize travel by a TAG- MVAC member, until it receives a countersigned Temporary Adviser Letter.
8. TAG-MVAC members do not receive any remuneration from the Organization for any work related to the TAG-MVAC. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

III. Operation

1. The TAG-MVAC shall normally meet at least once each year. However, WHO may convene additional meetings. TAG-MVAC meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

TAG-MVAC meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

- (a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).

(b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the TAG-MVAC and essential WHO Secretariat staff.

2. The quorum for TAG-MVAC meetings shall be two thirds of the members.
3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as “observers”. Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-State actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the advisory group. Invitations to observers attending as representatives from non-State actors will be subject to WHO internal due diligence and risk assessment including conflict of interest considerations in accordance with the Framework for engagement with non-State actors (FENSA). Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the TAG-MVAC at their own expense and be responsible for making all arrangements in that regard.

At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting recommendations of the TAG-MVAC.

4. TAG-MVAC members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the TAG-MVAC.
5. Reports of each meeting shall be submitted by the TAG-MVAC to WHO (the Assistant Director- General of the responsible Cluster). All recommendations from the TAG-MVAC are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the TAG-MVAC.
6. The TAG-MVAC shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.
7. Active participation is expected from all TAG-MVAC members, including in working groups, teleconferences, and interaction over email. TAG-MI4A members may, in advance of TAG-MVAC meetings, be requested to review meeting materials and to provide their views for consideration by the TAG-MVAC
8. WHO shall determine the modes of communication by the TAG-MVAC, including between WHO and the TAG-MVAC members, and the TAG-MVAC members among themselves.
9. TAG-MVAC members shall not speak on behalf of, or represent, the TAG-MVAC or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG-MVAC, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which members may gain access in performing TAG-MVAC related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, TAG-MVAC members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their TAG-MI4A-related activities shall be exclusively vested in WHO.
2. TAG-MVAC members and Observers shall not quote from, circulate or use TAG-MVAC documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.
3. WHO retains full control over the publication of the reports of the TAG-MVAC, including deciding whether or not to publish them.