COVAX: THE VACCINES PILLAR OF THE ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR STRUCTURE AND PRINCIPLES

COVAX

9 NOVEMBER 2020

Disclaimer: The work of the COVAX Facility is being accomplished across a range of complex matters and variables that continually evolve as more information on the pandemic becomes available, and involves contributions from a number of individuals and organisations. As a result, this document, including specific details on membership of various groups, should be taken as indicative as of the date of publication.

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INTRODUCTION: WHAT IS COVAX?

WHAT IS COVAX

Developing a vaccine against COVID-19 is one of the most pressing challenges of our time. The global pandemic has already caused the loss of more than one million lives and disrupted the lives of billions more. As well as reducing the tragic loss of life, introducing vaccines will prevent the loss hundreds of billions of dollars to the global economy every month.

Many leaders have called for a global solution to address this global issue. For a collaborative endeavor, that involves the best shared science to resolve, in the shortest possible time, a pandemic that involves every region and territory on the planet. In response, the Access to COVID-19 Tools (ACT) Accelerator – a groundbreaking collaboration to accelerate development, production and equitable access to COVID-19 diagnostics, treatments and vaccines – was launched in April 2020.

COVAX is the vaccines pillar of the ACT Accelerator, co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance, and the World Health Organization (WHO). Its goal is to help end the acute phase of the global pandemic by the end of 2021 by providing access to at least 2 billion doses of safe and effective COVID-19 vaccines to the most vulnerable in all participating economies. If it succeeds in this goal, through the appropriate allocation of safe and effective doses of vaccines in phases determined by epidemiology and public health to slow and ultimately to stop the pandemic, it could save millions of lives and transform the economic prospects of governments and individuals.

Developing one or more safe and effective COVID-19 vaccines is one of the most complex challenges of our time. Unlike with past vaccine development, scaling up manufacturing and completion of human trials for vaccine candidates must be done in parallel. Even with accelerated investment in manufacturing, and the completion of trials to ensure vaccine candidates are safe and effective, there is no scenario in which supply over the next 18 months will exceed demand – although at today's anticipated trajectory, some vaccine candidates could become available within this time frame.

COVAX is a global solution for equitable access: through portfolio diversification, pooling of financial and scientific resources, and economies of scale, participating governments and regional blocs can hedge the risk of backing unsuccessful candidates, just as governments with limited or no ability to finance their own bilateral procurement can be assured access to life-saving vaccines that would otherwise have been beyond their reach.

WHAT IS THIS DOCUMENT

The following document outlines the current working structure and overall guiding principles of collaboration between the organisations involved in implementing COVAX. Building on existing bodies wherever possible, and adapting to emerging needs, this working structure will continue to evolve as needed.

SECTION 1: OVERVIEW OF KEY BODIES

1. CROSS-CUTTING

1.1 COVAX COORDINATION MEETING (CCM)

Overview

The CCM is the high-level body that meets to coordinate efforts across the different elements of COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator. The CCM is chaired by the Board Chairs of CEPI and Gavi, and includes the institutional leads of all three organisations, providing a link to the established governance of each organisation. It meets to help coordinate, guide and resolve issues across COVAX.

Objectives

- Ensure alignment between partners and the wider ACT Accelerator
- Inform major workstream decisions
- Discuss major strategic questions
- Address bottlenecks as needed, including through high-level stakeholder management
- Take responsibility for progress towards goals

Areas of focus

The CCM provides guidance across the various COVAX workstreams, with a particular focus on the many areas of interdependency and collaboration.

Decision-making principles

- Each partner must act with integrity to further COVAX aims. Organisational Interest and Conflicts of Interest must be managed transparently with the highest degree of integrity.
- CCM acts as bridge and steering group and is therefore responsible for coordination and driving the work of COVAX.
- COVAX builds on existing management bodies rather than creating new management.
- For decisions beyond the mandate of COVAX or that may implicate or affect the broader work of the organisations, there must be explicit approval from relevant Boards.
- Financial accountability remains fully within each organisation. No decision can be taken that would contradict a decision by the respective Boards of CEPI and Gavi; exceptions must be approved by the organisation's Board.

Members

- **Co-chairs**: Jane Halton (Board Chair, CEPI); Ngozi Okonjo-Iweala (Board Chair, Gavi)
- **Institutional Leads**: Seth Berkley (Gavi); Richard Hatchett (CEPI); Soumya Swaminathan (WHO)
- **Workstream leads**: Aurélia Nguyen (Gavi); Kate O'Brien (WHO); Melanie Saville (CEPI)
- **Industry partner representatives**: Roger Connor (GSK), selected through International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); Mahima Datla (Biological E. Limited), selected through Developing Countries Vaccine Manufacturers Network (DCVMN)
- **Civil society representative**: Mesfin Teklu Tessema (International Rescue Committee)
- **UNICEF representative**: Omar Abdi
- **By invitation**: Chair of the Research and Development and Manufacturing Investment Committee (RDMIC), Chair of the Independent Product Group (IPG)

Format

- **Forum**: Video/teleconference
- **Frequency**: Fortnightly (once every two weeks)
- **Length**: Two hours

1.2 AREAS OF INTER-ORGANISATIONAL COORDINATION

The three lead COVAX organisations – CEPI, Gavi and WHO – coordinate closely on the following issues: costing; funding and resource mobilisation; indemnification and liability; consolidated data; Conflict of Interest principles; engagement of civil society organisations (CSOs); regulatory (including safety) preparedness and guidance; end-to-end operationalisation; and deals with manufacturers.

2. WORKSTREAM – DEVELOPMENT AND MANUFACTURING

2.1 RESEARCH AND DEVELOPMENT AND MANUFACTURING INVESTMENT COMMITTEE (RDMIC)

Overview

The Research and Development and Manufacturing Investment Committee is a multidisciplinary group with industry expertise that manages the allocations of funds under the Development and Manufacturing Workstream of COVAX. It provides investment decision recommendations for selection and progression of the portfolio of COVAX-funded vaccine candidate projects and cross-cutting enabling projects that accelerate vaccine R&D and manufacturing.

The RDMIC also reviews non-COVAX-funded vaccine development and manufacturing projects to ensure cross-portfolio challenges, interdependencies and decisions can be surfaced and addressed appropriately.

The RDMIC provides portfolio strategy and investment decision recommendations to rapidly identify, develop and manufacture COVID-19 vaccines that can be deployed at scale to address global health needs. The RDMIC operates as an expert advisory group, primarily to make investment recommendations that the CEPI Board (through its Executive and Investment Committee) reviews/endorses. Accountability for decision-making and investor requirements remains clearly with the respective institutional governance bodies.

Objectives

The principal objectives of the RDMIC are to:

- Drive portfolio strategy and investment decision recommendations aligned with overall COVAX strategic objectives.
- Define the target composition, diversity, investment allocation and risk profile of the portfolio of COVAX-funded vaccine candidate projects and cross-cutting enabling projects.
- Recommend project selection and investment decisions greater than US$ 5 million – for example, new project selections, stage gate reviews, portfolio reviews (+ down selections), major change requests.
- Oversee overall progress of COVAX-funded vaccine candidate projects and cross-cutting enabling projects.
- Identify and address cross-portfolio challenges and interdependencies.

Areas of focus

- Definition of COVAX-funded vaccine candidate and cross-cutting enabling project portfolio composition, diversity, investment allocation and risk.
- Recommendations for decisions on project prioritisation, selection and investment.
- Final endorsement of recommendations for new projects.
- Final endorsement of recommendations for project progression (stage gate reviews).
- Development/endorsement of recommendations for project budget overruns greater than US$ 5 million or timeline delays greater than three months.
- Monitoring of overall project progress and resolution of escalated project issues.
- Identification of cross-portfolio challenges, interdependencies and decisions.

Decision-making principles

Decision-making principles for RDMIC are:

- All members must act with integrity and impartiality at all times, in accordance with policies or principles of the COVAX Development and Manufacturing Workstream.
- Decisions are driven by consensus. If consensus cannot be reached, decision will be made by the RDMIC Chair.
- Voting requires quorum of at least two thirds of RDIMC core members and includes the RDMIC Chair and the CEO (or delegate) of the institution allocating funds.
- Technical aspects of proposals to the RDMIC will be actively and objectively reviewed through the Technical Review Group (TRG) prior to RDMIC.

Members

The RDMIC is comprised of the CEPI CEO, Gavi CEO, Bill & Melinda Gates Foundation President of Global Health, (ex-) industry R&D experts, (ex-) industry manufacturing experts, current active industry (non-vaccine) leaders and senior global public health leaders (including a CEPI Board member, to ensure linkages) and is accountable to the CEPI Board.

Extended members – including the Chair of the Technical Review Group and external strategic advisors, as appropriate – also attend RDMIC meetings to contribute expert R&D and manufacturing perspectives. Extended members are non-voting members.

Core (voting) members:

- Chris Viehbacher, Chair (Gurnet Point Capital)
- Seth Berkley (Gavi)
- Richard Hatchett (CEPI)
- Subhash Kapre (Inventprise)
- Michael King (Independent Consultant, retired Merck/MSD)
- Kiran Mazumdar-Shaw (Biocon)
- Trevor Mundel (Bill & Melinda Gates Foundation)
- John Nkengasong (Africa Centres for Disease Control and Prevention)
- Peter Paradiso (Independent Consultant)

Extended members:

- Melanie Saville, Technical Review Group Chair (CEPI)
- Luc Debruyne, Strategic Advisor (CEPI)

Format

- Forum: Video/teleconference
- Frequency: Weekly
- Length: Two hours

2.2 TECHNICAL REVIEW GROUP (TRG)

Overview

The Technical Review Group (TRG) is a cross-cutting, multidisciplinary advisory group with expertise in all areas of vaccine research and development, including enabling sciences, clinical development, manufacturing, regulatory affairs, public health and industry. The TRG is responsible for the overall technical review, oversight, support and steering of vaccine development projects under the Development and Manufacturing Workstream to meet the challenges of speed, access and manufacturing scale.

Each vaccine project is supported by a Vaccine Team composed of: a Project Leader; Project Manager; Contract Manager; and functional experts in preclinical studies, clinical development, manufacturing and regulatory issues.

In an "open session" (objectives below), TRG members provide recommendations for cross-cutting enabling projects; identify interdependencies; and approve formation of SWAT teams to address challenges in order to accelerate vaccine R&D and manufacturing across all vaccine candidates.

In a "closed session" (objectives below), TRG members with no Conflicts of Interest provide extensive technical review of specific vaccine development projects, and recommend selection and progression of the portfolio of COVAX-funded vaccine candidates to the RDMIC.

Objectives

The principal objectives of TRG closed sessions are to:

- Provide end-to-end oversight of project execution, to include review and monitoring of Vaccine Teams' progress, milestones and budgets;
- Review significant deviations in projects (scope, time or budget) and approve or escalate to RDMIC;
- Recommend project selection based on technical review and investment decisions less than US$ 5 million (e.g. new project selections, stage gate reviews, change requests);
- Support and provide guidance to Vaccine Teams through scientific, technical and operational review of projects and risks;
- Raise challenges or issues from Vaccine Teams to be addressed by SWAT teams; and
- Make stage gate recommendations to the RDMIC.

The principal objectives of TRG open sessions are to:

- Provide end-to-end oversight of SWAT team execution, to include review and monitoring of SWAT teams' progress, milestones and challenges;
- Approve working group creation, deliverables and timelines; and
- Provide technical support and guidance to SWAT teams and the Regulatory Advisory Group (RAG) on project-agnostic challenges and issues.

Areas of focus

TRG closed sessions

- Stage gate recommendations for projects based on review of milestones;
- Recommendations based on review of scientific, technical, financial, operational and risk reports from Vaccine Teams; and
- Review of budget overruns or project timeline delays, and recommendations for approval or escalation of budget overruns greater than US$ 5 million or timeline delays greater than three months to RDMIC.

TRG open sessions

- Technical review and recommendations for working group creation, deliverables and timelines; and
- Review of SWAT teams' deliverables and recommendations for addressing bottlenecks and common challenges across vaccine development projects.

Decision-making principles

Decision-making principles for the TRG are:

- All members must act with integrity and impartiality at all times, in accordance with policies or principles of the COVAX Development and Manufacturing Workstream.
- Technical review of development plans to be conducted by non-conflicted TRG members.
- Technical review of SWAT teams' inputs (cross-cutting, non-proprietary), to include additional experts (extended members) with express permission of the Chair.
- Extended members are observers and do not hold decision rights (to avoid Conflicts of Interest).
- Voting requires quorum of at least two thirds of TRG core members and includes the TRG Chair. Decisions are driven by consensus. If consensus cannot be reached, decision will be made by the TRG Chair.

Members

Core members

- Melanie Saville, Chair (CEPI)
- Vasee Moorthy (WHO)
- Derrick Sim (Gavi)
- Rebecca Grais (Médecins Sans Frontières – MSF)
- Emilio Emini (Bill & Melinda Gates Foundation)
- Paul Kristiansen (CEPI)

- Jakob Cramer (CEPI)
- Debra Yeskey (CEPI)
- Svein Rune Andersen (CEPI)
- Ingrid Kromann (CEPI)
- Nick Jackson (CEPI)
- Gabrielle Breugelmans (CEPI)

Additional members included in TRG open sessions

- Steve Lockhart (IFPMA)
- Norio Tamura (IFPMA)
- Ricardo Palacios (DCVMN)
- Weining Meng (DCVMN)
- Adriansjah Azhari (DCVMN)
- Michael King (Independent Consultant, retired MSF/Merck)
- Jean Lang (IFPMA)
- Jim Robinson (CEPI)
- Nicolas Havelange (CEPI)
- David Robinson (Bill & Melinda Gates Foundation)
- Peter Dull (Bill & Melinda Gates Foundation)
- Emer Cooke (WHO)
- Ivana Knezevic (WHO)

Format

- **Forum**: Video/teleconference
- **Frequency**: Weekly
- **Length**: One hour

2.3 SWAT TEAMS AND REGULATORY ADVISORY GROUP (RAG)

Overview

SWAT (Support Work to Advance Teams) are groups of experts focused on resolving technical issues and challenges common across all COVID-19 vaccine development projects to promote and accelerate vaccine development. SWAT core members represent diverse stakeholders in the vaccine development ecosystem, providing expertise in enabling sciences; clinical development and operations; and manufacturing to scale. The Regulatory Advisory Group (RAG), composed of regulators representing all global regions, works to resolve and provide guidance for harmonised pathways to address regulatory science challenges, in order to accelerate vaccine development.

SWAT teams include: (1) Clinical Development and Operations; (2) Enabling Sciences; and (3) Manufacturing. The RAG provides guidance for regulatory science challenges and interdependencies escalated by all three SWAT disciplines.

Objectives for all SWAT teams and RAG

- Focus on resolving common technical cross-project questions and challenges at speed;
- Act as an open source of information for COVAX Vaccine Teams (see definition in TRG section, above) and COVID-19 vaccine developers more broadly;
- Promote harmonisation and comparability across projects; and
- Bring together different stakeholders and coordinate with other players in the ecosystem to maximise efforts.

Areas of focus

Clinical Development and Operations SWAT

- Clinical and operational readiness by supporting: clinical trial sites in low- and middle-income economies; landscape analyses; and creation of databases or networks.
- Addressing vaccine safety considerations during development, including case definitions, planning towards clinical trials and vaccine safety surveillance.
- Clinical science elements for clinical trials, such as endpoint case definitions, adaptive trial designs, correlates of protection and optimisation options.

Enabling Sciences SWAT

- Assay standardisation through development of an international antibody standard; centralised laboratory capacity for clinical trials; defining type and performance of diagnostic assays; and addressing regulatory challenges in standardisation.
- Animal model testing network to ensure development of appropriate animal models and high-quality testing of vaccine candidates.
- Guidance on animal model evaluation for vaccine-mediated enhanced disease (VMED) and correlates of protection.

Manufacturing SWAT

- Drug product and drug substance strategy and capacity identification for scale-up and scale-out of products.
- Supply chain strategy to include securing raw materials, mutually agreed labelling and alignment with COVAX partners.
- Support for batch release assays (including potency assay requirements); mutual recognition of the process for timely national batch release; and support for additional analytical capacity.

Regulatory Advisory Group (RAG)

- Guidance for regulatory science challenges related to SWAT team activities, towards harmonisation and streamlined processes where feasible. Membership is focused on representatives of regulatory authorities from around the world.

Decision-making principles

- Core team experts are involved with decision-making in their area of expertise.
- SWAT team co-leads develop and assess work packages, as per deliverables description.
- If consensus cannot be reached on a topic and further expertise is required, the SWAT team co-leads can escalate the decision to the Technical Review Group (TRG).

Members

Core members for each SWAT team and the RAG define and revise key questions, deliverables and timelines as needed and drive activities according to defined deliverables. Core members are involved with decision-making, with additional experts joining working groups, workshops or core team meetings on an ad hoc basis.

Clinical Development and Operations SWAT: Core members

- Jakob Cramer, co-lead (CEPI)
- Peter Dull, co-lead (Bill & Melinda Gates Foundation)
- Hilary Marston (National Institutes of Health, USA)
- François Roman (IFPMA)
- Stephen Lockhart (IFPMA)
- Ricardo Palacios (DCVMN)
- Robert Chen (Brighton Collaboration)
- Farah Kumar (Aga Khan Foundation)
- Gabrielle Breugelmans (CEPI)
- Debra Yeskey (CEPI)
- Svein Rune Andersen (CEPI)
- Ana Maria Henao Restrepo (WHO)
- Peter Smith (London School of Hygiene & Tropical Medicine)
- David Kaslow (PATH)
- Sophie Mathewson (Gavi)
- Charlie Weller (Wellcome Trust)

Enabling Sciences SWAT: Core members

- Paul Kristiansen, co-lead (CEPI)
- Ivana Knezevic, co-lead (WHO)
- Jenny Hendriks (IFPMA)
- Karen Markar (Bill & Melinda Gates Foundation)

- Janet Lathey (National Institutes of Health, USA)
- Carolyn Clark (CEPI)
- William Dowling (CEPI)
- Valentina Bernasconi (CEPI)
- Debra Yeskey (CEPI)
- Svein Rune Andersen (CEPI)
- Sheetal Sharma (Safari Doctors)

Manufacturing SWAT: Core members

- Ingrid Kromann, co-lead (CEPI)
- Nicolas Havelange, co-lead (CEPI)
- David Robinson, co-lead (Bill & Melinda Gates Foundation)
- Alain Alsalhani (Médecins Sans Frontières – MSF)
- Mike Thein (IFPMA)
- Adriansjah Azhari (DCVMN)
- Carmen Rodriguez Hernandez (WHO)
- Diane Wilkinson (Vaccines Europe)
- Jim Robinson (CEPI)
- Debra Yeskey (CEPI)
- Svein Rune Andersen (CEPI)
- Dominique Maugeais (Gavi)

Regulatory Advisory Group (RAG): Core members

- Debra Yeskey, co-lead (CEPI)
- Svein Rune Andersen, co-lead (CEPI)
- Emer Cooke, co-lead (WHO)
- Marco Cavaleri (European Medicines Agency – EMA)
- Marion Gruber (Food and Drug Administration – FDA, USA)
- Dean Smith (Health Canada)
- Kristy Tomas (Therapeutic Goods Administration – TGA, Australia)
- Laurent Mallet (European Directorate for the Quality of Medicines – EDQM)
- May Ling Choong (Health Sciences Authority – HSA, Singapore)
- Mimi Darko (Food and Drugs Authority – FDA, Ghana)
- Patricia Aprea (National Administration of Drugs, Foods and Medical Devices – ANMAT, Argentina)
- Flavia Regina Souza Sobral (National Health Surveillance Agency – ANVISA, Brazil)
- Michael Weissman (TGA, Australia)
- Araki Yasuhiro (Pharmaceuticals and Medical Devices Agency – PMDA, Japan)
- Tiziana Scarna, Observer (Gavi)

Format

SWAT core teams

- **Forum**: Video/teleconference
- **Frequency**: Biweekly
- **Length**: One to one-and-a-half hours

RAG

- **Forum**: Video/teleconference
- **Frequency**: Monthly
- **Length**: Two hours

Working groups

- **Forum**: Video/teleconference
- **Frequency**: Weekly, plus monthly topic-specific workshops with extended members and developers
- **Length**: Weekly – One hour; workshops – two to four hours

3. WORKSTREAM – PROCUREMENT AND DELIVERY AT SCALE

3.1 COVAX FACILITY

Office of the COVAX Facility

Overview

As the legal administrator of the COVAX Facility, Gavi has established the Office of the COVAX Facility within the Gavi Secretariat to ensure a dedicated team is available to support Facility operations, and to mitigate disruption to Gavi's core work.

Managing Director

- Aurélia Nguyen, Gavi

Format

- Housed within the Gavi Secretariat

COVAX Shareholders Council

Overview

The COVAX Shareholders Council will* represent self-financing participants (SFPs) in the governance of the COVAX Facility. Membership of the COVAX Shareholders Council will be open to all SFPs in the COVAX Facility. The Council will convene SFPs with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility. It is expected that the Council will establish a smaller Executive Committee to prepare and guide its discussions. The Executive Committee will provide a clear link between the Council and other governance structures to ensure the consolidated advice and views of the Council is considered in relevant deliberations.

Members

- To be determined – potentially all SFPs and participants they choose to invite

Format

- To be determined
  **Provisionally approved by the Gavi Board*

COVAX AMC Engagement Group

Overview

The COVAX Advance Market Commitment (AMC) Engagement Group* will represent the AMC in the governance of the Facility. Membership of the AMC Engagement Group will be open to representatives from implementing economies, donors and other parties engaged in the financing and operation of the AMC portion of the Facility. The group will convene with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility, particularly as it relates to implementation in AMC-eligible countries. Within this body, an AMC Stakeholders Group will convene representatives from AMC donors; procurement organisations such as UNICEF and PAHO; and representatives of multilateral development banks or regional banks involved in the financing of the AMC. It will discuss its investments in the AMC; options for additional financing; and receive specific reporting on progress achieved against the objectives of the AMC.

Members

- To be determined – potentially implementing countries, donors and other parties engaged in the financing and operation of the Gavi COVAX AMC, and participants they choose to invite

Format

- To be determined
  **Provisionally approved by the Gavi Board*

COVAX Consensus Group

Overview

The COVAX Consensus Group* will be established to support effective operation of the COVAX Facility through consensus-based decision-making between various governing bodies, particularly in areas where disagreement may arise.

Members

- To be determined – potentially, Chair and Vice Chair of the Gavi Board; co-Chairs of the COVAX Shareholders Council; co-Chairs of the AMC Engagement Group; and – in an ex-officio, non-voting, capacity – the three institutional leads of the vaccines pillar of the ACT Accelerator (i.e. COVAX).

Format

- To be determined
  **Provisionally approved by the Gavi Board*

Independent Product Group (IPG)

Overview

The Independent Product Group (IPG) is established to make recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility; regularly review the COVAX Facility portfolio for balance; review updates on timing and availability of doses; and consider any implications for the COVAX Facility portfolio.

The IPG is primarily advisory, and it does not have decision-making powers. The aim of the IPG review process is to make a recommendation to the Office of the COVAX Facility on vaccine candidate prioritisation and portfolio balance. Once the Office of the COVAX Facility has negotiated the ensuing deal terms, taking into consideration independent technical advice from the Procurement Reference Group (PRG), the deal would then be considered by the Market-Sensitive Decisions Committee (MSDC).

The IPG will:

- Regularly review data and information relating to vaccine candidates (for example, such as that received from manufacturers, WHO, CEPI and the RDMIC Secretariat);
- Provide guidance and independent technical advice to the Office of the COVAX Facility to inform the selection of candidates to be prioritised for deal-making by the COVAX Facility, and eventually considered by the MSDC;
- Regularly review the SARS-CoV-2 vaccine pipeline and the COVAX Facility portfolio, 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 and the Gavi Board;
- Engage with other bodies including, but not limited to, the RDMIC, PRG, SAGE Working Group on COVID-19 Vaccines, etc.

Members

- Marie-Paule Kieny, Chair (Inserm)
- Rafi Ahmed (Emory University)
- Delese Mimi Darko (FDA, Ghana)
- Michel de Wilde (independent consultant)
- Jill Gilmour (independent consultant)
- Jaap Goudsmit (Harvard University)
- Jorge (George) Kalil (University of Sao Paulo)
- César Muñoz-Fontela (Bernhard Nocht Institute for Tropical Medicine)
- Connie Schmaljohn (NIAID Integrated Research Facility)
- Kanta Subbarao (Doherty Institute)

Format

- **Forum**: Video/teleconference
- **Frequency**: Weekly
- **Length**: Two hours

Procurement Reference Group (PRG)

Overview

Once vaccine candidates have been selected to be funded by the Facility, informed by recommendations of the IPG, the Procurement Reference Group (PRG) will then be responsible for providing independent advice to the Facility to ensure an appropriately risk managed COVAX portfolio from a commercial perspective considering vaccine candidates' probability of success and timeline for supply delivery. Guidance will pertain to the implementation of the COVID-19 vaccine procurement strategy, and key business terms of proposed advance purchase commitments with the manufacturers of these vaccine candidates. Key terms include: volumes; pricing; proportion of firm order commitment vis-à-vis options; performance metrics; trigger for call; and recourse remedies for managing individual supplier risk, as well as the overall COVAX portfolio.

The PRG is primarily advisory, and it will not have decision-making powers. Based on recommendations from the PRG, the Office

of the COVAX Facility will advance negotiations with manufacturers and bring recommendations on final deal terms to the MSDC for approval.

Members

- To be determined

Format

- To be determined

Gavi Board

Overview

The Board of Gavi, the Vaccine Alliance is responsible for overseeing the role of the Gavi Secretariat and the Alliance in the Facility, and will have ultimate responsibility for decisions and effective implementation of the COVAX Facility.

In this role, it will:

- take responsibility to ensure that the Gavi Secretariat operates within the mandate granted to it;
- provide strategic direction and policy-making;
- receive regular reports from the Office of the COVAX Facility on operational progress and performance;
- receive updates from relevant Board Committees (e.g. Audit and Finance Committee) on COVAX Facility matters; and
- provide strategic oversight of the COVID-19 programme and effective implementation, including country engagement.

Members

- The list of current Gavi Board members is available on the Gavi website here.

Market-Sensitive Decisions Committee (MSDC)

Overview

The Market-Sensitive Decisions Committee (MSDC) is established by the Gavi Board to provide oversight and make decisions which are market and/or commercially sensitive. With Gavi established as the administrator of the COVAX Facility, the MSDC will undertake this function for transactions related to the COVAX Facility, including for the Gavi COVAX AMC.

Members*

- Ngozi Okonjo-Iweala, Board Chair (independent member)
- Sarah Goulding, Board Vice-Chair (independent member)
- Etleva Kadilli, Board alternate (UNICEF)
- Muhammad Pate, Board member (World Bank)
- Violaine Mitchell, Board alternate (Bill & Melinda Gates Foundation)
- Lia Tadesse, Board member (Ethiopia)
- Arsen Torosyan, Board member (Armenia)
- Daniel Graymore, Board member (United Kingdom)
- Jan Paehler, Board member (European Commission)
- Carmen Coles Tull, Board alternate (United States of America)
- Maty Dia, Board member (Civil society organisations)
- David Sidwell, Board member; Audit and Finance Committee Chair (independent member)
- Helen Rees, Board member; Programme and Policy Committee Chair (independent member)
- Seth Berkley, non-voting member (CEO, Gavi)
- Three representatives from the COVAX Shareholders Council

*Membership of MSDC with respect to COVAX-related transactions; with the exception of representatives of the COVAX Shareholders Council, all MSDC members must be Gavi Board members or alternate Board members.

Audit and Finance Committee (AFC)

Overview

The Audit and Finance Committee (AFC) is established by the Gavi Board to support the

Board in fulfilling its oversight responsibilities in a timely manner in respect of the organisation's financial management; risk and control framework, including internal and external audit; and adherence to appropriate standards of good practices and ethics. The AFC will undertake this function in relation to Gavi's role as the legal administrator of the COVAX Facility.

With respect to the COVAX Facility, the AFC will be responsible for:

- ensuring funding availability for COVAX Facility operations, including review of the financial implications of Facility-related transactions;
- ensuring the COVAX Facility is properly represented in Gavi's Annual Financial Report; and
- monitoring risk to Gavi and the COVAX Facility.

Members

- David Sidwell, Chair; Board member (independent member)
- Teresa Ressel, Board member (independent member)
- Beniamin Carcani, Committee delegate (World Bank)
- Etleva Kadilli, Board alternate (UNICEF)
- Kwaku Agyeman-Manu, Board alternate (Ghana)
- Emmanuel Maina Djoulde, Committee delegate (Cameroon)
- Andreas Karlberg Pettersen, Committee delegate (Norway)
- Carmen Coles Tull, Board alternate (United States of America)
- Gianmarco Cocozza, Committee delegate (Italy)
- Tom Morrow, Committee delegate (United Kingdom)
- Rafael Vilasanjuan, Board alternate (Civil society organisations)

3.2 COUNTRY READINESS AND DELIVERY (CRD)

Overview

The Country Readiness and Delivery (CRD) workstream is led by WHO, UNICEF and Gavi, and it includes implementing and donor agencies and partners working together at the global and regional levels to: (1) develop and disseminate adaptable global goods (e.g. guidance, trainings, tools, advocacy materials); and (2) support all countries and economies to prepare for COVID-19 vaccine introduction and to achieve high acceptance and uptake.

The CRD workstream is composed of a coordination working group that has oversight of seven other sub-working groups: (1) communications, advocacy and training; (2) data and monitoring; (3) vaccine introduction; (4) vaccination demand; (5) supply and logistics; (6) costing; and (7) innovation to scale. CRD working groups collaborate closely across the ACT Accelerator and beyond to promote a cohesive approach to COVID-19 vaccine readiness for introduction and deployment.

The CRD workstream will develop technical resources and support capacity building of countries for COVID-19 vaccine introduction. Workstream deliverables include: a country readiness assessment tool and dashboard; guidance for a National Deployment Vaccine Plan; adaptable technical guidance across a range of programmatic areas (e.g. supply chain and logistics, demand generation and community engagement, data and monitoring); training packages; communications/advocacy materials; and recommended indicators for monitoring preparedness and use.

Members

Coordination Working Group

- Ann Lindstrand, Co-Lead (WHO)
- Ann Moen, Co-Lead (WHO)
- Benjamin Schreiber, Co-Lead (UNICEF)
- Nedret Emiroglu (WHO)
- Shoshanna Goldin (WHO)
- Patrick Sagna (Dalberg)

- Zeenat Patel (Gavi)
- Alex de Jonquieres (Gavi)
- Helen Matzger (Bill & Melinda Gates Foundation)
- Sunil Bahl (WHO)
- Daniel Ngemra (UNICEF)
- Antoinette Ba (UNICEF)
- Alba Maria Ropero (PAHO)
- Oleg Benes (WHO)
- Adama Sawadogo (UNICEF)
- Marta Gacic-Dobo (WHO)
- Diane Summers (UNICEF)
- Diana Chang-Blanc (WHO)
- Ulla Griffin (UNICEF)
- Jim Robinson (CEPI)
- Kent Ranson (World Bank)
- Sulzhan Bali (WB)
- Kathy Clark (IFRC)

Sub-working group: Communications, Advocacy and Training

- Shoshanna Goldin, Lead (WHO)
- Mindy Frost (WHO)
- Vicky Houssiere (WHO)
- Lisa Menning (WHO)
- Shushan Mebrahtu (UNICEF)
- Alba Maria Ropero Alvarez (PAHO)
- Katja Schemionek (Gavi)
- Jhilmil Bahl (WHO)
- Tamer Elmaghraby (WHO)
- Denise Traicoff (CDC)
- Diane Scott (BMGF)
- Carla Toko (VillageReach)

Sub-working group: Data and Monitoring

- Marta Gacic-Dobo, Lead (WHO)
- Hope Johnson (Gavi)
- Laura Craw (Gavi)
- Mamadou S. Diallo (UNICEF)
- Tove Ryman (Bill & Melinda Gates Foundation))
- Roberta Pastore (WHO)
- Pernille Jorgensen (WHO)
- Mark Katz (WHO)
- Martha Velandia (WHO)
- Jan Grevendonk (WHO)
- Carolina Danovaro (WHO)
- Jason Mwenda Mathiu (WHO)
- Apophia Namageyo (CDC)
- Garrett Livingston Mehl (WHO)
- Jotheeswaran Amuthavalli Thiyagarajan (WHO)

Sub-working group: Demand

- Diane Summers, Co-Lead (UNICEF)
- Susan Mackay, Co-Lead (GAVI)
- Corbin Kappler (UNICEF)
- Lisa Menning (WHO)
- Neetu Abad (CDC)
- James Angus Thomson(UNICEF)
- Kate Bagshaw (JSI)
- Lora Shrimp (JSI)
- Helena Ballester Bon (UNICEF ESARO)
- Naureen Navqi
- Emily Ramos (UNICEF)

- Matthew Steele (BMGF)
- Ohail Agha (BMGF)
- Kathleen Clark (IFRC)
- Gwendolyn Eamer (IFRC)
- Robert Kanwagi (World Vision)

Sub-working group: Supply and Logistics

- Adama Sawadogo, Co-Lead (UNICEF)
- Karan Sagar, Co-Lead (Gavi)
- Kone Souleymane, Co-Lead (WHO)
- Michelle Seidel (UNICEF)
- Patrick Gaparayi (UNICEF)
- Claude Mangobo (WHO)
- Maricel Castro (WHO)
- Serge Ganivet (UNICEF)
- Dereje Haile (UNICEF)
- Oleg Benes (WHO)
- Lennox Oweg (UNICEF)
- Thomas Sorensen (UNICEF)
- Srihari Dutta (UNICEF)
- Nasrin Musa (WHO)
- Chandrasegarar Soloman (UNICEF)
- Mike Brison (Gavi)
- Karuna Luthra (Gavi)
- Nora Rodriguez (PAHO)
- Kelly Hamblin (BMGF)
- Khin Devi Aung (UNICEF)
- Morio, Matt (PATH)
- Dorcas Noertoft (UNICEF)
- Sarah Abdulhady (WHO)
- Zhang Guomin (CDC China)
- Sonia Freitas (UNICEF)
- Isabelle Cantin (UNICEF)
- Olayinka Sanusi (UNICEF)
- Hailu Kenea (UNICEF)
- Joselito Nuguid (UNICEF)
- Anne-Laure Maiola (UNICEF)
- Jose Medina Valle (UNICEF)
- Pablo Panadero (UNICEF)
- Olamide Folorunso (UNICEF)
- Jean-Cedric Meeus (UNICEF)
- Samuel Kweku Ocran (UNICEF)
- Sviatlana Kavaliova (UNICEF)
- Olga Kosyak (UNICEF)
- Tom Ziraguma (UNICEF)
- Hamadou Modibo Dicko (UNICEF)
- Amany Ghoniem (WHO)
- Daniel Bridgen (WHO)
- Michael Zanardi (UNICEF)
- Teleb Nadia (WHO)
- Wendy Prosser (JSI)
- Jessica Crawford (Village Reach)
- David Muhia (UNICEF)
- Andisheh Ghazieh (UNICEF)
- Silvia Uneddu (UNICEF)
- Hussein Kamara (UNICEF)
- Leon Cases Gonzalez (UNICEF)

Sub-working group: Vaccine Introduction

- Diana Chang Blanc, Lead (WHO)

- Alejandro Ramirez Gonzalez (WHO)
- Santosh Gurung (WHO)
- Ioana Ghiga (WHO)
- Nathalie Chenavard (WHO)
- Hermanthi Dassanayake (WHO)
- Nadia Teleb (WHO)
- Louise Henaff (WHO)
- Terri Hyde (CDC)
- Christoph Steffen (WHO)
- Liudmila Mosina (WHO)
- Antoinette Ba (UNICEF)
- Ado Bwaka (WHO)
- Ahmadu Yakubu (UNICEF)
- Anissa Sidibe (Gavi)
- Stephen Sosler (Gavi)
- Reena Doshi (CDC)
- Yalda Momeni (UNICEF)
- Emily Nickels/Kendall Krause (Bill & Melinda Gates Foundation)
- Eltayeb Elfakki (WHO)
- Jason Mathiu (WHO)

Sub-working group: Costing

- Ulla Griffin, Lead (UNICEF)
- Logan Brenzel (BMGF)
- Stephen Resch (Harvard University)
- Allison Portnoy (Harvard University)
- Karene Yeung (WHO)
- Raymond Hutubessy (WHO)
- Nathalie Vande Maele (WHO)
- Alex Adjagba (UNICEF)
- Marcia Attaran (UNICEF)
- Anne Cronin (Gavi)
- Simon Allen (Gavi)
- Laura Boonstoppel (Thinkwell)

Format

- **Forum**: Video/teleconference
- **Frequency**: Varied
- **Length**: Varied

3.3 LEARNING, MONITORING AND EVALUATION

Objectives

COVAX has ambitious goals and objectives. It presents many challenges, new ways of working and opportunities for all stakeholders involved. As such, there is a strong desire to ensure learning, monitoring and evaluation from early stages of design of the COVAX pillar through to its eventual results while balancing the realities of trying to move fast to have impact during a pandemic.

Although the overall approach is still being finalised in consultation with key stakeholders, the following components are currently in consideration:

- A holistic theory of change that documents key intended results, risks and assumptions;
- A set of Key Performance Indicators that will be used to monitor results across the entire results chain, from inputs through to impact;
- A monitoring report that compiles key results and learning;
- A multi-stage evaluation approach, beginning with an evaluability and baseline assessment, for example.

This learning, monitoring and evaluation work will engage a broad range of COVAX stakeholders and employ a mixed-methods approach (gathering both qualitative and quantitative data and inputs), building on and making use of existing documents, tools and processes where possible. Key inputs from partners will be critical to ensure alignment throughout these efforts across the COVAX pillar.

4. WORKSTREAM: POLICY AND ALLOCATION

4.1 WHO STRATEGIC ADVISORY GROUP OF EXPERTS (SAGE) ON IMMUNIZATION

Overview

In accordance with WHO's mandate to provide guidance to Member States on health policy matters, the Strategic Advisory Group of Experts (SAGE) on Immunization is tasked with developing evidence-based immunisation policy recommendations. It is the principal external expert group advising the WHO Director General on issues related to vaccines, immunisation and the health systems to deliver vaccines. The SAGE terms of reference (ToRs) lay out that SAGE advises the WHO Director-General on six areas, the third of which is "immunization programme response to current public health priorities."

SAGE comprises 15 independent experts, who serve in their personal capacity and represent a broad range of affiliations and a broad range of disciplines encompassing many aspects of immunization and vaccines. In addition to the mix of expertise, geographic and gender balance is considered in the selection of members. SAGE members, including the Chairperson and the Vice-Chairperson, are appointed by the WHO Director-General after a public call for nominations and rigorous selection process. After determination of eligibility, nominations are submitted to a selection panel. Members are selected on the basis of their qualifications and ability to contribute to the accomplishment of SAGE's objectives. Declaration of Interests of all SAGE members are assessed by WHO at the time of appointment and in advance of each SAGE meeting.

Members

- Alejandro Cravioto, SAGE Chair (Mexico)
- Kari Johansen, SAGE Vice-Chair (Sweden)
- Rakesh Aggarwal (India)
- Ilesh Jani (Mozambique)
- Jaleela Jawad (Bahrain)
- Noni MacDonald (Canada)
- Shabir Madhi (South Africa)
- Peter McIntyre (New Zealand)
- Ezzeddine Mohsni (Jordan)
- Kim Mulholland (Australia)
- Kathleen Neuzil (United States of America)
- Hanna Nohnyek (Finland)
- Folake Olayinka, (United States of America)
- Andrew J. Pollard (United Kingdom)
- Firdausi Qadri (Bangladesh)

SAGE Working Group on Covid-19 vaccines

Overview

SAGE Working Groups provide evidence-based information and options for recommendations together with implications of the various options to be discussed by SAGE in an open public forum. Working Groups, with support of the WHO Secretariat perform or coordinate, systematic assessment of the evidence such as analysis of data addressing efficacy, effectiveness, safety, feasibility, and economic aspects of immunisation policy to address questions developed by the Working Group in order to propose appropriate vaccine policy recommendations to SAGE.

In June 2020, SAGE established the Working Group on COVID-19 vaccines following an open call for nominations issued on 24 April 2020 and closed on 11 May 2020. In total, 102 nominations were received.

This Working Group is requested to advise WHO and its Member States on the use of initially pre-licensed vaccines, followed by updates as additional information on product use becomes available. The timeliness of setting up this group has ensured a coordinated approach with the vaccine Research and Development (R&D) community, in order to accelerate timelines and maximise global efforts to make evidence-informed policy decisions for the best use of a vaccine against COVID-19. The ultimate goal of a vaccine against COVID-19 is to rapidly contain the pandemic, save lives, protect health care systems, and restore global economies.

Specifically, the Working Group has been asked to:

- provide continuous review of the available evidence on the progress of candidate vaccines against COVID-19, and provide regular updates to SAGE;
- provide guidance for the development of prediction models to determine the optimal age groups and target populations for vaccine introduction and guide vaccine introduction for optimal impact, and contribute to updates of target product profiles of vaccines for outbreak and for endemic use;
- prepare policy advice to SAGE on the accelerated use of vaccines (pre-licensure and post-licensure) to mitigate the public health impact of COVID-19, to possibly curtail the ongoing pandemic, as well as to prevent or reduce the risk of spread of disease in the future. This will include recommendations for early allocation of vaccines when vaccine supply is still limited;
- provide guidance to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available, in close collaboration with Global Advisory Committee on Vaccine Safety (GACVS).
- link to the terms of reference: https://www.who.int/immunization/sage/sage_wg_covid-19/en/

While SAGE Working Groups do not permit observers, it was agreed that in this exceptional situation ex officio membership would be implemented. Ex officio membership was offered to four chairs of related WHO advisory committees, and the chairs of the six WHO Regional Immunization Technical Advisory Committees.

Members

- Hanna Nohynek, SAGE Member, Chair of the Working Group (Finnish Institute for Health and Welfare, Finland)
- Folake Olayinka, SAGE Member (John Snow, Inc., USA)
- Muhammed Afolabi, Expert (London School of Hygiene & Tropical Medicine, UK)
- Celia Alpuche, Expert (Instituto Nacional de Salud Publica, Mexico)
- Hyam Bashour, Expert (Al-Sham Private University, Syria)
- David Durrheim, Expert (University of Newcastle, Australia)
- Ruth Faden, Expert (Johns Hopkins Berman Institute of Bioethics, USA)
- Nicholas Grassly, Expert (Imperial College London, UK)
- Sonali Kochhar, Expert (University of Washington, USA)
- Eusebio Macete, Expert (Manhiça Health Research Centre, Mozambique)
- Kayvon Modjarrad, Expert (Walter Reed Army Institute of Research, USA)
- Sarah Pallas, Expert (Centers for Disease Control and Prevention, USA)
- Mary Ramsay, Expert (Public Health England, UK)
- Peter Smith, Expert (London School of Hygiene & Tropical Medicine, UK)
- H. Keipp Talbot, Expert (Vanderbilt University Medical Center, USA)
- Cristiana Toscano, Expert (Federal University of Goiás, Brazil)
- Yin Zundong, Expert (Chinese Center for Disease Control and Prevention, China)
- Klaus Cichutek, Ex-Officio Member/Chair, WHO Expert Committee on Biological Standardization (Paul-Ehrlich-Institut, Germany):
- Peter Figueroa, Ex-Officio Member/Chair, PAHO Regional Immunization Technical Advisory Group (University of the West Indies, Jamaica)
- Adam Finn, Ex-Officio Member/Chair, European Technical Advisory Group of Experts on Immunization (University of Bristol, UK)
- Gagandeep Kang, Ex-Officio Member/Chair, South-East Asian Regional Immunization Technical Advisory Group (Christian Medical College, India)

- David Kaslow, Ex-Officio Member/Chair, Product Development for Vaccines Advisory Committee (PATH, USA)
- Ziad Memish, Ex-Officio Member/Chair, Eastern Mediterranean Regional Immunization Technical Advisory Group/Member, Strategic and Technical Advisory Group for Infectious Hazards (Ministry of Health, Saudi Arabia)
- Christopher Morgan, Ex-Officio Member/Chair, Western Pacific Regional Immunization Technical Advisory Group (Jhpiego, Australia)
- Saad Omer, Ex-Officio Member/Member, Global Advisory Committee on Vaccine Safety (Yale Institute for Global Health, USA)
- Helen Rees, Ex-Officio Member/Chair, African Regional Immunization Technical Advisory Group (University of the Witwatersrand, South Africa)

4.2 ALLOCATION MECHANISM

The Facility will apply the WHO-developed Fair Allocation Framework as the basis for vaccine allocation decisions for Facility participants, operationalised through the Allocation Mechanism. The Allocation Mechanism governance will comprise the Joint Allocation Taskforce (JAT) and the Independent Allocation Validation Group (IAVG).

Joint Allocation Taskforce (JAT)

Overview

The Joint Allocation Taskforce (JAT), comprised of staff from the WHO and the Office of the COVAX Facility, will, based on a data-driven allocation model, prepare a Vaccine Allocation Decision (VAD) proposal for review and validation by the Independent Allocation Validation Group (IAVG). The JAT will review all the data inputs needed for the allocation model and verify its output. Some flexibility to enable adjustments for clearly defined reasons, such as operational considerations, will be accommodated and fully documented. The JAT will respond to any requests for clarification from the IAVG.

The JAT will be convened by the Office of the COVAX Facility and WHO, with Terms of Reference (ToRs) jointly defined by Gavi, WHO and CEPI in the coming weeks, aiming for finalisation by mid-November.

Members

- To be comprised of Gavi and WHO staff members, with technical consultations undertaken as needed

Format

- To be determined

Independent Allocation Validation Group (IAVG)

Overview

The Independent Allocation Validation Group (IAVG) will be established as an independent body to validate the VAD proposal put forward by the JAT. Composed of technical experts, the IAVG will validate that the proposed VADs are technically informed, based on latest available data and evidence, and that Conflicts of Interest are identified, documents and managed appropriately. They may also request clarifications from the JAT, and for the model to be rerun if needed, before making their final determination. The VAD is characterised as a strong recommendation with any adjustments being made on an exceptional basis for clearly pre-defined reasons, such as specific operational considerations. The VAD, once validated by the IAVG, will be passed to the Office of the COVAX Facility for implementation with support from procuring agencies.

It is envisaged that the IAVG will be comprised of independent experts jointly nominated by the core COVAX partners (WHO, Gavi Secretariat and CEPI), with observers from CSOs and representatives of economies participating in the COVAX Facility. The ToRs for the IAVG are being defined jointly by the lead COVAX organisations, according to established existing processes for constituting expert bodies, aiming for finalisation by mid-November 2020. A nomination process for IAVG membership will be triggered upon finalisation of the ToRs, also in line with existing processes. Areas of expertise for the IAVG will be established based on the final ToRs but will likely include: immunisation programmes and service delivery; vaccine safety evaluation and monitoring; access to medicines and health products; and emergency public health response, among others.

Members

- To be determined

Format

- To be determined

4.3 POLICY AND ALLOCATION WORKING GROUPS

Vaccine Strategy Sub-Working Group

Overview

The Vaccine Strategy Sub-Working Group, led by WHO, was established at the outset of COVAX and was active in the initial months while various workstreams were being initiated; it is currently not an active workstream and will be reinitiated as needed. Its work has flowed in to other workstreams related to, for example, allocation, policy, country readiness and delivery, costing, funding and procurement.

Its tasks were: (i) assuring that the COVAX Pillar has an aligned global COVID-19 vaccine strategy that includes detail on the goals of a vaccination programme and general targets for achieving the goals; (ii) addressing COVAX-wide strategic topics, such as risks to the vaccination strategy, and core scenarios to feed planning and delivery efforts. This allows for pre-empting of strategic topics and the creation of aligned material, while also preventing duplication among workstreams. Close coordination and iteration was required between sub-workstreams with overlapping and inter-dependent thinking.

The sub-working group was established to:

- reach alignment on important definitions and assumptions to use the same language and numbers across organisations;
- ensure the learnings from our work to date are translated into an actionable action plan that mitigates the risks identified, with clear accountability and timelines; and
- continue to identify and reflect on high-priority strategic topics that have cross-workstream impact.

The sub-working group was structured around sprints on critical questions. The workstream met twice weekly to review analyses and draw inferences from those analyses that were then passed to other workstreams as relevant.

The primary areas of focus were:

- defining the overarching, high-level goals of a COVID-19 vaccination strategy;
- developing an approach for identifying priority populations and target groups for vaccination; and
- identifying high-level uncertainties and risks of the COVID-19 vaccine initiative and actions to address and mitigate these.

Members

- Kate O'Brien, Lead (WHO)
- Joachim Hombach (WHO)
- Tania Cernuschi (WHO)
- Annelise Wilder Smith (WHO)
- Raymond Hutubessey (WHO)
- Mariangela Simao (WHO)
- Sylvie Briand (WHO)
- Analia Porras (WHO)
- Zeenat Patel (Gavi)
- Stephen Sosler (Gavi)
- Anissa Sidibe (Gavi)
- Jakob Cramer (CEPI)
- Melanie Saville (CEPI)
- Jim Robinson (CEPI)
- Helen Matzger (Bill & Melinda Gates Foundation)
- Orin Levine (Bill & Melinda Gates Foundation)
- Peter Dull (Bill & Melinda Gates Foundation)
- Jane Barratt (International Federation on Ageing)

Vaccine Policy Sub-Working Group

Overview

- This topic is handled through the SAGE processes described earlier in this section.

Members

- See WHO SAGE section above

Access and Allocation Sub-Working Group

Overview

The Access and Allocation Sub-Working Group, led by WHO, brings together a range of COVAX partners who work together to design:

- the operationalisation of the WHO-developed Fair Allocation Framework,
- the governance of the Allocation Mechanism, and
- the scope, governance and operationalisation of the COVAX Emergency Buffer.

The Access and Allocation Sub-Working Group is composed of four working groups:

1. Allocation Mechanism governance;
2. Allocation process design and data needs;
3. Emergency Buffer; and
4. Allocation IT requirements and integration with other existing systems.

The working groups meet on a regular basis to drive forward this work across all relevant partners.

Members

Allocation Mechanism governance

- Mariangela Simao, Co-Lead (WHO)
- Sylvie Briand, Co-Lead (WHO)
- Claudia Nannei (WHO)
- Tania Cernuschi (WHO)
- Ioana Ghiga (WHO)
- Analia Porras (PAHO)
- Anissa Sidibe (Gavi)
- Sophie Mathewson (Gavi)
- Keightley Reynolds (Gavi)
- Elen Høeg (CEPI)
- Karrar Karrar (Save the Children)

Allocation process design and data needs

- Mariangela Simao, Co-Lead (WHO)
- Sylvie Briand, Co-Lead (WHO)
- Claudia Nannei (WHO)
- Tania Cernuschi (WHO)
- Ioana Ghiga (WHO)
- Analia Porras (PAHO)
- Ann Moen (WHO)
- Kateryna Chepynoga (WHO)
- Jeffrey Brown (WHO)
- Yejin Lee (WHO)
- Anissa Sidibe (Gavi)
- Kim Harper (Gavi)
- Hannah Kettler (Gavi)
- Sophie Mathewson (Gavi)
- Keightley Reynolds (Gavi)
- Mike Brison (Gavi)
- Elen Høeg (CEPI)
- Ann Ottosen (UNICEF Supply Division)
- Yalda Momeni (UNICEF SD)
- Gian Gandhi (UNICEF SD)
- Mounir Bouazar (UNICEF SD)
- John Fitzsimmons (PAHO Revolving Fund)

- Murat Ozturk (PAHO RF)
- Cuauhtemoc Ruiz (PAHO RF)

Emergency Buffer

- Mariangela Simao, Co-Lead (WHO)
- Sylvie Briand, Co-Lead (WHO)
- Soce Fall, Co-Lead (WHO)
- Ioana Ghiga (WHO)
- Reinhilde Van De Weerdt (WHO)
- Claudia Nannei (WHO)
- Tania Cernuschi (WHO)
- Analia Porras (PAHO)
- Kim Harper (Gavi)
- Talha Jalal (Gavi)
- Maya Malarski (Gavi)
- Elen Høeg (CEPI)

Allocation IT requirements and integration with other existing systems

- Claudia Nannei (WHO)
- Jeffrey Brown (WHO)
- Kateryna Chepynoga (WHO)
- Yejin Lee (WHO)
- Erwan Rolland (WHO)
- Sandra Orogodo (WHO)
- Ann Moen (WHO)
- Oleg Benes (WHO)
- Jayantha Liyanage (WHO)
- Keightley Reynolds (Gavi)
- Luigi Capriotti (UNICEF)
- Sunil Bahl (WHO)
- Tifenn Humbert (WHO)
- Ioana Ghiga (WHO)
- Swathi Iyengar (WHO)
- Ann Lindstrand (WHO)
- Houda Langar (WHO)
- Guillaume Queyras (WHO)
- Jean Baptiste Nikiema (WHO)
- Cuauhtemoc Ruiz (WHO)
- Tania Cernuschi (WHO)
- Ellen Hynes (WHO)
- Caroline Griffin (Gavi)
- Quamrul Hasan (WHO)
- Stephen Jones (UNICEF)
- James McGonagle (WHO)
- Liudmila Mosina (WHO)
- Alba Maria Ropero (WHO)
- Awandha Raspati Mamahit (WHO)
- Marta Gacic-Dobo (WHO)
- Anne Yu (WHO)
- Murat Ozturk (PAHO RF)
- Kim Harper (Gavi)
- Socorro Escalante (WHO)
- John Fitzsimmons (PAHO RF)
- Laura Craw (Gavi)
- Lisa Hedman (WHO)
- Ludy Suryantoro (WHO)
- Jason Mathiu (WHO)
- Lucy Boulanger (WHO)
- Lisa Wei (Gavi)
- Gemma Orta-Martinez (UNICEF)

- Sarah Garnger (WHO)
- Jinho Shin (WHO)
- Manisha Shridhar (WHO)
- Shoshanna Goldin (WHO)
- Anthony Bellon (UNICEF)
- Alex Beecher (Gavi)
- Sophie Mathewson (Gavi)
- Elen Høeg (CEPI)

SECTION 2: PRINCIPLES

1. GOVERNING PRINCIPLES

The key principles agreed upon by the three lead organisations, to guide good governance in the COVAX collaboration, are as follows:

- to ensure a comprehensive view on the investment of public funds, to be able to take the right decisions in a timely manner;
- to select appropriate members of critical advisory groups;
- to ensure that decision-making is done in an impartial and fair manner with appropriate consideration given to Conflicts of Interest;
- to ensure Individual and Organisational Conflicts of Interest are identified and managed according the agreed principles for managing Conflicts of Interest for the COVAX Coordination Meeting (CCM) and its committees; and
- to provide transparency on critical discussions and progress, providing in a timely manner.

2. PRINCIPLES FOR MANAGING CONFLICTS OF INTEREST FOR THE COVAX COORDINATION MEETING (CCM) AND ITS COMMITTEES

Background

a) The Gavi Alliance is a global vaccine alliance, bringing together public and private sectors to save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries.

b) The Coalition for Epidemic Preparedness Innovations (CEPI) accelerates development of vaccines against emerging infectious diseases and enables equitable access to these vaccines during outbreaks.

c) The World Health Organization (WHO) is an inter-governmental organisation and specialised agency of the United Nations and is the directing and coordinating authority on international health, and provides leadership on global environmental health matters, shapes the health research agenda, sets health norms and standards, articulates evidence-based policy options, provides technical support to countries, and monitors and assesses health trends.

d) In order to join forces in the fight against the COVID-19 pandemic and to develop, manufacture and distribute a vaccine against COVID-19, Gavi, CEPI and WHO have joined forces and set up an ad hoc coordination mechanism under the name of COVAX Coordination Meeting (CCM).

e) The CCM is co-led by the Chairs of the Gavi and CEPI Boards and includes Representative Members, as described in the COVAX Management Document.

f) The CCM will be advised by its Committees which may comprise Representative Members and/or Unaffiliated Members, as defined below.

g) Representative Members may be required to consider matters that have a direct impact on the interests of governments, organisations or institutions that they represent or have been associated with in the recent past.

h) Unaffiliated Members will be appointed in their personal capacity to serve on the Committees.

i) Members may face Conflicts of Interest in advising and decision making in their role on the CCM and Committees.

j) Organisational Interest and Conflicts of Interest must be managed transparently with the highest degree of integrity to safeguard against any perception that participation of any Member confers undue advantage in decisions of the CCM or its Committees.

Definitions

The following definitions apply in this Policy:

1. **CCM** means the COVAX Coordination Committee.

2. **CEPI** means the Coalition for Epidemic Preparedness Innovations.

3. **Committees** means the advisory bodies to the CCM, including, its sub-committees, advisory and review bodies, portfolio groups and vaccine teams, including: the Research and Development and Manufacturing Investment Committee (RDMIC), the Independent Product Group (IPG), the Technical Review Group (TRG), SAGE workstreams, sub-groups and all advisory or other bodies convened under the COVAX Pillar.

4. **Conflict of Interest** means a situation where a Member has an actual, potential or perceived Interest that may affect the Member's conduct in the decision-making process at CCM or its Committees.

5. **DCVMN** means Developing Countries Vaccine Manufacturers Network.

6. **Family** means any spouse, domestic partner, parents, siblings, children, and any other relative who resides in the same household as a Member and any other familial relationship that could create the appearance of a conflict.

7. **Financial Interest** arises when a Member or Family may benefit financially from a transaction or from any other financial arrangement under discussion by the CCM or its Committees.

8. **Gavi** means the Gavi Alliance.

9. **IFPMA** means the International Federation of Pharmaceutical Manufacturers & Associations.

10. **Interest** means a Financial Interest, Personal Interest or Organisational Interest.

11. **Member** means a Representative Member and/or an Unaffiliated Member of a Committee convened under the COVAX Pillar.

12. **Organisational Interest** means when a Member or Family is an officer, director, trustee, partner, employee of, or is directly linked in any manner to[1], an entity that may obtain an advantage, profit, right, share or may benefit in any manner from a recommendation the Member should vote on.

13. **Organisational Member** means each of CEPI, DCVMN, Gavi, IFPMA, WHO and any other organisation or institution that has assigned a Representative Member to sit on a Committee.

14. **Personal Interest** means when a Member or Family may personally benefit from a transaction or other arrangement under discussion by the CCM or its Committees.

15. **Representative Member** means a person sitting on the CCM or a Committee and representing an Organisational Member.

16. **Unaffiliated Member** means a person serving on a Committee in their personal capacity.

17. **WHO** means the World Health Organisation.

Principles

The Following Principles shall apply to the CCM and Committees:

a) Members are expected to act with integrity within the CCM and its Committees and to be transparent in the disclosure of any Interest, particularly in regard to recommendations that the CCM or Committees make on allocation and disbursement of resources.

b) Unaffiliated Members are expected to bring their experience, and in the case of Representative Members, their experience and affiliations, to advance the goals and objectives of the CCM and its Committees, as described in the COVAX Management Document.

c) Members must ensure that in participating in the CCM and Committees, their activities and other duties do not conflict with their responsibilities and must use good judgment to avoid Conflicts of Interest.

d) Members may not allow themselves to obtain any advantage through their position or role on the CCM or any Committee.

e) A Member who previously had a relationship with an organisation (different from their current affiliation), that would create a perceived Conflict of Interest, will be considered to have an Organisational Interest in the original organisation for 12 months counted since the cessation of the relationship with that organisation, in any matters that might create any kind of Conflict of Interest.

f) Members must disclose all Interests in entities that may benefit from recommendations of the CCM or its Committees upon joining the CCM or a Committee and at the beginning of any meeting of the CCM or a Committee meeting where recommendations with financial implications are made. Such declarations will be noted in the meeting minutes.

g) Members must recuse themselves from all discussions and recommendations in relation to the matters where they have a Financial or Personal Interest. Organisational Interest will be evaluated on a case-by-case basis, and the Chair of the meeting may request the conflicted person to refrain from voting on a recommendation or to also withdraw from discussions.

[1] "Directly linked in any manner" means any type of agreement by which the Member or Family has a relationship with an entity, whether such relationship is formalised through an employment, participation, joint venture, agency, secondment or any other type of contract.