

REGULATORY SYSTEMS STRENGTHENING
TECHNICAL ADVISORY GROUP ON WHO LISTED AUTHORITIES (TAG-WLA)
TERMS OF REFERENCE

[version: August 2022]

BACKGROUND

The introduction of a framework for designating and publicly listing a regulatory authority as a WHO Listed Authority (WLA) is designed to provide a transparent and evidence-based pathway for regulatory authorities to be globally recognized as meeting and applying WHO and other internationally recognized standards and guidelines, as well as good regulatory practices. The designation of a regulatory authority as a WLA is intended to promote access and the supply of safe, effective and quality medical products and the optimal use of limited resources by facilitating reliance on the work products and decisions of trusted agencies in the decision-making of regulatory authorities, the WHO Prequalification Programme, and procurement agencies.

To ensure impartiality and transparency of the WLA decision-making process, WHO will call upon the Technical Advisory Group on WHO Listed Authority (TAG-WLA) to provide advice to WHO on the listing or possible delisting of a regulatory authority, thereby providing an additional level of assurance that due process was followed and that WHO decisions are supported by findings.

The Technical Advisory Group on WHO Listed Authority (TAG-WLA) (the “TAG-WLA”) will act as an advisory body to WHO in this field.

I. Functions

In its capacity as an advisory body to WHO, the TAG-WLA shall have the following function:

- Provide advice on whether the listing/delisting recommendation of the WHO is supported by the findings from the evaluation process.

II. Composition

1. The TAG-WLA shall have 15 members¹, who shall serve in their personal capacities to represent the broad range of expertise relevant to evaluating the performance of candidate WLAs. Members should have a wide knowledge of and senior level experience in regulatory systems for medicines and vaccines, or related fields. In the selection of the TAG-WLA members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

¹ Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.

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2. Members of the TAG-WLA, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meeting of the TAG-WLA;
 - 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-WLA shall be appointed to serve for a period of 3 years, shall be eligible for reappointment but may not serve for more than two consecutive terms. A Chairperson is eligible for reappointment as a member of the TAG-WLA, 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-WLA members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government 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-WLA 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-WLA. Their appointment to the TAG-WLA 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-WLA members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise 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-WLA members to complete a new declaration of interest form. This may be before a TAG-WLA meeting or any other TAG-WLA -related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG-WLA member's participation in the TAG-

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WLA 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-WLA member is invited by WHO to travel to an in-person TAG-WLA 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-WLA member, until it receives a countersigned Temporary Adviser Letter.
8. TAG-WLA members do not receive any remuneration from the Organization for any work related to the TAG-WLA. 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-WLA shall normally meet at the request of WHO to review the WLA recommendations of one or more countries. TAG-WLA meetings will be convened by WHO and will be held virtually, via video or teleconference, or in-person (at WHO headquarters in Geneva or another location, as determined by WHO).

TAG-WLA 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-WLA and essential WHO Secretariat staff.
2. The quorum for TAG-WLA 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

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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-WLA 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-WLA.

4. TAG-WLA 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-WLA.
5. Reports of each meeting shall be submitted by the TAG-WLA to WHO (the Assistant Director-General of the Access to Medicines and Health Products (MHP)) not later than 20 working days after the TAG-WLA meeting. All recommendations from the TAG-WLA 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-WLA.
6. The TAG-WLA 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-WLA members, including in working groups, teleconferences, and interaction over email. TAG-WLA members may, in advance of TAG-WLA meetings, be requested to review meeting documentation and to provide their views for consideration by the TAG-WLA.
8. WHO shall determine the modes of communication by the TAG-WLA, including between WHO and the TAG-WLA members, and the TAG-WLA members among themselves.
9. TAG-WLA members shall not speak on behalf of, or represent, the TAG-WLA or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG-WLA, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall

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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-WLA 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-WLA 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-WLA -related activities shall be exclusively vested in WHO.
2. TAG-WLA members and Observers shall not quote from, circulate or use TAG-WLA documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

WHO retains full control over the publication of the reports of the TAG-WLA, including deciding whether or not to publish them.