



# **COVAX Facility**

## **Consultation with the self-financing group – Day 2**

July 17, 2020

## DAY 2

# Welcome and recap from Day 1

# Meeting preparation – Day 2

Agenda for 17 July Consultations – ~3 h

## Topic

### Welcome and recap from Day 1

Participant discussion/ overflow questions from Day 1

### Deep dive 2: Terms of participation - agreements with the Facility

1. Overview of the different agreements
2. Financial commitments
3. Non-financial commitments

Participant discussion

### Deep dive 3: COVAX Facility governance

Governance

Participant discussion

### Timelines and next steps

1. What to expect – between now and 31 Aug
2. General questions for wrap-up of the consultation

# Housekeeping

We have a full house today, so we kindly ask you to...

- **Please click the ‘raise your hand’ button** if you would like to speak. We ask participants to share questions/comments verbally during the Q&A as much as possible
- **Please state your name and where you are from before sharing a comment or question**
- **Please save questions for the relevant part of the agenda** focusing comments on the topics currently being discussed
- Please make **time bound interventions**. Given the time constraints, we will proceed directly to the content and not have opening statements
- **Please respect Chatham House Rules** – none of the comments raised on the line should be attributed
- You are invited to use **informal forms of address**
- We anticipate convening additional sessions and following-up in writing to respond to unanswered questions over the next several weeks
- **Share any further input offline to [covax@gavi.org](mailto:covax@gavi.org)**

# Participant discussion/ overflow questions from Day 1

## Questions for input

After reflecting on the discussion from Day 1, do you have any new questions you would like to ask?

# Deep dive 2:

## Terms of participation - agreements with the Facility

# Clearly defined participation principles will support the ambitious undertaking of the Facility

## Global access

- Ensure everyone can secure access to safe and efficacious vaccine to protect health security globally
  - Open to all, no one is prevented from participating due to income
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## Impact orientation and transparency

- Single minded in its goal to ensure equitable access to COVID-19 vaccines
  - Coordinated strategy for vaccination as supply constrained in the short term
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## Solidarity and collective ownership

- Commitment of participants to collaborative global effort - everybody contributes so that everyone can benefit
  - Clear political and financial commitments - all participants asked to contribute based on their capacities
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## Complementarity with other funding

- End to end solution – complementary investments to drive rapid availability of supply at scale
- Manufacturers requested to disclose third party funding for R&D or manufacturing, which will be considered in contractual conditions
- Vaccines from any manufacturer considered including those not in the CEPI/BMGF portfolio



# Overview of the different agreements

# Overview of the participation agreements



## Commitment Agreements

These will be participant-specific and will set out the specific financial commitment to be made by the participant to the Facility. Sections will be included on expected doses to be made available for procurement.



## Principles of Participation

These principles will provide the basis on which self-financing participants join the Facility. The Principles will be attached to and referenced in the Commitment Agreements.

# DRAFT Key terms of the agreement (1/3)

Term	Proposal
<b>Parties</b>	<ul style="list-style-type: none"><li>• Gavi, the Vaccine Alliance (on behalf of the COVAX Facility).</li><li>• The relevant participant, acting through its appropriate ministry of state.</li></ul>
<b>Role of Gavi as administrator of the Facility</b>	<ul style="list-style-type: none"><li>• Enter into legally binding commitment agreements with Self-Financing participants</li><li>• Convene the Independent Product Group</li><li>• Negotiate and enter into volume guarantees with a range of vaccine manufacturers</li><li>• Monitor the performance of the COVAX Facility</li><li>• Convene the Shareholders Council and providing regular reporting to the participants</li><li>• Day-to-day management of the Facility</li></ul>

# DRAFT Key terms of the agreement (2/3)

Term	Proposal
Expectations of participants	<ul style="list-style-type: none"><li>Financial commitment to purchase a pre-defined number of doses<ul style="list-style-type: none"><li>Upfront payment</li><li>Speed premium</li></ul></li><li>Non-financial commitments</li></ul>
Financing of commitment	<ul style="list-style-type: none"><li>Participant's commitments will need to be legally binding</li><li>Based on the participant's credit rating profile and its ability to provide financial commitments both as an up-front down payment and over time, the commitment may require a security, for example an additional financial guarantee from a strongly rated commercial financial institution or development finance institutions</li></ul>

**Details follow**

# DRAFT Key terms of the agreement (3/3)

Term	Proposal
Facility Term	<ul style="list-style-type: none"><li>• The term of the Facility will be defined to include a first phase ending by an agreed date or a date at which doses sufficient to cover 20% of the population have been offered for procurement</li><li>• The parties will reassess whether to continue at the end of the first phase</li></ul>
Pharmaceutical Manufacturers	<ul style="list-style-type: none"><li>• The Facility will enter into advance Vaccine Purchase Commitment Agreements with Pharmaceutical Manufacturers, based on applicable terms and conditions and payment mechanisms that may include up-front payments, deferred payments and such instruments to enable the delivery of the vaccines as structured by the Facility.</li><li>• Key terms around the commitments made by vaccine manufacturers include:<ul style="list-style-type: none"><li>— Use all payment advances towards the COVID-19 vaccine program</li><li>— Keep the Facility informed of progress in its COVID-19 vaccine program</li><li>— Deliver its production of its COVID-19 vaccine program to participants on agreed terms and conditions</li><li>— Requirements to inform the Facility of public funding</li></ul></li></ul>

# Financial commitments

# COVID-19 vaccine development differs from “traditional” vaccine market

## “Traditional” vaccine market

- Countries and health systems purchase licensed vaccines from individual companies
- Individual companies invest in R&D, spreading risk across their entire vaccine portfolio (incl. non-vaccines and/or financial investor risk)
- Individual companies invest in manufacturing only after vaccines have been demonstrated to be effective in clinical trials

## COVID-19 vaccine development

- COVID-19 is global and affects everyone – this requires equitable access to vaccines at the same time to stop the acute phase of pandemic
- World needs large numbers of doses urgently with multiple countries “competing” for allocation of volume
- 160+ candidates exist from numerous companies, with 20+ (and counting) in clinic, but none so far has been demonstrated to be effective in clinical trials



- Manufacturing investments in capacity and raw materials needs to happen now alongside R&D to accelerate vaccine availability
- **This is only possible if**
  - **Risk can be shared across a diverse portfolio with candidates from multiple companies**
  - **Manufacturers commit to an exceptional approach and minimal returns pricing**

# Existing vaccines cost \$20-50 for HICs, with prices typically tiered for UMIC and L(M)ICs

Price per dose for vaccines (US \$)

Vaccine	HIC	UMIC	L(M)IC
PCV	\$48.2	\$19.9	\$5.4
Rotavirus	\$20.8	\$9.4	\$3.6
HPV	\$50.9	\$11.6	\$4.6



**Other vaccines are priced at \$20-50 for HICs** – the final price for COVAX vaccines will also be dependent on factors such as the product and technology involved

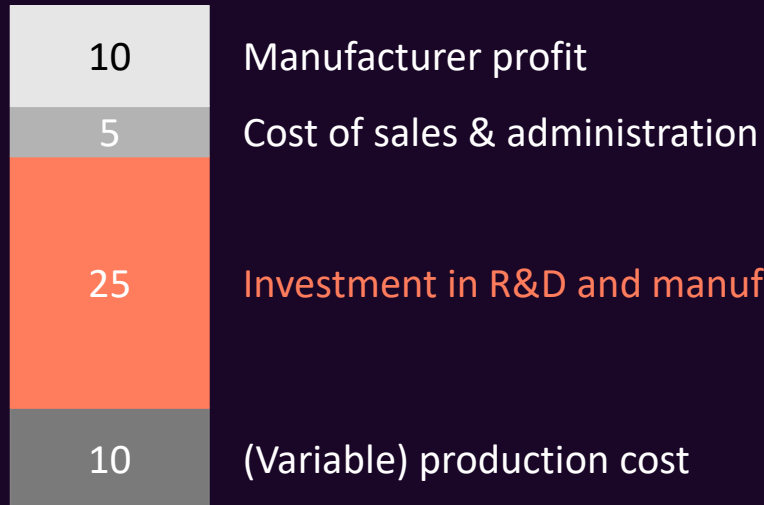
**Pricing is also often tiered** for UMICs and L(M)ICs, and a 1 : 2 : 5 tiering for L(M)IC : UMIC : HIC has been assumed for the current analysis



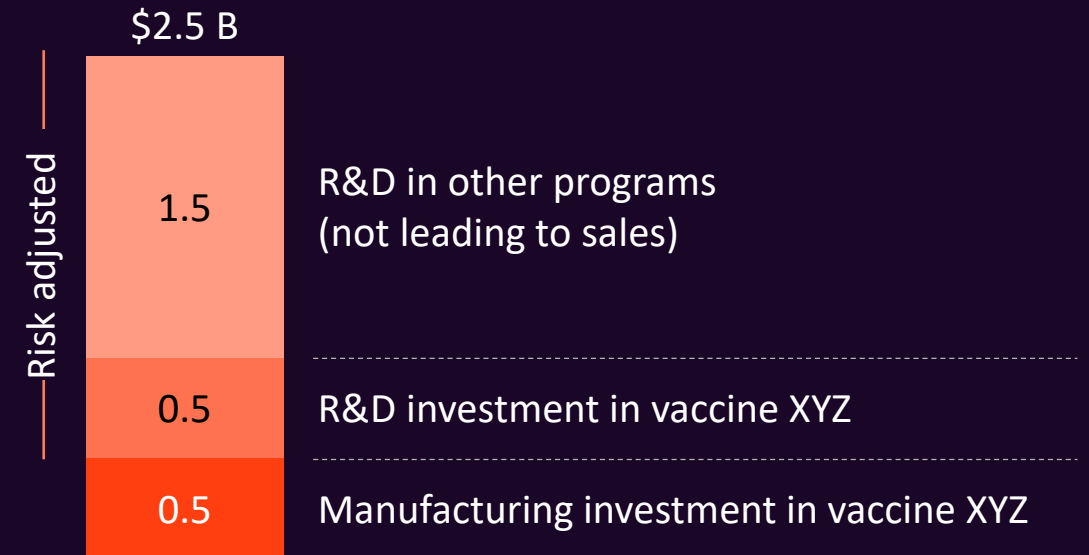
# Commercial prices for vaccines cover production cost as well as a “charge” for past investments in R&D & manufacturing

ILLUSTRATIVE breakdown of commercial price (US \$) for “traditional” vaccine market

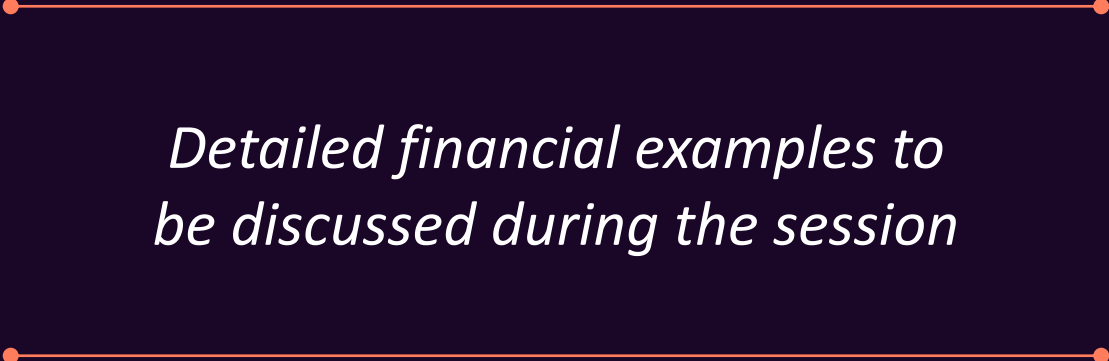
\$50/dose for vaccine XYZ



R&D and manufacturing investment amortised over 100 M doses



- Upfront investments in R&D and manufacturing are borne by developers/manufacturers, “at risk”
- Developers/manufacturers expect to recover their investment (including profit and cost of capital) through pricing of commercially available vaccines



*Detailed financial examples to  
be discussed during the session*

# Non-financial commitments

# For discussion: Non-financial commitments

## Ensure unrestricted movement of vaccine doses from domestic manufacturers

Participants agree to **not impose embargoes** or any **impediments to access**, **support timely National Regulatory Authority (NRA) release**, **import/export** of vaccines, and prioritize cargo space for vaccine shipments

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## Facilitate regulatory clearance

Participants are encouraged to promote and leverage **regulatory convergence, collaboration and reliance** as much as possible **to fast-track the path to vaccine licensure**

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## Contribute to global information repository

Participants agree to **contribute data** (e.g. epidemiological and virological) **to global information repositories** to build the overall body of knowledge (e.g. to inform vaccine development and vaccination strategies) to the benefit of all

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## Provide transparency on bilateral supply agreements

Participants commit to **being open and transparent about their own COVID-19 vaccine supply agreements with the Facility**, which will help the Facility optimizing its portfolio of investments to the benefit of all

# The global pandemic requires an aligned approach on issues relating to liability and indemnification for COVID-19 vaccines under COVAX

The global pandemic presents **unprecedented circumstances** in terms of the speed of development and the scale of use of COVID-19 vaccines

There is an **unknown risk of potential liability** arising from COVID-19 vaccines

**Mechanism to compensate** persons who have sustained unexpected SAEs following vaccination

There is a **high urgency to avoid a potential delay** to widespread vaccine delivery

The Liability Task Force which sits within COVAX is looking at these issues. The Task Force will engage with multiple stakeholders involved and affected by these issues to understand the issues and identify potential solutions.

## Questions for input

Do you have any experience in addressing the aforementioned issues of liability risk (including through national legislation) and compensation in the context of the deployment of vaccines, including recently licensed vaccines?

If yes, could you please share with us your solutions and experiences to address these issues?



Please email [covax@gavi.org](mailto:covax@gavi.org) with input

# Deep dive 3:

## Proposed COVAX Facility governance<sup>1</sup>

1. Pending Gavi board approval

# Guiding principles to enable the design of the Facility's Governance

## PROPOSAL

### Structural considerations

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- **Build on existing governance structures** and not recreate or unnecessarily expand existing mechanisms (principle of ACT-Accelerator)
- **Ensure an accountable and representative governance framework** to all stakeholders
- Be in place for the **entire lifespan of the Facility**

### Objectives

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- Enable the Facility to enter into **time and commercially sensitive transactions with varying terms**, accounting for different manufacturer profiles and needs
- **Anticipate potential needs to adapt and adjust the use of funds**, given uncertainties (e.g., disease epidemiology)
- **Ensure representation of all participants** and provide sufficient visibility



# Self-financing participants form a 'Shareholders Council'

## PROPOSAL

### Members/ composition

- Representatives of self-financing participants

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### Meeting cadence

- Monthly - TBC

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### Role & Responsibility

- Provide strategic guidance to COVAX management on areas related to the status of vaccines under development
- Share information with the Secretariat and each other and receive access to regular updates from Secretariat
- Appoint members to MSDC
- Additional responsibilities being defined

# Existing governance/advisory bodies of the COVAX Facility

## PROPOSAL

### Gavi board



### MSDC

Market Sensitive  
Decisions  
Committee



### SAGE

Strategic Advisory  
Group of Experts



### RDMIC

R&D and  
Manufacturing  
Investment Committee



Portfolio



Allocation



Financing



Operations



# Newly proposed governance/advisory bodies of the COVAX Facility

## PROPOSAL

Shareholders council

Dose Allocation body

Independent product group

Portfolio



Allocation



Financing





Operations



# Role and composition of proposed governance bodies (1/2)

## PROPOSAL

		Affiliation	Composition	Role
<b>Gavi board</b>			<ul style="list-style-type: none"><li>Gavi, WB, BMGF, UNICEF, WHO, Governments of developing countries (5), Governments of donor countries (5), CSO, IFPMA, DCVMN, , independents, research institutes</li></ul>	<ul style="list-style-type: none"><li>Oversee role of Gavi in the implementation of the Facility to ensure consistency with the mandate given to Gavi including full oversight of the Gavi COVAX AMC</li></ul>
<b>MSDC</b>	Market sensitive decisions committee	 *Expanded	<ul style="list-style-type: none"><li>Board (Vice) Chair, AFC Chair, PPC Chair, UNICEF, WB, Gavi, BMGF, Governments of developing countries (2), Governments of donor countries (3), CSO</li><li>TBC - Self-financing participants (3), COVAX AMC participant</li></ul>	<ul style="list-style-type: none"><li>Review the business terms of the proposed COVAX volume guarantee agreements that the Facility would enter into with manufacturers</li></ul>


# Role and composition of proposed governance bodies (2/2)

## PROPOSAL

		Affiliation	Composition	Role
SC	Shareholders Council	*NEW	<ul style="list-style-type: none"><li>Self-financing participant representatives</li></ul>	<ul style="list-style-type: none"><li>Provide strategic guidance to COVAX management on areas related to the status of vaccines under development</li><li>Share information with the Secretariat and each other and receive access to regular updates from Secretariat</li><li>Appoint [3] members of the Shareholders Council to the MSDC</li></ul>
RDMIC	Research & development & manufacturing investment committee	CEPI	<ul style="list-style-type: none"><li>CEPI, Gavi, BMGF, (ex) industry R&amp;D and manufacturing experts, public health expert</li></ul>	<ul style="list-style-type: none"><li>Drive CEPI portfolio strategy &amp; investment decisions aligned with overall COVAX strategic objectives</li><li>Decide CEPI investment allocation and requirements across the portfolio</li><li>Make project selection and investment decisions</li></ul>

# Role and composition of proposed advisory bodies

## PROPOSAL

		Affiliation	Composition	Role
<b>IPG</b>	Independent product group	*NEW	<ul style="list-style-type: none"> <li>5-7 independent experts, selected by panel from Gavi, WHO, CEPI, IFPMA and DCVMN</li> </ul>	<ul style="list-style-type: none"> <li>Provide independent advice to e.g., COVAX Facility members, Gavi, the MSDC and inform selection of vaccine candidates for Facility</li> <li>Assess whether candidates have met criteria for eventual purchase</li> <li>Review overall portfolio, consider updates in clinical development, manufacturing and supply</li> </ul>
<b>SAGE</b>	Strategic Advisory Group of Experts	 World Health Organization	<ul style="list-style-type: none"> <li>15 experts in the fields of epidemiology, public health, vaccinology, infectious diseases, drug regulation, immunization delivery, safety, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Advise WHO on overall global policies and strategies, incl. vaccines, research and development, delivery of immunization and its linkages with other health interventions</li> </ul>
<b>tbd</b>	Dose allocation body (tbd)	*NEW	<ul style="list-style-type: none"> <li>To be defined – independent technical experts</li> </ul>	<ul style="list-style-type: none"> <li>Review and analyze data/ documentation, provide technical input</li> <li>Make allocation recommendations in accordance with final technical design, approved by Member States, of the WHO Allocation Framework</li> </ul>

# Participant discussion

## Questions for input

What is the appropriate composition of the Shareholders Council? How do we make it a working body (representative body)?

Would there be an interest in an executive body of the Shareholders Council?

Do we need a forum to bring together the three groups of participants into the same body (self-financing, AMC-supported, AMC donors)?

What information is critical to be shared in regular updates?



# Closing: Timelines and next steps

# What to expect – between now and 31 Aug

# COVAX Facility engagement plan for the self-financing group

Date	Key activity	Description
Week of July 20	Consultation follow-ups <i>AMC consultations</i> <sup>1</sup>	Including written responses to outstanding questions
Week of July 27	Term sheet consultations	Regional consultations on the term sheet
Week of Aug. 3	Individual term sheets	Individual term sheet sent to all interested parties
Week of Aug. 10	Term sheet and governance consultation	Consultations to address remaining questions about the term sheet and governance
Aug. 17-31	Additional consultations	Pending

1. For the COVAX AMC eligible group

# What to expect – between now and 31 August



**Week of 3<sup>rd</sup> August**

Draft **term sheets** sent to all that have expressed interest



**Week of 10<sup>th</sup> August**

Participate in further **consultations on the term sheet and governance of the Facility**



**31<sup>st</sup> August**

Deadline to make **binding commitments** to become a Facility Participant

# General questions for wrap-up of the consultation

## Questions for input

What questions do you still have?

What else do you need in order to get to the final commitment? And how can we best meet that need?

CEPI





# Appendix



# Meeting presenters Day 1 & 2 (1/2)

Presenter	Title	Organization
Andrew Witty	Co-lead, WHO COVID-19 Vaccine Programme	WHO
Richard Hatchett	CEO	CEPI
Seth Berkley	CEO	GAVI
Soumya Swaminathan	Chief Scientist	WHO
Mel Saville	Director of Vaccine Development	CEPI
Derrick Sim	Director of Vaccine Demand & Supply	GAVI
Thomas Cueni	Director General	International Federation of Pharmaceutical Manufacturers
Sai Prasad	President	Developing Countries Vaccine Manufacturers Network

# Meeting presenters Day 1 & 2 (2/2)

Presenter	Title	Organization
Kate O'Brien	Director, Department of Immunization, WHO Vaccines and Biologicals	
Emer Cooke	Director, Regulation of Medicines and other Health Technologies	WHO
Aurelia Nguyen	Managing Director, Vaccines & Sustainability Department	GAVI
Anthony Brown	Senior Legal Counsel	GAVI
Marie-Ange Saraka-Yao	Managing Director, Resource mobilisation, Private Sector Partnerships & Innovative Finance Department	GAVI
Dick Wilder	General Counsel and Director of Business Development	CEPI