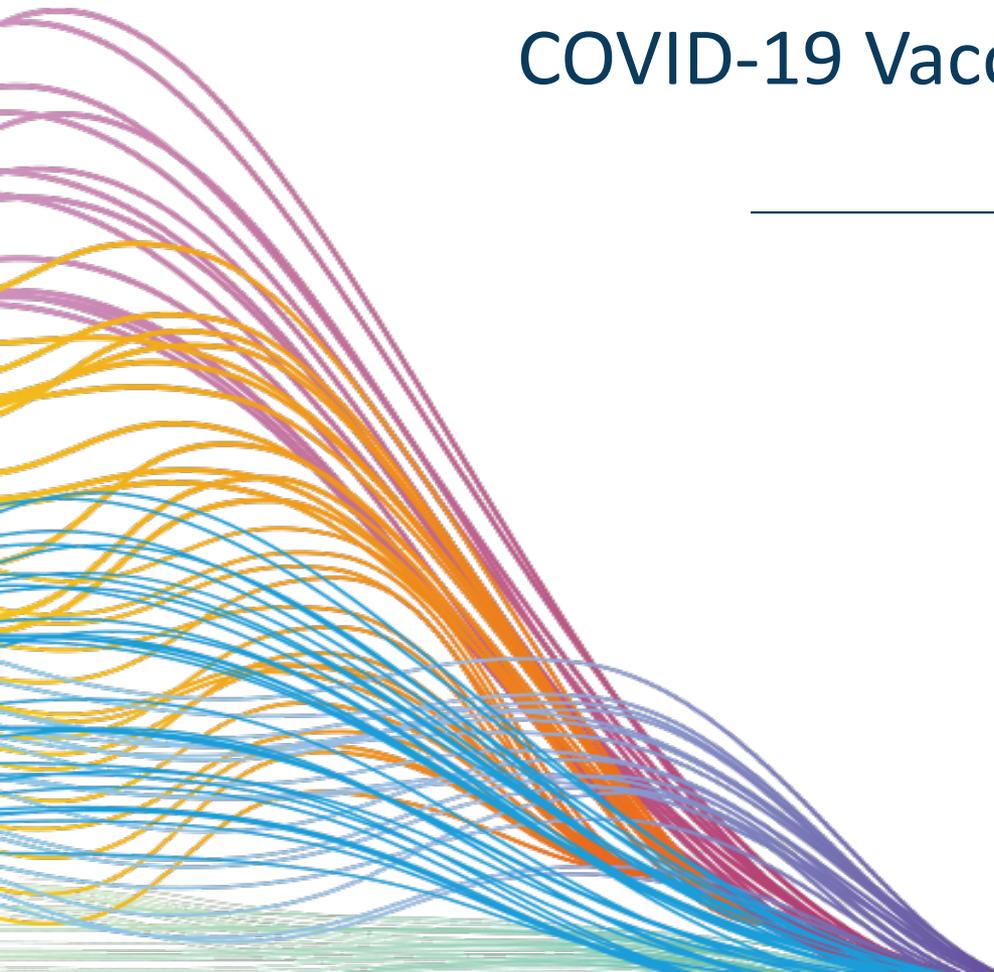


COVID-19 Vaccination & COVAX rollout

WHO Member States Information Session

22 APRIL 2021



Upcoming ACT-Accelerator Events

Dr Usman Mushtaq

Key upcoming events:

- 23 Apr **ACT-A 1-Year Event**
- 24-30 April World Immunization Week
- 5 May Facilitation Council Technical Pre-Brief
- 12 May 6th ACT-A Council (HSC; Vx production)
- 21 May ACT-A @ Global Health Summit
- 24 May – 1 June World Health Assembly

ACT-A 1-Year Event - 23 Apr, 15:00-16:30 CEST

Objectives:

- Amplify public & political **awareness of ACT-A** progress, challenges & needs
- Promote ongoing **ACT-A Financing Appeal** of Norway & South Africa

Proposed Run of Show

Head of State segment

- **From Vision to Reality:** ACT-A progress – DG & Co-Founders
- **ACT-A Appeal:** Challenges & needs - Council Co-Chairs South Africa and Norway

Principals segment

- **Media Q&A with ACT-A Principals**

Delegations can follow the livestream and submit questions [HERE](#)

6th ACT-A FACILITATION COUNCIL

PRE-BRIEF, 5 MAY 12.30-14.00 CEST

DRAFT AGENDA

1. **Health Systems Connector**
2. **Look ahead to the 6th Council**

Delegations can register [HERE](#)

6th COUNCIL, 12 MAY 12.30-15.00 CEST

DRAFT AGENDA

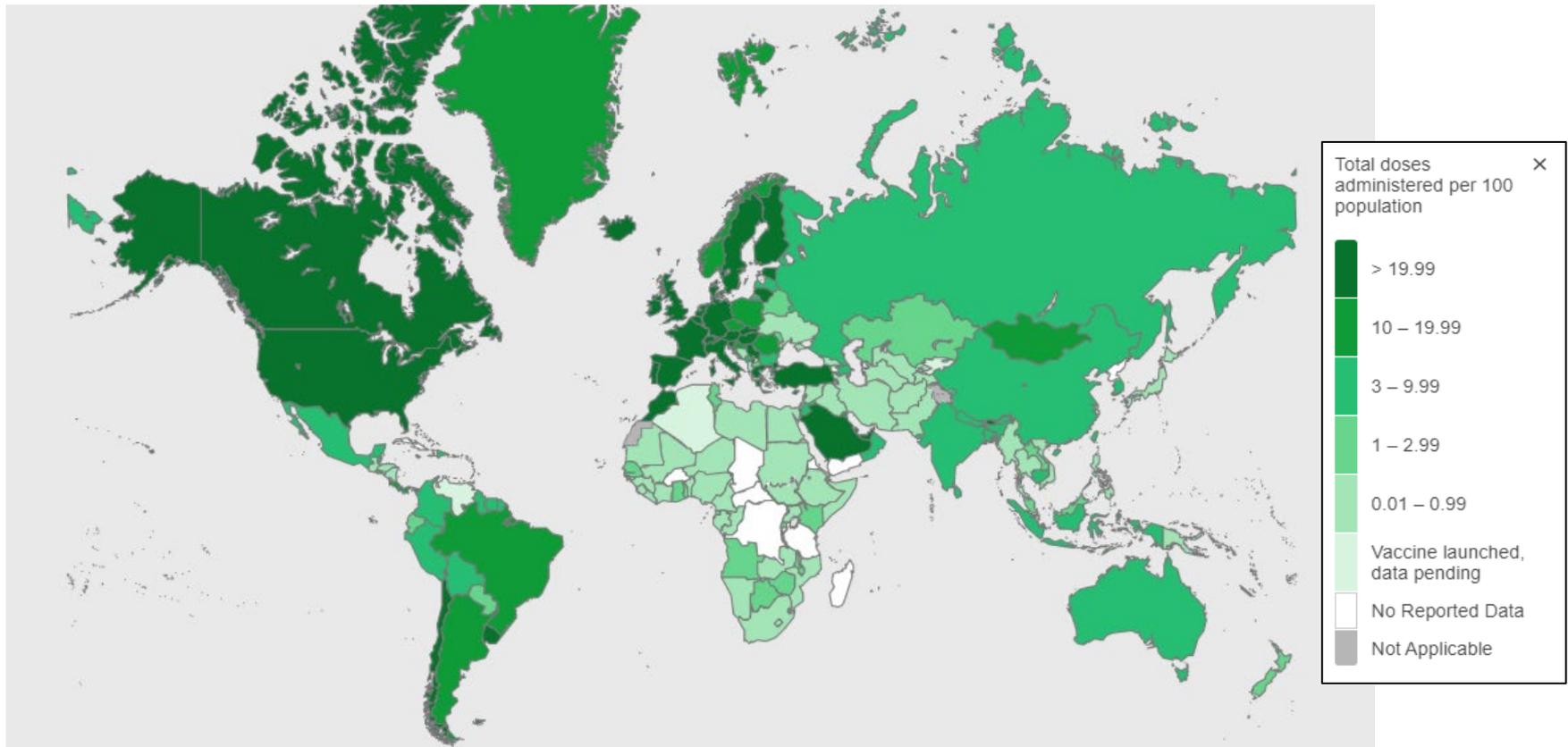
1. **Health Systems Connector: facilitating uptake & delivery of COVID-19 tools**
 - Interactive panel discussion with countries & council members
2. **Scale up of vaccine manufacturing**
 - Interaction with COVAX Task Force on expanding vaccine production

Proceeding will be livestreamed for all Member States on the [ACT Accelerator site](#)

Overview of COVID-19 Vaccine Rollout

Dr. Soumya Swaminathan

944 m doses of COVID-19 vaccine have been administered¹ in 205 countries, areas, territories & economies²



15 economies have not yet started vaccination

1. Source: Bloomberg. 77% in top 10 countries (largely high income and/or vaccine-producing countries); 2. Source of this list of 220 countries, areas, territories & economies: 218 economies listed by World Bank + WHO Member states Cook Islands + Niue

SOURCE for map: WHO COVID-19 Dashboard at <https://covid19.who.int/>

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.

Of WHO's 194 Member States, 179 have started COVID-19 vaccination

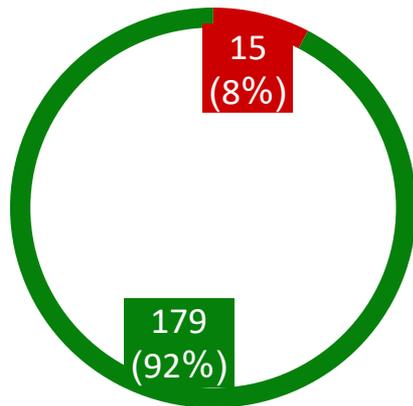
at least 1 additional MS received vaccine & can start in the coming days

Status of COVID-19 vaccine roll out

■ Started ■ Not started

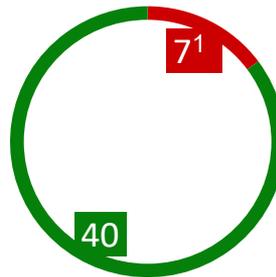
WHO Member States

N= 194



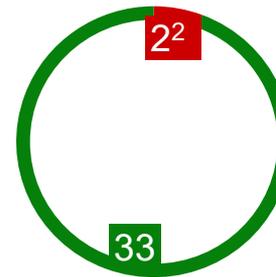
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N= 47



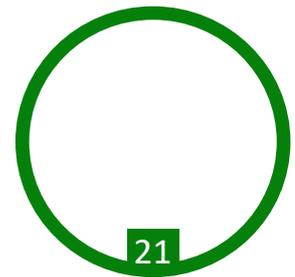
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N= 35



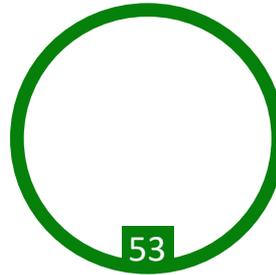
EMRO

N=21



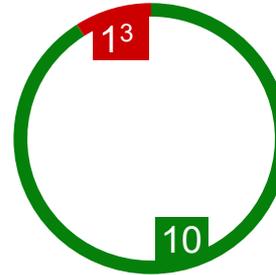
EURO

N= 53



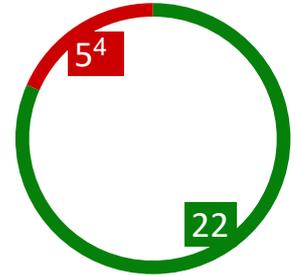
SEARO

N= 11



WPRO

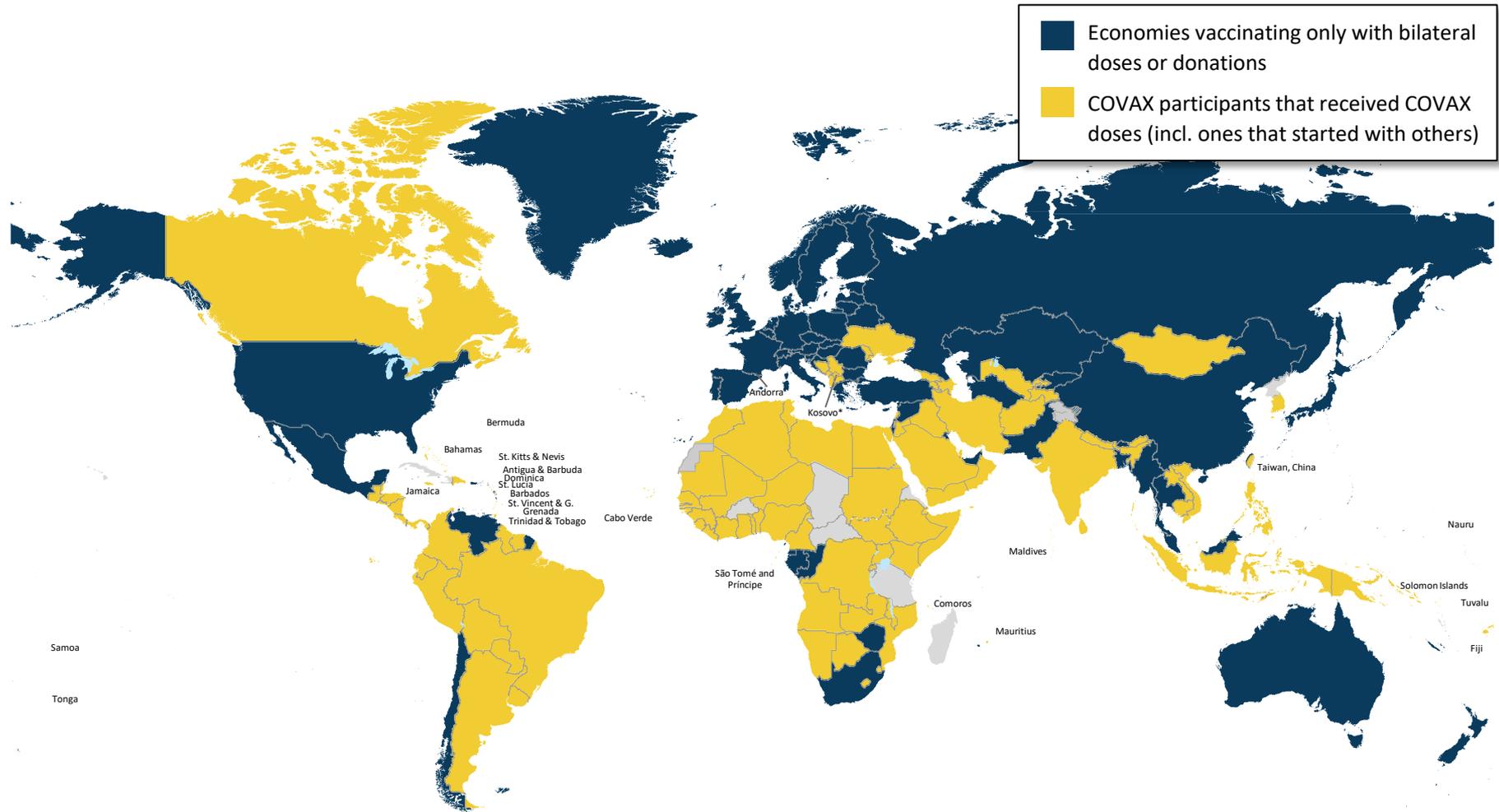
N=27



1 Burkina Faso, Burundi, Central African Republic, Chad, Eritrea, Madagascar, United Republic of Tanzania
 2 Cuba, Haiti
 3 Democratic People's Republic of Korea
 4 Kiribati, Samoa, Vanuatu, Cook Islands, Niue

COVAX has now shipped 40.8M doses to 117 participants

incl. 59 LMIC/LICs; 35 participants started their first campaigns thanks to COVAX doses



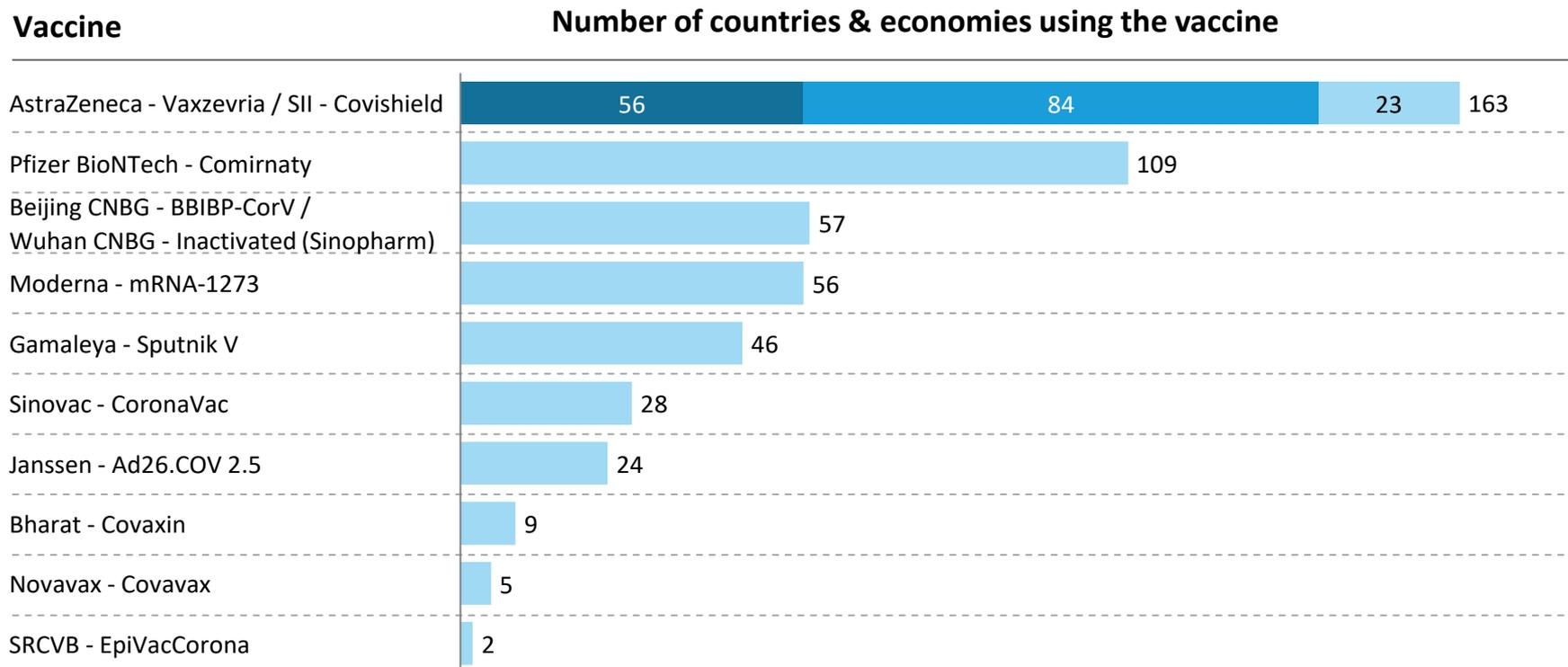
Note: The designations employed and the presentation of these materials do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and 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 the 11 COVID-19 vaccines now in use, AstraZeneca & Pfizer products are the most prevalent

■ SII - Covishield only
■ AstraZeneca - Vaxzevria only

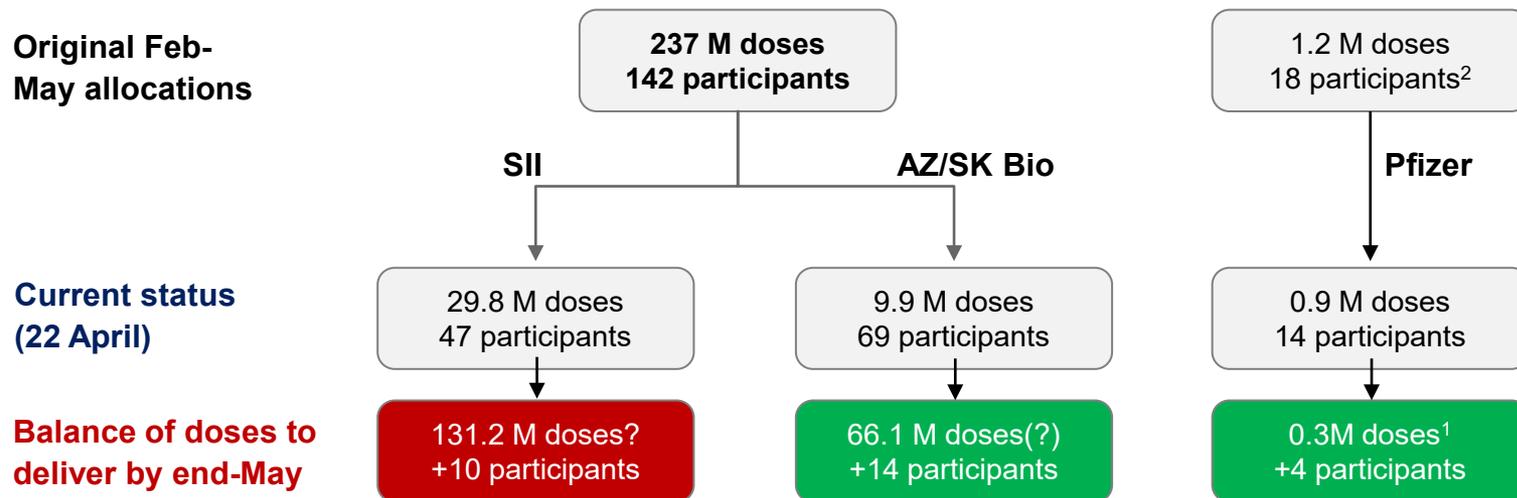


45 economies are using 1 vaccine; 160 are using 2 or more vaccines

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

COVAX supply through AZ/SK Bio & Pfizer is improving; but SII risk for deliveries is increasing...



- **AZ/SK Bio** aims to deliver balance of allocations in 2 shipments (late Apr & May)
- **Pfizer** aims to complete 1st wave in early May & start next 47 countries (14 m doses)
- **SII** COVAX deliveries uncertain in coming months & COVAX exploring contingencies (e.g. AZ/SK Bio June volumes)

6 urgent & ongoing initiatives to increase supply to COVAX

- 1** SII: working with Govt of India COVAX supply for coming months
- 2** AZ/SK Bio: accelerate release, rollout & target territory
- 3** Expedite delivery of newly EUL'd products through COVAX (e.g. J&J)
- 4** Pursue donations of vaccines that have WHO Emergency Use Listing (e.g. New Zealand, France)
- 5** Expedite EUL review of new products (e.g. Sinopharm, Sinovac, Gamaleya)
- 6** Expand global manufacturing capacity of COVID-19 vaccines



We must leverage this unique moment to build **sustainable regional health security** through expanding **LMIC vaccine manufacturing capacity**

On April 16, WHO issued a call for EOI to establish mRNA vaccine technology transfer hub; to be followed by other technologies: [Link](#)

There is an urgent, near-term need to **unlock additional COVID vaccine supply...**

- Address bottlenecks of existing supply chain, in particular Fill/Finish
- Increase number of facilities producing COVID vaccines

...but a long-term solution is also critical to **ensure equitable access to vaccines and ensure regional health security**

- Currently a severe lack of manufacturing capacity in LMIC regions
- Regions with production capacity first in line to vaccinate population

The COVID Vaccine Capacity Taskforce was launched to address these challenges, with Pillar 3 focused on a long-term solution

Pillar 1 Immediate response



Unlocking bottlenecks

- Implement immediate upstream supply chain solutions
- Create input supply visibility partnership
- Expand Fill/Finish match making mechanisms / partnerships

Pillar 2 Short-term response



Bilateral Tech Transfer

- Promote voluntary bilateral tech transfer to existing manufacturers
- Stimulate workforce development

Pillar 3 Longer-term



Multilateral Tech Transfer and LMIC capacity expansion

- Ensure Tech Transfer hubs and/or voluntary Tech Transfers
- Multilateral training and transfer to existing and new facilities (both COVID and routine vaccines)
- Support member states to establish sustainable regional health security

Pillar 3 | Approach to establish hubs for tech transfer to LMICs

Envisioning a global network of technology transfer hubs dedicated to LMIC uptake



Centralized hubs¹ would facilitate multilateral tech transfer to many regionally distributed LMIC manufacturing sites

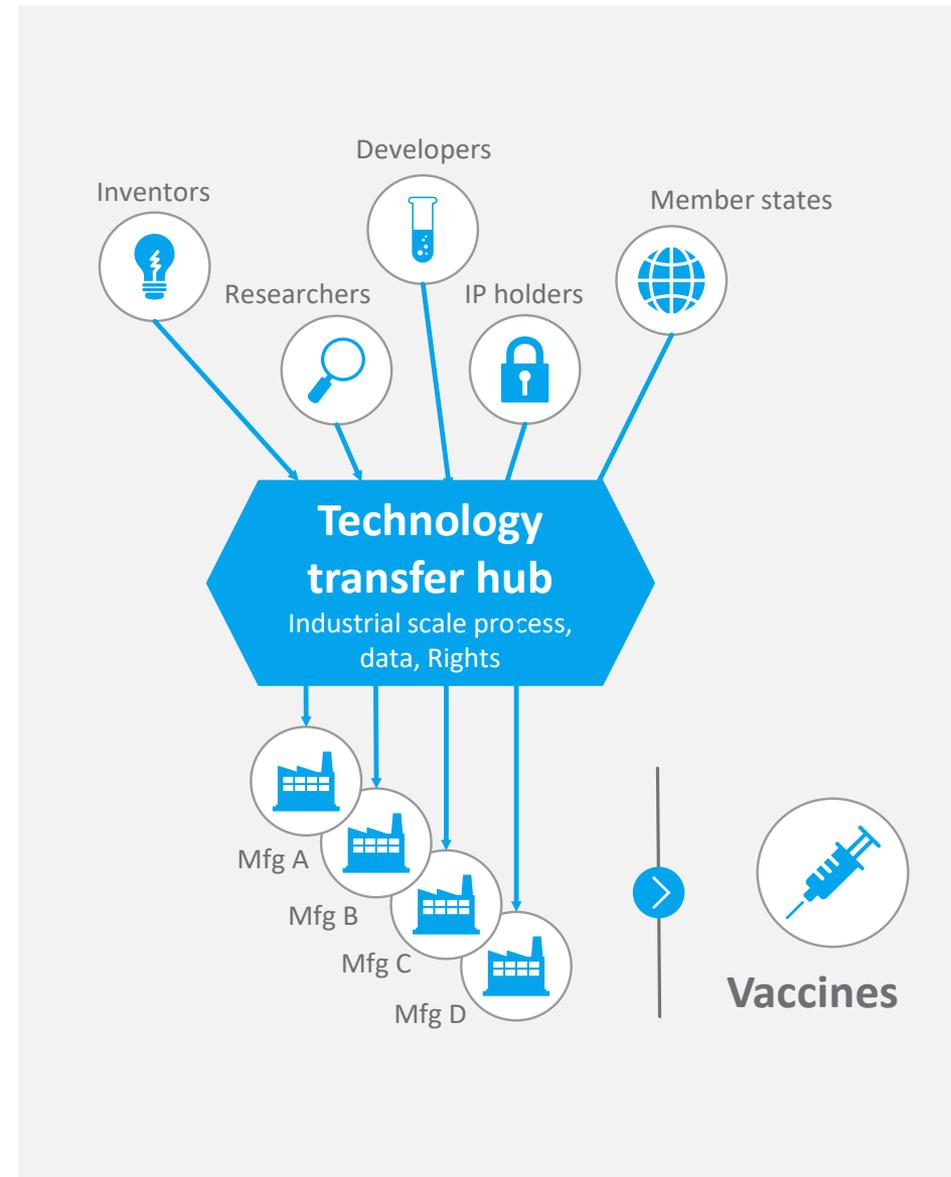


LMICs Recipients acquire technology to rapidly scale production of best candidate vaccines during pandemics



Recipient facilities would pursue sustainable business models between pandemics

1. Manufacturers could voluntarily serve as centralized hubs if interested



Allocation & regulatory update

Dr Mariângela Simão

COVAX has announced 3rd allocation round (14m doses Pfizer)¹

	Round #1	Round #2	Round #3
Announced	3 February	2 March	12 April
Period	February-March	January-May	April-June
Vaccine & Number of doses	Pfizer 1.2M doses	SII & AZ/SK Bio 237M doses	Pfizer 14M doses
Number of participants	18 participants	142 participants: 60 SII; 82 AZ/SK Bio	47 participants

1. Q3 allocation expected to be conducted by mid-May
Source: COVAX

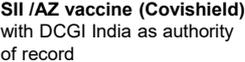
Regulatory timeline of key Vx candidates

<https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-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 - Comirnaty	Dec. 12, 2020 Emergency Use	Dec. 2, 2020 Emergency Use	Dec. 21, 2020 Cond. Authorization ¹	Dec. 31, 2020 Emergency use	EMA
 AZ with EMA as authority of reference	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	No FDA approval	Not applicable	1 COVAX node	Apr. 15, 2021, 1 COVAX node	EMA
 AZ South Korea w/ MFDS Korea as authority of record	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	-	-	-	Feb. 15, 2021 Emergency use	DCGI (India)
 Sinopharm / BIBP ⁴				April 2021 (Earliest)	NMPA
 Sinovac	No FDA approval		No EMA approval	May 2021 (Earliest)	NMPA
 Moderna – mRNA-1273	Dec. 18, 2020 Emergency Use	Jan. 8, 2021 Emergency Use	Jan. 6, 2021 Cond. Authorization ¹	April 2021 (Earliest)	EMA
 Janssen – Ad26.COV 2.5	Feb. 27, 2021 Emergency Use		Mar. 11, 2021 Cond. Authorization ¹	Mar. 12, 2021 Emergency use	EMA
 The GAMALEYA NATIONAL CENTER				Rolling submission started - Add. data awaited	Russian NRA
 CanSino – Ad5-nCOV				Rolling submission of data from April 2021	NMPA
 Sinopharm / WIBP ³					NMPA
 NOVAVAX				Novavax submitted EOI on 23 Feb	EMA

Key messages

- **WHO EUL:** Pfizer BioNTech – Comirnaty, SII – Covishield, Janssen – Ad26.COV 2.5, AstraZeneca – Vaxzevria/AZD1222
- **AstraZeneca:** WHO EUL for selected European nodes with EMA as authority of record (1 COVAX node and non-COVAX for donations)
- Focus on assessment of Beijing CNBG - BBIBP-CorV, Sinovac - CoronaVac and Moderna - mRNA-1273
- **Gamaleya:** Additional data (NonCLIN, CLIN, CMC) required. Inspections in April, May and June 2021. EUL decision after inspections
- **Novavax** pre-submission meeting planned for May 7
- **Bharat and CureVac / Bayer** have submitted an EOI
- **BioCubaPharma** is in discussions to submit EOI

*. SII/Novavax needs to be specified

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 Institute of Biological Products Co-Ltd

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/>

SAGE recommendations update

Dr Kate O'Brien

Rare safety related events have prompted regulatory and policy reviews of AstraZeneca vaccines: positive benefit-risk assessment

AstraZeneca – Vaxzevria and SII - Covishield

Regulatory authorities

The image shows three overlapping screenshots of regulatory press releases. The leftmost screenshot is from MHRA, dated 7 April 2021, titled 'MHRA issues new advice on possible link between COVID-19 vaccine AstraZeneca and rare, unlikely to occur blood clots'. The middle screenshot is from the European Medicines Agency (EMA), dated 7 April 2021, titled 'AstraZeneca's COVID-19 vaccine: EMA to provide further context on risk of very rare blood clots with low blood platelets'. The rightmost screenshot is also from EMA, dated 14/04/2021, titled 'EMA confirms overall benefit-risk remains positive'.

[MHRA 7 April](#)

[EMA 7 April](#)

[EMA 14 April](#)

Overview of messages

- Very rare events - potential causal link to vaccines
- **“EMA confirms overall benefit-risk remains positive”**
- **MHRA: “benefits of vaccination continue to outweigh any risks”**
- **EMA: Updates to product information leaflet sections 4.4 Special warnings and precautions for use & 4.8 Undesirable effects (very rare adverse event)**
- **EMA’s human medicines committee (CHMP) is conducting a further assessment using more data**

WHO Safety

The image is a screenshot of a press release from the World Health Organization's Global Advisory Committee on Vaccine Safety (GACVS). The title is 'Global Advisory Committee on Vaccine Safety (GACVS) review of latest evidence of rare adverse blood coagulation events with AstraZeneca COVID-19 Vaccine (Vaxzevria and Covishield)'. The release is dated 16 April 2021. The text discusses a review of evidence for a rare adverse event called Thrombotic Thrombocytopenia Syndrome (TTS) associated with the AstraZeneca COVID-19 vaccine. It mentions that the GACVS is still investigating the biological mechanism for this syndrome and that the benefits of the vaccine are not considered to be outweighed by the risks.

[WHO GACVS 16 April](#)

Key messages

- Review of global data
- The **biological mechanism** for this syndrome of TTS is still being investigated
- A **‘platform specific’ mechanism** related to the adenovirus-vectorized vaccines is not certain but cannot be excluded

Policy

- **Some countries have adjusted their policy use recommendations to specify age**
- **Some of them have reversed or adjusted these policies**
- **SAGE has updated interim recommendations based on GACVS statement and including other updates (22 April)**

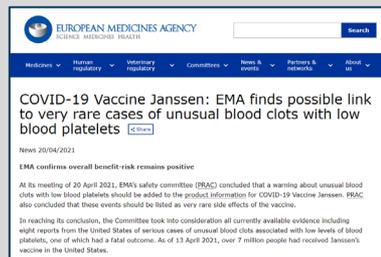
Rare safety related events have prompted regulatory and policy reviews of Janssen COVID vaccines

Janssen – Ad26.COV 2.5

Regulatory authorities



[CDC & FDA 13 April](#)



[EMA 20 April](#)

Overview of messages

- **US CDC & FDA have paused** use of Janssen vaccine in the US. Full safety assessment is ongoing
- **“EMA confirms overall benefit-risk remains positive”**
- **EMA: Updates to product information leaflet** sections 4.4 Special warnings and precautions for use & 4.8 Undesirable effects (very rare adverse event)
- **No other regulatory changes by EMA**

WHO Safety

- **GACVS will continue to monitor & assess evolution of data from all countries**

Policy

- **Limited set of countries have paused roll-out** (e.g. South Africa)
- **Limited set of countries have adjusted their policy use recommendations** to specify age (e.g. Italy to over 60s)
- **WHO SAGE is monitoring and assessing evolution of data & regulatory decisions**

Disclaimer - Update of SAGE recommendations on AstraZeneca and SII vaccine products

As of 22/04 at 12:00 CET, the April 2021 update to the SAGE Interim Recommendations on AstraZeneca group of vaccines is not yet finalized and the listed revisions are still subject to change.

The updated document will be available online shortly at this location on the WHO website:

https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

Update of SAGE policy recommendations on AstraZeneca and SII vaccine products (22 April)

No substantial change in policy

- ✓ Overall recommendations remain the same
- ✓ Benefits of these vaccines largely outweigh the risks
- ✓ Latest data allowed more precision in recommendation language and characterization of risks

Overview of changes

- ChAdOx1-S vaccine products are considered as **equivalent and interchangeable**
- More data on **efficacy of vaccines in 65+**
- **Opened multi-dose vaccine vials to be maintained at 2°C to 8°C** during the in-use period
- **Text on precautions now includes** Thrombosis with Thrombocytopenia Syndrome (TTS)

WHO COVID-19 Partners Platform

Dr Kate O'Brien

Member States can upload their resource needs on the WHO Partners' Platform in the coming weeks

Context

- COVID-19 vaccination campaigns **require significant financial resources for operational needs and vaccine purchase**
- In order to contribute to the funding of these campaigns, **donors need to have a clear view on resource needs of Member States**
- **From April 30th**, Member States will have the **opportunity to upload their resource needs on the WHO Partners' Platform**
- This platform can be used as **a tool to have discussions with MoF, MoH, immunization partners, donors, and other stakeholders**

Overview of the WHO Partners' Platform



- The WHO Partners' Platform is accessible via this [link](#)
- There will be **two ways to upload resource needs**:
 1. Upload the CVIC tool Excel spreadsheet
 2. Use a manual drop-down menu

4 reasons why uploading your needs on the Platform is important

1

Prepare, plan and cost needs associated to your COVID-19 vaccination campaign - WHO has released a new version 2.1 of the “COVID-19 vaccine introduction and deployment costing tool” (CVIC) tool, available [here](#)

2

Help you identify the gaps between country plan needs and existing resources

3

Get access to transparent donor information to help mobilize resources globally

4

Use the Platform to inform discussions with MoF, MoH, immunization partners, donors, and other stakeholders