



**Expression of Interest for
supply of COVID-19 vaccines**

Public version, 4 August 2020

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

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

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**

26 respondents to EOI

Anhui Zhifei Longcom
Biopharmaceuticals
Astrazenica
Aurobindo Pharma Limited
Beijing Biominhai
Beijing Institute of Biological Products
Bharat Biotech International Limited
Biological E Limited
Chengdu
Chumakov
FSUE
GSK
Indian Immunological
Janssen
Merck MSD
NingBo RongAn Biological Medicine
Novavax
Panacea Biotec
Pfizer
Sanofi Pasteur
Shionogi & Co.
Serum Institute of India
Sinocelltech
Sinovac
SK Bioscience
Stemirna Therapeutics
Takeda
Walvax Biotechnology
Wuhan

- **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**

Following up with 7 additional manufacturers

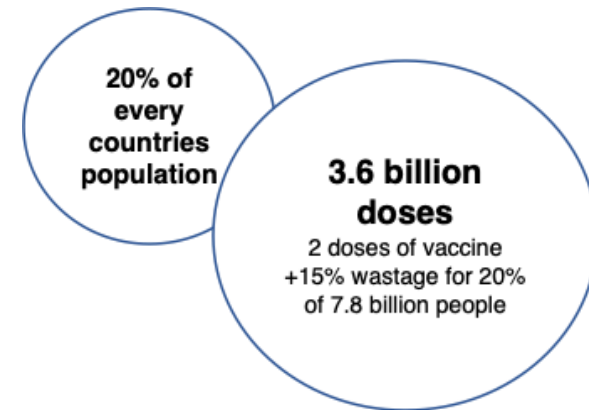
Fiocruz
Biomanghinous
CSL
Innovio
Moderna
Kunming Institute
VGH

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.**

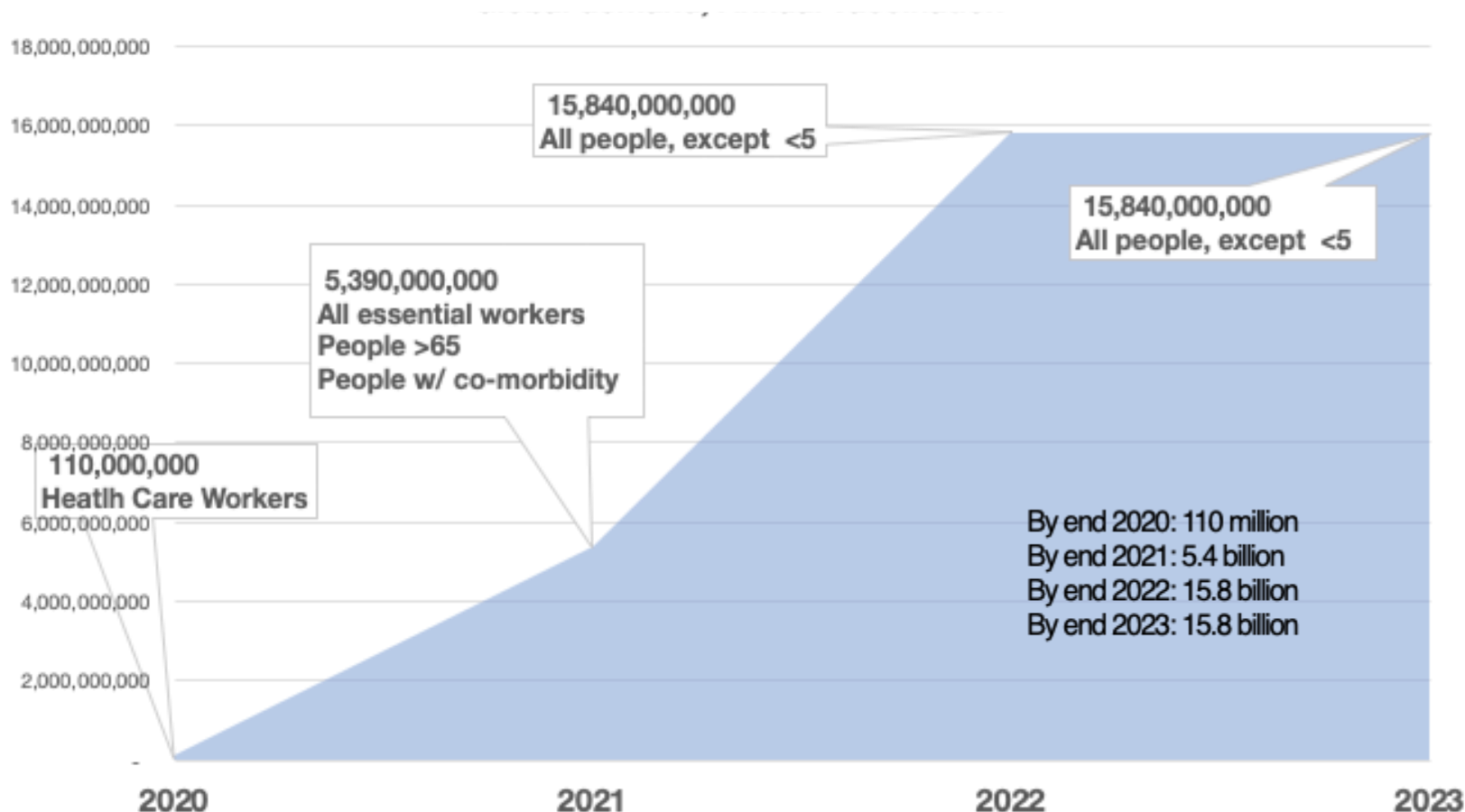
The current draft allocates as follows:

- 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.



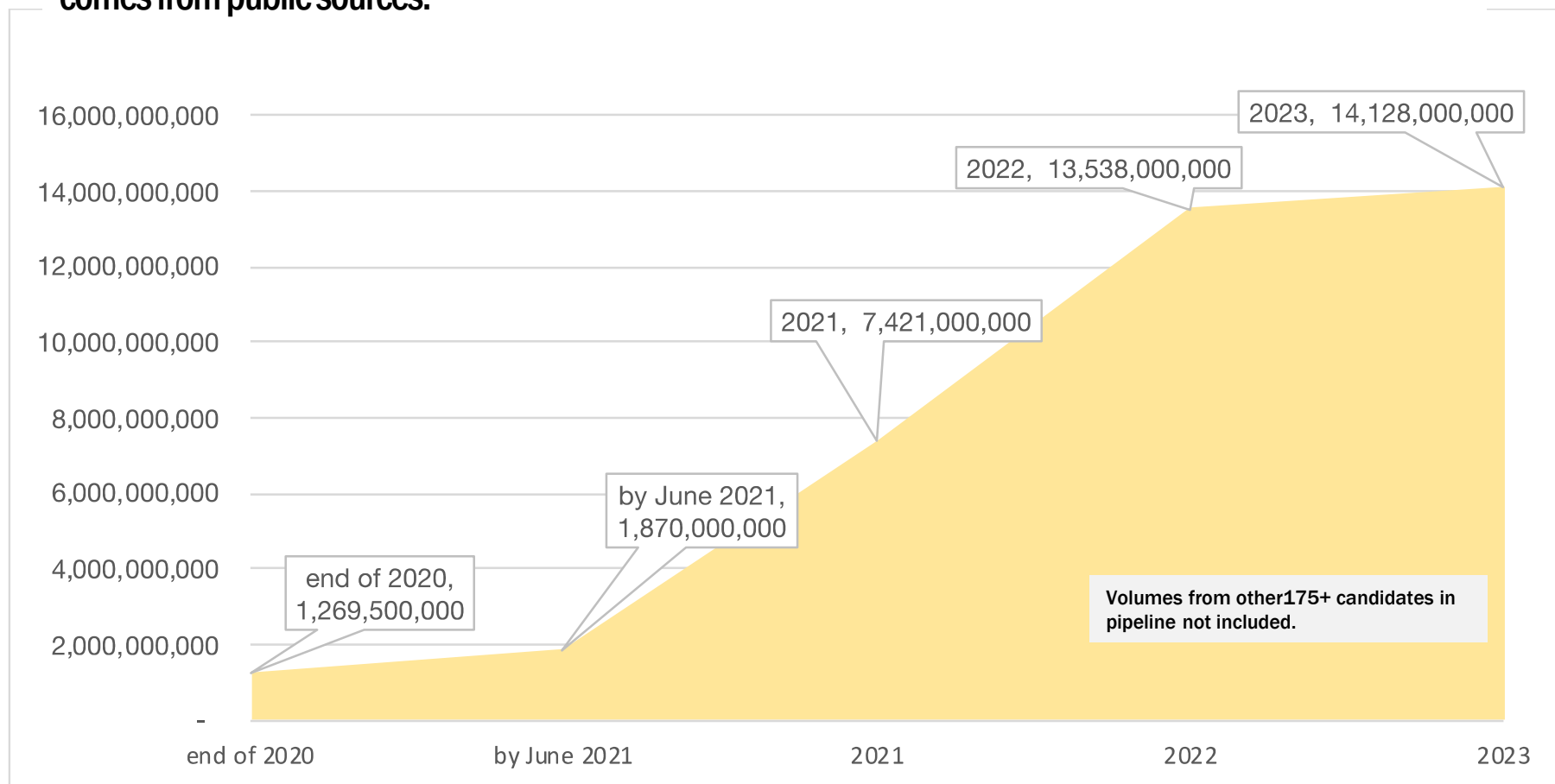
Global demand scenario

This scenario models the following demand curve: 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



How many doses were indicated by manufactures globally?

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

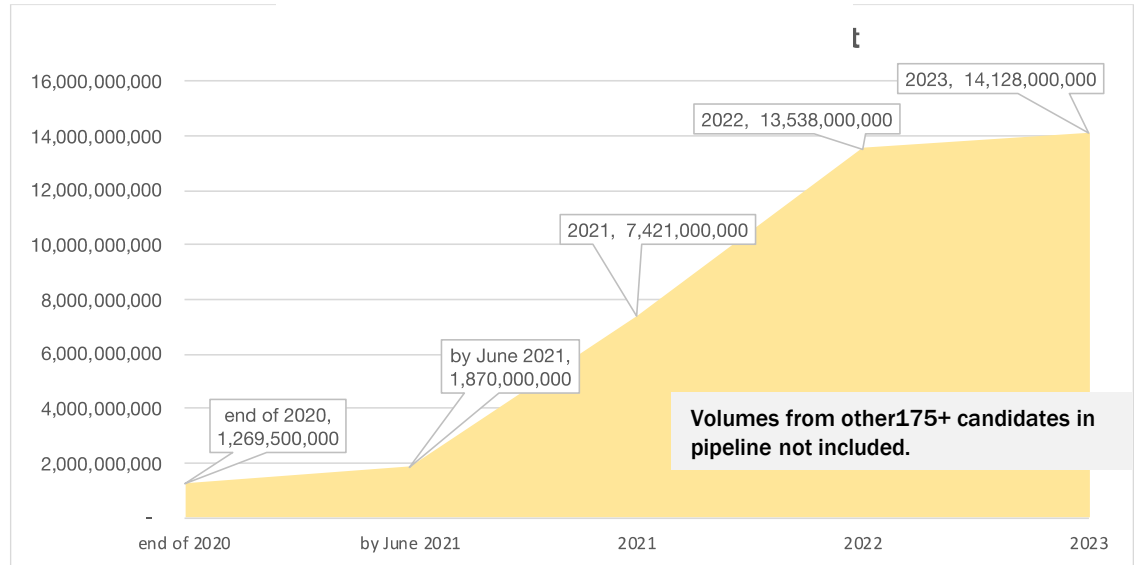


Global indicated volumes compared with global demand scenario

Indicative Volumes

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

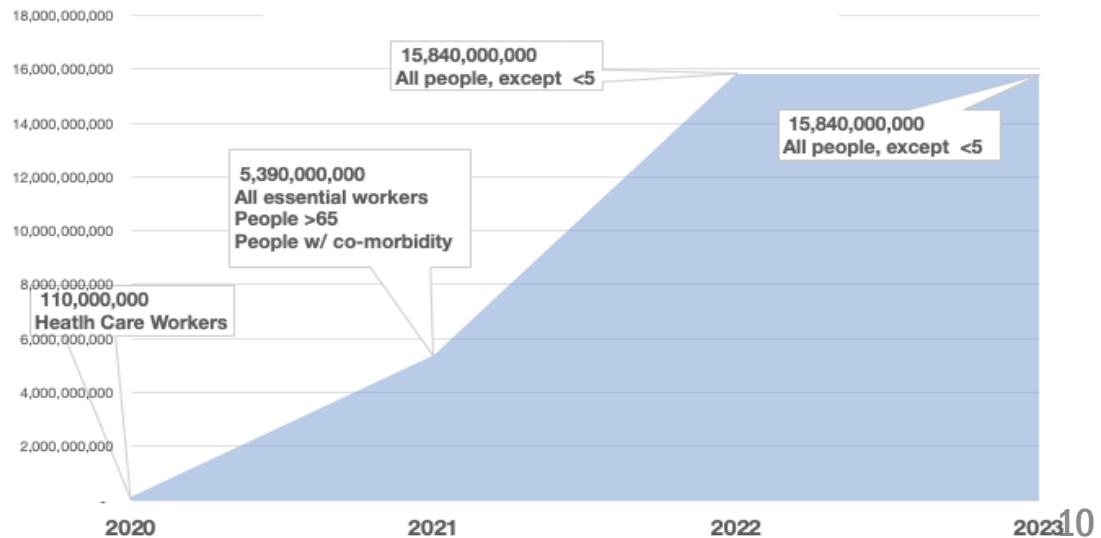
By end 2020: 1.3 billion
 By June 2021: 1.8 billion
 By end 2021: 7.4 billion
 By end 2022: 13.5 billion
 By end 2023: 14.1 billion



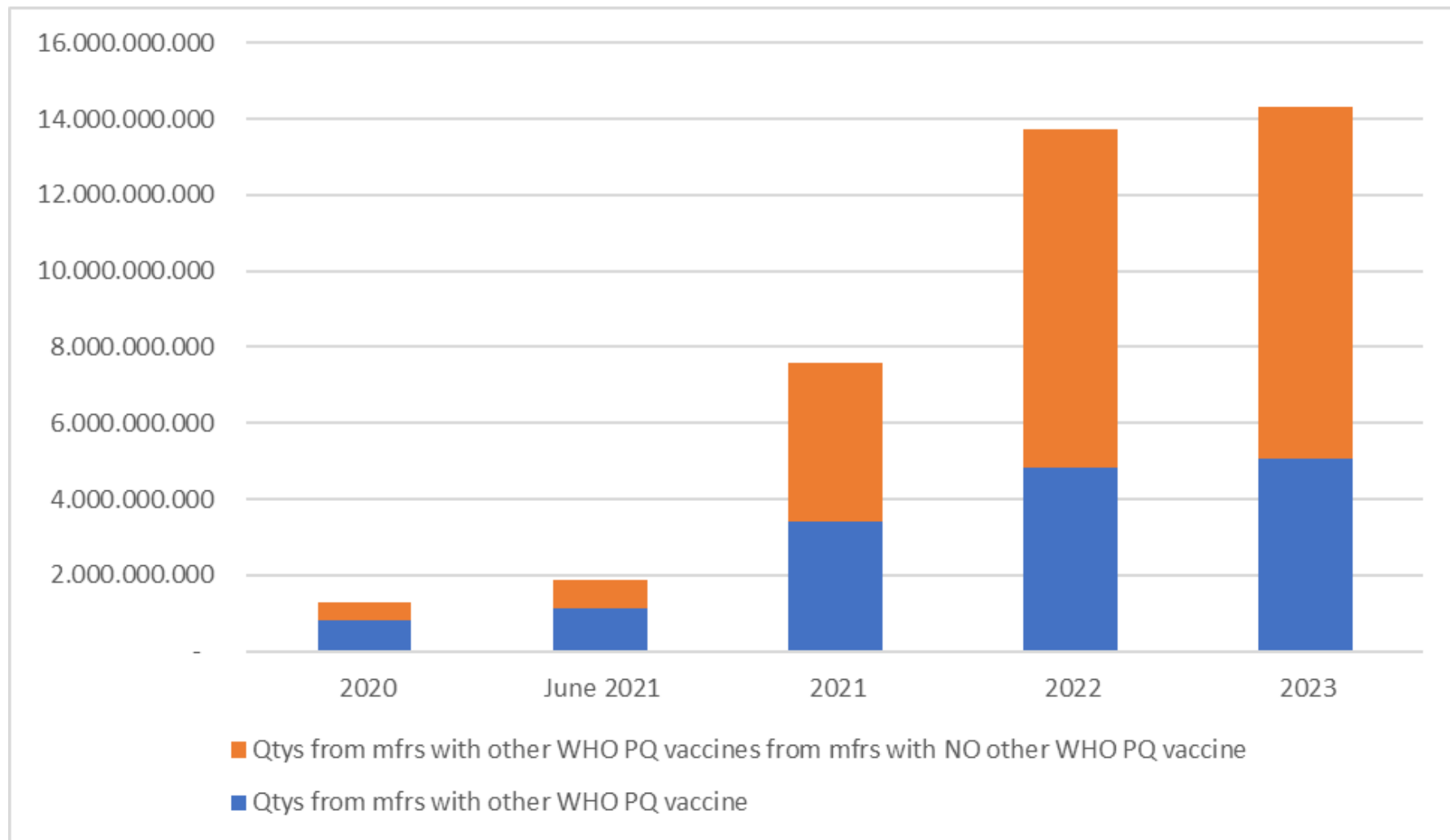
Demand Scenarios

Global demand scenario, annual vaccination

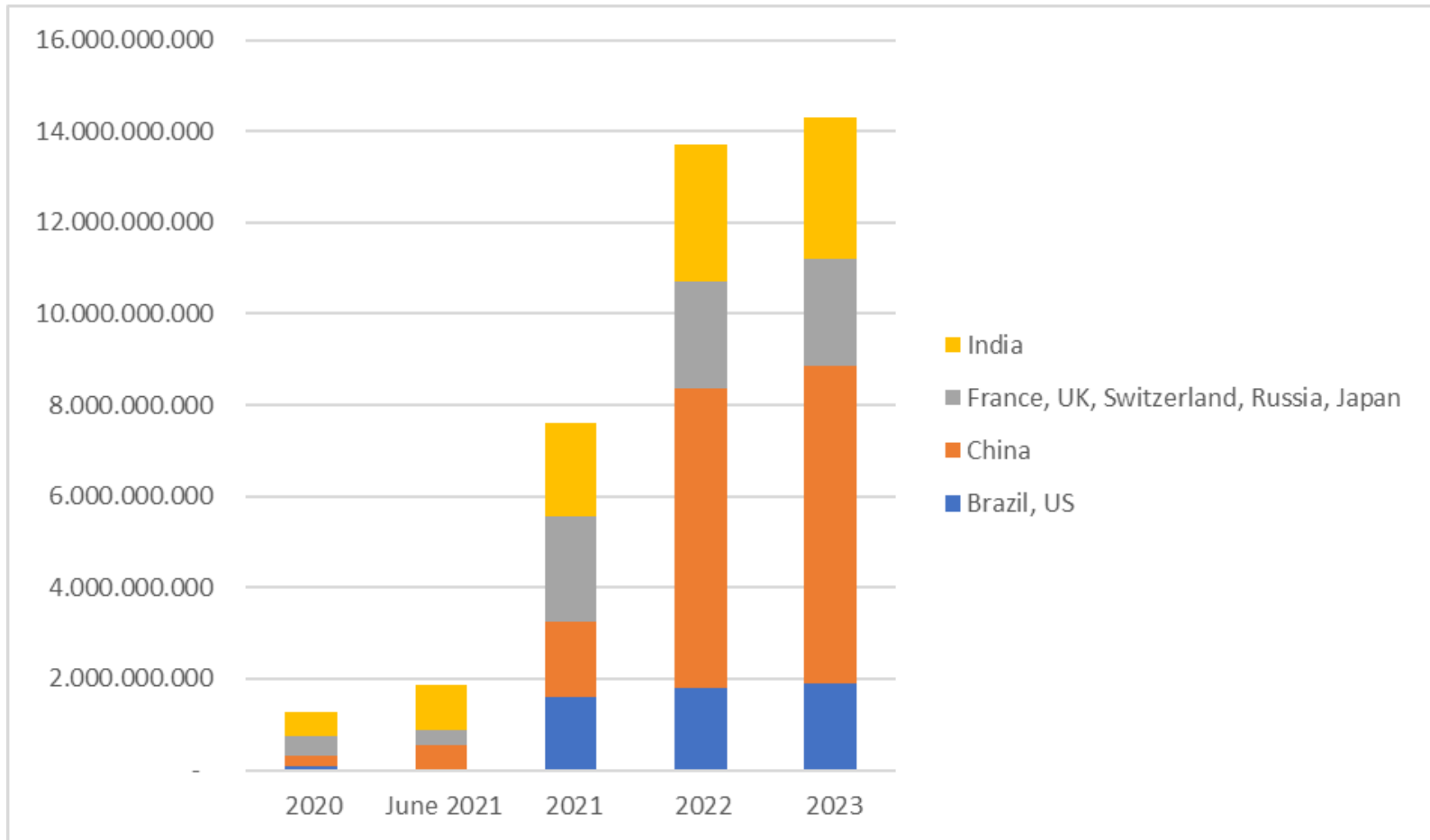
By end 2020: 110 million
 By end 2021: 5.4 billion
 By end 2022: 15.8 billion
 By end 2023: 15.8 billion



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

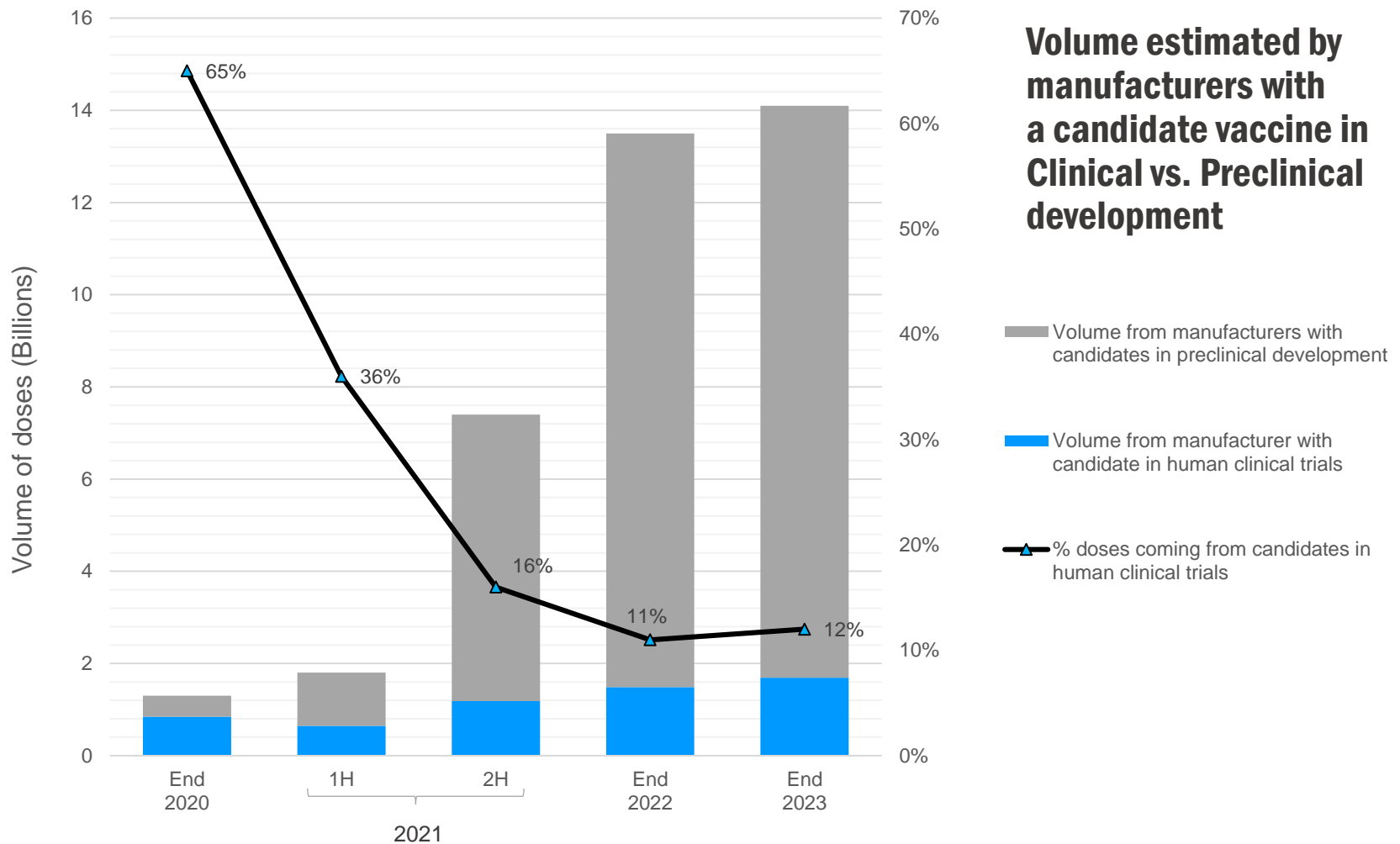


Projected annual manufacturing quantities by location of manufacturing



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

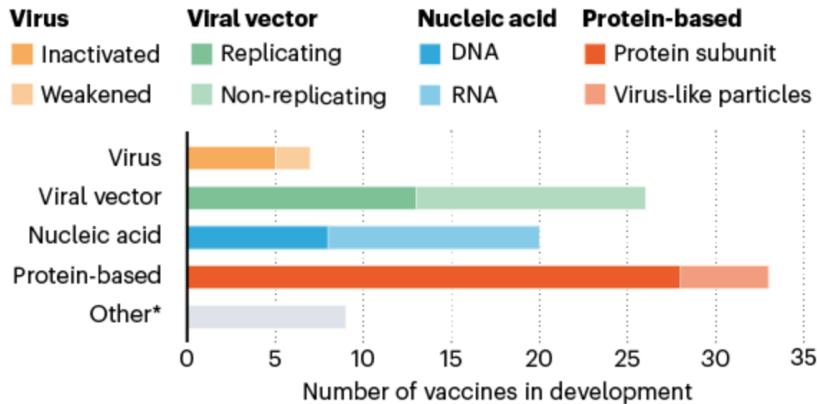
How far along in development are candidate vaccines?



Vaccine platform

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

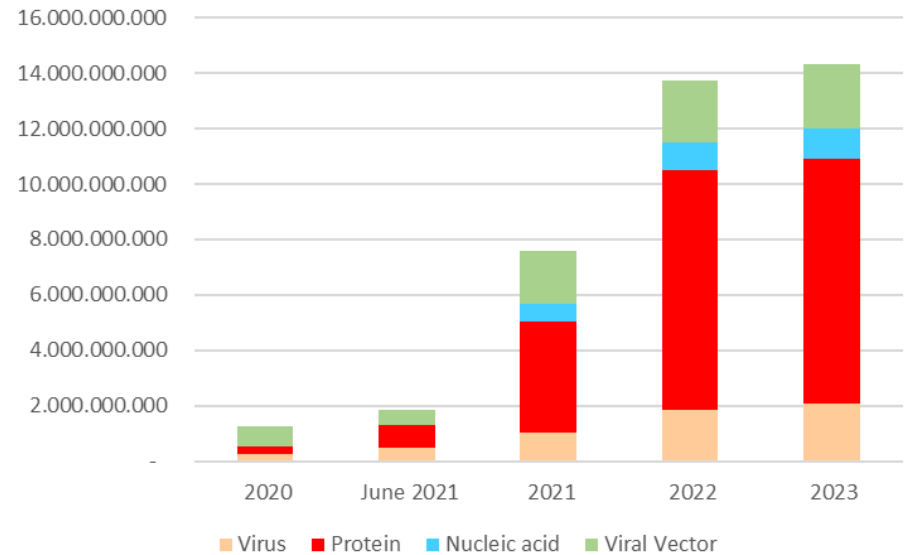
AN ARRAY OF VACCINES



* Other efforts include testing whether existing vaccines against poliovirus or tuberculosis could help to fight SARS-CoV-2 by eliciting a general immune response (rather than specific adaptive immunity), or whether certain immune cells could be genetically modified to target the virus.

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Qty by Platform by Year - *indicative*



Vaccine platforms have different risks and pace

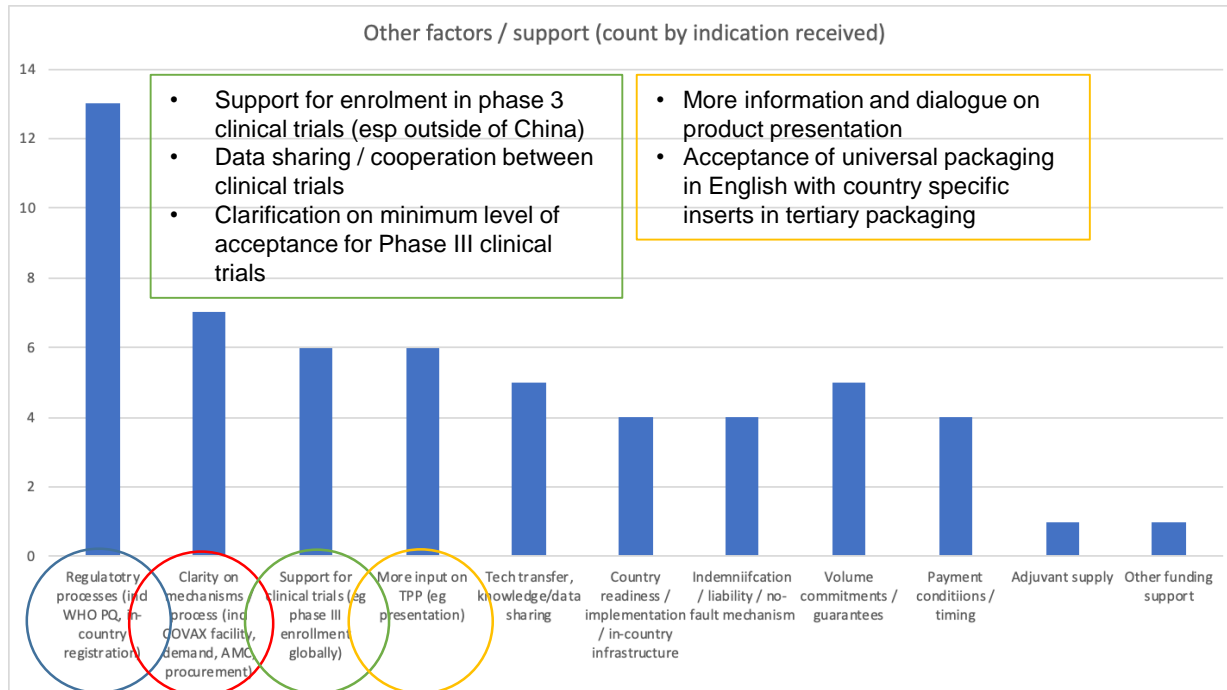
PLATFORM	Indicated global volumes 2020-23	Manufacturers indicating platform and volumes
Virus: Weakened or inactivated. More safety testing. Majority of current Vx.	5.7 billion 17%	Beijing Biom., Biejing Inst., Bharat1, Bharat2, Chum, NingBo, Panacea, Sinovec, Wuhan, Indian Imm.
Viral vector: Modified. Safer. Ebola is a replicating viral vector Vx. No non-replicating Vx has been licensed.	17 billion 49%	Anhui, BioE, FSUE, Novavax, Sanofi, Sinoceltec, Walvax1
Nucleic acid: Easy to develop and mfr, 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, AstraZenica, 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



- 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

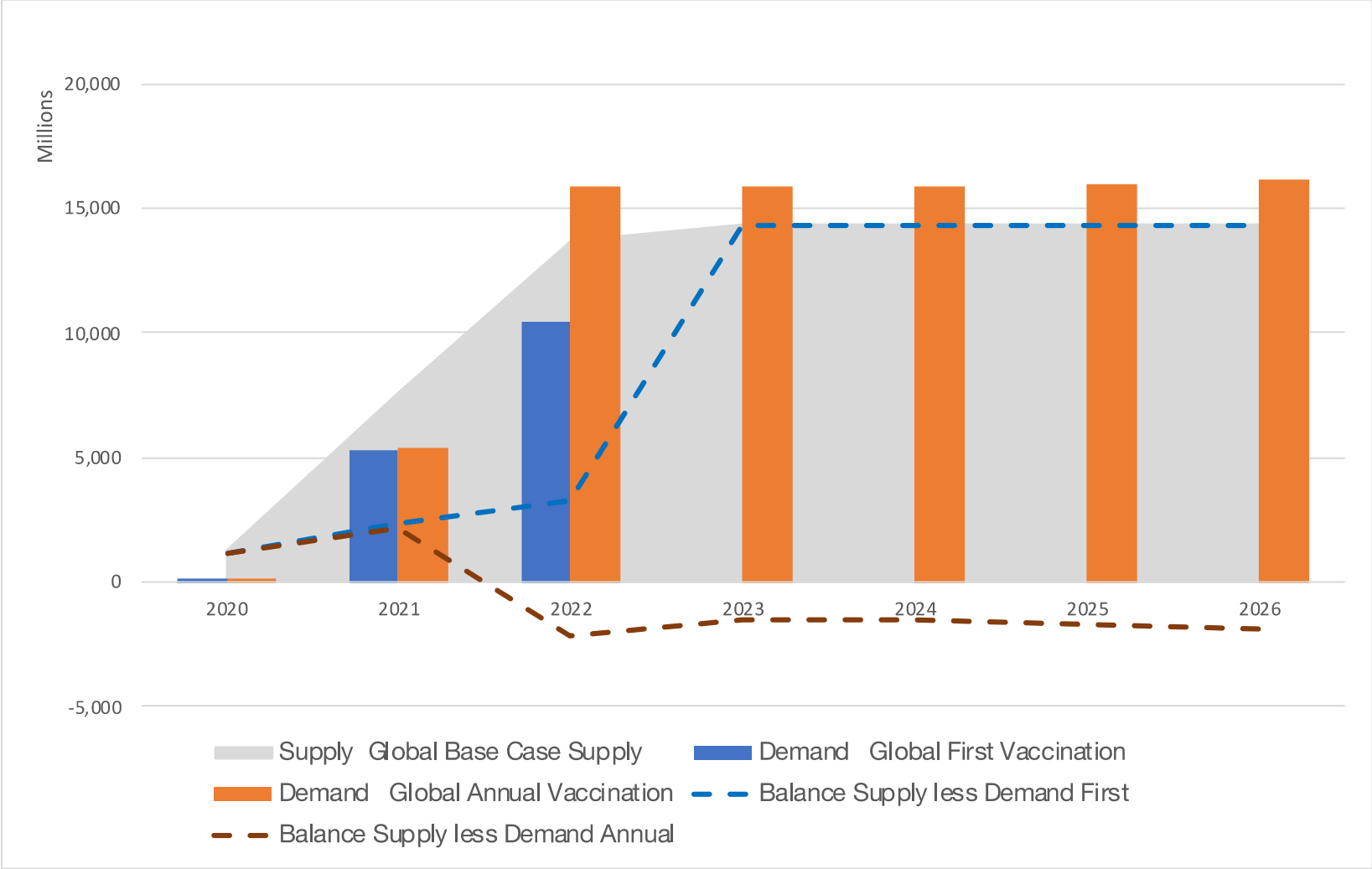
Vaccine specifications

[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 vial 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

COVAX EOI Volume Implications (Demand vs. Supply Scenarios)

Global Base case supply vs. Base case demand



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

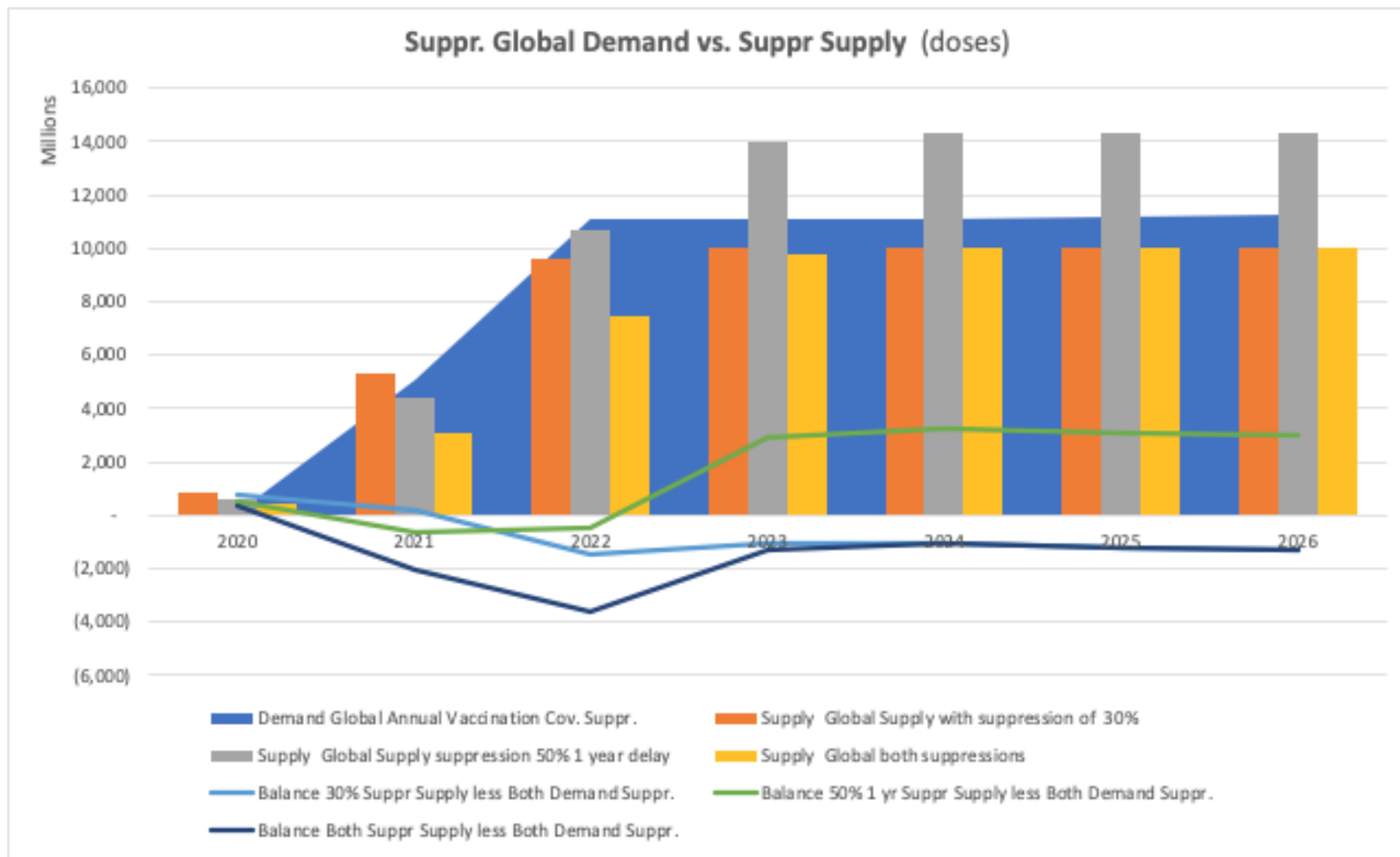
Suppressed Supply assumptions

- 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.

Global Suppressed supply vs. Suppressed demand



COVAX EOI Key Takeaways and Proposed Actions



Key Messages

- Overall, including given the volumes not included, the supply situation could not be more optimistic in terms of massive scale up of Covid-19 vaccine.
- Unprecedented rapid pursuit for discovery and scale-up of a vaccine. Reducing what would normally take 10-20 years to potentially 1-3 years
- The vaccine portfolio has a good mix of platforms, manufacturing locations and partnerships
- Quantities in 2020-2021 will be tight. Demand 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 roll-out starting in late 2022; likely that annual vaccination or booster will be needed
- Potential high dependency on manufacturers that have never taken a vaccine through WHO PQ
- Manufacturers need 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

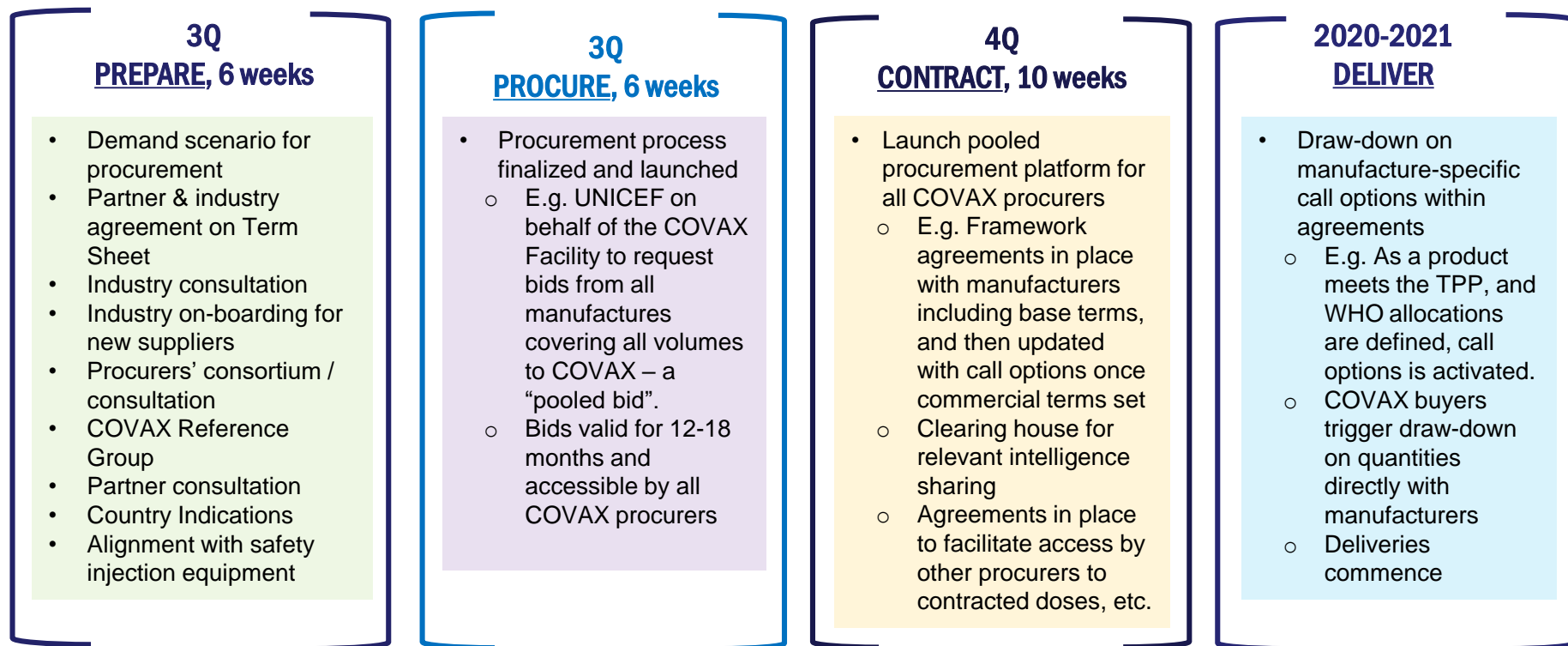
“The durability of immunity [to common coronaviruses] that is protective, ranges from 3 to 6 months to almost always less than 1 year”
Director, NIH, A. Fauci

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



COVAX Procurement Timeline and Next Steps

Procurement Timeline and Next Steps



Procurement enablers:

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



Thank You

For questions or more information, please contact:

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