

## Terms of Reference for the Product Development for Vaccines Advisory Committee (PDVAC) (AG44)

Established in 2014, the Product Development for Vaccines Advisory Committee (PDVAC) is an independent standing WHO committee of experts which provides external advice to WHO related to priority infectious disease pathogens, associated vaccine and monoclonal antibody approaches and related manufacturing and delivery technologies. The committee's remit covers disease areas where there is, or may be, substantial disease burden in low- and middle-income countries (LMICs), where no vaccine related products currently exist, but where there is ongoing product development activity which may benefit from WHO guidance, or technologies that could expedite availability and access of vaccine products in LMICs. PDVAC may also have a role where vaccines are already licensed, and development of improved products, including those based on novel manufacturing technologies or innovative vaccine delivery approaches is a priority for WHO and its member states.

PDVAC also provides, as called upon by WHO, a standing forum of external subject matter experts for conducting evaluations and recommendations within the scope described above. As an example, in the context of the Covid-19 pandemic response and the work of the COVAX Manufacturing Task Force (MTF), PDVAC reviews the evaluations and suggestions from the MTF related to selection of priority platform manufacturing technologies for technology transfer (TT), and selection of regional hubs for COVID-19 vaccine and routine vaccine TT, and the TT recipients. It communicates its recommendation to WHO.

PDVAC also provides, in the context of the Immunization Agenda 2030 (IA2030), and specifically strategic priority area 7 on Research and Innovation, reviews of the outputs, workplans, and reports from the SP7 working group (WG) consultations on defining country and regional priorities. It works closely with the SP7 WG to develop an integrated strategy on research and development priorities and targets for R&D in immunization, across all three levels (country, regional, global).

PDVAC is briefed on Strategic Advisory Group of Experts (SAGE) recommendations within the product development. PDVAC may also provide input to WHO, when requested, into vaccines and biologicals, their associated technologies and related activities that fall outside of its primary scope (for example in support of the WHO Research and Development Blueprint to prevent pandemics).

The Advisory Group ("PDVAC") will act as an advisory body to WHO in this field.

### I. Functions

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

- Assess and offer guidance to WHO on optimal methodologies and strategic approaches to determine the full value for vaccines, monoclonal antibodies, and related technologies, in the context of other disease interventions and competing R&D priorities (including the development of products that are targeted solely to high-income country markets but that may offer benefit in LMIC contexts);

- Advise WHO on the global public health priority pathogens, based on full value of vaccine assessments developed in partnership with immunization stakeholders at the country and regional levels, and activities that are needed to advance development and access of vaccines and related products in LMICs;
- Review, assist in development, and make recommendations to WHO on preferred product characteristics (PPCs) for a class of potential vaccines, specifically from the perspective of LMICs, with the goal of informing target product profiles to accelerate product development and reduce the timeframe to access of vaccines in LMIC contexts;
- Review, assist in development, and make recommendations to WHO on technical R&D roadmaps for vaccines, monoclonal antibodies, and related technologies that articulate the research, product development, and capacity needs, and proactively optimally position a candidate for successful LMIC licensure and a positive policy recommendation;
- Review, assist in development, and make recommendations to WHO on Preferred Policy Profiles (also called Evidence Considerations for Vaccine Policy Development) for vaccines and monoclonal antibodies, prior to phase III efficacy studies to guide evidence that would be helpful to collect prelicensure and align on expectations for licensure and policy assessment;
- Develop and propose to WHO criteria for selection of target vaccine manufacturing technologies that may be suitable for technology transfer to regional manufacturing hubs, and for selection of technology hubs and technology recipients; to provide independent assessment of the landscape of target manufacturing technologies for potential technology transfer and to synthesise recommendations of potential manufacturers in accordance with criteria;
- Horizon scanning to i) identify pathogen areas where vaccines do not currently exist and are urgently needed, particularly in low- and middle-income countries (LMICs), and to monitor the evolving vaccine candidate pipeline; and ii) identify novel platforms and technologies which could contribute to improved manufacturing processes, improved immunological responses, and/or easier vaccine delivery;
- Advise WHO on building consensus among global stakeholders, particularly with respect to product development strategy, including clinical endpoints and regulatory pathways;
- Highlight access and/or introduction issues or gaps that might occur during vaccine approval and uptake in LMICs, that should be considered and potentially addressed during early product development.

## **II. Composition**

1. PDVAC shall have up to [20] members<sup>1</sup>, who shall serve in their personal capacities to represent the broad range of disciplines relevant to vaccine and monoclonal antibody product development. In the selection of the PDVAC members, consideration shall be given

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

to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

2. Members of PDVAC, including the Chairperson (see 3. below), shall be selected and appointed by WHO<sup>2</sup> following an open call for experts. Members of PDVAC shall be appointed to serve for a period of 3 years and shall be eligible for reappointment<sup>3</sup>. Their appointment 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.
3. The Chairperson's functions include the following:
  - to chair PDVAC meetings;
  - to liaise with the WHO Secretariat between meetings.

When appointing a Chairperson, consideration shall be given to gender and geographical representation. A Chairperson is eligible for reappointment as a member of PDVAC 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.

4. PDVAC 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 on PDVAC 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 PDVAC. Their appointment to PDVAC is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, PDVAC 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 PDVAC members to complete a new declaration of interest form. This may be before a PDVAC meeting or any other PDVAC-related activity or engagement, as decided by WHO. Where WHO has made such a request, the PDVAC member's participation in the PDVAC activity or engagement is subject to a determination that their participation would not give rise to a real, potential, or apparent conflict of interest.

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7. Where a PDVAC member is invited by WHO to travel to an in-person PDVAC 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 an PDVAC member, until it receives a countersigned Temporary Adviser Letter.
8. PDVAC members do not receive any remuneration from the Organization for any work related to the PDVAC. 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. PDVAC shall normally meet at least once each year. However, WHO may convene additional meetings. PDVAC meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

PDVAC 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 PDVAC and essential WHO Secretariat staff.

2. The quorum for PDVAC 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 internal due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of PDVAC 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 PDVAC.

4. PDVAC may decide to establish smaller working groups (sub-groups of PDVAC) 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 PDVAC for review at one of its meetings.
5. PDVAC members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of PDVAC.
6. A yearly report shall be submitted by PDVAC to WHO (the Assistant Director-General of the responsible Cluster). All recommendations from PDVAC are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues, or other matters considered by PDVAC.
7. PDVAC 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 PDVAC members, including in working groups, teleconferences, and interaction over email. PDVAC members may, in advance of PDVAC meetings, be requested to review meeting documentation and to provide their views for consideration by PDVAC.
9. WHO shall determine the modes of communication by PDVAC, including between WHO and PDVAC members, and PDVAC members among themselves.
10. PDVAC members shall not speak on behalf of, or represent, PDVAC or WHO to any third party.

#### **IV. Secretariat**

WHO shall provide the secretariat for PDVAC, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide PDVAC 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 PDVAC-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, PDVAC 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 PDVAC-related activities shall be exclusively vested in WHO.

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