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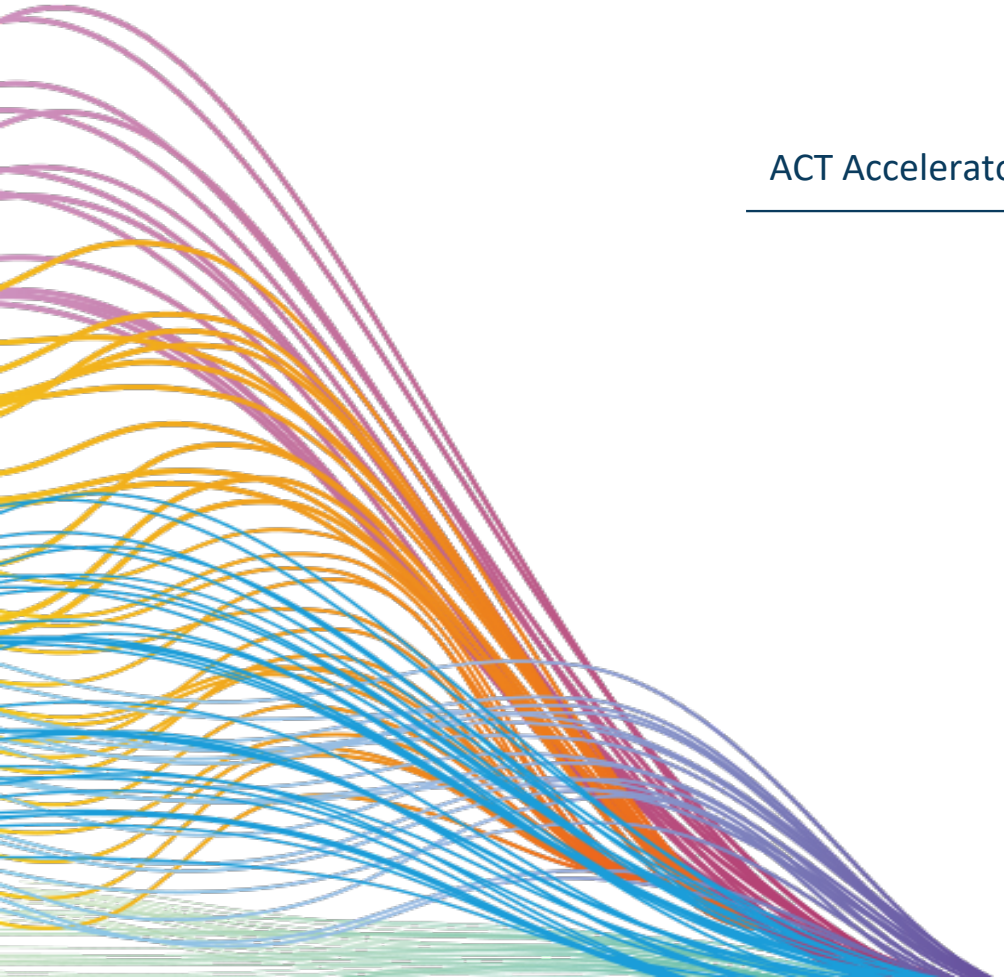

# MS COVID BRIEFING

## ACT Accelerator Update, COVID-19 Vaccination & Evolving Issues

**10 JUNE 2021**

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# ACT-A events & recent developments

Dr Bruce Aylward, Senior Advisor to the Director-General

# 4 major ACT-A/COVAX events of past 2 weeks emphasize equity for Vx, Dx, Tx, PPE

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**G20/EC Global Health Summit** (21 May)


**IMF "Proposal to end the Pandemic"** (21 May & 1 Jun)


**World Health Assembly** incl. IPPPR (24 May – 1 Jun)

**Gavi COVAX AMC Summit** (2 June)

# IMF ‘Proposal to End the Pandemic’

**Vaccinate 40% in all countries by end-2021 & 60% by mid-2022**

- immediate grant of $4bn to COVAX
- end trade & export barriers
- donate at least 1bn doses

**Invest $50B to end pandemic in 12 months**

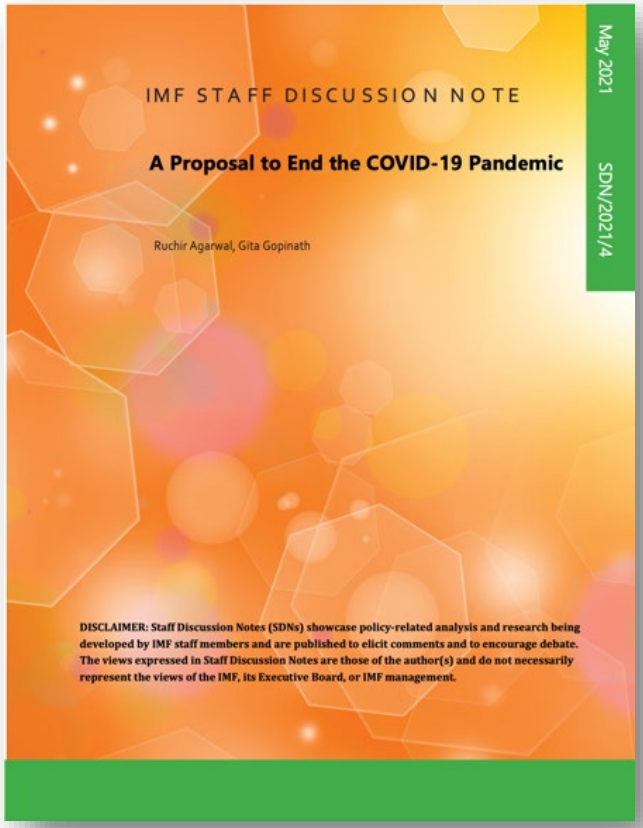
- $35bn in grants (incl 22bn for ACT-A)
- $15bn from MDBs

**Manage disease & risks in parallel**

- widespread testing, Tx, PPE (invest $30 Bn)

**Track & secure against downside risks**

- invest at-risk to increase Vx production
- scale up genomic surveillance



# World Health Assembly: ‘Sprint to Sept’ & ‘Drive to Dec’

***Director-General Dr Tedros Adhanom Ghebreyesus opening remarks, 24 May***

“I call on Member States to support a massive push to **vaccinate at least 10% of every country by September**, and a **“drive to December” to vaccinate at least 30% by the end of the year**.

**Sprinting to our September goal means we must vaccinate 250 million more people in LMICs in just four months**, with all health workers and the most at-risk groups as the first priority.”

# AMC Summit announcements to COVAX (2 June)

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- **US$ 2.4 Bn** (total $9.6 Bn for procurement & $775 Mn for delivery)
- **Vx dose donations 54Mn**
- **1.8bn doses for AMC countries**


**$800 Mn USD**

**$50 Mn USD**

**$50 Mn USD**

**220 Mn CAD**

**100 Mn EUR**

**> 71 Mn EUR**

# June 9: US announces 500M dose donations ahead of G7

EUROPE NEWS JUNE 10, 2021 / 8:07 AM / UPDATED AN HOUR AGO

**Biden to announce donation of 500 million Pfizer doses, urge others to join in**

By Steve Holland, Andrea Shalal 5 MIN READ

**US has bought and will donate 500 million doses of Pfizer's vaccine worldwide**

By Kaitlan Collins and Maegan Vazquez, CNN
Updated 1905 GMT (0305 HKT) June 9, 2021

**US 'to buy 500 million Covid vaccine doses for world'**

7 hours ago

Coronavirus pandemic

- President Joe Biden announced on June 9 that the US will donate **500M doses** of the **Pfizer-BioNTech vaccine** over the next **2 years**
  - **200M** doses will be distributed **2021**, shipments starting in Aug
  - **300M** in the first half of **2022**
- Donations will **go through COVAX** aimed at the to AMC92 countries
- Biden plans to announce **further details** as part of the **G7 meeting**

# Upcoming Key Events for ACT-Accelerator

| | |
|---|---|
| **G7 Summit** | 11-13 June |
| **7th Facilitation Council** | July, date tbc |
| **ACT-A Strategic Review** | July-Sept, tbc |

# Global vaccine roll-out & regulatory themes

Dr. Soumya Swaminathan, WHO Chief Scientist

Dr. Mariângela Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals

# 2.2 Bn doses of COVID-19 vaccine now administered1 in 215 countries, areas, territories & economies[2]

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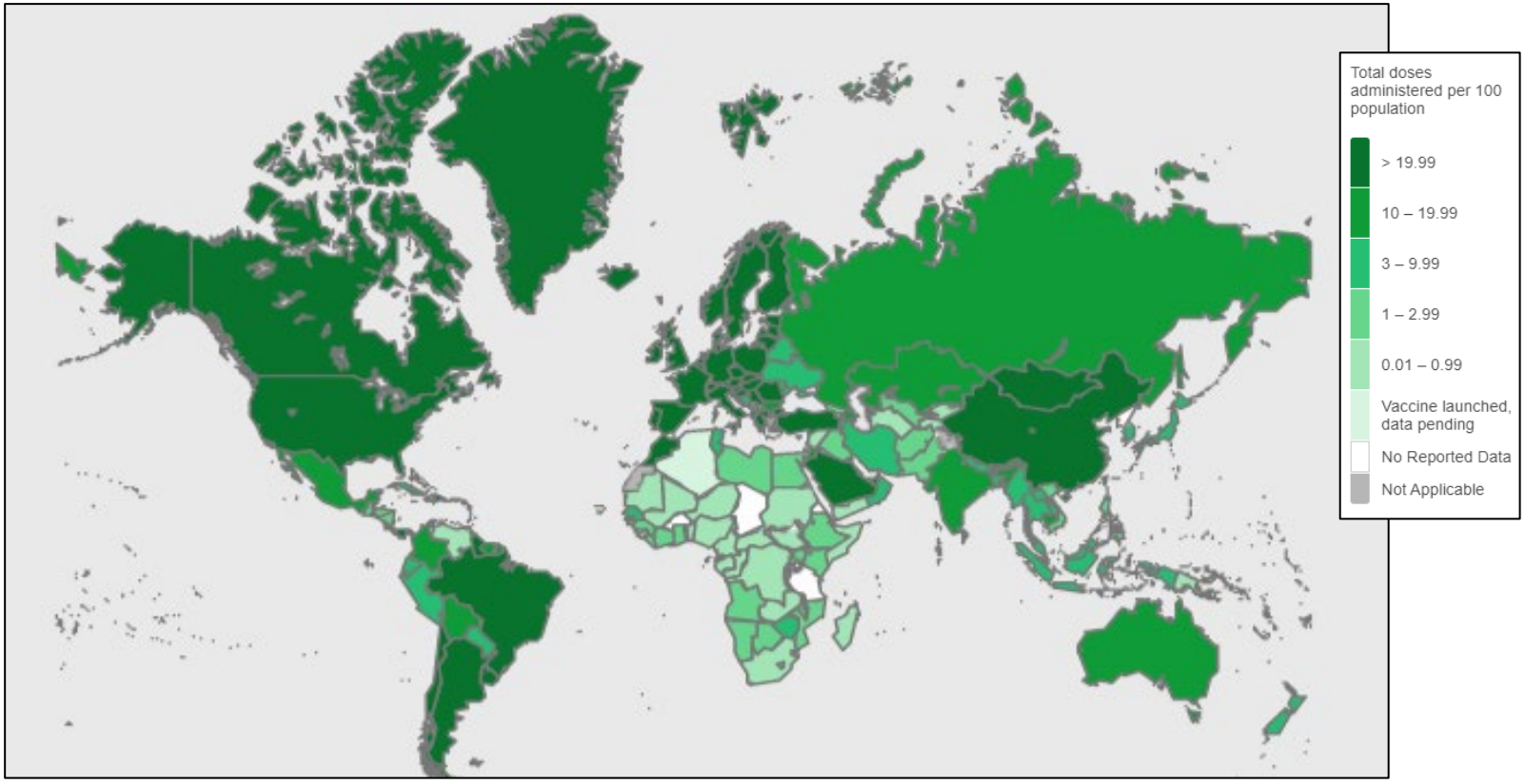
Total doses administered per 100 population[3]




Vaccination **has not yet started in 5 countries[2]**

Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

1. Source of data: Bloomberg; 2. Total of 220 countries, areas, territories & economies: 218 economies listed by World Bank + WHO Member states Cook Islands + Niue
3. WHO COVID-19 Dashboard at https://covid19.who.int/ ; 4. Including donations of doses through COVAX

# COVAX has now shipped 81.8M doses to 129 participants

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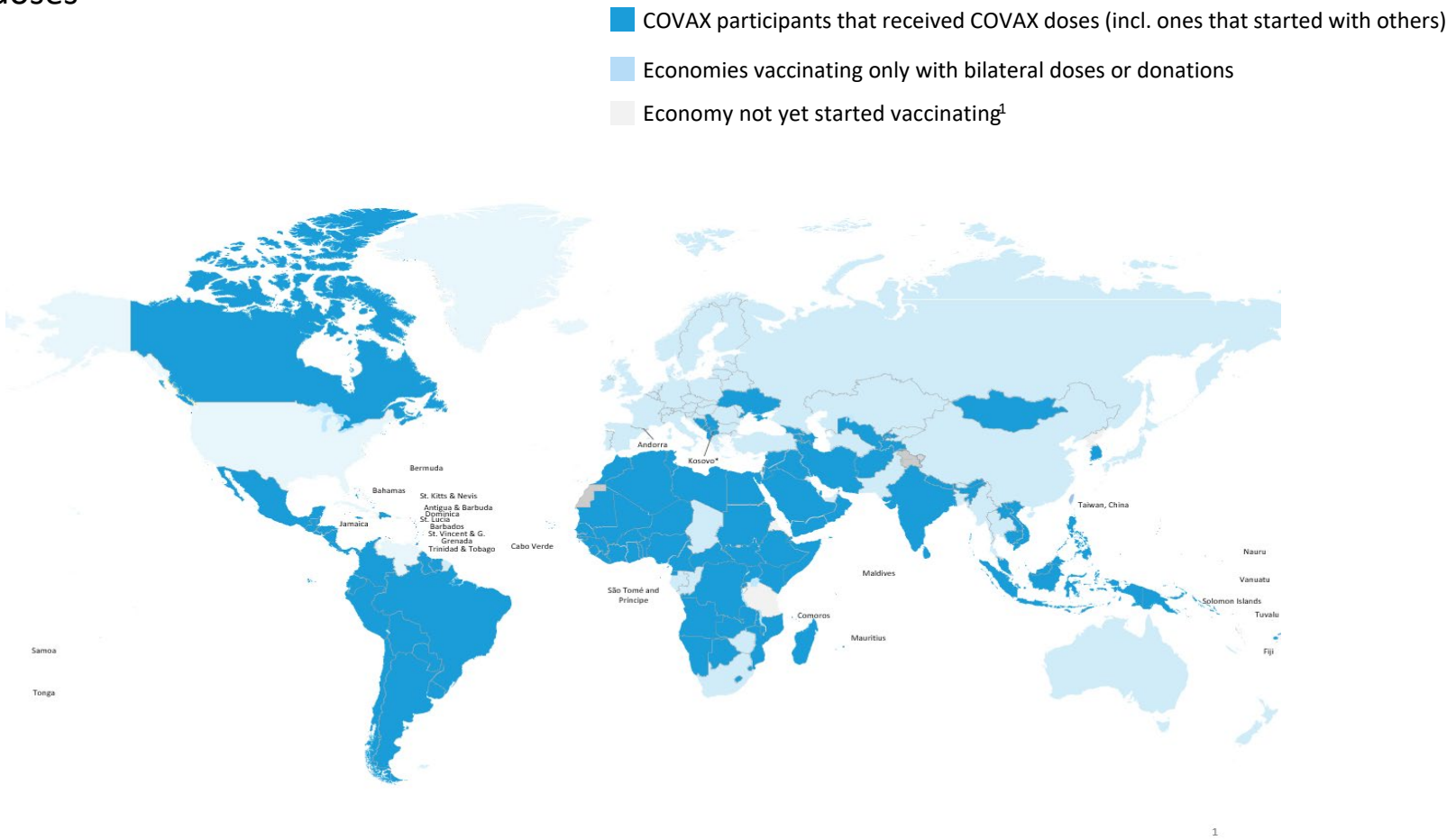
Incl. 67 LMIC/LICs; 40 participants started their first campaigns thanks to COVAX doses




1. Burundi, Eritrea, United Republic of Tanzania, Haiti, Democratic People's Republic of Korea

Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

*Kosovo: All references to Kosovo should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Source: COVAX, WHO COVID -19 dashboard, Our World in Data; Government websites; Press research

# Of WHO's 194 Member States, 189 have now started COVID-19 vaccination

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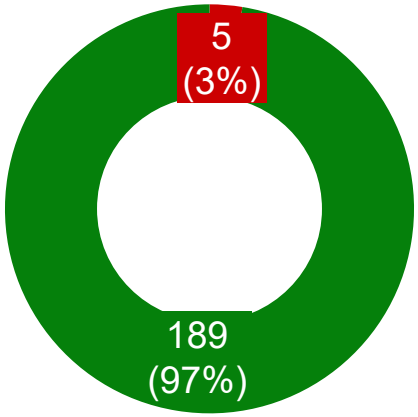
**Status of COVID-19 vaccine roll out** Started Not started

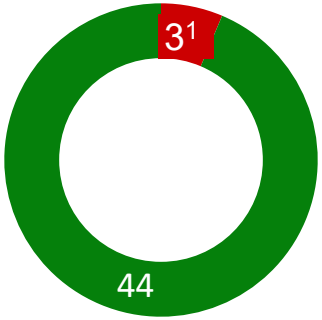
## WHO Member States

N= 194



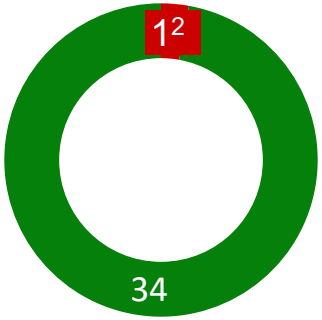

## AFRO

N= 47



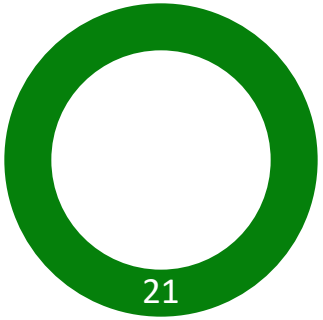

## AMRO

N= 35



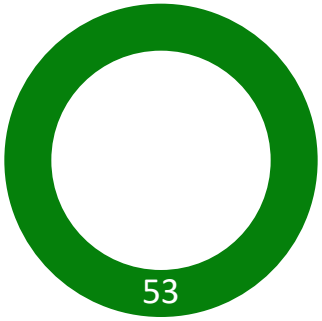

## EMRO

N=21



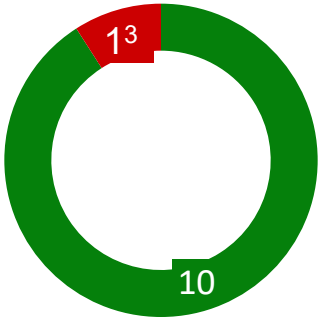

## EURO

N= 53



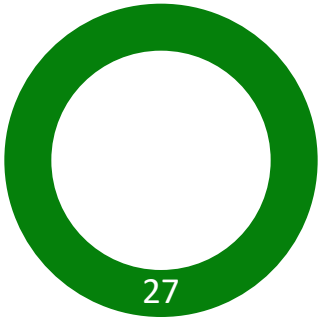

## SEARO

N= 11




## WPRO

N=27




1. Burundi, Eritrea, United Republic of Tanzania
2. Haiti
3. Democratic People's Republic of Korea

Source: WHO COVID-19 dashboard, COVAX, Our World in Data; press reports

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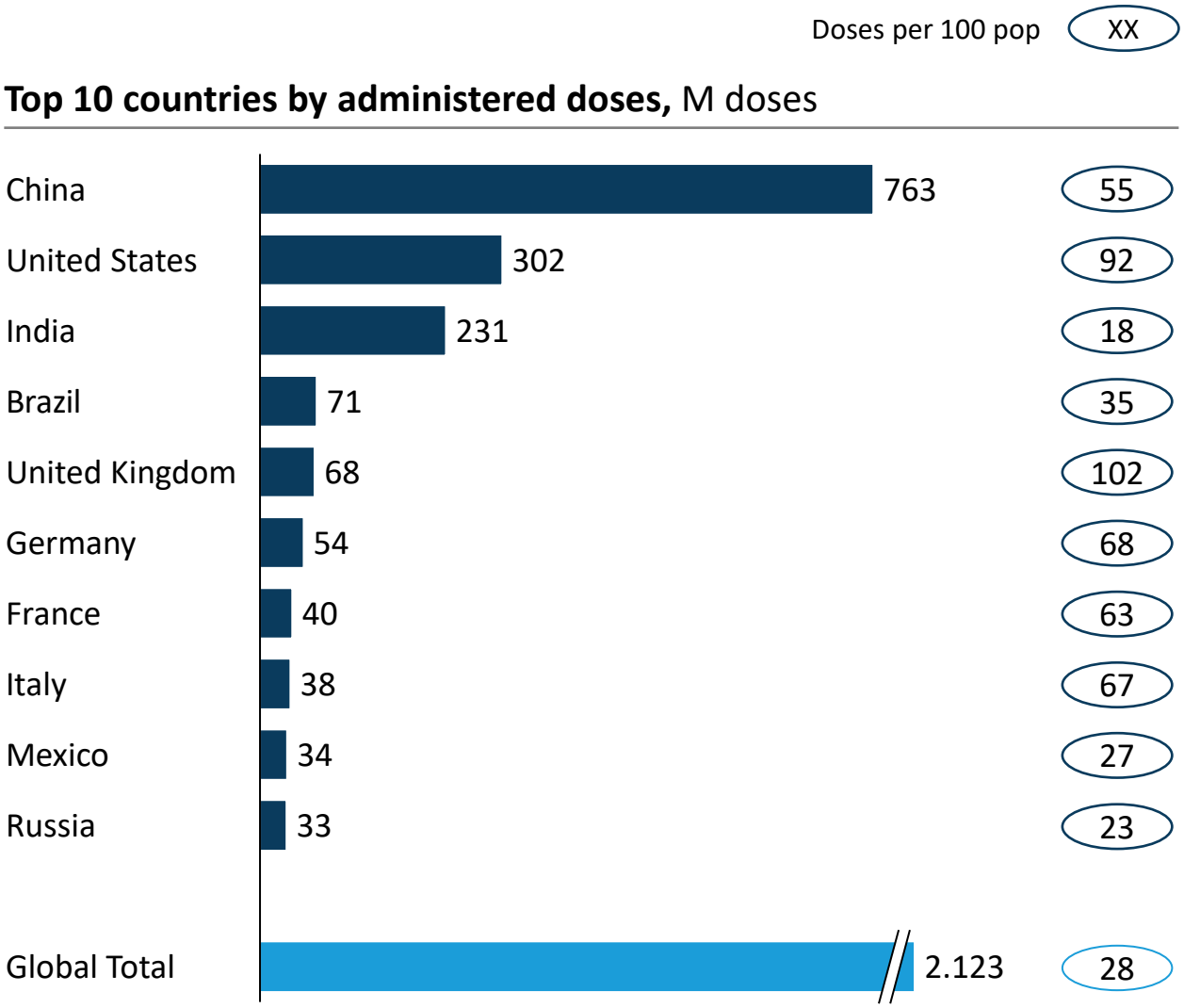
# 10 countries administered 77% of all doses




Source: Bloomberg

**61%**

of all doses were administered by **top 3** countries

# Upcoming COVAX Allocation Rounds: impt updates

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**Round 4:** Jul/Aug AZ doses for SII participants waiting 2nd doses (~16 m)

**Round 5:** J&J, Pfizer & remaining AZ supply for Q3 (total max. 66 m)

Allocation team **assessing transition to Phase 2 strategy for subsequent rounds** (i.e. coverage, mortality rates/trend, absorptive capacity)

**Distribution of 'additional doses'** between allocation rounds continues to be managed by **SWAT & JAT** (e.g. FR dose-sharing, re-distributions)

# Countries now announced further sharing of 145+ m doses, most through COVAX, but timing still challenge (i.e. Q3 gap)

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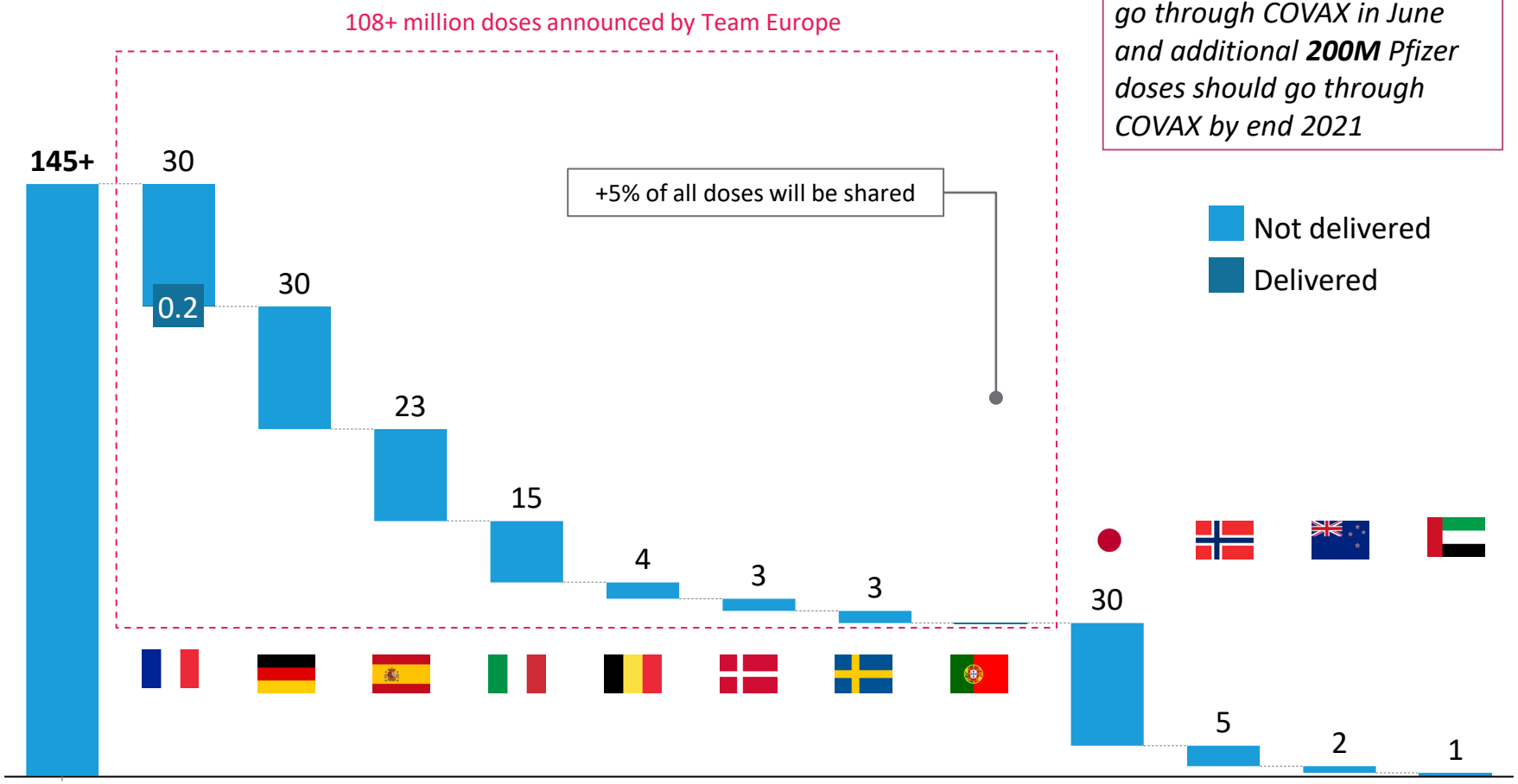
*Doses to be shared* (as of 10 June 2021), M doses

*White house announcement that **75%** of **80M** doses will go through COVAX in June and additional **200M** Pfizer doses should go through COVAX by end 2021*




NOTE: all figures are rounded
Source: Gavi

# COVAX Supply chain & Manufacturing Taskforce
# Status update for the four workstreams

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| Workstream and conveners | Status to date |
|---|---|
| 1 **Immediate COVAX Response (1-3 months)** *Resolve upstream supply constraints* — CEPI | • Initiated **engagement with WTO and WCO and industry stakeholders** to identify options for **facilitation of customs and trade**<br>• Launching **"Input supply marketplace/Exchange"** |
| 2 **Mid-Term COVAX Response (until 2022)** *Expansion of workforce and match-making between manufacturers* — CEPI, Gavi | • Identified **resourcing bottlenecks**, reaching out to **relevant training providers;** developing intervention plan to facilitate **critical workforce travels and immunization**<br>• Developed proposal to improve **Fill Finish matchmaking** |
| 3 **New and expanded sustainable capacity in LMICs** *Technology hub to enable multilateral tech transfers* — World Health Organization | • Completed call for **Expression of Interest for mRNA** hub tech transfer with **50+ respondents** and **initiated due diligence process**<br>• Issued **concept note** consulting key stakeholders and launching **working groups with partners** to support implementation |
| 0 **Shared fact base / Task Force Coordination Office** — CEPI, Gavi, World Health Organization, unicef | • Developed and shared **ecosystem mapping**<br>• Developing a **common supply outlook for expected Vx supply in 2021-23** |

# Travel for Vx workforce

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## Key challenges around travel of Vx workforce

- Difficulties for technical support personnel to enter some countries to **solve manufacturing glitches**
  - E.g., need to be vaccinated, go through quarantine, long travel approval processes, differentials in paperwork required between regions
- Currently there exist **little to no travel exemptions** for Vx workforce
- Travel restrictions for Vx workforce can lead to **disruptions of production** and supply

Member states should look into all available options to facilitate the travel of Vx workforce

# With the addition of Sinovac on 1 June, 8 vaccines have now received WHO EUL

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## 8 vaccines listed

Pfizer/BioNTech,

AZ/SII

AZ x 2 (SK/Bio; EU sites)

J&J

Moderna

Sinopharm (BIBP only)

Sinovac

**SAGE Interim Policy Recommendations** exist for all products with WHO EUL

## Pending

Gamaleya – pending documentation; GcP inspections in April (with EMA); GMP inspections in 4 sites from May 10 to June 3 (2 with EMA)

**IMPT: many donations will require further EULs due to non-COVAX production sites!**

# WHO validated Sinovac COVID-19 vaccine for emergency use and issued interim policy recommendations on 1 June

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## Emergency use listing

On June 1st, WHO **validated the Sinovac-CoronaVac COVID-19 vaccine for emergency use**, giving stakeholders assurance that it meets international standards for safety, efficacy and manufacturing.

---

## Policy recommendations from WHO's Strategic Advisory Group of Experts on Immunization (SAGE)

On the basis of available evidence, **WHO recommends the vaccine for use in adults 18 years and older**, **in a 2-dose schedule** with a **spacing of two to four weeks**.

Vaccine efficacy results showed that the **vaccine prevented:**

- **Symptomatic disease in 51% of those vaccinated**
- **Severe COVID-19 and hospitalization in 100%**

While limited adults over 60 were enrolled in clinical trials, **WHO is <u>not</u> recommending an upper age limit for the vaccine** given data collected during subsequent real-world use (efficacy and no heightened safety concerns)

# WHO published a simplified naming scheme for variants with neutral language (Greek letters)

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| | New WHO name | Transmissibility | Immune evasiveness | Vaccine effectiveness[2] |
|---|---|---|---|---|
| **Ancestral** | … | ___ | ___ | ✓ |
| **D614G** | … | + | ___ | ✓ |
| **B.1.1.7** | Alpha | +++ | ___ | ✓ |
| **B.1.351** | Beta | + | ++++ | ✓ |
| **P.1** | Gamma | ++ | ++ | ✓ |
| **B.1.429** | Epsilon | + | + | ✓ |
| **B.1.526** | Iota | + | + | ✓ |
| **B.1.617.2** | Delta | ++++[1] | ++[3] | ✓ |

1. Relative transmissibility to B.1.1.7 yet to be fully defined
2. Effectiveness from real world evidence vs. severe illness, not all vaccines are effective vs. all variants and importance of 2-doses, especially for B.1.617.2 for which 1 dose of mRNA or AZ is only approx. 30% effective
3. May carry more immune escape than P.1, to be determined

# Global vaccination strategy - progress to date

Dr. Kate O' Brien, Director, Department of Immunization, Vaccines and Biologicals

# Updating the Global Vaccination Strategy

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DRAFT – FOR DISCUSSION

## Objective

1. Inform and **motivate an equitable** approach to **COVID-19 vaccination** as part of the pandemic control strategy

2. **Confirm/update global goal** for vaccination based on specified changes in the global context

## Methodology

- Specify socio-economic and health **goals** and **strategy** along a continuum
- Estimate **resource requirements to achieve each goal by country type:**
  - Number of doses
  - Supply projections
  - Costing and financing
- Assess each goal by performing high-level **feasibility analysis**
- Evaluate against **3 future scenarios** on epi, demand, supply, resources

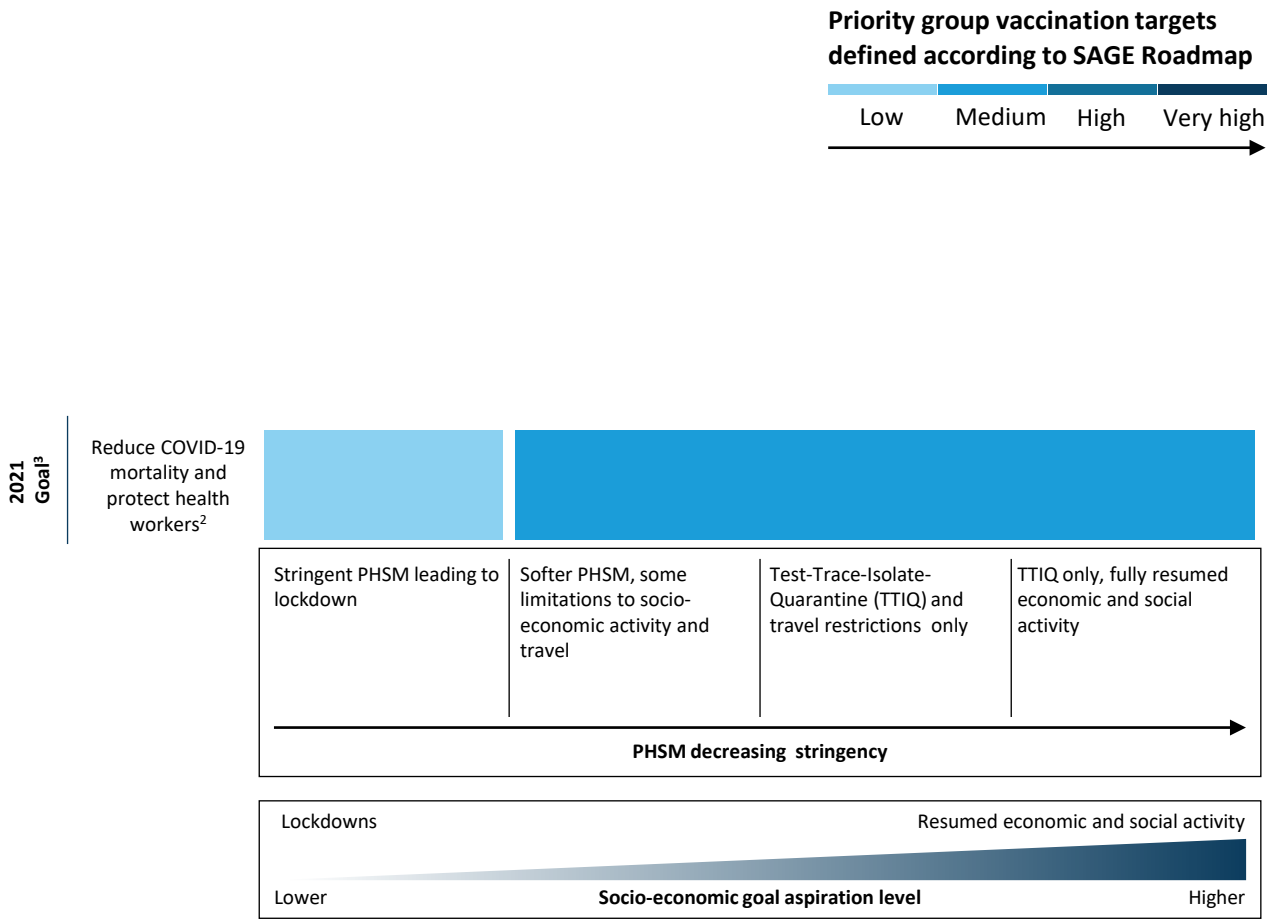
## Output & deliverables

**WHO global COVID-19 vaccine strategy document endorsed by SAGE, including:**

- **Framework for goal-setting** with the associated resource requirements per goal
- **Most impactful uncertainties**, i.e., factors that would influence achievement of goals
- **High-level goal synthesis** and updated **global goal**

# Goal framework: Socio-economic goals and vaccination

## 2022 goals development[1]




**Goals (global and countries) to be revisited as the pandemic unfolds and new epi data/information becomes available**

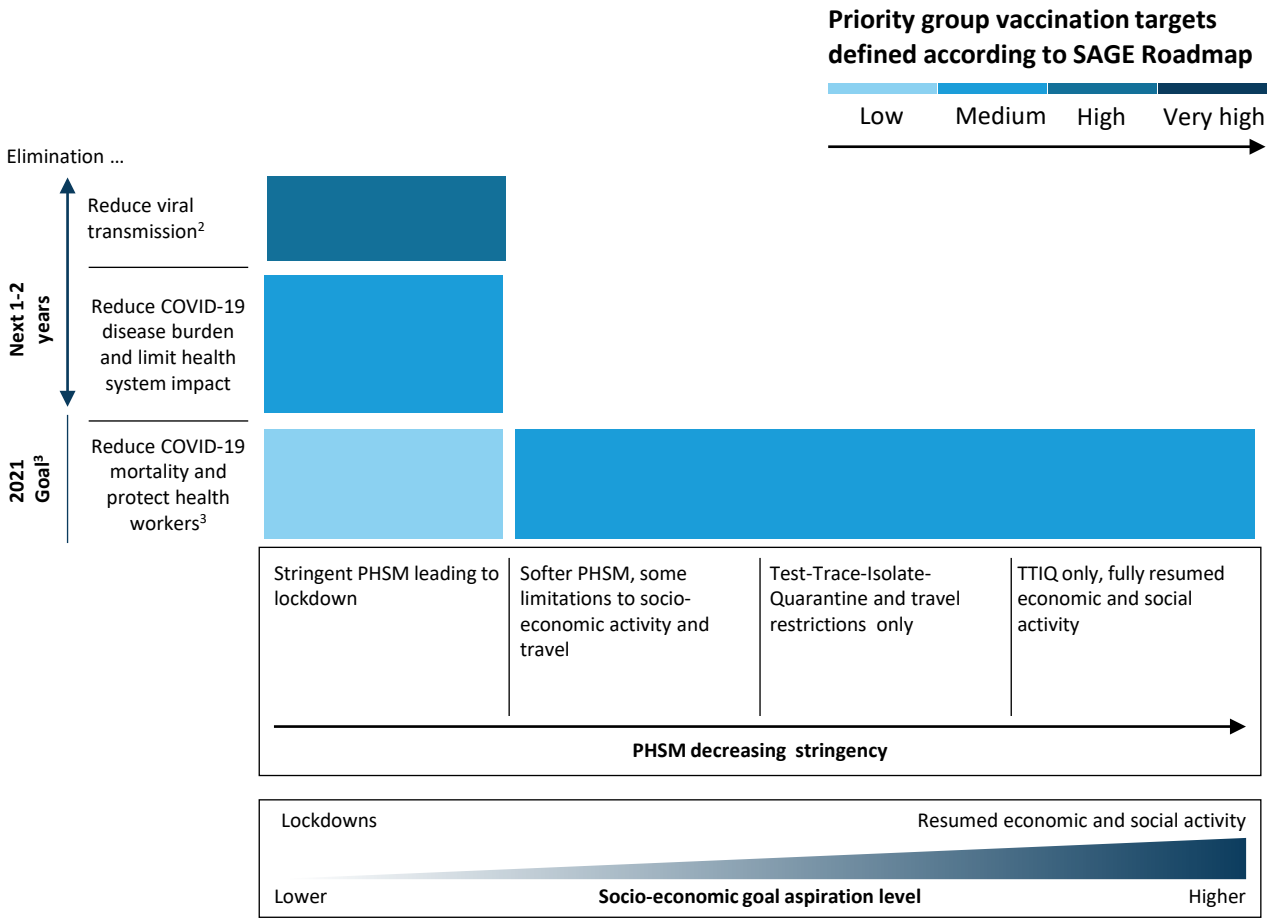
**Countries are setting socio economic goals of increasing aspiration,** aiming to lift PHSM

To do so while avoiding high mortality from COVID-19 and protecting health workers, **countries need to increase their vaccination targets**

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China);
2. Maps to SPRP 2021 strategic goals of "Protecting the vulnerable" and "Reducing mortality and Morbidity from all causes"

# Goal framework: Health dimension

## 2022 goals development[1]

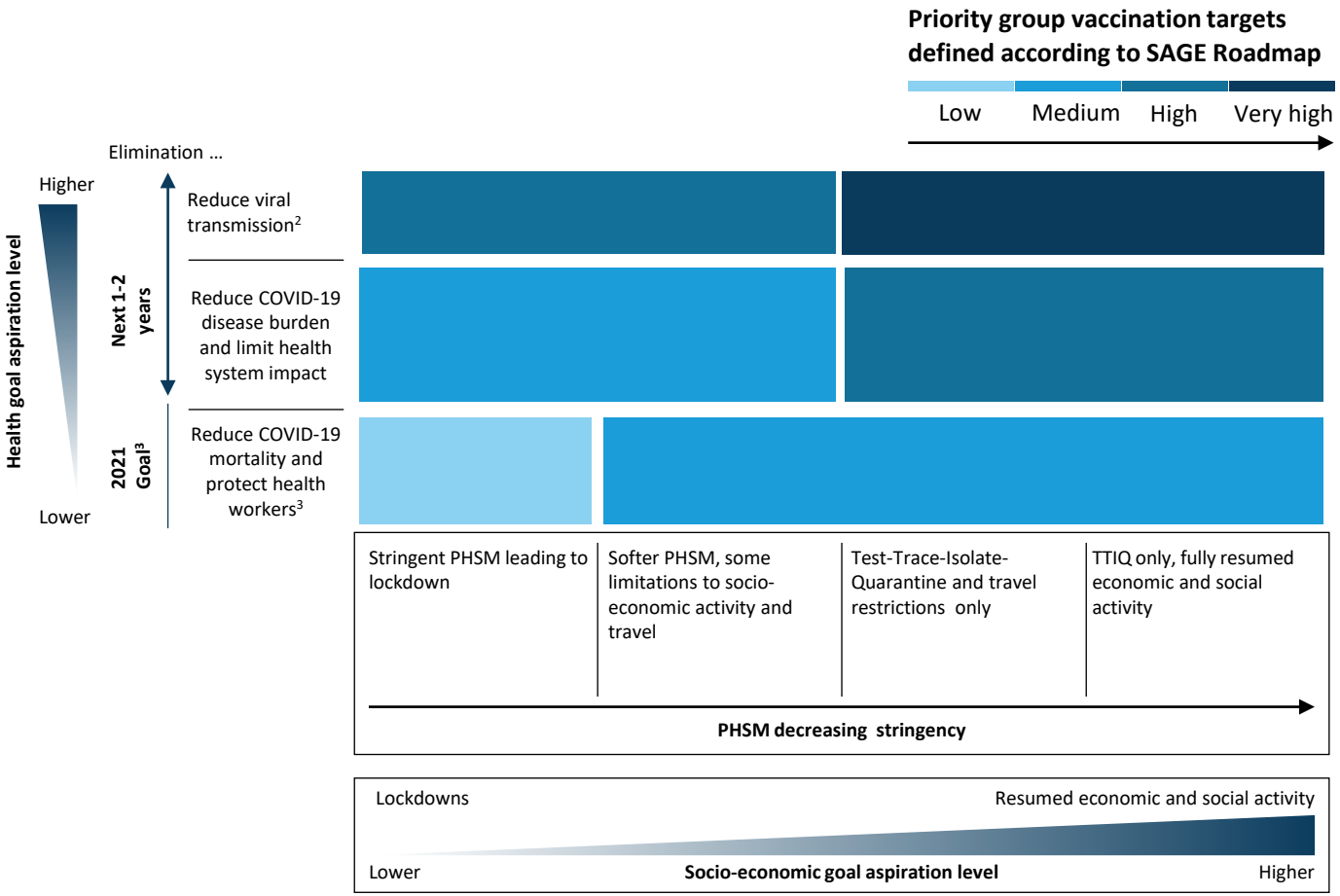



Countries may also wish to **increase their health goal aspiration level, from mortality reduction and health system protection to reducing viral transmission**, for instance to reduce emergence and transmission of VoCs

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China);
2. Maps to SPRP 2021 "Suppress transmission" strategic goal;
3. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”

# Goal framework

## 2022 goals development[1]




**Goals (global and countries) to be revisited as the pandemic unfolds and new epi data/information becomes available**

Ultimately, countries have a **continuum of socio economic and health goals** they can pursue (non-exhaustive). Each will require a different level of vaccination ambition, different by **country type**

The framework focuses on vaccination, however must be considered within the **broader Strategic Preparedness Response Plan**

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China); 2. Maps to SPRP 2021 "Suppress transmission" strategic goal; 3. Maps to SPRP 2021 strategic goals of “Protecting the vulnerable” and “Reducing mortality and Morbidity from all causes”

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# Goal-synthesis and deliberation

- **A** **What are the resources required** to get to different socio-economic and health goals (doses, supply, financing)?
- **B** **Given a specific goal, is it feasible for a given country type and in a given time frame?**
- **C** **Where are countries currently heading** in terms of goals?
- **D** What is the **potential impact of some countries moving faster** than others?
- **E** **Should we set a global goal and what should it be** ?

# Considerations for setting a global goal

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**Preliminary analysis shows that…**

## Goals

1. **Countries setting ambitious but diverse goals**
2. WHO has already indicated (SPRP 2021) a strategic objective to **suppress transmission** using vaccination among other tools
3. **Additional institutions proposing time-bounded steps** on the goal trajectory

## Requirements to meet goal

4. **Global supply may be adequate, however distribution across countries is an obstacle** particularly in the short term and for LICs
5. **System and financial constraints can affect** achievement of country goals
6. **Certain amounts of capital need to be mobilized** that, even if available, might not be attractive for countries (due to debt, tradeoffs on other health priorities, etc.)

# Step-wise approach to set the global goal

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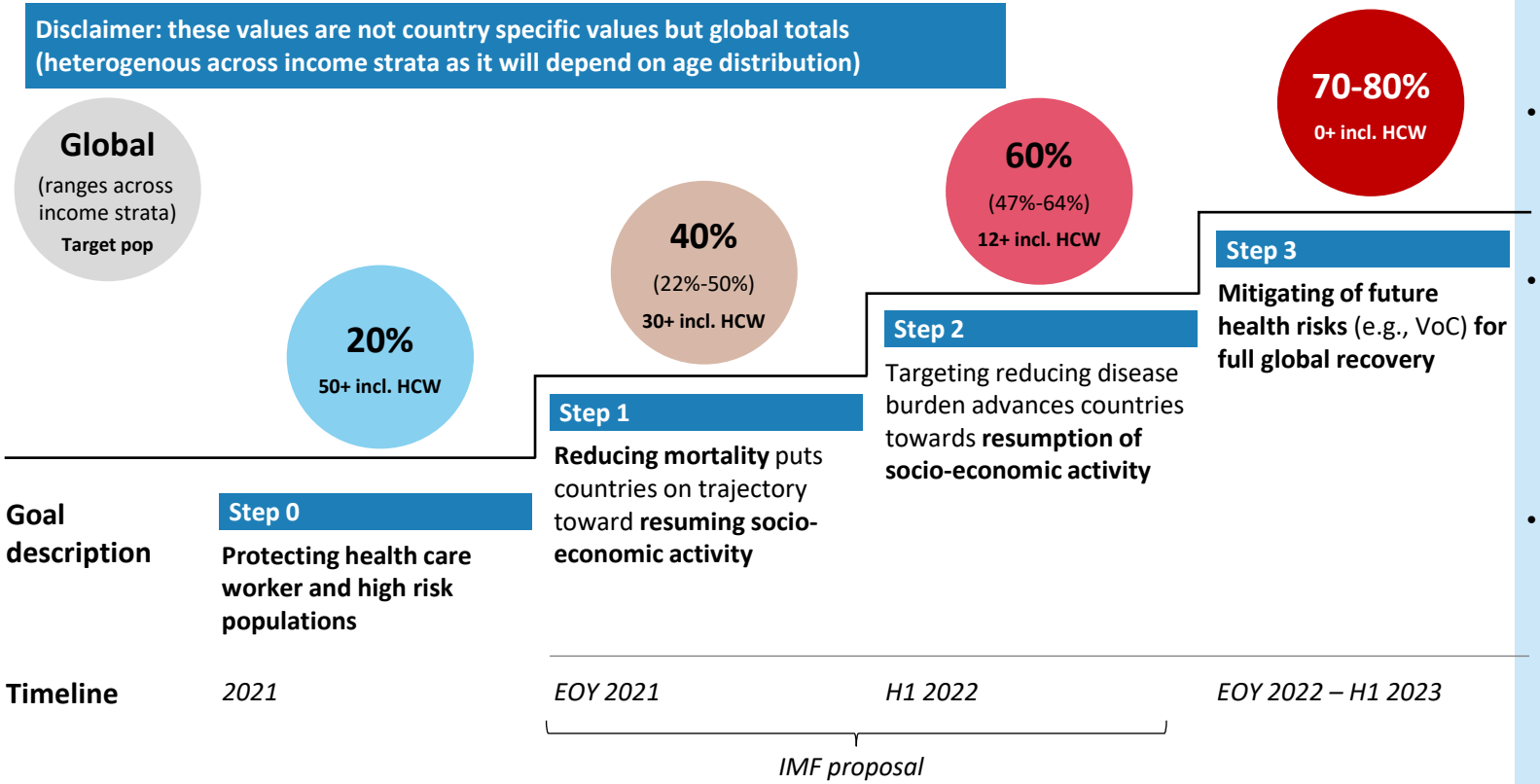
**Disclaimer: these values are not country specific values but global totals (heterogenous across income strata as it will depend on age distribution)**




- Moving to **full global recovery** advances through **several goal targets**.
- Global coverage is driven by an **analysis of what is required to achieve certain Vx goal** (target population, etc.)
- Timing of those targets depends on the **supply, program absorptive capacity and financing**

1. https://blogs.imf.org/2021/05/21/a-proposal-to-end-the-covid-19-pandemic/
2. Refers to actual population coverage
3. The IMF targets apply to each country, i.e., 40% vaccinated for each and every country regardless of age distribution, which differs from our age-based global coverage proposal.

Source: https://www.washingtonpost.com/opinions/2021/05/31/why -we-are-calling-new-commitment-vaccine-equity-defeating-pandemic/

# Timeline to complete Global vaccination work – including consultations

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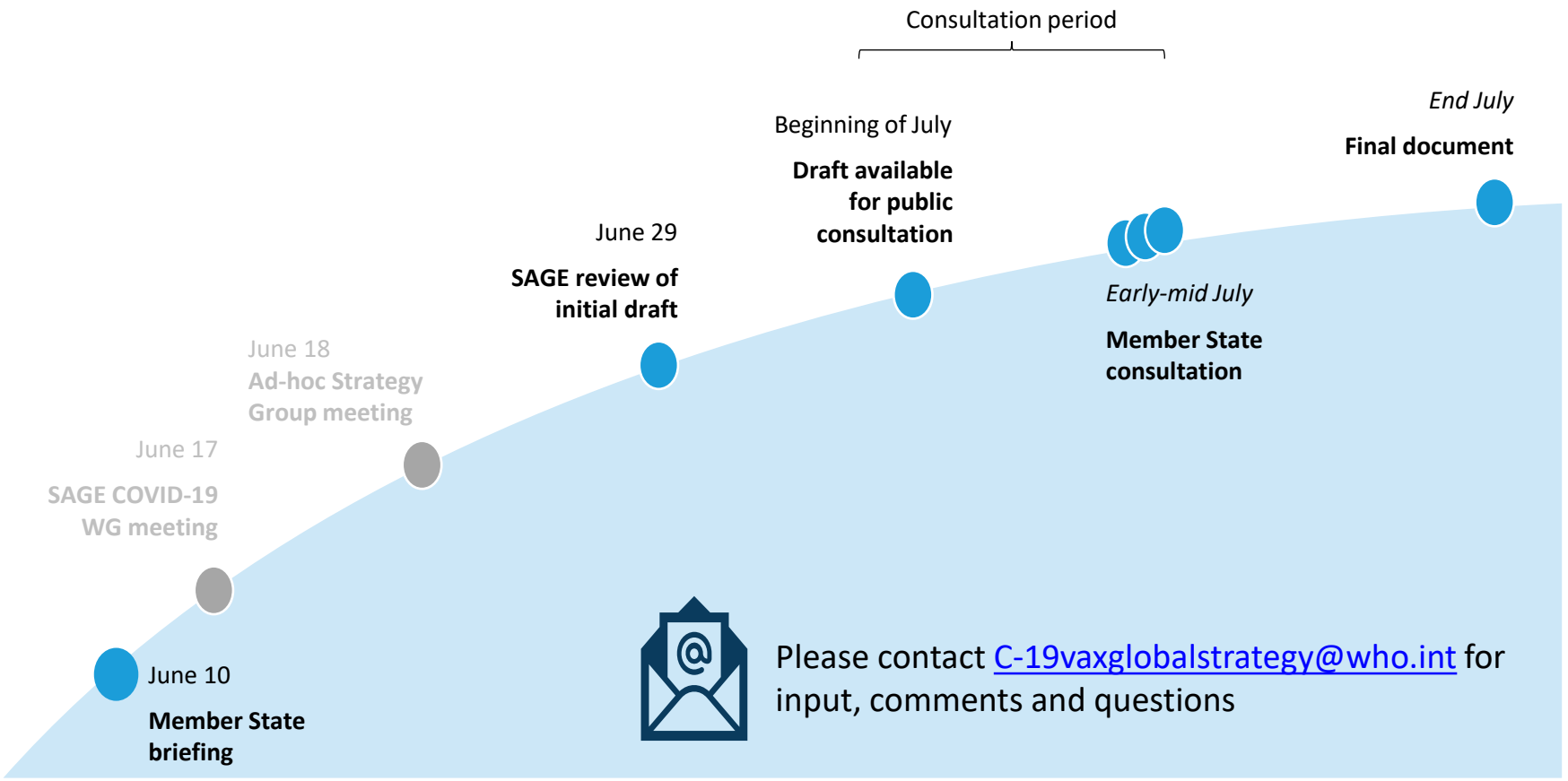

# Backup

# Of the 17 COVID-19 vaccines now in use, AstraZeneca & Pfizer products are used in the greatest number of countries

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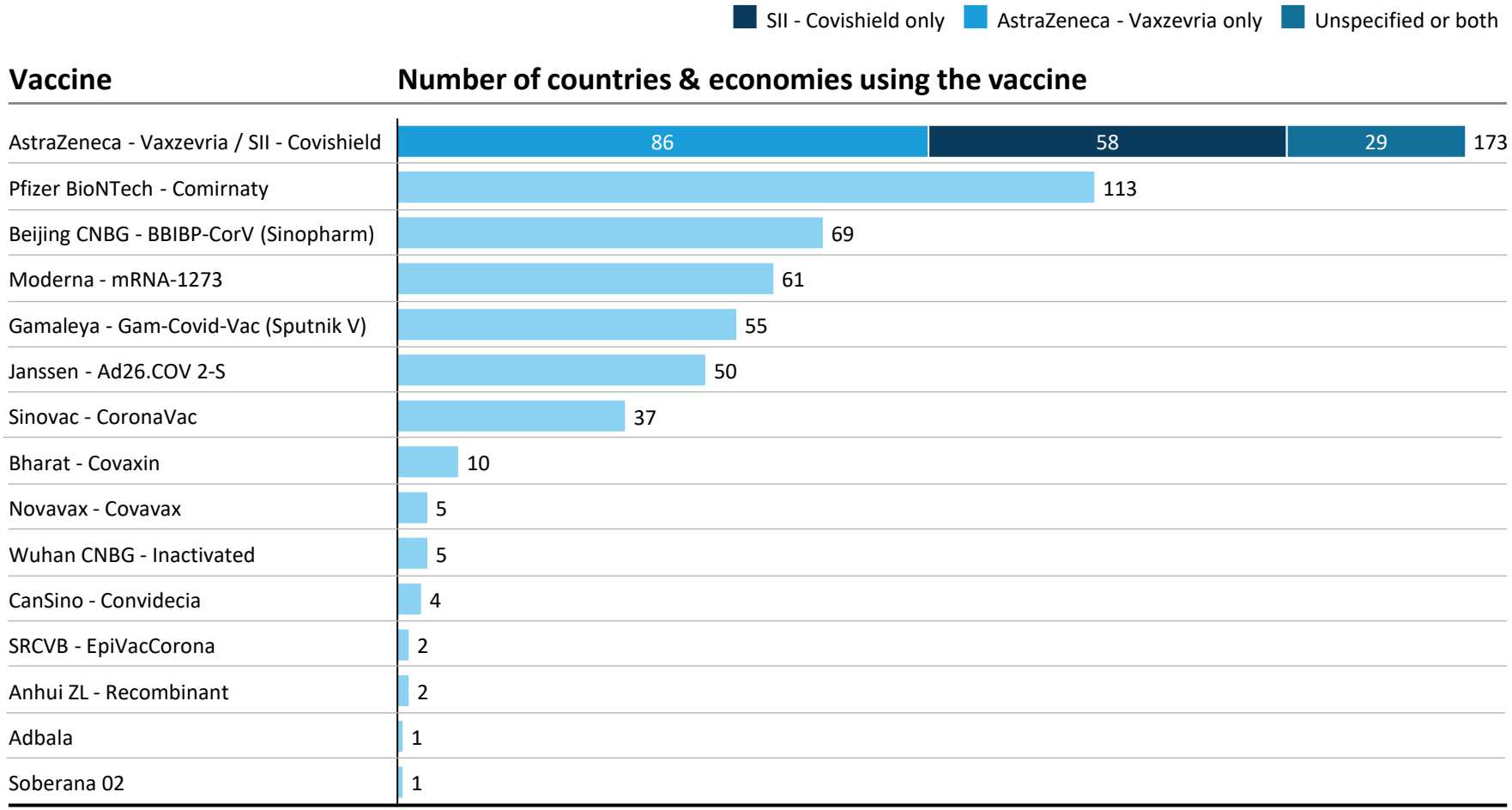


**29 economies are using 1 vaccine; 184 are using 2 or more vaccines**

1. World Bank classification (2021) of 218 economies. Note: The term country, used interchangeably with economy, does not imply political independence but refers to any territory for which authorities report separate social or economic statistics.

Source: Our World in data, WHO, Government websites; Press research

# HICs administered 67x more doses per person than LICs

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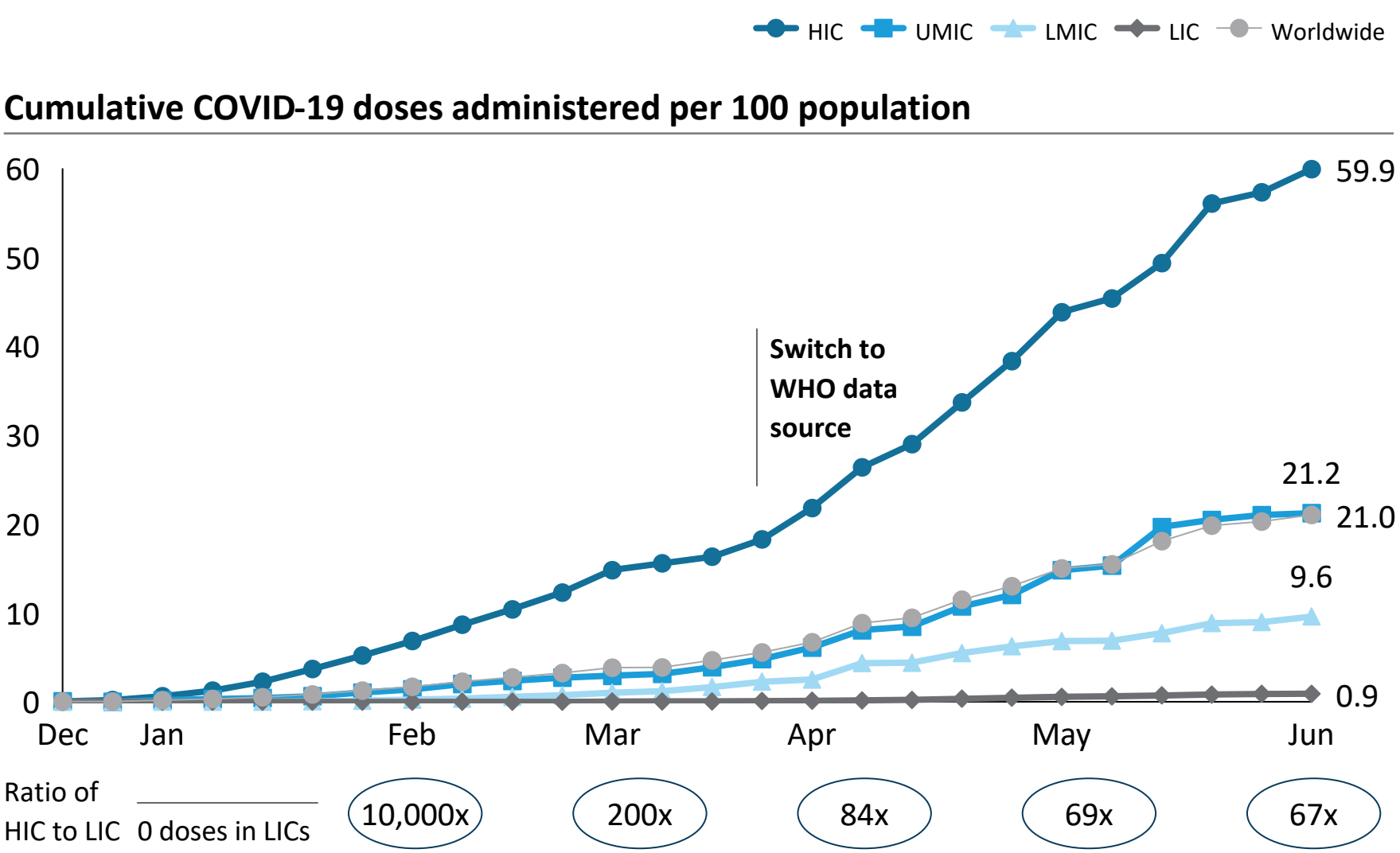
## Cumulative COVID-19 doses administered per 100 population




SOURCE: Our World in Data (Dec-Mar 7); WHO Dashboard (Mar 12 onwards); source for income groups: World Bank. Using the latest available values for each week.

UPDATED JUNE 3

# Regulatory timeline of key vaccine candidates

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**Link to Status of COVID-19 Vaccines within WHO EUL-PQ evaluation process**

Legend (timing of approval)
- Approval / Emergency use
- Decision expected date
- No info
- COVAX Facility product

## Estimated dates of approval / Emergency use

| Vx candidates | | FDA | MHRA | EMA | WHO EUL/PQ | Regulatory authority of record |
|---|---|---|---|---|---|---|
| Pfizer BioNTech | Pfizer BioNTech - Comirnaty | Dec. 12, 2020 Emergency Use | Dec. 2, 2020 Emergency Use | Dec. 21, 2020 Cond. Authorization[1] | Dec. 31, 2020 Emergency use | EMA |
| AstraZeneca | AstraZeneca - Vaxzevria | No FDA approval | Dec. 30, 2020 Emergency Use[2] | Jan. 29, 2021 Cond. Auth.[1] (non-Covax) | Apr. 15, 2021 (donations only) | EMA |
| **AZ with EMA** as authority of reference | AstraZeneca – AZD1222 | No FDA approval | Not applicable | 1 COVAX node | Apr. 15, 2021, 1 COVAX node | EMA |
| **AZ with EMA** as authority of reference<br>**AZ South Korea w/ MFDS Korea as** authority of record | AstraZeneca – AZD1222 | Not applicable | Not applicable | Not applicable | Feb. 15, 2021 Emergency use | MFDS (Rep. Korea) |
| **SII /AZ vaccine (Covishield)** with DCGI India as authority of record | SII - Covishield | - | - | - | Feb. 15, 2021 Emergency use | DCGI (India) |
| **Sinopharm / BIBP[4]** | Beijing CNBG - BBIBP-CorV | | | | May 7, 2021 Emergency use | NMPA |
| sinovac | Sinovac - CoronaVac | No FDA approval | | No EMA approval | June 1, 2021 Emergency use | NMPA |
| moderna | Moderna – mRNA-1273 | Dec. 18, 2020 Emergency Use | Jan. 8, 2021 Emergency Use | Jan. 6, 2021 Cond. Authorization[1] | April 30, 2021 Emergency use | EMA |
| janssen | Janssen – Ad26.COV 2-S | Feb. 27, 2021 Emergency Use | | Mar. 11, 2021 Cond. Authorization[1] | Mar. 12, 2021 Emergency use | EMA |
| THE GAMALEYA NATIONAL CENTER | Gamaleya – Sputnik V | | | | Rolling submission started - Add. data awaited | Russian NRA |
| 康希诺生物 CanSinoBIO | CanSino – Ad5-nCOV | | | | Rolling submission of data from April 2021 | NMPA |
| **Sinopharm / WIBP[3]** | Wuhan CNBG - Inactivated | | | | | NMPA |
| NOVAVAX * | Novavax – Covavax* | | | | Novavax submitted EOI on 23 Feb | EMA |

## Key messages

- **WHO EUL:** Pfizer BioNTech – Comirnaty, SII – Covishield, Janssen - Ad26.COV 2.5, AstraZeneca – Vaxzevria/AZD1222, Moderna mRNA-1273, Beijing CNBG - BBIBP-CorV, Sinovac-CoronaVac
- **AstraZeneca:** WHO EUL for European nodes (1 COVAX node and non-COVAX for donations)
- **Gamaleya - Gam-Covid-Vac**: Additional data (NonCLIN, CLIN, CMC) required. Inspections in April, May and June 2021.
- **Bharat and CureVac / Bayer** submitted EOI
- **BioCubaPharma** is in discussions to submit EOI

1. Conditional marketing authorization 2.Temporary authorisation of supply of the vaccine in the emergency use setting (which is distinct from a marketing authorisation) 3. Wuhan Institute of Biological Products Co Ltd 4. Beijing Bio-Institue of Biological Products Co-Ltd
*. SII/Novavax needs to be specified

SOURCE: https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08Feb2021.pdf; https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/

# WS3: EOI process was initiated Mid April for mRNA tech, closed on May 31 - Due diligence process ongoing

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

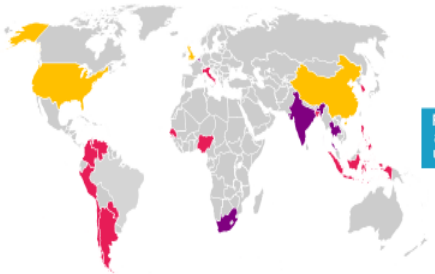
AS OF 07JUNE2021

Today

| Call for EOI posted | EOIs submitted | Due diligence | Selection and implementation |
|---|---|---|---|
| EOI call for mRNA tech issued on April 16 | Call closed on May 31, 50+ answers received | Top-down review *(Criteria-by-criteria assessment)* | Final assessment to be led by WHO committee (PDVAC) |
| | | Bottom-up due diligence *(Detailed questionnaire and government support letter)* | Similar process to be run for recipients in order to initiate training |
| | | | Subsequent EOIs for other techs to be issued as well (VV, Proteins) |

AS OF 07JUNE2021

**25+ Responses from potential tech donors and/or sites for hubs**



Potential **tech donor only** (based in China, UK, USA)

Potential **tech donor & hub site** (based in Belgium, India, South Africa, Thailand)

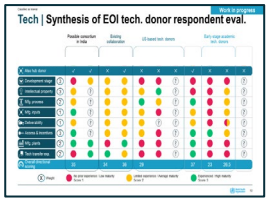
Potential **hub site only** (based in Argentina, Bangladesh, Chile, Colombia, India, Indonesia, Italy, Nigeria, Paraguay, Peru, Philippines, Senegal, South Korea, Venezuela)

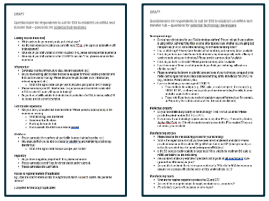
Preliminary – answers still under review

**25+ Responses from countries/ manufacturers more likely to be possible recipients**

Potential interest for establishing **recipient site** (based in Argentina, Brazil, China, Colombia, Cuba, Egypt, India, Indonesia, Kenya, Morocco, Nicaragua, Pakistan, Paraguay, Peru, Rwanda, South Africa, Thailand, Tunisia, Uganda, Uruguay, Vietnam)

Note: 5 recipients requalified as possible hubs on 09.06 following additional information received



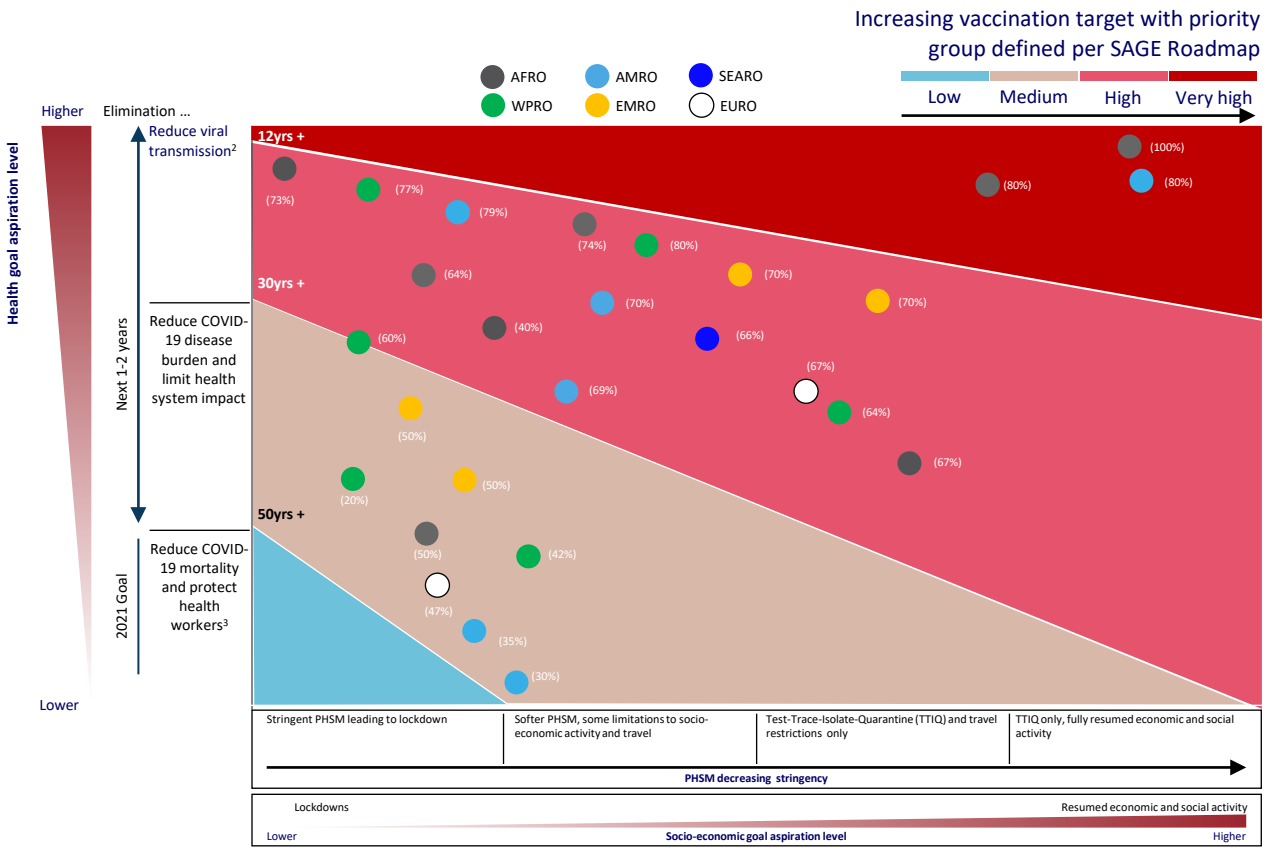



# Goal framework: health goals and vaccination

## 2022 goals development

June 10, 2021

**DRAFT FOR DISCUSSION**




Countries have been setting goals beyond 20% total pop: goals are clustered between 50-75% of total population range

Most countries are probably targeting **resumed socio-economic activity while reducing disease burden**. Some countries may be targeting reduced transmission

Variance in goals decreases with income level (HICs consistently ambitious)

HICs and UMICs have deals backing their goals

1. Indicative framework as other countries have achieved same goals with different combinations (e.g., China); 2. Maps to SPRP 2021 "Suppress transmission" strategic goal; 3. Maps to SPRP 2021 strategic goals of "Protecting the vulnerable" and "Reducing mortality and Morbidity from all causes"