COVAX Facility
Information session with industry

August 12, 2020

Welcome & objectives of the meeting

Objectives

1. **Provide update on the COVAX Facility and operational aspects**

2. **Provide an opportunity to discuss and clarify key issues relevant to industry**

Agenda & housekeeping

Agenda

Topic	Presenter
Welcome & Objectives of the meeting	Derrick Sim (Gavi)
Agenda & housekeeping	Derrick Sim (Gavi)
Facility & Gavi COVAX AMC overview	Derrick Sim (Gavi)
Allocation, policy, regulatory, safety & monitoring	Claudia Nannei & Carmen Rodriguez (WHO)
Overview of economies participation & agreements with Facility	Santiago Cornejo (Gavi)
COVAX Facility governance	Wilson Mok (Gavi)
Liability and Indemnification	Anthony Brown (Gavi)
Procurement update	Yalda Momeni & Gian Gandhi – (UNICEF SD)
Participant Q&A	

Housekeeping

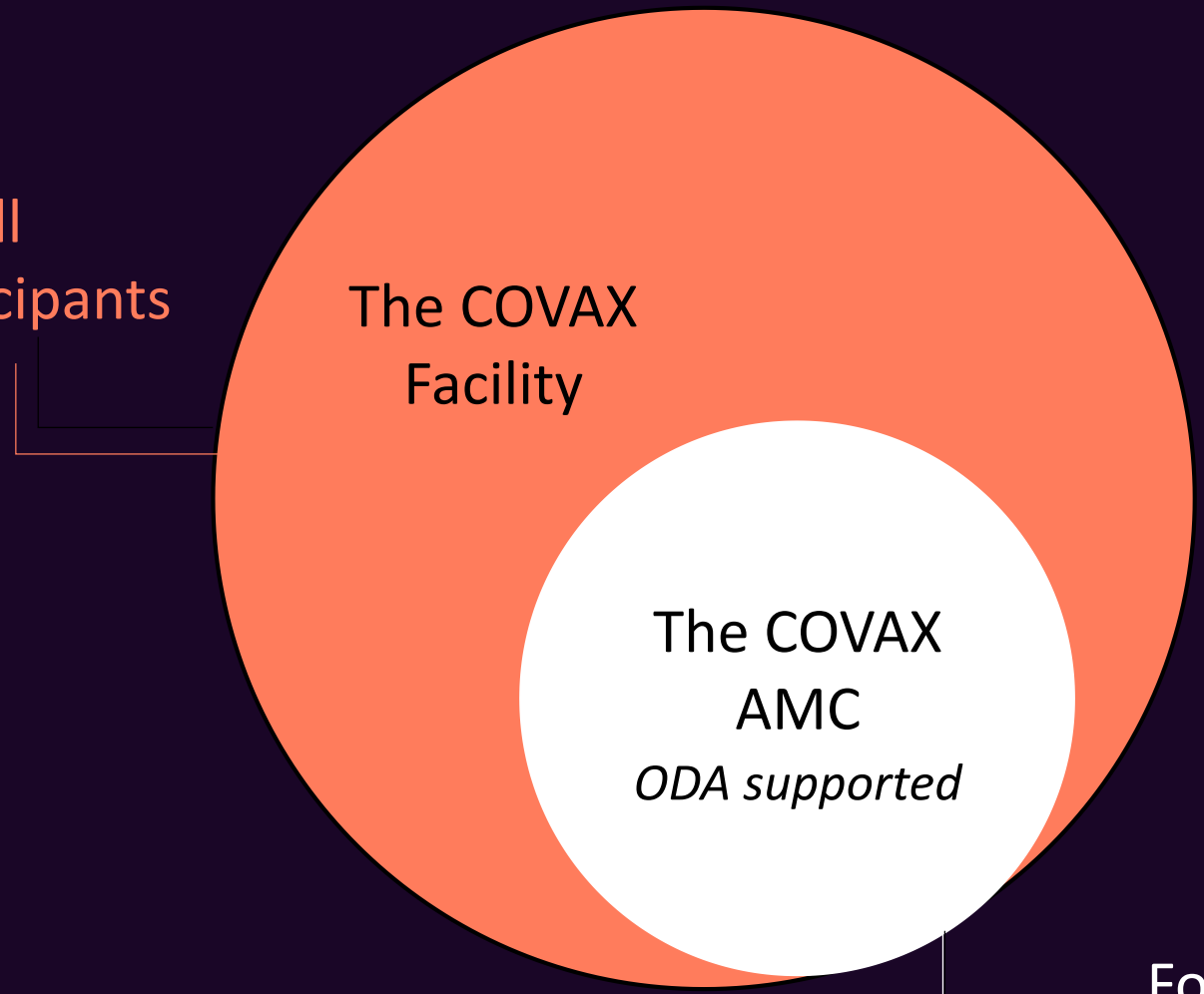
We have a full house today, so we kindly ask you to…

- **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 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
- **Share any further input offline to covax@gavi.org**

Facility & Gavi COVAX AMC overview

The COVAX Facility serves all participants

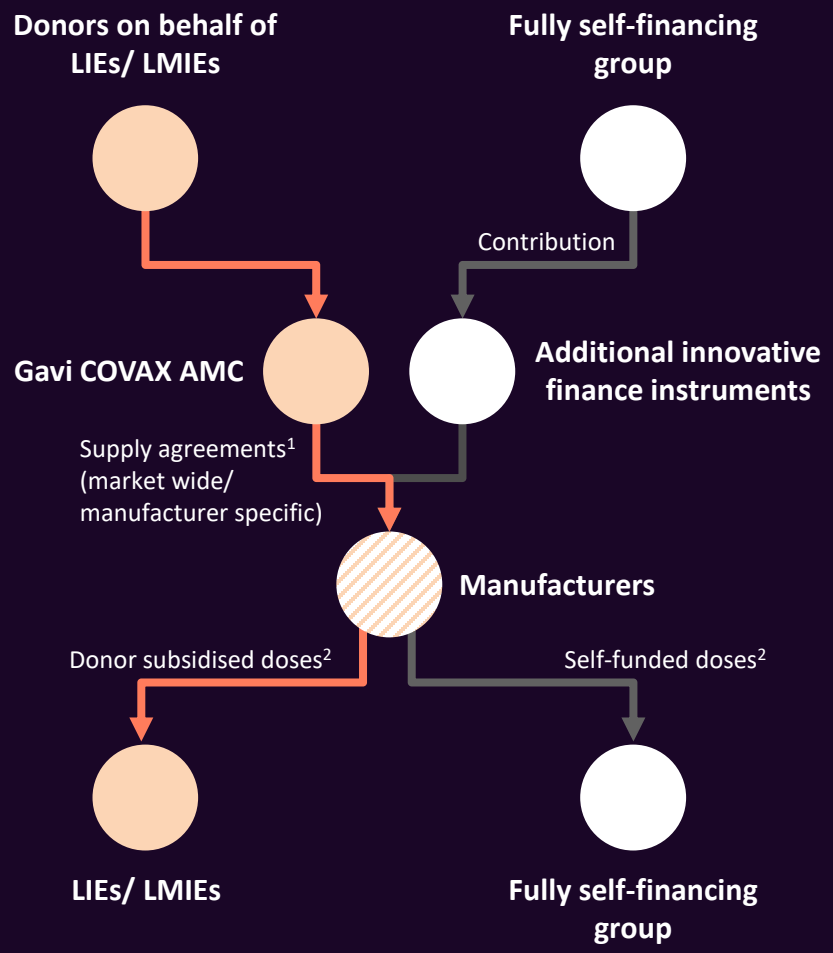
The COVAX AMC is an instrument for ODA-eligible participants



The Gavi COVAX AMC

- A **financing instrument** for the procurement of vaccines
- Works to ensure that **no economy is left without access to a future COVID-19 vaccine**
- Administered by **Gavi**
- Initially funds procurement through the Facility
- Draws upon the lessons of the pneumococcal AMC

Funding raised (to date): nearly $600 Mn



1. Agreements with manufacturers would be unified across full scope of economies participating in the Facility, but ODA funding will only be used to support LIEs, LMIEs and IDA-eligible UMIEs
2. Financing for procurement incremental to contribution

The ‘COVAX AMC Group’: Eligibility

- The **‘COVAX AMC Group’**: The scope of economies eligible for support through the AMC
- This definition of scope focuses Gavi support on the **poorest economies in the world** today, uses **recognised World Bank definitions,** and it is **completely transparent**
- **92 economies eligible for COVAX AMC:**
  - All low-income economies and lower middle-income economies
  - World Bank classification (i.e. economies with a GNI per capita <US$ 4,000) based on either 2018 or 2019 GNI data, and
  - Other IDA-eligible economies

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

	HIEs and UMIEs	LIEs, LMIEs and IDA-eligible UMIEs
Vaccine Access (COVAX Facility)	• Participants expected to fully self-finance their participation in the global Facility	• Financial support for vaccine procurement and access through the COVAX AMC
Procurement mechanisms	• **TBD –** leverage existing procurement mechanisms	• Support from the Alliance through UNICEF and utilising PAHO Revolving Fund
Delivery	• No support provided	• Support through alternative means, incl. existing Gavi mechanisms – Cash grant (Ops) and CCEOP – Technical assistance

- **Level and extent of support** (e.g. co-financing, delivery, etc.) provided to the COVAX AMC Group to be determined 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

Timeline of COVAX AMC policy decisions

Date	Milestone	Description
End July	Gavi Board meeting	Decision on the **scope of eligibility** for the COVAX AMC Group
End September	Gavi Board meeting	Decision on the **level and extent of support** to be provided to the COVAX AMC Group

Allocation, policy, regulatory, safety & monitoring

Three components inform the formulation of vaccination strategies

2: Strategic Advisory Group of Experts (SAGE)

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

1: Allocation Framework

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

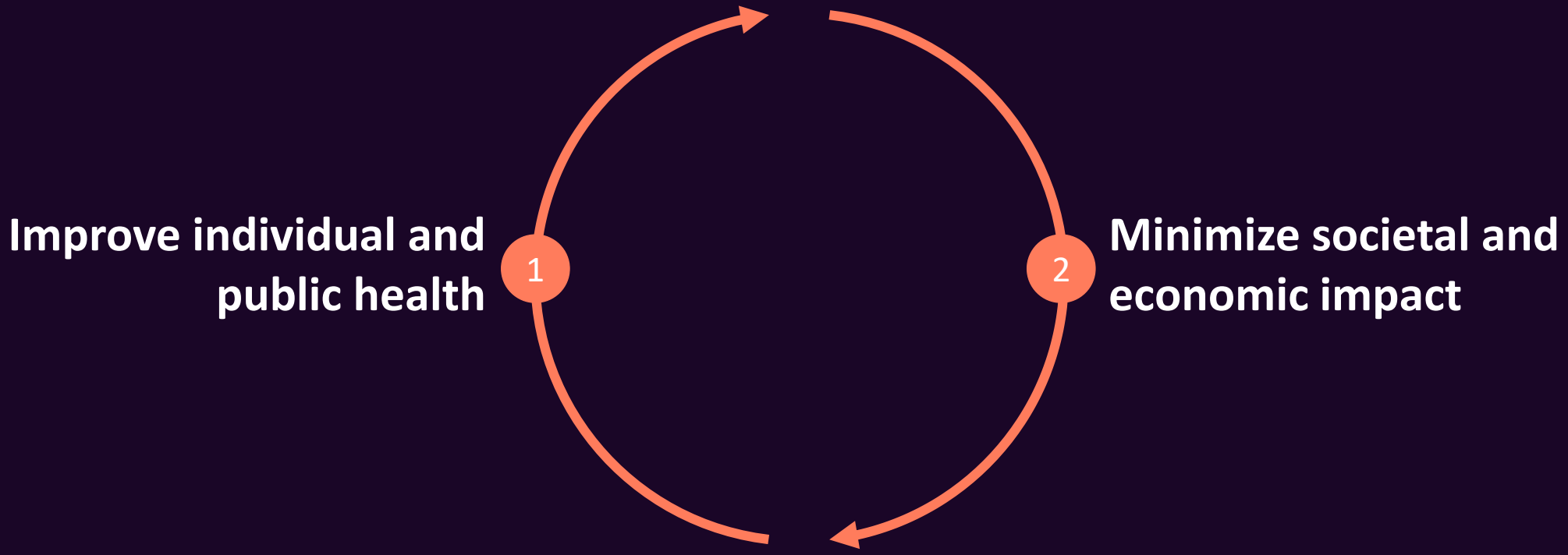
Participant

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 two main goals of a vaccination program are inextricably linked



To significantly reduce the impacts of COVID-19 in the safest, quickest and most effective way, it is not necessary to vaccinate the entire population

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

Goals

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

Priorities

Health and social care workers	High-risk adults	Further priority groups
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.	**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

*Participants receive doses proportionally to their total population**

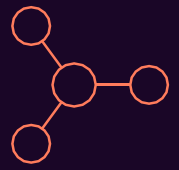
Timing is based on participants' need, vulnerability and COVID-19 threat

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: Vx candidates use different technology platforms with implications for how they can be used

Different technologies …



Protein

Nucleic Acid

Viral vector

Inactivated

… with different characteristics

Vaccine characteristics and study settings (e.g. trial population or regional setting) affect deployment:

- Immunogenicity (e.g. sub-optimal effect on elderly populations)
- Safety profile (e.g. women of childbearing age)
- Ability to scale-up manufacturing
- Cold chain requirement (e.g. -70C°)
- …

One vaccine may be **more suitable for a target group and/or a specific region than another**

Vaccines are **unlikely to be interchangeable**

Need for guidance and policy advice for specific vaccine candidates

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
3. Preparing **policy advice** on the accelerated use of vaccine candidates, including recommendations for early allocation of vaccines when vaccine supply is still limited
4. 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 sub-working groups:

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

Regulatory, safety & monitoring

Features of PQ and EUL

Prequalification (PQ)

Quality, safety and efficacy and PSPQ for international supply

CMC, clinical and programmatic assessment performed by WHO independent experts

Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)

Pre-submission meetings encouraged

Post-PQ monitoring

Emergency Use Listing (EUL)

Assessment of limited data for use during PHEs

Assessment performed by WHO independent experts in collaboration with Mature Regulatory Authorities (WLA)

Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)

Pre-submission meetings encouraged

EUL process similar for all product streams

Requirements differ (ex. for vaccines: programmatic suitability)

Post- deployment monitoring. RMP in dossier/collection in countries.

EUL procedure for vaccines

Pre emergency

1. Establishment of assessment platform
2. Eligibility and assessment of products
3. Roster of experts

Emergency

1. Roster of experts
2. WHO decision on EUL
3. Policy recommendations
4. Publication of review outcomes

Post deployment

1. Monitoring
2. Post EUL changes

Covid-19 **Pandemic** **Merge pre-emergency and emergency roster of experts**

Facilitating access of COVID 19 vaccines (1/2)

Roadmap

- Mapping regulatory requirements for emergency use during PHE
- Interactions & agreement with regulatory authorities
- Involvement of regulators of potential impacted countries in the EUL review to accelerate decision-making process
- Identifying priority countries may be complex due to changing COVID-19 situation: relevant epidemiological factors

- Exploring options through involvement of reference NRAs and regulatory networks in the EUL process

Pre-submission phase

Facilitating access of COVID 19 vaccines (2/2)

- Assessment of available quality, safety and efficacy data.
- Sharing reports with all regulatory authorities for decision making process.
- Promotion of reliance principles in other countries based on facilitated pathways
- WHO member states have the sovereignty for decision-making

Discussion with Regional offices establishment of a mechanism for expedited approval in countries and monitoring performance of vaccines deployed to countries

Think out of the box, Unite, Collaborate & Cooperate

- WHO is encouraging regulatory networks to consider joint reviews, fast track approvals of Clinical trials and when appropriate emergency authorisations
- Prepare a roadmap for each vaccine, which will include expected option and collaboration with country regulators to facilitate local authorisation for emergency use.
- Substantial achievements made by AVAREF to facilitate coordinated reviews and approvals for preventive, diagnostic and therapeutic interventions for COVID-19
- Regulatory updates meetings held with regions in America, Europe, Central Asia, East Mediterranean, South East Asia and with regulatory networks such as AVAREF, Southern African Development Community, African Medical Device Forum and more

Opportunities to use regulatory networks and reliance

Additional information EUL:

Procedure and Questions and Answers

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Target product profile

https://www.who.int/docs/default-source/blue-print/who-target-product-profiles-for-covid-19-vaccines.pdf?sfvrsn=1d5da7ca_5&download=true

Contact: Carmen Rodriguez Hernandez Team lead Vaccine PQ, RPQ

rodriguezhernandezc@who.int

EUL@who.int

Overview of economies 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
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
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
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

Status of expressions of interest

STATUS AS OF AUGUST 10

HIC: 41 EOIs, 0.5+ B people

UMIC: 39 EOIs, 1.0+ B people

LIC/LMIC: 92 AMC-eligible economies[1], 3.8+ B people

1. AMC-eligible economies are not required to submit an expression of interest; the final scope of AMC-eligible economies was determined by the Gavi Board at its meeting on 30 July

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.

Proposed COVAX Facility governance[1]

1. Pending Gavi board approval

Guiding principles behind the Facility's Governance

PROPOSAL

Structural considerations

- **Build on Gavi's existing Board and Committees,** with new governance bodies established to ensure appropriate oversight, to avoid unnecessarily expanding 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

- 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

The details of the governance arrangements, including terms of engagement with civil society and other non-funded/non-funding participants, are still being refined as the Facility is established

Self-financing participants form a ‘Shareholders Council’

PROPOSAL

Members/ composition

- Representatives of all **self-financing participants**
- Could additionally include representatives of **AMC Stakeholders Group** and/or for **observers** e.g. CSOs, regional bodies

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Meeting cadence

- **Monthly - TBC**

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 (e.g. overview of the Facility’s processes on dose allocation)
- Representatives from Shareholders Council **included on MSDC for review of COVAX-related agreements**

Self-Financing Participants in collaboration with Facility would agree and establish the final terms of reference and operating procedures. Shareholders Council may establish a form of Steering Committee to liaise with the existing governance bodies to take key decisions

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
	Gavi The Vaccine Alliance	Gavi The Vaccine Alliance	World Health Organization	CEPI
Portfolio		✓	✓	✓
Allocation			✓	
Financing	✓	✓		✓
Operations	✓			

Newly proposed governance/advisory bodies of the COVAX Facility

PROPOSAL

	Shareholders council	Independent allocation body	Independent product group
Portfolio	✓		✓
Allocation	✓	✓	
Financing	✓		
Operations	✓		

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

PROPOSAL

		Affiliation	Composition	Role
Gavi Board		Gavi The Vaccine Alliance	• Gavi, WB, BMGF, UNICEF, WHO, Governments of developing countries (5), Governments of donor countries (5), CSO, IFPMA, DCVMN, independents, research institutes	• 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
MSDC	Market sensitive decisions committee	Gavi The Vaccine Alliance *Expanded	• Board (Vice) Chair, AFC Chair, PPC Chair, UNICEF, WB, Gavi, BMGF, Governments of developing countries (2), Governments of donor countries (3), CSO • TBC - Self-financing participants (3), COVAX AMC participant	• Review the business terms of the proposed COVAX volume guarantee agreements that the Facility would enter into with manufacturers

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

PROPOSAL

		Affiliation	Composition	Role
Shareholders Council		*NEW	• Self-financing participant representatives	• 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
RDMIC	Research & development & manufacturing investment committee	CEPI	• CEPI, Gavi, BMGF, (ex) industry R&D and manufacturing experts, public health expert	• Drive CEPI portfolio strategy & investment decisions aligned with overall COVAX strategic objectives • Decide CEPI investment allocation and requirements across the portfolio • Make project selection and investment decisions

Role and composition of proposed advisory bodies

PROPOSAL

		Affiliation	Composition	Role
IPG	Independent product group	*NEW	• 5-7 independent experts	• Provide independent advice to e.g., COVAX Facility members, Gavi, the MSDC and inform selection of vaccine candidates for Facility • Assess whether candidates have met criteria for eventual purchase • Review overall portfolio, consider updates in clinical development, manufacturing and supply
SAGE	Strategic Advisory Group of Experts	World Health Organization	• 15 experts in the fields of epidemiology, public health, vaccinology, infectious diseases, drug regulation, immunization delivery, safety, etc.	• Advise WHO on overall global policies and strategies, incl. vaccines, research and development, delivery of immunization and its linkages with other health interventions
Independent allocation body		*NEW	• To be defined – independent technical experts	• Review and analyze data/ documentation, provide technical input • Make allocation recommendations in accordance with final technical design, approved by Member States, of the WHO Allocation Framework

Liability and Indemnification

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

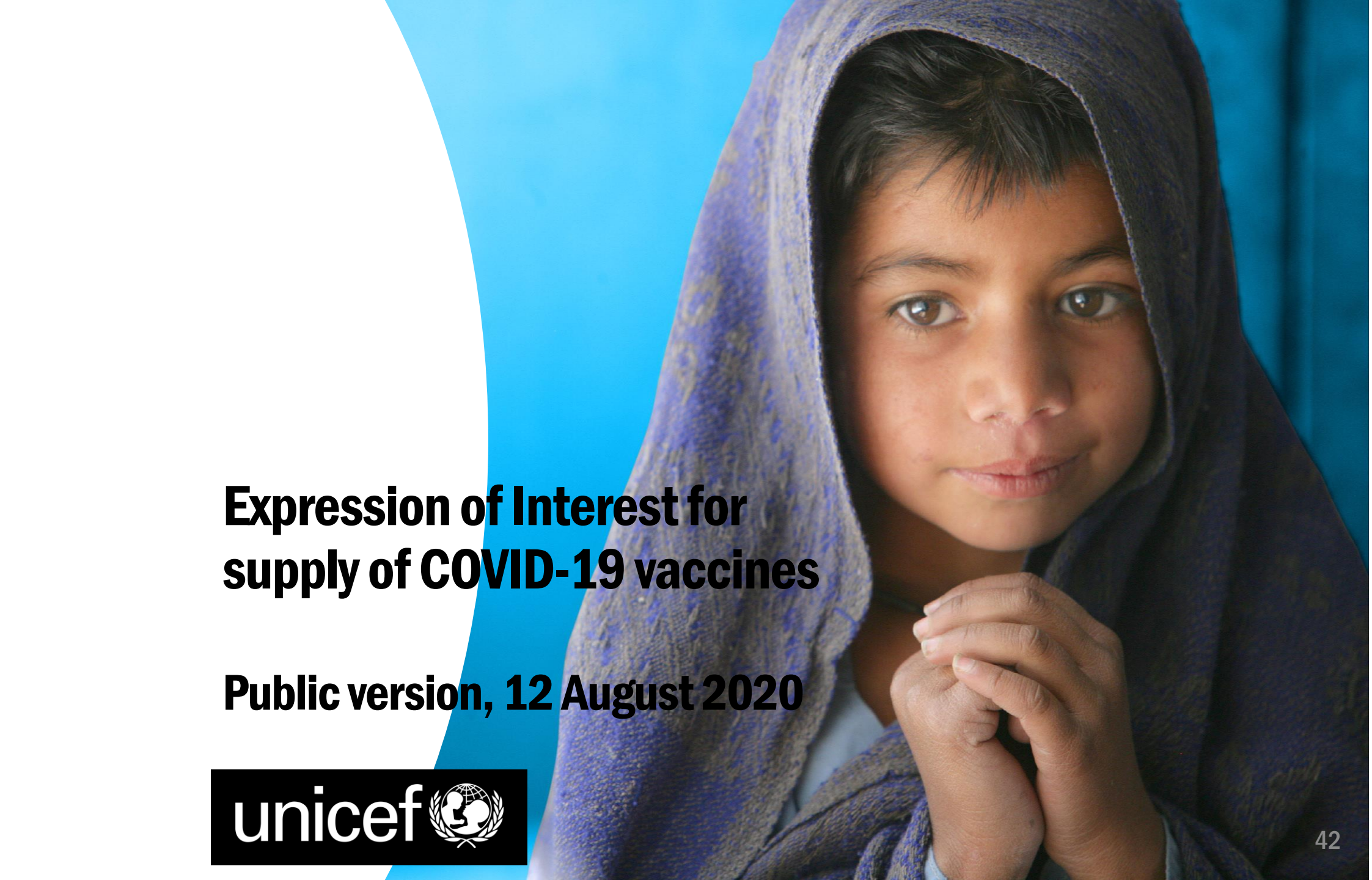
There is an **unknown risk of potential liability** arising from COVID-19 vaccines

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.

Procurement Update



Expression of Interest for supply of COVID-19 vaccines

Public version, 12 August 2020

unicef

Public briefing on the Covid-19 vaccine

- Provide a briefing to all interested stakeholders on the findings of the Expression of Interest (EOI) issued to Covid-19 vaccine developers and manufacturers

- Contribute to the understanding of the potential global vaccine supply and demand situation and vaccine characteristics

- Inform COVAX procurement timeline and facility design.

High level readout from Expression of Interest

unicef | for every child

Expression of Interest (EOI) overview

UNICEF issued an EOI on 15 June 2020 on behalf of COVAX to vaccine developers / manufacturers. Information provided and compiled as of 1 July 2020.

- EOI Objectives: Understand manufacturing plans and help inform design elements of COVAX and procurement approach

- Information requested:
  - Production volumes
  - Manufacturing platforms
  - Timing of availability
  - Product presentation
  - Pricing policy
  - Support needed (e.g. on licensure pathway, registration…)

- Confidential briefings of the consolidated feedback were provided to technical COVAX partners

- Public briefing being made available to all stakeholders

unicef

Contents of Public Briefing

- Background on EOI
- Respondents
- Indicated production volumes and timing, including in comparison with priority demand estimates
- Volumes by vaccine platform
- Product presentation
- Pricing policies
- Support needed by developers/manufacturers
- Key messages

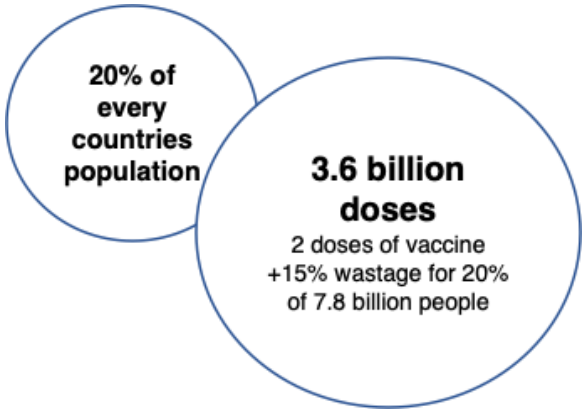
Respondents to EOI

Anhui Zhifei Longcom Biopharmaceuticals
AstraZeneca
Aurobindo Pharma Ltd
Beijing Minhai Biotechnology Co.
Beijing Institute of Biological Products
Bharat Biotech International Limited
Biological E Limited
Chengdu Institute of Biological Products
Chumakov
FSUE
GSK
Indian Immunologicals Ltd
Janssen
Merck MSD
NingBo RongAn Biological Medicine
Novavax
Panacea Biotec
Pfizer
Sanofi Pasteur
Shionogi & Co.
Serum Institute of India
SinoCellTech
Sinovac
SK Biopharmaceuticals
StemiRNA Therapeutics
Takeda
Walvax Biotechnology Co.
Wuhan Institute of Biological Products

- 10 with manufacturing in China
- 6 in India
- 3 in the USA
- 2 in each of Belgium, Russia, Japan
- 1 in each of France, S. Korea, Switzerland and the UK

How much vaccine is needed globally?

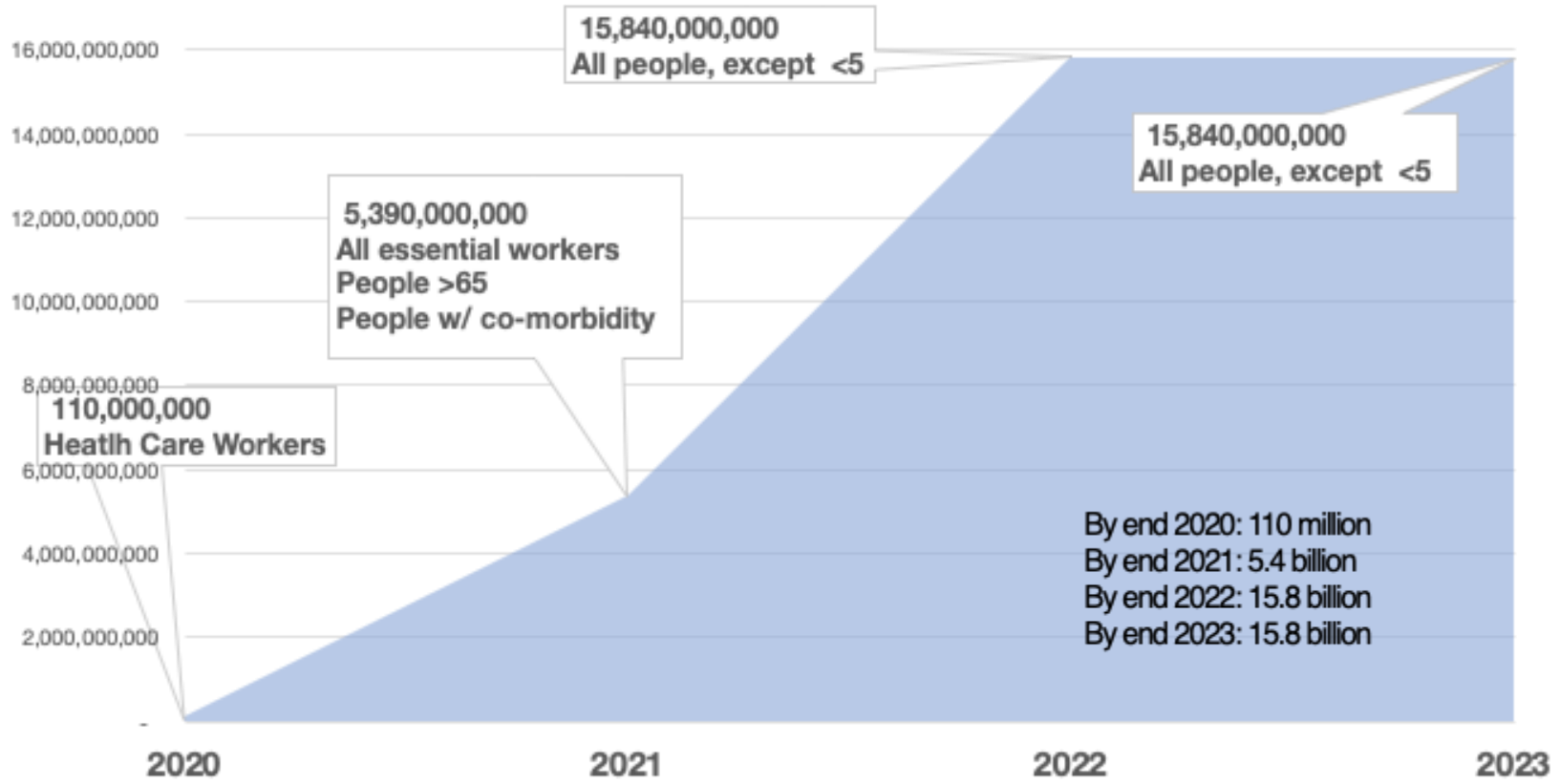
- Global vaccine demand depends **on how long immunity lasts, the effectiveness of the vaccine & the number of doses per vaccine course** (assumption is 2 doses per course)
- **The ACT-A goal is to secure "2 billion doses by 2021"**
- **WHO is developing a framework to allocate Covid-19 vaccines. The current draft allocates as follows:**
  - Every country receives doses for 3% of their population to reach health and social care workers with an immunisation course
  - Then, every country receives second allocation for up to 20% of their population to reach people over the age of 65 and people at higher risk of critical Covid-19 disease due to underlying conditions
  - Combined, these amounts exceed the 2 billion dose target for ACT if we assume they are needed prior to end 2021. The higher of the two volumes was used.



unicef

Global demand scenario

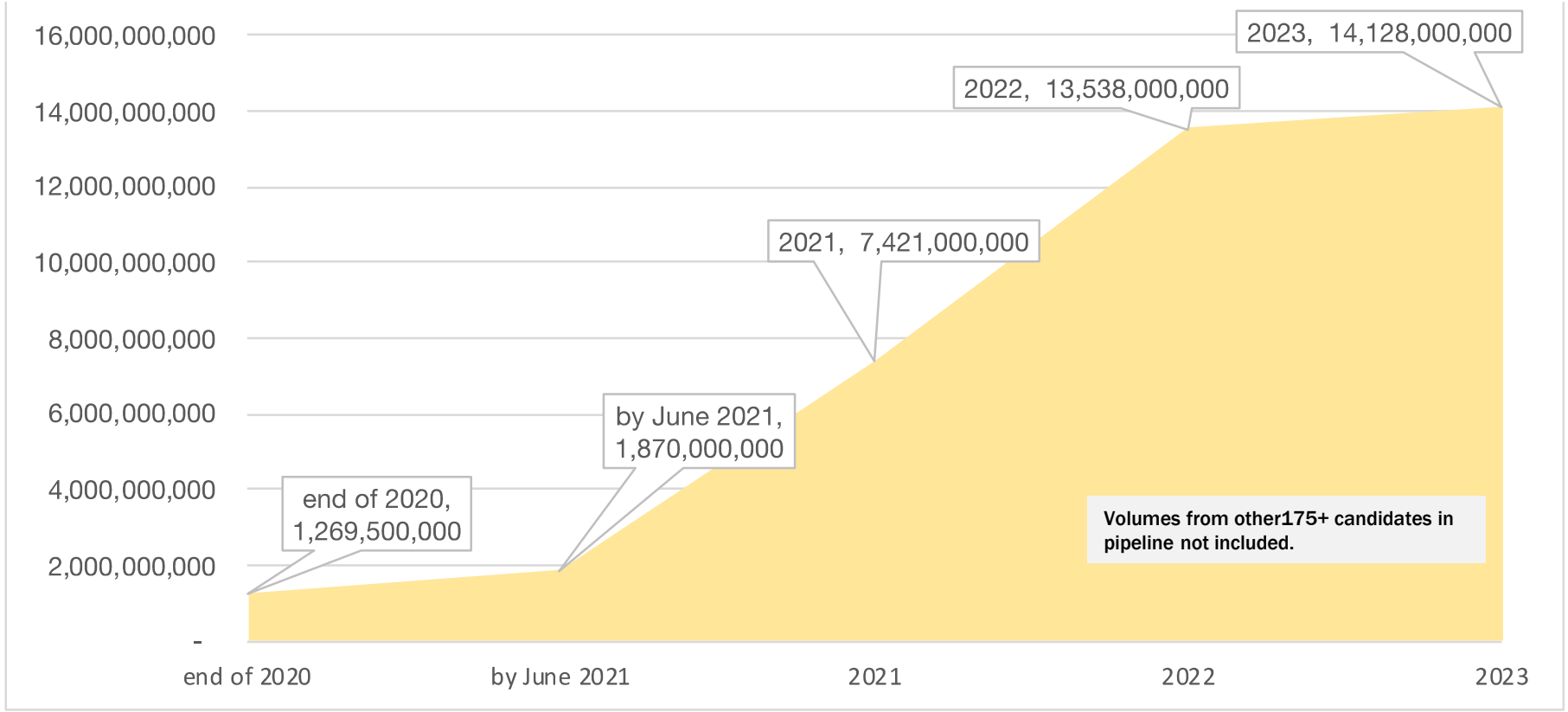
This UNICEF demand scenario uses the following global demand assumptions: 3% of population provided with COVID-19 vaccine by end 2020, 20% of population by end 2021; an annual vaccination of the full population* thereafter



*Children under the age of 5 have been excluded due to lack of this age group being included in clinical trials thus far

How many doses were indicated by manufactures globally?

Number of doses available, as indicated in EOI or publicly stated. Approximately 20% of aggregate total volumes comes from indications found in public sources.

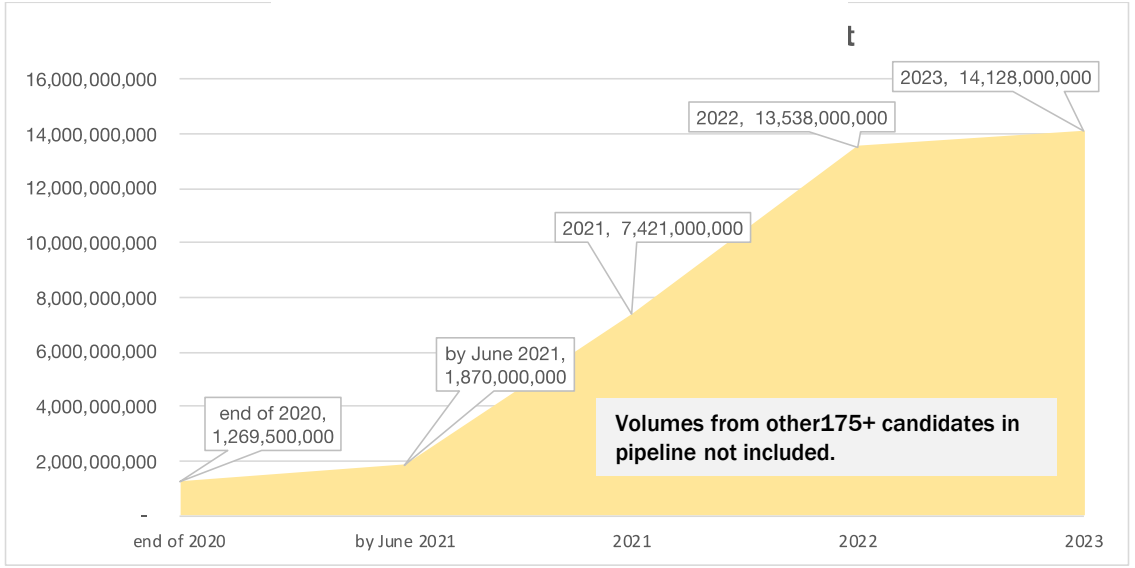


Global supply volumes compared with global demand scenario

Indicative Supply Volumes

Number of doses available, as indicated in EOI or as publicly stated
(NB: Data unqualified)

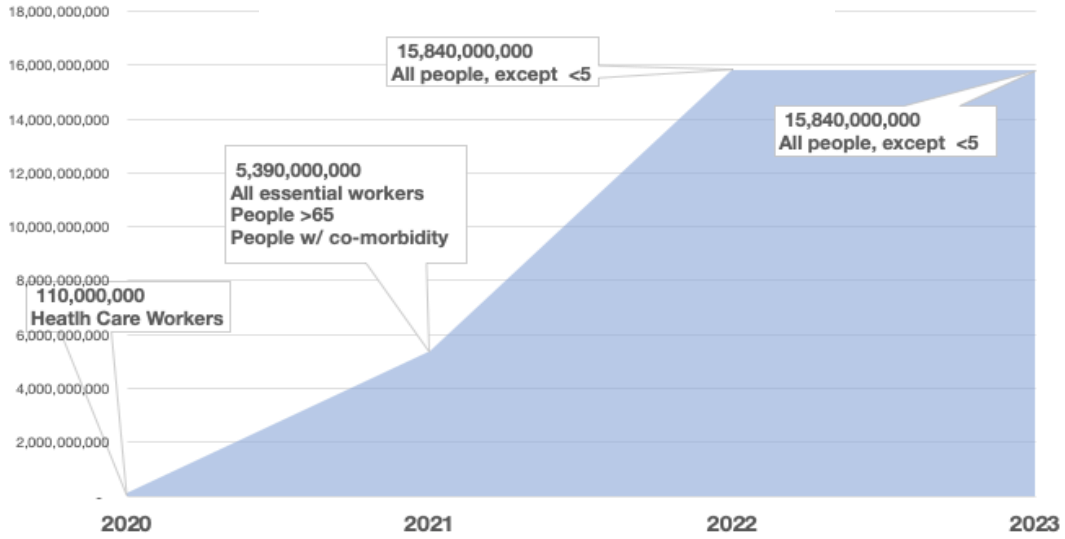
By end 2020: 1.3 billion
By June 2021: 1.8 billion
By end 2021: 7.4 billion
By end 2022: 13.5 billion
By end 2023: 14.1 billion



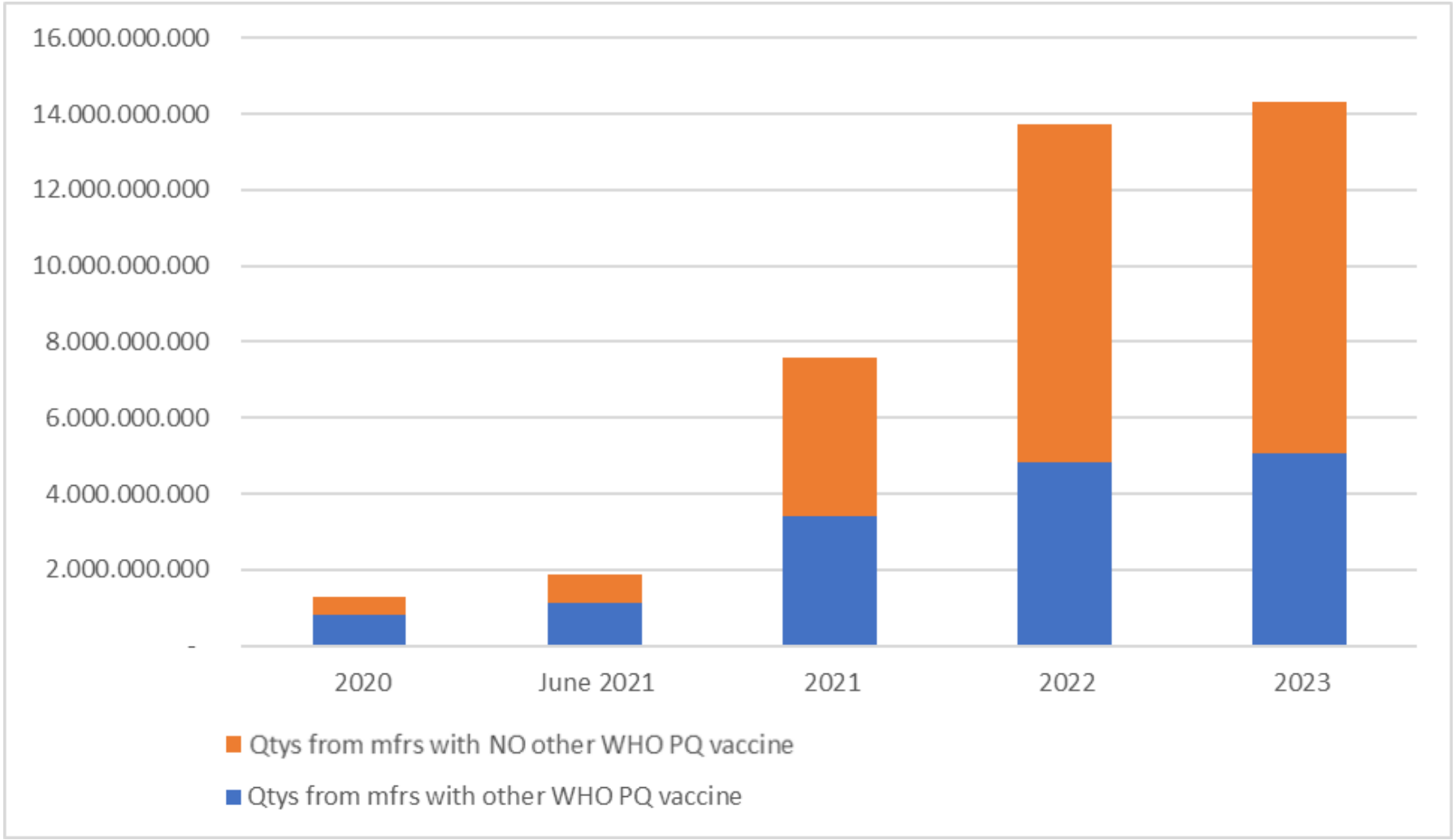
UNICEF Demand Scenario

Global demand, inclusive of annual vaccination

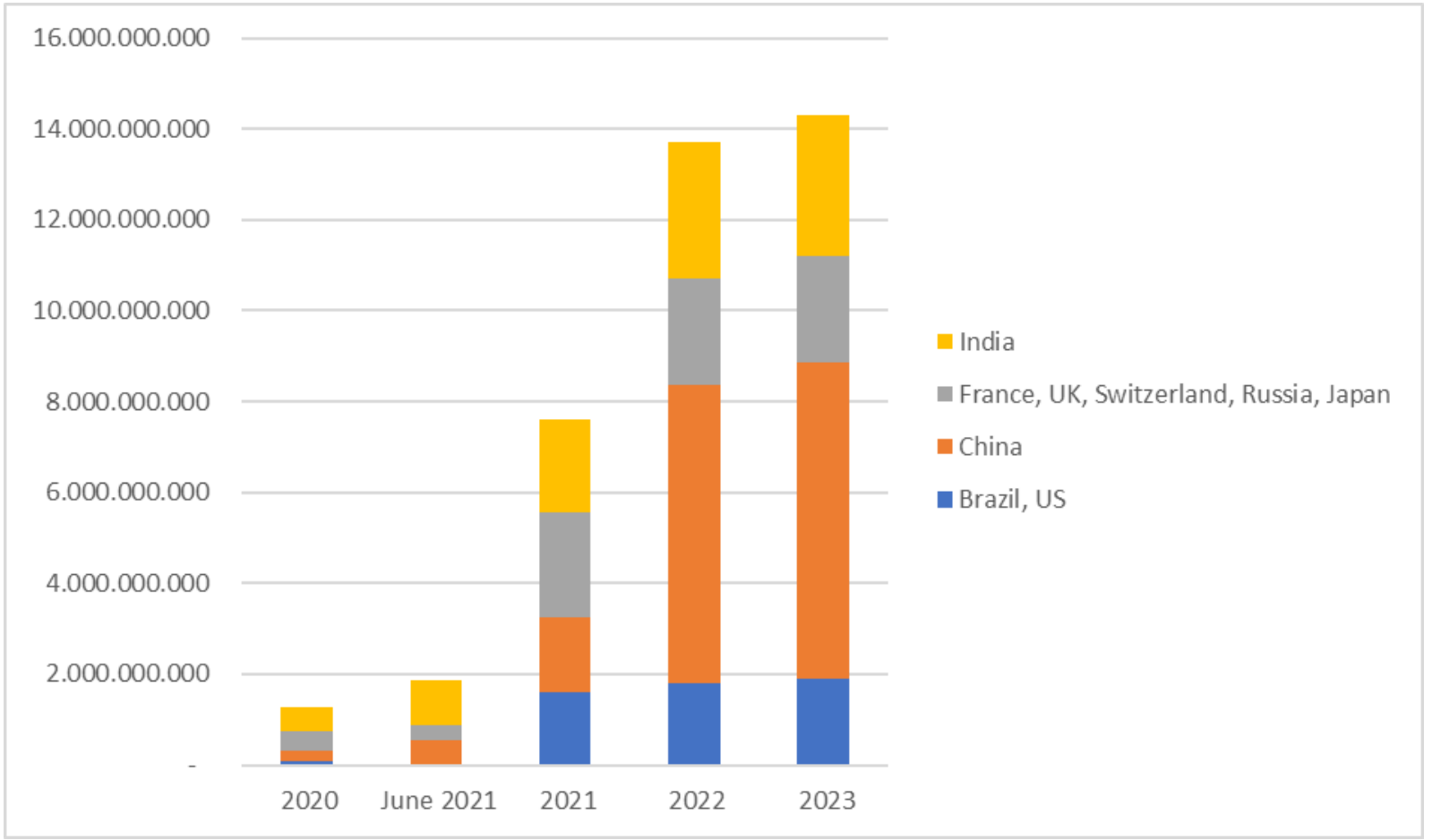
By end 2020: 110 million
By end 2021: 5.4 billion
By end 2022: 15.8 billion
By end 2023: 15.8 billion



Projected annual manufacturing volumes from manufacturers with or without another WHO prequalified vaccine

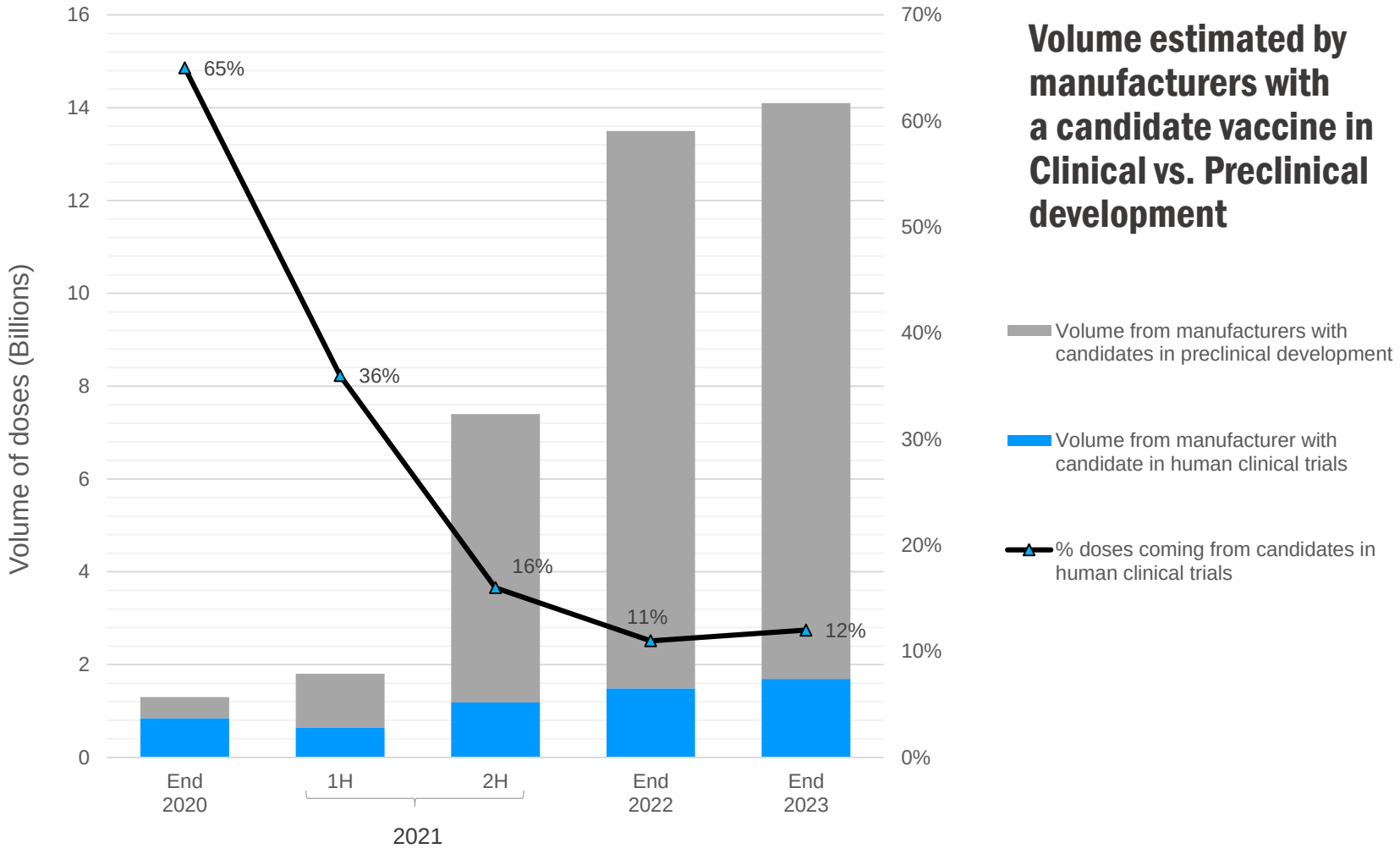


Projected annual manufacturing quantities by location of manufacturing



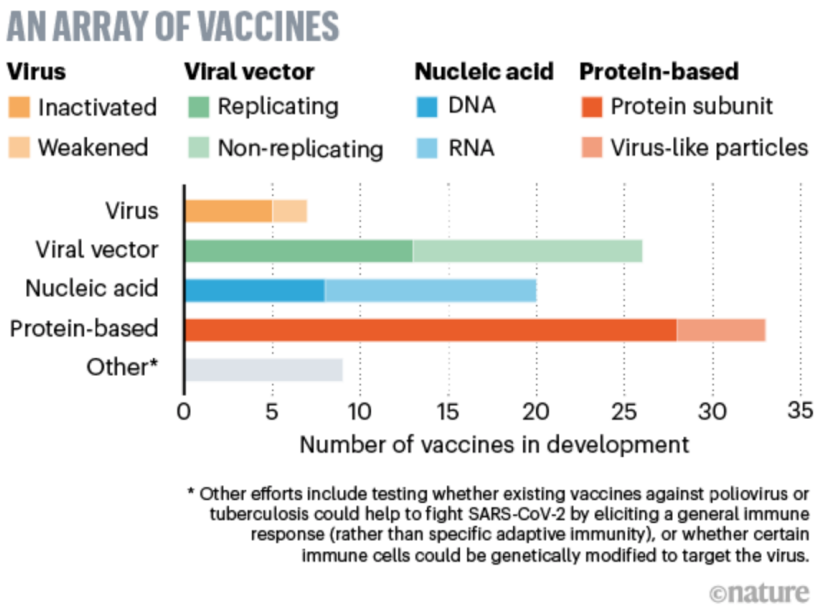
- In 2020, 19% are from mfrs in China; 22% are from mfrs in India
- In 2023, 49% are from China; 22% from India

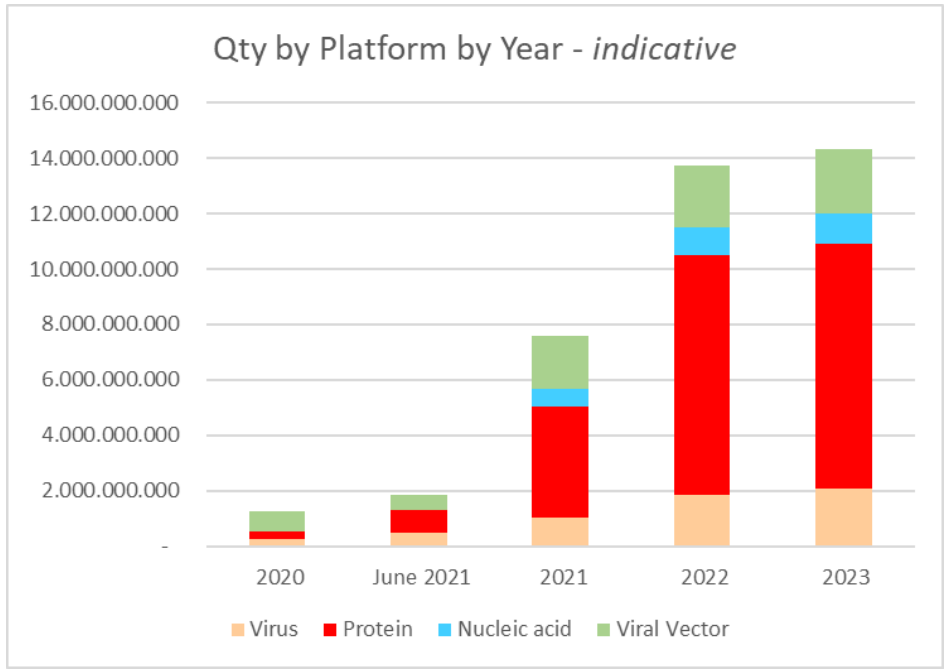
How far along in development are candidate vaccines?



Vaccine platform

In 2020/2021, volumes spread across platforms by 2022/2023, protein subunit candidates account for majority of volumes indicated





Vaccine platforms have different risks and pace

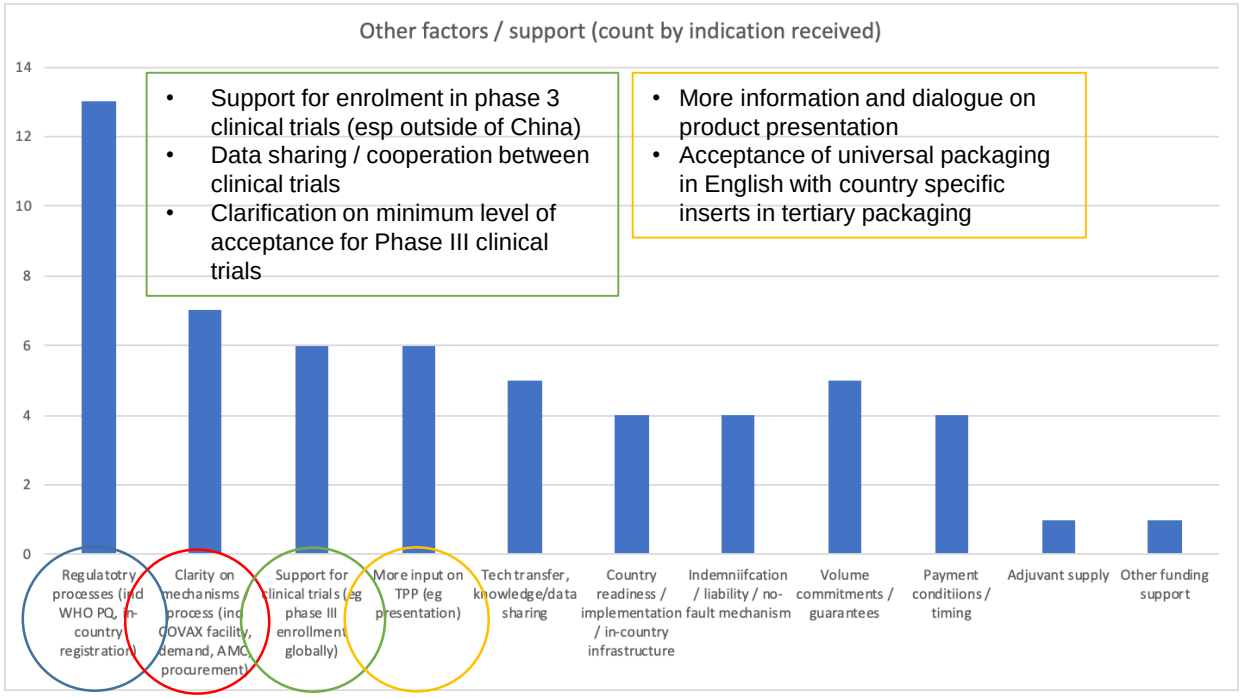
PLATFORM	Indicated global volumes 2020-23	Manufacturers indicating platform and volumes
Virus: Weakened or inactivated. Often requires more safety testing. Majority of current vaccines (Vx).	5.7 billion 17%	Beijing Biom., Beijing Inst., Bharat1, Bharat2, Chum, NingBo, Panacea, Sinovac, Wuhan, Indian Imm.
Viral vector: Modified. Safer. NB: While an rVSV (Ebola) is licensed, and is a replicating viral vector Vx, no non-replicating Vx has been licensed.	17 billion 49%	Anhui, BioE, FSUE, Novavax, Sanofi, SinoCellTech, Walvax1
Nucleic acid: Easy to develop and manufacture, but no RNA or DNA Vx has been licensed.	4.2 billion 12%	Walvax3, StemiRNA, Pfizer
Protein-based: Require adjuvants and multiple doses. Can be hard to manufacturer.	7.4 billion 22%	Bharat3, Chengdu1, Chengdu2, Janssen, Merck, Shionogi, Walvax2, AstraZeneca, SII, Aurobindo

Risks and support identified by manufacturers

Regulatory pathway, country licensing, indemnity, clinical trials, COVAX design

- Streamlining / harmonizing regulatory processes at national and global level
- Accelerated PQ process (ref lessons learned from Ebola)
- Creation of an emergency use pathway
- Support to in-country registration

- Consultation with industry on mechanisms & processes
- Information on what type of support is available to manufacturers & when
- Communication & consultation with industry on demand, programmatic policy & approaches



- Support for enrolment in phase 3 clinical trials (esp outside of China)
- Data sharing / cooperation between clinical trials
- Clarification on minimum level of acceptance for Phase III clinical trials

- More information and dialogue on product presentation
- Acceptance of universal packaging in English with country specific inserts in tertiary packaging

- Technical matchmaking (company) specific
- Push/pull funding for adjuvants, fill/finish capacity
- Adjuvant matchmaking
- Validation of country readiness
- Consultation with industry on CCE requirements

Feedback on COVAX pricing policy

Respondents indicate that they will want to have a tiered pricing approach, based on GNI.

Some commit to a single/flat price vaccine for all buyers during the pandemic phase, followed by tiered pricing.

Most indicate a need for some type of volume guarantee.

- Of the 28 respondents, 21% did not respond to pricing policy
- Of those that provided a response:
  - 50% suggested tiered price (11)
  - 41% suggested flat/single price followed by tiered price (9)
  - 9% suggested flat/single price (2)

1 respondent provided specific idea on tiering:
- Single/flat price for LICs/Gavi countries
- Single/flat price for MICs
- Multiple prices for HICs

Nearly all indicated they did not have visibility on COGS from which to indicate a price.
Many wanted more visibility on COVAX scope and design before able to give a price indication

Vaccine specifications

[NB: Most information just indicative]

- All **liquid** except some **freeze-dried** products (Freeze dried can be more stable but require another manufacturing step; i.e. slower to scale; and more room for administration error)
- All indicated **intramuscular injection**, except one nasal atomisation
- Majority indicated **2-dose course**, a few indicated single dose, one indicated single dose with booster, one indicated 3-dose course
- Majority indicated vaccine would be provided in a **multi-dose vial**
  - Number of doses per via to be decided (8)
  - >50 doses per container (2)
  - A plan for vial size - 1, 2, 5 or 10 (6)
  - Pre-filled syringe (5)
- Most have target temperature requirement of stability between 2°C and 8°C.

➢ But stability data takes time … **so could expect minus (-60°C) temperature requirement** and shorter shelf life during 2020-2021

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COVAX EOI Volume Implications (Demand vs. Supply Scenarios)

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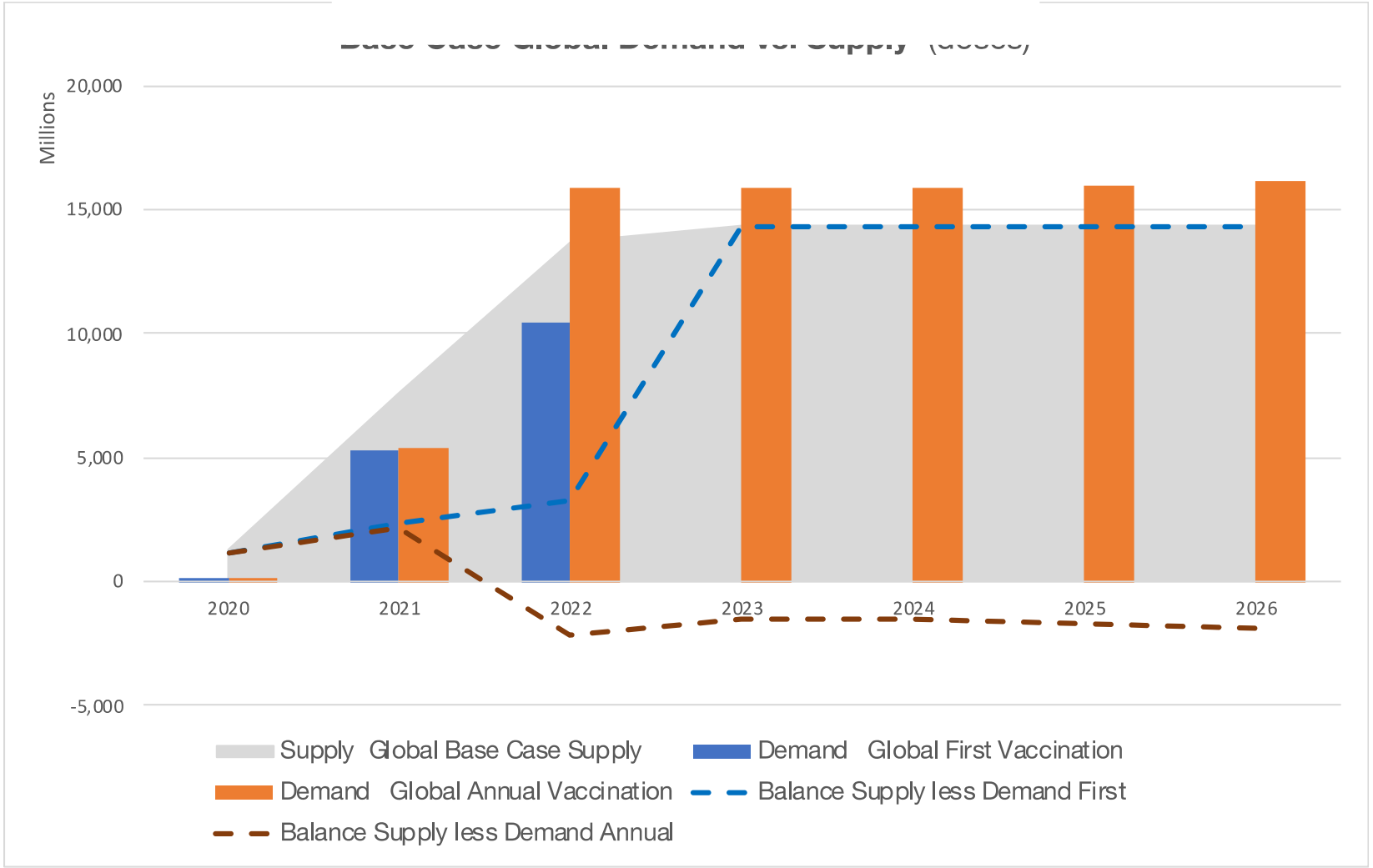
Scenario: Global Base case supply vs. Base case demand

UNICEF demand analysis



Aggregate Demand & Supply scenario analyses

(based on EOI responses and available demand estimates)

Base Case

- Supply volumes per EOI responses
- Demand per Global Forecast, inclusive of annual vaccination need

Suppressed Supply assumptions

- Aggregate volumes lowered by 30%
- 50% of aggregate volumes are delayed by 12 months
- Both suppressions looked at in combination

Suppressed Demand assumptions

- Coverage rates
  - Healthcare workers: 90% coverage
  - Essential workers: 80% coverage
  - Over 65 year olds: 80% coverage
  - Rest of population: 70% coverage
- Country readiness
  - 25% of demand in low resourced settings is delayed 12 months – *not included in global calculation*
- Vaccine presentation
  - Different presentations may have impact on wastage rate, more frequent deliveries, etc.

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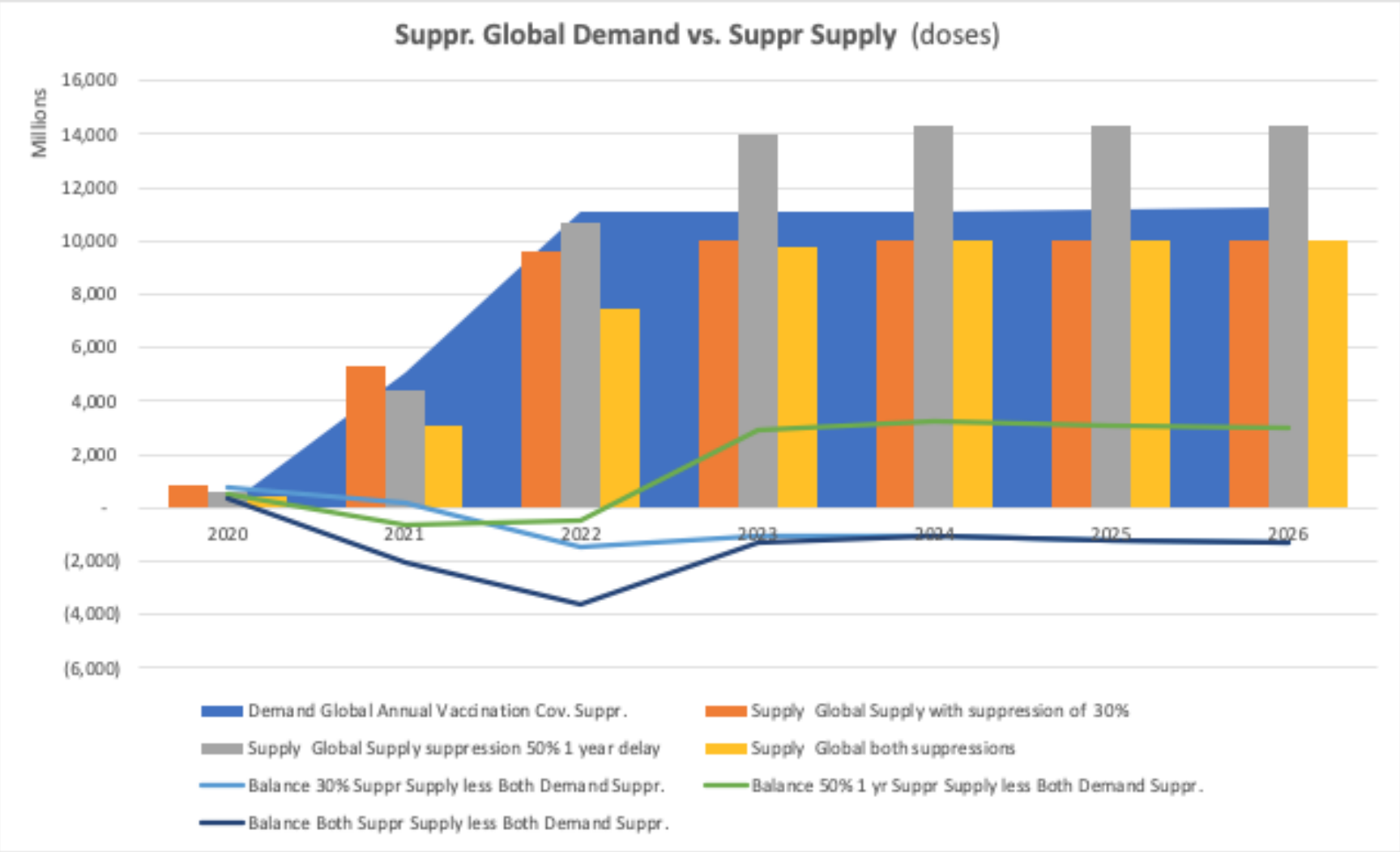
Scenario: Global Suppressed supply vs. Suppressed demand

UNICEF demand analysis



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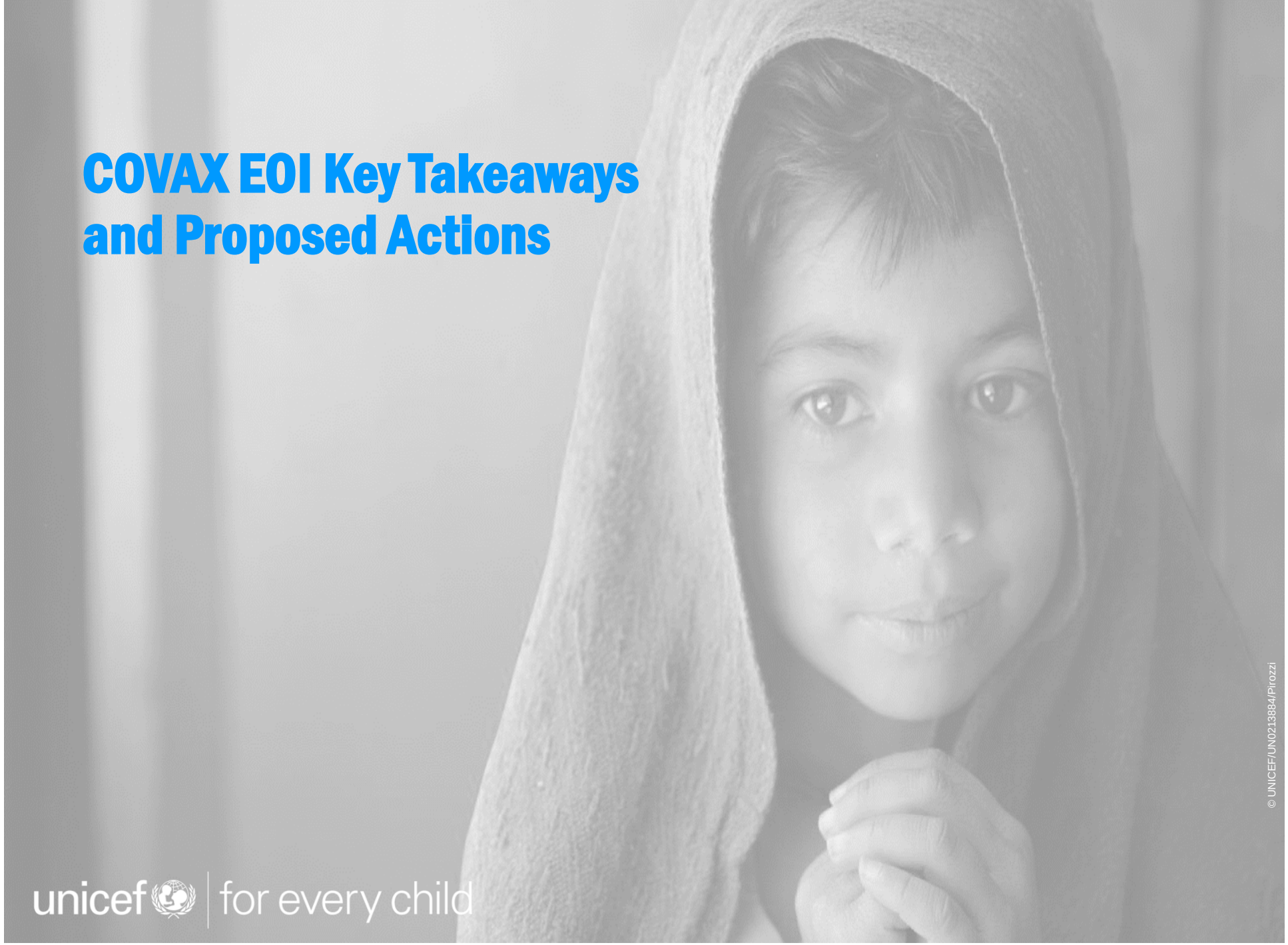
COVAX EOI Key Takeaways and Proposed Actions



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Key Messages

- Overall, and despite the fact that production volumes were not indicated by some manufacturers, the aggregate supply situation could not be more optimistic with massive and accelerated scale up of COVID-19 vaccine production planned
- Unprecedented rapid pursuit for discovery and availability of a vaccine, reducing what would normally take 10+ years to potentially 1-3 years
- The global COVID-19 vaccine portfolio has a healthy mix of platforms, manufacturing locations and partnerships
- Quantities in 2020-2021 will be tight compared to aspirational demand. Careful dose allocation will be key to maximise impact (country readiness, basis for allocation, etc.)
- It could be reasonable to assume that a vaccine will be available for widespread global roll-out starting in late 2022; but also likely that annual vaccination or booster doses will be needed
- Potential high dependency on manufacturers that have never taken a vaccine through WHO PQ
- Manufacturers have signalled a need for support and clear pathways on what could be major bottlenecks to supply:
  - WHO emergency use listing (especially in the context of large array of platforms)
  - Country licensure and registration requirements
  - Liability and indemnification

Will a COVID-19 vaccine be a silver bullet?

- Indications of global vaccine production is positive.
- The impact of a vaccine depends on **how long immunity lasts** and **the effectiveness of the vaccine**
- Likely to be different vaccines with different efficacy, different durations of protection, different and presentations
- Short duration and modest effectiveness may imply **booster vaccination or annual vaccination**
- The development of an antiviral medicine remains important. Most therapeutic research is currently around monoclonal antibodies/plasma – which is hard to scale, especially in low resource countries.

"We think that it will protect for about a year"
AstraZeneca CEO

"The durability of immunity [to common coronaviruses] *that is protective, ranges from 3 to 6 months to almost always less than 1 year"*
Director, NIH, A. Fauci

50% effective:
the WHO and FDA minimum standard for COVID-19 Vx

COVAX Procurement Timeline and Next Steps

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Procurement Timeline and Next Steps

3Q
PREPARE, 6 weeks

- Demand scenario for procurement
- Partner & industry agreement on Term Sheet
- Industry consultation
- Industry on-boarding for new suppliers
- Procurers' consortium / consultation
- COVAX Reference Group
- Partner consultation
- Country Indications
- Alignment with safety injection equipment

3Q
PROCURE, 6 weeks

- Procurement process finalized and launched
  - E.g. in early phase, COVAX Facility enters into Advance Purchase Agreements with manufacturers.
  - UNICEF procurement process and engagement with manufacturers will be guided by these agreements.

4Q
CONTRACT, 10 weeks

- Launch pooled procurement platform for all COVAX procurers
  - E.g. Framework agreements in place with manufacturers including base terms, and then updated with call options once commercial terms set
  - Clearing house for relevant intelligence sharing
  - Agreements in place to facilitate access by other procurers to contracted doses, etc.

2020-2021
DELIVER

- Draw-down on manufacture-specific call options within agreements
  - E.g. As a product meets the TPP, and WHO allocations are defined, call options is activated.
  - COVAX buyers trigger draw-down on quantities directly with manufacturers
  - Deliveries commence

Procurement enablers:

- COVAX country membership scope defined
- Membership will need to address licensing/pre-licensure, indemnification, vaccine injury compensation, level of commitment, etc.
- COVAX allocation/delivery trigger process outlined
- Country readiness, including pharmacovigilance systems, and cold chain

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Thank You

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Participant Q&A