



COVAX

COVAX FACILITY INDEPENDENT PRODUCT GROUP TERMS OF REFERENCE

1. Purpose

The Independent Product Group (“IPG”) is established to provide scientific advice on COVID-19 vaccines and make technical recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility, by regularly reviewing the COVAX Facility portfolio for balance and review updates on availability of vaccines and consider any implications for the COVAX Facility portfolio.

The IPG is not deemed to be a committee of the Board in that its primary role is essentially an advisory function as contemplated under Article 20 of the Statues. As outlined in these Terms of Reference the IPG does not have decision-making powers. The aim of the IPG review process is to make a technical recommendation to the Office of the COVAX Facility on vaccine candidate for inclusion in the COVAX vaccine portfolio and portfolio balance. After considering IPG’s technical advice, the Office of the COVAX Facility decides to negotiate the ensuing deal terms, taking into consideration independent technical advice from the Procurement Reference Group (PRG), the deal is then considered by the Market Sensitive Decisions Committee (MSDC).

Words and expressions used in this Terms of Reference shall, unless the context requires otherwise, have the meaning attributed to them in the Board and Committee Operating Procedures.

2. Membership

The membership, resources, responsibilities, and authorities of the IPG to perform its role effectively is stipulated in these Terms of Reference which may be amended as and when required or deemed necessary.

A. Composition and size

The composition of the IPG shall allow it to function efficiently and effectively in fulfilling its functions and responsibilities. The composition of the IPG is intended to comprise individuals suitably competent in the affairs and issues falling within the Terms of Reference to be able to provide the Office of the COVAX Facility with sound advice on matters set out in this Terms of Reference.

The IPG shall comprise not less than five persons and no more than fifteen comprising members and observers. A majority of the IPG members shall comprise independent scientific and technical experts with a minority of observers. Independent experts should be institutionally

independent of the Gavi Secretariat, Board and Board Committees. IPG members will serve in their personal capacities and will not represent their employers, government, Gavi partner organisations or organisations engaged in the ACT Accelerator.

Observers may include Board and Alternate Board Members and other ex-officio members. Observers must adhere to confidentiality and declare any conflicts of interest.

The selection of IPG members shall be guided by the following criteria: credibility and independence; commitment and availability to participate in meetings; geographical and gender diversity; absence of conflict of interest.

Independence should be determined by considering the following questions, the answers to which will assist in ascertaining independence:

- Is the candidate institutionally independent of the Secretariat, Board, Board Committees and any committees or advisory bodies affiliated with the ACT Accelerator Vaccine Pillar (such as CEPI, DCVMN, IFPMA or WHO)? If the candidate is not institutionally independent, would the affiliation be of potential benefit in terms of providing cross-linkage to other groups?
- Is/has the candidate been an employee of the Gavi Secretariat within the last three years?
- Does/has the candidate had, within the last three years, a material business relationship with Gavi Alliance, whether directly as a partner, shareholder, contractor, grantee, director or senior employee of a body that has such a relationship with Gavi Alliance?
- Does/has the candidate had, within the last three years, a material business relationship with any of the organisations involved in the ACT Accelerator Vaccines Pillar (i.e., CEPI, DCVMN, IFPMA and WHO), whether directly as a partner, shareholder, contractor, grantee or a senior employee of a body that has such a relationship with any of the ACT Accelerator Vaccines Pillar bodies.
- Does/has the candidate had association with pharmaceutical/biotech industry or academic spin offs which may benefit from the recommendation of the IPG?
- Has the candidate received remuneration from Gavi, CEPI or WHO within the last three years?
- Does the candidate have any close family ties with any of Gavi's advisers, Board or Board Committee members, or senior employees?
- Does the candidate have any conflict of interest, as defined in Gavi's Conflicts of Interest Policy for Governance Bodies, and if so, can they be managed appropriately?

B. Competencies and skills

Each member of the IPG should have expertise, experience and knowledge of vaccine development and delivery. Collectively, IPG members should also have a balance of skills, recent and relevant expertise, experience and knowledge of the following:

- Coronavirus vaccines and/or COVID-19 vaccines
- Immunology, animal models and assays for vaccine evaluation
- Clinical evaluation of vaccines including vaccine evaluation in large randomised clinical trials
- Regulatory expertise in vaccine evaluation
- Vaccine manufacturing and GMP issues
- Epidemiology/public health/ health policy expertise
- Expertise in immunization programmes and service delivery
- Vaccine safety evaluation and monitoring

All IPG members shall be able to act independently, ask relevant questions, act professionally and maintain the highest ethical standards and loyalty to the interests of Gavi and the organisations engaged in the ACT Accelerator Vaccines Pillar.

The overall balance of skills on the committee shall be periodically evaluated.

The criteria for the IPG membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

Each member of the IPG will be required to participate in a programme of induction, training and familiarisation with the work of the IPG to enable Committee members to keep abreast of current developments in the work of the IPG and the work of the Vaccines Pillar of the ACT Accelerator more broadly.

The Chair of the IPG shall:

- Be one of the Independent Members of the IPG
- Plan, lead and facilitate the conduct of Committee meetings
- Facilitate and summarise discussions objectively and with clarity seeking to gain consensus and exert authority when necessary
- Ensure all Committee members appropriately contribute to deliberations and regularly participate in meetings
- Collaborate with the Office of the COVAX Facility as appropriate
- Collaborate with relevant bodies engaged in providing independent technical advice or governance of the ACT-Accelerator such as the CEPI RDMIC, PRG etc.
- Collaborate closely with the Gavi Chief Executive Officer (CEO) and the Office of the COVAX Facility on all matters relating to the inclusion of suitable candidates in the COVAX Facility's portfolio of vaccine candidates and the status of the portfolio
- Report to the Board through the Office of the COVAX Facility on relevant and material matters as appropriate; and
- Participate in and advise on the selection of new IPG members in conjunction with the IPG Selection and Oversight Panel, including providing guidance on matters relating to the independence of candidates.

In the event that the Chair is unable to attend a scheduled meeting, the Chair will, after consultation with other IPG members, nominate a suitable substitute (i.e., an independent member) from the membership of the IPG.

In the event that an IPG member is unable to attend a scheduled meeting, s/he cannot designate a replacement. If an IPG member has two consecutive absences from IPG meetings, the Chair will discuss with that IPG member the viability of his or her continued involvement on the Committee.

C. Appointment and term

All IPG members shall be appointed by the IPG Selection and Oversight Panel, comprised of the Gavi CEO, CEPI CEO and the WHO Chief Scientist. IPG members shall be appointed once every year, with a maximum of three consecutive terms. The IPG Selection and Oversight Panel shall select the Committee Chair ("Chair") every year, with a maximum of three consecutive terms. IPG Committee member and Chair terms shall be concomitant. All nominees to the IPG should be evaluated by the IPG Selection and Oversight Panel to ensure that individual meets the

membership requirements set out in 2. A & 2. B above including an independence test and ensure the individual's competencies fit with the required competencies of the IPG.

The work of the IPG will be supported by the Office of the COVAX Facility. The Office of the COVAX Facility shall:

- Provide the link between the IPG, the PRG, the MSDC and the COVAX Facility;
- Assist the IPG in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support the IPG are provided in a timely manner and after meetings.

It is expected that meetings will take place remotely. IPG members shall receive reasonable costs for their participation in each IPG session in accordance with Gavi's policies.

1. Authority

The IPG shall maintain open communications between IPG members and the COVAX Facility as appropriate.

The Committee shall have the power to delegate on an exceptional basis its authority and duties to the IPG Chair or individual committee members as it deems appropriate. This may include engagement with the CEPI RDMIC, COVAX PRG, MSDC, SAGE WG.

The IPG shall have reasonable access to information, Gavi personnel, Personnel of the Office of the COVAX Facility and relevant other Gavi parties, and external expertise, particularly relating to parties engaged in/ other governance bodies of the ACT-Accelerator as appropriate.

The mandate of the IPG is established in these Terms of Reference.

2. Responsibilities

It is the responsibility of the IPG to:

- A. Regularly review data and information relating to vaccine candidates currently in COVAX Portfolio and development of next generation of COVID-19 vaccine - i.e., variant-adapted, mucosal vaccine, broad spectrum COVID-19/coronavirus vaccine (received from manufacturers, WHO, CEPI and the RDMIC Secretariat).
- B. Provide guidance and independent technical advice to the Office of the COVAX Facility.
- C. Regularly review the SARS-CoV-2 vaccine pipeline and the COVAX Facility portfolio on a rolling basis, taking into consideration updates related to clinical development, manufacturing and supply and provide advice on both the pipeline and COVAX Facility portfolio to the Office of the COVAX Facility.
- D. Regularly monitor areas of interest and policy topics relevant to COVID-19 vaccine development and their implications on the COVAX vaccine portfolio and countries programmatic feasibility, while recognizing that COVAX will continue to rely on SAGE guidance.
- E. Engage with other bodies including, but not limited to, the CEPI RDMIC, PRG, SAGE Working Group etc.

3. Mode of Operation

A. Meeting attendance

If required, Observers may be invited to attend to ensure cross-linkage with other bodies but may not speak or participate in the proceedings except at the invitation of the IPG Chair. Observers are expected to uphold standards of confidentiality and declare all conflicts of interest.

Members of the Office of the COVAX Facility shall make themselves available to attend all IPG meetings as appropriate. Other observers may attend meetings under exceptional circumstances and contingent upon IPG Chair approval.

IPG members shall prepare for and actively participate in Committee meetings.

B. Frequency of meetings

Committee meetings will be scheduled based on the business needs driven by the COVAX Facility workplan. It is foreseen that the Committee shall normally convene once a quarter and on as needed basis. This may be modified, if deemed necessary by the IPG Chair. It is intended that all meetings shall take place remotely.

C. Notice of meetings

The Committee shall establish a calendar of activities every month so that meetings are known well in advance.

Notice of each meeting confirming the date, time, and venue shall be forwarded to each member of the Committee and other invitees not less than one week prior to the date of such meeting and sent by email. The notice will normally include an agenda and relevant supporting papers for the agenda items to be discussed. Unless otherwise explicitly indicated, all papers shall be retained in confidence for their specific reference and may not be circulated or distributed in any manner or form.

Occasionally ad-hoc meetings may be required at short notice; in the event of such a meeting being planned the purpose and justification of any such meeting will be clearly communicated to members. In this case, the Chair may call a meeting on less than seven business days' notice if, in their reasonable opinion, there exist exceptional circumstances requiring an IPG meeting to be held on short notice and provided however that the minimum notice that must be provided to IPG members is two business days. For such ad-hoc meetings, the quorum must be met.

D. Agenda

The IPG Chair shall establish meeting agendas with the Secretary of the Committee and in consultation with IPG members and relevant members of the Secretariat. The IPG agenda and calendar of activities shall include matters for current consideration and emerging issues within its area of responsibility.

E. Quorum

The quorum for the IPG shall be a simple majority of IPG members.

F. Conflicts of Interest

All IPG members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by IPG members when required.

At the commencement of each meeting, each IPG member shall declare any actual or perceived conflict of interest arising in the matters before the Committee. The relevant provisions in the Statutes, By-laws and the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

G. Confidentiality

All IPG members shall complete a Confidentiality Agreement and shall adhere to any obligations regarding the use, confidentiality and non-disclosure of Confidential Information specified in the agreement. Where Confidential Information is subject to additional conditions, IPG Members may be requested to provide confirmation that they will adhere to these conditions however the Secretariat will endeavour to ensure that these requests are limited.

H. Voting/ Decision-making

Recommendations will be made by consensus. In the event that consensus cannot be reached, a vote will be considered approved if a majority of those present in the meeting and entitled to vote, vote in favour of the decision.