



#### Final ACT-A Facilitation Council composition<sup>1</sup>

#### **Governments**

#### Regional groups

- League of Arab States: Bahrain
- Association of South East Asian Nations (ASEAN): Vietnam
- African Union (AU): South Africa
- Caribbean Community (CARICOM):
   Saint Kitts and Nevis
- Commonwealth of Independent States (CIS): Uzbekistan
- Forum of Small States: Singapore
- New Partnership for Africa's Development (NEPAD): Rwanda
- Community of Latin American and Caribbean States (CELAC): Mexico<sup>3</sup>
- Pacific Island Forum (PIF): Tuvalu
- South Asian Association for Regional Cooperation: Nepal

#### **Founding Donors**

- Canada
- France
- Germany
- Italy
- Japan
- Norway
- Saudi Arabia
- Spain
- United Kingdom

#### Market Shapers<sup>2</sup>

- Brazil
- China
- India
- Indonesia
- Republic of Korea
- Russia

#### **Co-hosts**

World Health Organization & European Commission

#### Non-government partners

- Bill & Melinda Gates Foundation
- Wellcome Trust
- World Economic Forum

#### **Envoys & Invitees**

- WHO Envoys x2
- CSO x 2
- ICC

<sup>1</sup> USA & World Bank observers to the Council meeting 2 South Africa is also a market shaper & founding member 3 founding member

#### goals

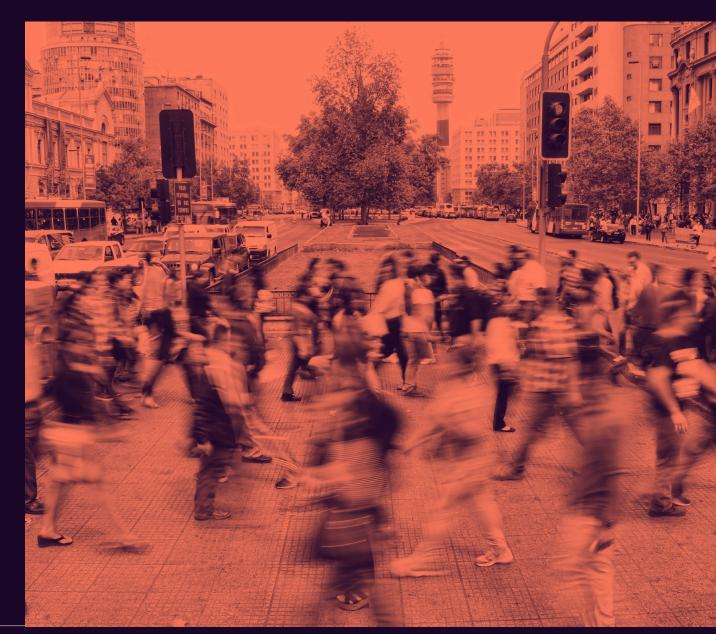
To support the largest actively managed portfolio of vaccine candidates globally

To deliver 2 billion doses by end of 2021

To offer a compelling return on investment by delivering COVID-19 vaccines as quickly as possible

To guarantee fair and equitable access to COVID-19 vaccines for all participants

To end the acute phase of the pandemic by the end of 2021



#### COVAX Facility focused on transparency, global access and impact

Bold ideas and brilliant innovation for the worst global health crisis in 100 years

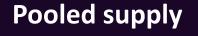
#### **Pooled demand**











Manufacturers

Provides manufacturers access to a massive, demand-assured market

Consolidates buying power and provides participants access to a broad and activelymanaged portfolio

#### 92 COVAX AMC-eligible countries and economies

**Low income**: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep.,

Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Principe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe

<u>Additional IDA eligible</u>: Dominica, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

Gavi Board approved in July 2020, based on 2018 and 2019 World Bank GNI data

### Additional vaccine support will be provided to the AMC92 group and tailored to individual health systems



#### LICs, LMICs and IDA-eligible UMICs

Vaccine Access (COVAX Facility)	<ul> <li>Financial support for vaccine procurement and access through the COVAX AMC</li> </ul>
Purchase mechanisms	<ul> <li>Support from the Alliance through UNICEF and PAHO Revolving Fund</li> </ul>
Delivery	Support for cold chain equipment and technical assistance

- Level and extent of support (e.g. cost-sharing, delivery, etc.) provided to the AMC92 to be discussed by the Board at the end of September
- Support may be differentiated within the group. All options explored will aim to ensure that participants do not face any significant barriers to accessing a COVID-19 vaccine

### Three components inform the formulation of vaccination strategies

### 2: Strategic Advisory Group of Experts (SAGE)

Provides guidance and policy advice in the context of <u>specific candidates</u>, e.g. on vaccination strategies

#### 1: Allocation Framework

Sets frame for overarching public health goals and priorities (candidate independent)



#### **Participant**

Responsible for final decision on policy, allocation and vaccination strategy

### 3: Regulatory, Safety & Monitoring

Provides guidance on regulatory issues, safety and monitoring both for candidate specific and system specific approaches



### 1: The global allocation framework secures fair, equitable and necessary access

#### **Initial view for Vaccine Allocation Mechanism**

#### Goals

**Reducing COVID-19 mortality & protecting health systems** will significantly improve the well-being of populations and reduce the impact on societies and economies

#### **Priorities**

Those goals, in the context of scarce supply, leads to prioritization of specific population groups for vaccination

These could include health and social care workers, older adults, and others with high risk conditions. High risk settings are also a consideration. Specific policy recommendations from SAGE, based on product performance and safety evidence and with evolving data on transmission and disease will be made

#### **Timing**

Given the ubiquitous nature of COVID-19, an initial allocation should be received by all as products become available

**Eventually,** timing would be **based on a risk assessment of participants**' vulnerability and COVID-19 threat

## 1: We have continued to develop the draft Allocation Framework and Allocation Mechanism for Vaccines based on MS feedback

Groups identified on this slide are 'indicative' and do not constitute WHO policy

Goals

Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

#### **Further priority groups**

#### **Priorities**

#### Health and social care workers

All participants receive doses to cover 3% of their population.

This would be enough to cover all workers involved in health and social care work.

#### **High-risk adults**

All participants receive additional doses beyond the 3% to total 20% of their population (in tranches).

This could include the elderly, adults with comorbidities or others depending on locally relevant risk factors

#### Participants receive doses to cover more than 20% of their population.

This would cover additional priority populations.

**Timing** 



If protracted severe supply constraints remain, timing is based on participants' vulnerability and COVID-19

threat

#### A buffer will also be set aside for emergency deployment based on immediate needs

Note: The fundamental principle applies that all participants receive doses at the same rate to the extent possible, notwithstanding likely practical limitations to be further worked out (e.g. minimum delivery volumes)

# 2: Strategic Advisory Group of Experts (SAGE) on Immunization: Introduction and setup

SAGE is the principal advisory group to WHO for vaccines, providing guidance and policy advice for specific vaccine candidates

- 1 Providing continuous review of the available evidence on the progress of specific vaccine candidate
- 2 Providing **guidance** for the development of prediction models to determine the optimal age groups and target populations for the introduction of a specific vaccine candidate
- Preparing **policy advice** on the accelerated use of vaccine candidates, including recommendations for early allocation of vaccines when vaccine supply is still limited
- Providing **guidance** to ensure equitable access to vaccination, and guidance on the safety of vaccines when safety data from wider population use become available

#### **Sub-working groups**

SAGE's review, guidance and policy advice is informed by three subworking groups:

- Vaccination goals & prioritization
- Evidence gathering on vaccines in clinical trials
- Vaccine impact modelling

### WHO SAGE Policy development: steps and processes

- 1. Values Framework for the allocation and prioritization of COVID-19 vaccination: Principles, objectives and target groups of a COVID-19 vaccination programme
- 2. Guidance on prioritization of target populations under supply constrained situations: development of use case scenarios of limited vaccine under different epidemiological settings
- 3. Policy recommendations on the use of COVID-19 vaccines once registered; under consideration of product-specific data and attributes, and with consideration of the regulatory approval process (emergency use or full registration)

#### **Status update**

Endorsed by SAGE and published Sept 14 2020

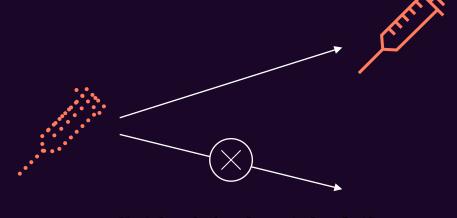
In development, discussion item at SAGE plenary meeting October 5-7

Timelines depends on registration by countries or Emergency Use Listing/ prequalification by WHO; process iterative as products come along

### No single vaccine is guaranteed to succeed or has enough capacity



- Many vaccines in development none guaranteed to succeed
- No single manufacturer has the capacity to supply the global volume required

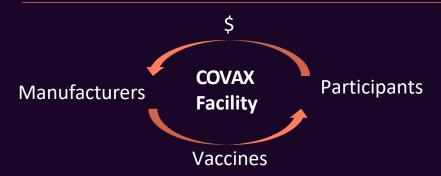


Individual deals might fail

A diversified portfolio is needed to diversify risk and create capacity to scale

#### The overall financial structure of the Facility

#### The COVAX Facility cost principles



- Negotiate to achieve minimal returns pricing
- Costs passed through to participants "asis"
- Full transparency
- / Participant choice & optionality
- Participants involvement in Facility governance

#### **Three COVAX Facility cost categories**

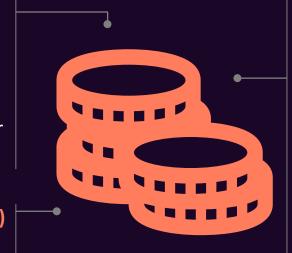
#### Speed / access premium (~15-20%)

Payments made to manufacturers:

- To accelerate investments manufacturers would otherwise delay (e.g., technology transfer)
- As down payments for Advance Purchase Agreements

#### Ex-factory cost(~80-85%)

Variable cost to manufacturers of producing the doses



#### Facility operating costs (<3%)

- Cost of limiting risk exposure and reducing upfront payment requirements (e.g., insurance and interest associated with debt financing)
- Management fees (e.g., staff costs)

### Participants have the option to select between two participation arrangements upon joining the COVAX Facility

#### **Committed Purchase Arrangement**

- Lower down-payment
- Financial commitment / guarantee to purchase doses

#### **Optional Purchase Arrangement**

- Higher upfront payment
- Options to decide on purchasing doses
- Small risk-sharing guarantee

#### Upfront payments and financial guarantees due from selffinancing participants by 9 October

**Optional Purchase Arrangement** 

**Upfront** payment

#### \$1.60/dose

15% Down- payment to provide the Facility with sufficient upfront capital

\$3.10/dose

100% of pro-rata share of the Facility preapproval costs

Financial guarantee

#### \$8.95/dose

All inclusive cost (\$10.55) minus upfront payment (\$1.60)— the amount equivalent to the exposure the Facility is taking on participants' behalf

#### \$0.40/dose

Risk-sharing guarantee to cover potential residual liability resulting from countries opting out of doses that Gavi has committed to purchase from manufacturers



In both arrangements, Gavi will accept a financial guarantee from their Ministry of Finance or Central Bank if the country's long-term foreign currency credit rating is equal to or greater than <u>B2/B/B</u> from at least one of the indicated credit rating agencies (Moody's/Fitch/S&P) OR if the total amount of the guarantee is less than \$100,000.

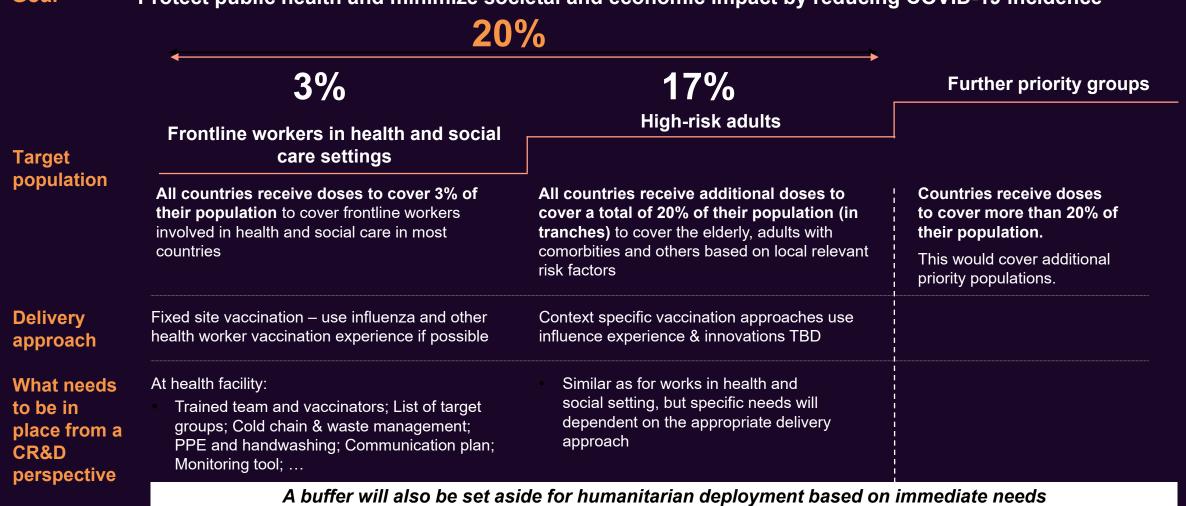
If the country does not meet either of these conditions, Gavi will accept a financial guarantee from a multilateral development bank, or from a financial institution with a foreign currency credit rating of <a href="mailto:BBB/BBB/BBB">BBB/BBB (Moody's/Fitch/S&P)</a>.

#### Specific vaccination delivery approaches need to be defined for different target groups

Groups identified on this slide are 'indicative' and do not constitute WHO policy

Goal

Protect public health and minimize societal and economic impact by reducing COVID-19 incidence



#### Vaccine availability projected to be available in Q1 2021;

preparation must start now

Current expectation of vaccine availability and delivery timelines

Target Launch Window (Q2 2021)

Focus of next pages

Vaccine Supply Scenarios\*

Vaccine Allocation for AMC Countries



#### Key activities for the upcoming months

# Country Readiness & Delivery Working Group

**Coordination** 

Comm's, advocacy & training

Supply & logistics

Vaccine Introduction

Demand

Data & monitoring

#### What we do:

- A Develop tools, guidance and SOPs to support countries getting ready for implementation
- B Secure access to products and manage procurement and delivery to countries
- Mobilizing resources to support country readiness through targeted TA and Cold Chain Investments

#### What takes place at country level:

Use Country Readiness Assessment tool to plan for COVID-19 vaccine introduction

Preparing for vaccine introduction (i.e. develop National Deployment and Vaccination Plan)

### B: To secure access to at least 2BN doses of vaccine to be delivered by end 2021

Approach: A pooled tender to be issued jointly by UNICEF and PAHO in early Q4 2020

Procurement objectives: Expedite access to COVID-19 vaccines for the AMC 92 economies and FSF economies

Tender Invitees	Open to all manufacturers with candidate vaccine in clinical trials.
Tender Timelines	RFP to be issued within the next few weeks, and expected to be a rolling/dynamic tender
Timing of Tender Awards	Early Q4 2020 for first awards (i.e. Gavi APCs followed by supply agreements) with first deliveries in Q1 2021
Independent advice on vaccine selection: Independent Product Group	Will provide guidance and independent advice to the COVAX facility on vaccine candidate selection for the COVAX portfolio, based on technical assessment. Membership under discussion
Independent advice on procurement: Procurement Reference Group	Will provide guidance and independent advice to the COVAX facility on implementation of Procurement Strategy and establishment of APCs. Membership under discussion

Allocation Mechanism	Driven by WHO
Procurement Channels	Gavi secures supply through APCs AMC 92 economies: Use UNICEF and PAHO channel for purchase and delivery Self-financing economies: Can use above channels or self-purchase directly with manufacturers
Delivery to countries	Will require a tightly coordinated effort (Country Readiness, WHO PQT etc.)







#### **Country Commitment** Status as of 5 Oct 2020

28 COIs

19 signed Commitment Agreements

11 Commited Purchase Arrangement

**8 Optional Purchase Arrangement** 

Committed Purchase	% of Total Population	Down- Payment	Financial Guarantee	Need for External Guarantor?
Bahamas	20%	\$251,520	\$1,406,940	No
Belize	30%	\$382,080	\$2,137,260	Yes
Bermuda	20%	\$40,908	\$228,826	No
Colombia	10%			
Jamaica	10%	\$947,520	\$5,300,190	No
Panama	13%	\$1,795,040	\$10,041,005	No
Paraguay	30%	\$6,847,680	\$38,304,210	No
Peru	20%	\$21,102,080	\$118,039,760	No
St. Kitts & Nevis	20%	\$33,920	\$189,740	To be clarified
Trinidad & Tobago	33%			
Venezuela	20%			

Optional Purchase	% of Total Population	Upfont- Payment	Financial Guarantee	Need for External Guarantor?
Argentina	10%	\$28,117,000	\$3,628,000	Yes
Brazil				
Cayman Islands	20%	\$81,840	\$10,560	No
Chile				
Costa Rica	20%	\$6,316,560	\$815,040	No
Mexico	20%	\$159,876,920	\$20,629,280	No
Suriname	20%	\$727,880	\$93,920	No
Turks & Caicos	20%	\$48,360	\$6,240	No





#### **Pending Countries with COI**

Committed Purchase	% of Total Population	Down- Payment	Financial Guarantee	Need for External Guarantor?
Antigua and Barbuda	20%	\$62,720	\$350,840	To be clarified
Barbados	20%	\$183,680	\$1,027,460	Yes
British Virgin Islands	20%	\$19,200	\$107,400	To be clarified
Cuba	20%	\$7,249,280	\$40,550,660	Yes
Curaçao	20%	\$104,960	\$587,120	To be clarified
Dominican Republic	20%	\$17,356,800	\$97,089,600	No
Ecuador	20%	\$11,291,520	\$63,161,940	Yes
Guatemala	20%	\$11,466,240	\$64,139,280	No
Montserrat	20%	\$1,600	\$8,950	No
Uruguay	20%	\$2,223,360	\$12,436,920	No

#### **Others**

Committed Purchase	% of Total Population	Down- Payment	Financial Guarantee	Need for External Guarantor?
Anguilla	20%	\$9,600	\$53,700	No
Aruba	20%	\$68,480	\$383,060	No
Sint Maarten	20%	\$27,520	\$153,940	To be clarified

#### Timeline and next steps

#### Friday Sept 18th

Receive signed Commitment Agreement signed by fully selffinancing participants

#### **Friday Oct 9th**

Upfront payment and financial guarantee received from fully self-financing participants

#### ~October - December

COVID-19 vaccine programme open for applications from AMC 92