Terms of Reference for the Technical Advisory Group on Local Production and Technology Transfer of Health Products

Strategic local production of medicines, vaccines and other health technologies in low- and middle-income countries has assumed huge significance in the context of the global COVID-19 pandemic. Many low- and middle-income countries experienced inequitable access to priority health products (medicines, vaccines, biologics, medical devices, in-vitro diagnostics, etc.) during the pandemic.

In May 2021, the World Health Assembly adopted resolution WHA74.6 on “Strengthening local production of medicines and other health technologies to improve access”. This resolution covers important aspects of local production and urged Member States “to strengthen their leadership, commitment and support in promoting the establishment and strengthening of quality and sustainable local production of medicines and other health technologies that follows good manufacturing practices” while keeping view of their local contexts. Resolution WHA74.6 also urges the Director General of WHO “to support Member States upon their request in promoting quality and sustainable local production of medicines and other health technologies”.

In the context of resolution WHA74.6, WHO announced a new initiative, the World Local Production Forum: Enhancing access to medicines and other health technologies with the Local Production and Assistance Unit as the WLPF Secretariat. The World Local Production Forum provides the global community – Member States, industry, academia, civil societies, UN agencies, international organizations, and other stakeholders – with a regular global platform to address challenges, harness opportunities, nurture partnerships and collectively shape the direction of local production. One recommendation from the first WLPF in June 2021 is the formation of a WHO Technical Advisory Group to provide strategic and technical advice to the Local Production and Assistance Unit in supporting Member States.

The Technical Advisory Group (the “TAG”) will act as an advisory body to the Local Production and Assistance Unit, WHO in the field of promoting and strengthening sustainable local production and technology transfer to improve access to quality, safe and effective health products.

I. Functions

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

1. To provide advice to the Local Production and Assistance Unit on the overall work in implementing resolution WHA74.6 on strengthening local production;

2. To identify and describe current and future challenges related to sustainable local production and technology transfer of quality, safe and effective health products to support the work of WHO with the Member States towards reaching the relevant Sustainable Development Goals targets;
3. To provide advice to WHO on global policies and strategies on strengthening local production and technology transfer of health products and their linkages with other health systems elements, to support Universal Health Coverage and Global Public Health Security;

4. To provide advice to WHO on the strategic local production of priority health products to improve equitable, timely access and health security, particularly in low- and middle-income countries;

5. To provide technical advice to WHO on topics related to sustainable local production and technology transfer of quality, safe and effective health products and their ecosystems, such as policy coherence, financing, business and market environments, investments, human capital, infrastructure, research and development, production efficiencies and capabilities, collaborations/partnerships, market intelligence and so forth;

6. To advise WHO on innovations in manufacturing and health technologies to enable low- and middle-income countries to meet local/regional-specific public health needs;

7. To provide advice to achieve impact from local production and technology transfer on access to essential health products.

II. Composition

1. The TAG shall have up to 15 members\(^1\), who shall serve in their personal capacities to represent the broad range of disciplines relevant to local production and technology transfer of health products. In the selection of the TAG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of the TAG, 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;
   - 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 shall be appointed to serve for a period of 2 years and shall be eligible for reappointment. A Chairperson is eligible for reappointment as a member of the TAG, 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 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

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\(^1\) Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.
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 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. Their appointment to the TAG 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 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 members to complete a new declaration of interest form. This may be before a TAG meeting or any other TAG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the TAG member’s participation in the TAG 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 member is invited by WHO to travel to an in-person TAG 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 member, until it receives a countersigned Temporary Adviser Letter.

8. TAG members do not receive any remuneration from the Organization for any work related to the TAG. 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 shall normally meet at least once each year. However, WHO may convene additional meetings. TAG 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 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 and essential WHO Secretariat staff.

2. The quorum for TAG 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 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 decisions and recommendations of the TAG.

4. The TAG may decide to establish smaller working groups (sub-groups of the TAG) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the TAG for review at one of its meetings.

5. TAG 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.

6. Reports of each meeting shall be submitted by the TAG to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from the TAG 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.

7. The TAG 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.

8. Active participation is expected from all TAG members, including in working groups, teleconferences, and interaction over email. TAG members may, in advance of TAG meetings, be requested to review meeting documentation and to provide their views for consideration by the TAG.

9. WHO shall determine the modes of communication by the TAG, including between WHO and the TAG members, and the TAG members among themselves.
10. TAG members shall not speak on behalf of, or represent, the TAG or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the TAG, 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 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 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-related activities shall be exclusively vested in WHO.

2. TAG members and Observers shall not quote from, circulate or use TAG 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, including deciding whether or not to publish them.