

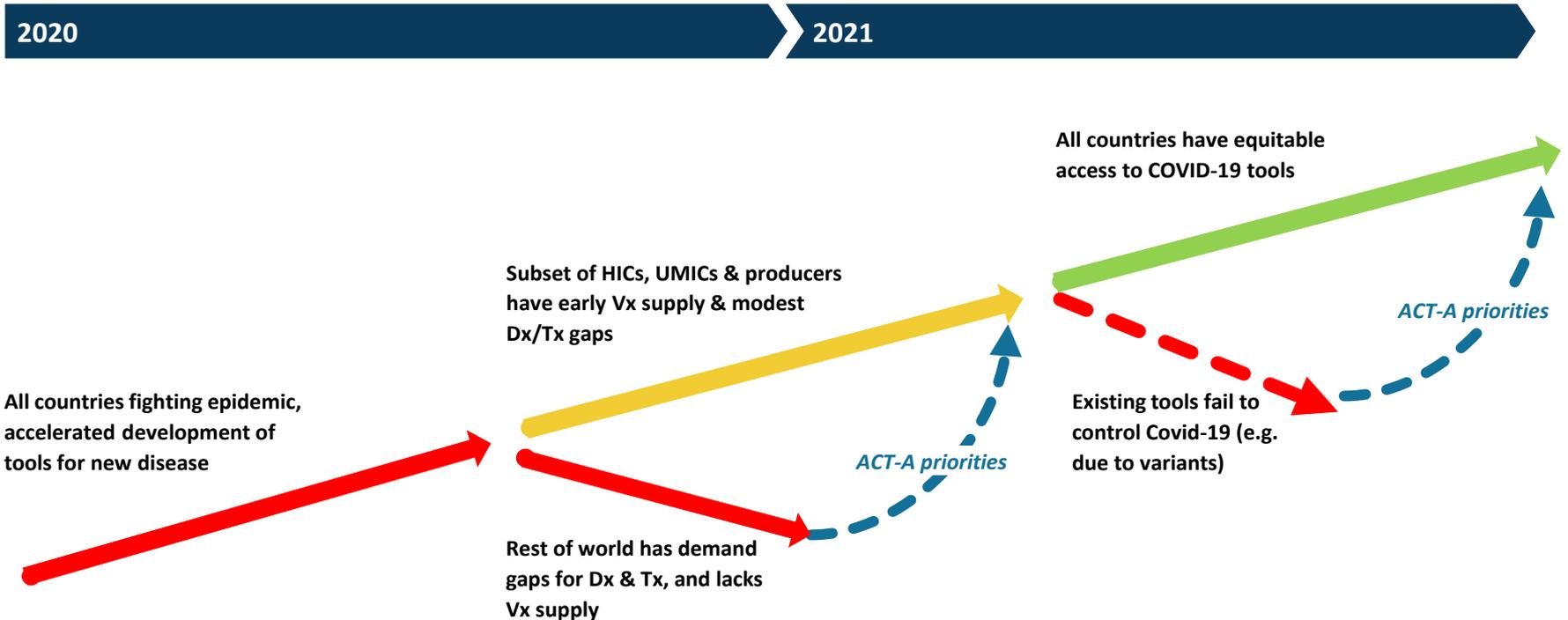
ACT Accelerator: Near Term Priorities

MS COVID-19 Briefing
7 January 2021

Near term ACT-A Priorities

1. Refreshed & Prioritized **Strategy & Budget** (28 Jan briefing)
2. Operationalized **Allocation Mechanism** (14 Jan briefing)
3. Accelerated **Vaccine Rollout** (today)

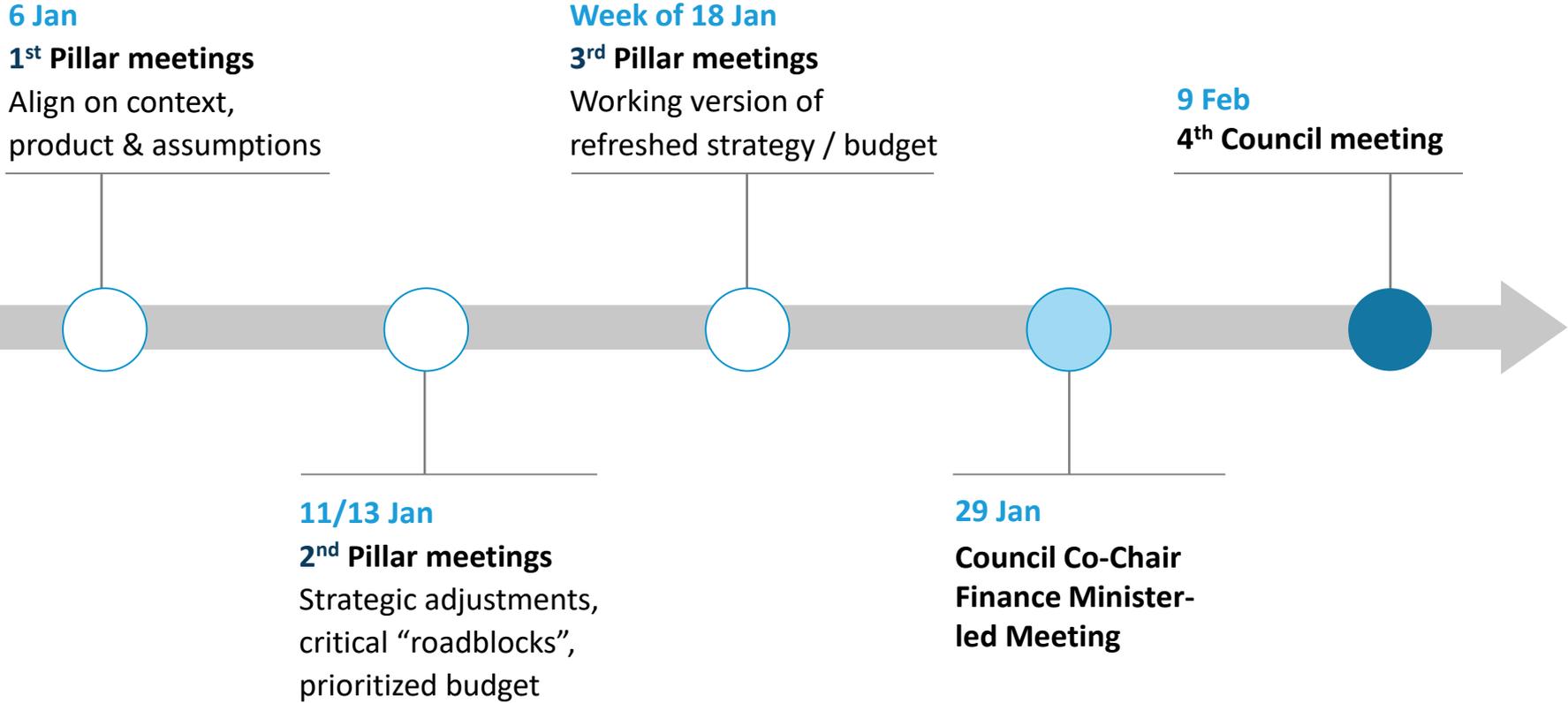
The refreshed ACT-A strategy & priorities will be framed in terms of known and emerging risks to equitable access to Covid-19 tools



Potential ACT-A prioritization (2021)

- address AMC & UMIC Vx supply gaps
- understand / generate Dx, dexa, PPE, O2 demand
- address evolving supply gaps for Tx, Dx
- intensify R&D to enhance tools and mitigate risks

The **timeline for the Strategy & Budget refresh** is driven by a Council Finance Meeting (29 Jan) in advance of the 4th Council



Accelerating Vaccine Rollout

Priorities at 7 January 2021

MS COVID-19 Briefing

State of Vaccines (data at 6 January 2021)

COVID-19 vaccination doses administered per 100 people, Jan 6, 2021



Total number of vaccination doses administered per 100 people in the total population. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

World



Source: Official data collated by Our World in Data. Dates refer to when the data was reported.

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State of Vaccines: campaigns have started in 42 countries

(data as of 6 January 2021)

Legend

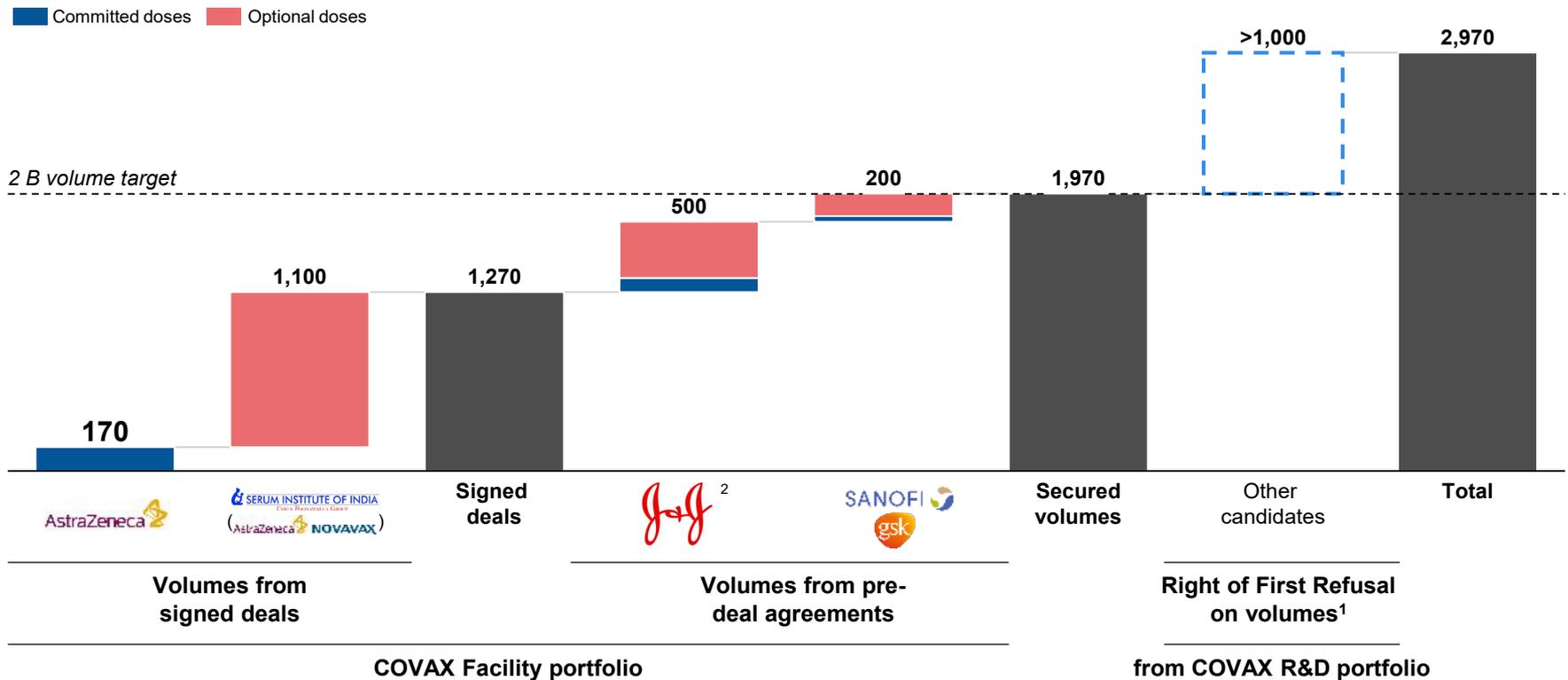
 Ongoing vaccination campaign

Country classification by income level ¹	# of countries per income group	# of countries where vaccination has started	% of countries where vaccination has started	List of countries where vaccination has started
HIC	83	36	43%	Austria, Bahrain, Belgium, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kuwait, Latvia, Lithuania, Luxembourg, Malta, Norway, Oman, Poland, Portugal, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, UAE, UK, USA
UMIC	56	6	11%	Argentina, Bulgaria, China, Costa Rica, Mexico, Russia
LMIC	50	0	0%	-
LIC	29	0	0%	-
Total	198	42	21%	-

1. World Bank classification (2021)
Source: World Bank; Our World in data

COVAX has negotiated to contract ~3 Bn doses (December 2020)

COVAX secured volume, in M doses (2021 and 2022)



1. The COVAX Facility has secured right of first refusal on some candidates that received investments from the COVAX R&D portfolio (led by CEPI)

2. Single dose regimen; no adjustment to 2 dose regimen

Principles for dose-sharing with COVAX (December 2020)



COVAX is accelerating its work to supplement the Facility’s procured doses with donations. **The Principles for Dose-Sharing** now provide a way for high-income economies to make additional volumes from bilateral deals available primarily to AMC participants, for this purpose **on an equitable basis.**



The following Principles for Shared Doses aim to maximize their impact:

- Safe and effective
- Early availability
- Rapidly deployable
- Unearmarked
- Substantive quantity



Shared doses are ideally paid for by the dose-sharing country, including ancillary costs. The Facility ensures these doses are distributed equitably, effectively & transparently while supporting readiness in AMC economies.



“COVAX welcomes commitments by potential dose-sharing countries and manufacturers to adopt these principles and to partner with COVAX to provide additional doses for equitable distribution.”

COVID-19 Vaccines - outlook for equitable access thru COVAX

Medium term (3-6 months) - consolidate



- 2 billion doses
- Deals & pre-Deals: AZ, SII/AZ, SII/Novavax, J&J, Sanofi/GSK, +++
- Regulatory pathways; Indemnification framework; Compensation mech
- Country readiness (100:100 initiative)

Near term (1-3 months) – accelerate



- Regulatory (*see next slides*)
- Deals: Pfizer discussion ongoing
- Donations Framework; early endorsers: EC, France, Canada, Norway
- Early rollout-out activity (*see next slides*)
- Rapid staffing of Allocation Mechanism (*see next slides*)

Planning for a potential COVAX Facility early rollout activity (e.g. Pfizer vaccine)

Priority: planning for a potential ‘early rollout’ activity (i.e. with limited quantities of Pfizer vaccine)

Key objectives

Meaningful public health impact with limited doses
(e.g. target centralized HCWs)

Ensure continuity for countries
(e.g. subsequent deliveries of same vaccines, in meaningful volumes within a reasonable timeframe)

Gain critical learnings in 1st wave for full-scale up

Ensure no doses go idle, with timely delivery

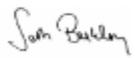
COVAX Facility letter on potential early 'early rollout' activity issued to all participating countries/economies (6 January 2021)

	<p>Participants) and VIT (Self-financing Participants); this with respective countries.</p> <p>Dose allocation and a distribution plan will be reconvened later. Allocation Targetface and/or known and Reserve Group.</p>
by 23 January	<p>COVAX Facility finalizes and communicates distribution activity with Pfizer vaccine, vaccine distribution plan contingent on final confirmation of doses to be made.</p>

Please be assured that whether or not you are part of a small scale, first vaccine, the COVAX Facility is fully committed to ensuring that vaccines will be accessible as quickly as possible in 2021. We will be back in touch soon to.

Should you have any questions, please do not hesitate to reach out to us by email at info@covax.org.

Best regards,



Dr Seth Berkeley
CEO
Gov, the Vaccine Alliance

06 January 2021

Dear COVAX Participants,

Since our December letter, some countries have started rolling out Moderna's COVID-19 vaccine in addition to the Pfizer vaccine and under a similar emergency use authorization by a Stringent Regulatory Authority (SRA). One country is now rolling out the AstraZeneca vaccine after approval by its SRA. We have also seen encouraging seroprevalence and preliminary efficacy results of additional vaccine candidates, which are going through the regulatory process.

COVAX remains fully committed to delivering vaccines to Facility Participants as quickly as feasible. We expect first doses to Facility Participants to be delivered in quarter 1 of 2021, with volumes increasing to more significant levels in quarter 2 and continuing to increase over the course of the year.

As a result of ongoing negotiations with Pfizer, and separate discussions with a number of potential donor-sharing countries, the Facility may be in a position to initiate a small scale 'first wave' of deliveries using the Pfizer vaccine as early as end of January or February, if your country meets the stringent criteria outlined below for this initial small scale 'first wave', and wishes to be considered for inclusion, please email info@covax.org by 15 January 2021.

Despite the delivery challenges of the Pfizer mRNA vaccines, its ultra-cold chain (-80°C storage, with short term storage of up to 5 days in refrigerators at 2-8°C before use) and non-standard 0.5 ml syringe requirements, as well as the limited volumes anticipated to be available in the coming weeks, a properly designed small scale roll out to health workers can further our goal of equitable access to COVID-19 vaccines, provide important learning, and achieve a meaningful public health impact. Vaccines which do not require an ultra-cold chain are expected to begin to become available later in the first quarter. Consequently, while the initial 'first wave' roll out with the Pfizer vaccine may be limited, a much more significant roll-out is anticipated soon afterwards.

To be eligible for consideration for a potential small scale 'first wave' roll out using the Pfizer vaccine, a COVAX Facility Participant must:

- have expressed an interest in mRNA vaccines, plans to initiate vaccination before May 2021, and is willing to receive more than 1 type of vaccine in the national response¹,
- agree to use standard labels² and to rely on WHO Emergency Use Listing or Emergency Use Authorization or equivalent by a WHO designated SRA to grant national regulatory authorization (or, an import authorization) for the Pfizer vaccine in January 2021, and

¹ Although the Vaccine Transfer Plan (VTP) for AEMC Participants, the VTP for self-financing Participants are a subsequent communication.
² without additional words or a language other than Spanish, French, Arabic, English, Chinese or Russian.

Target Date	Step
by 15 January	Facility Participants evaluate readiness, meet minimum criteria, and agree to use Pfizer in February . AEMC Participants may wish to link partners in their evaluation words.
Deadline for Participants to confirm their commitment in a draft NMP or first wave plan	confirming initial plans can be met in January, of health and authorizing authority confirms.
15-23 January	COVAX lead agencies for delivery - WHO, Gov, and submitters. Readiness will be assessed based on draft NMP or first wave plan (AEMC Participants).

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For the 1st early rollout activity (e.g. with the Pfizer vaccine), countries would need to...

- ✓ Express an **interest in mRNA vaccines**, plan to initiate **vaccination before May 2021**, and willingness to use **more than 1 type of vaccine** in the national response¹
- ✓ Agree to use **standard labels**² and rely on **WHO EUL** or **EUA**³ to grant national regulatory authorization for the Pfizer vaccine in January 2021
- ✓ Have necessary **indemnity & liability** frameworks in place in January 2021 and **agreement with Pfizer** to indemnify it for product liability claims

Have the **Minister of Health** or other authorizing authority confirm in writing that:

- ✓ The above conditions for using the Pfizer vaccine can be **fully met in January 2021**
- ✓ Essential elements of an **early rollout plan** are **in place** (incl. target group, vaccination strategy, sites, UCC, sufficient ancillary materials, training plan, safety monitoring & reporting process; plan to address financing)

1. through the Vaccine Request Form (VRF) for AMC participants, the VIF for self-financing participants, or a subsequent communication
 2. Without additional inserts or a language other than Spanish, French, Arabic, English, Chinese or Russian
 3. or equivalent by a Stringent Regulatory Authority

Main country requirements for early, 1st wave activity

Identifying potential 'early rollout countries'

(e.g. Pfizer activity)

Steps involving Countries/Economies

Letter sent out

Participants to **confirm interest** with verification that minimum criteria can be met (incl. AMC MoH or equivalent)

COVAX establishes a **short list of participants** that are **confirmed ready**

COVAX to **review country submissions and readiness** based on draft NDVP or first wave plan as well as VRF or VIF

Dose allocation and a distribution plan to be recommended by the COVAX **Interim Joint Allocation Taskforce** and/or **Interim Independent Allocation of Vaccine Group**.

First wave country notification

Date

- Jan 6
- Jan 18
- Jan 19-28
- Jan 29

Steps involving Regions

Regional engagement cross-agencies - general update (demand, supply) and cross-agency alignment

The table is a dense grid of data with multiple columns. The columns include headers such as 'Region/Country', 'AMC', 'COVAX', 'Vaccine', 'Status', 'Date', 'Supply', 'Demand', 'Allocation', 'Notes', and 'Comments'. The rows are color-coded in alternating shades of green and yellow, representing different regions or countries. The data appears to be organized by region, with each region having a set of rows detailing various metrics and dates.

WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (1/2)

- BNT162b2 (Pfizer vaccine) has been shown to have an **efficacy** of 95% against symptomatic SARS-CoV-2 infection.
- No data are available related to **impact on transmission** or viral shedding.
- Vaccination is recommended for persons aged 16 years and above.
- The **recommended schedule** is two doses given intramuscularly with an interval of 21–28 days between the doses.
- The need for **flexibility** in the schedule was acknowledged and current data support an extension up to 42 days (6 weeks).
- The same product should be used for both doses. There are **no studies on interchangeability** with other vaccines against COVID-19 .

WHO interim recommendation for the use of mRNA BNT162b2 (Pfizer-BioNTech) (2/2): *Vaccination of specific populations*

- BNT162b2 is not a live vaccine, the mRNA does not enter the nucleus and is rapidly degraded. Animal studies show no toxicity to the fetus, but no data on safety in pregnant women exist.
- SAGE recommends not to use BNT162b2 in **pregnancy** until more data are available, except where the benefit outweighs risks, such as health workers at high risk of exposure or women with significant comorbidities.
- Vaccination can be offered to **breastfeeding women** if part of risk group, and WHO does not recommend discontinuation of breastfeeding after vaccination.
- Vaccination can be offered to **people living with HIV** in accordance to the prioritization roadmap

Expediting Regulatory Review of COVID-19 Vaccines/Products

Priority: expediting regulatory review of key products (data at 7 Jan)

Stringent Regulatory Authority & WHO approvals

- Pfizer multiple SRAs & WHO (30 Dec)
- Moderna US, CAN; EMA (week of 4 Jan); WHO (TBD)
- AZ/Oxford UK; (EMA, FDA, WHO decision Feb/Mar)

National Regulatory Authority (NRA) approvals

- SII/AZ India (WHO decision Jan/Feb)
- Bharat Biotech India ('clinical trial use')
- Sputnik Russia, Argentina; (WHO in discussion)
- Sinopharm China, UAE, Bahrain; (WHO inspection Jan/Feb)
- Sinovac TBD; (WHO site inspection Jan/Feb)

WHO PQ/EUL Updates for COVID-19 Vaccines

PQ/EUL update on COVID-19 vaccines

Status of applications/assessments

https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_Dec2020.pdf

List of SRAs from which approval will be acceptable, under exceptional circumstances, for product eligibility under the COVAX Facility

https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

EUL Pfizer report

<https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-mrna-vaccine-nucleoside-modified-comirnaty%C2%AE>

PQ/EUL update on Immunization Equipment

- Two brands of 0.3 ml AD syringes were PQed 31 December 2020
- ultra-low shipment supplement to WHO shipping guidelines to be published in Q1 2021
- WHO specifications for ULT freezers and associated power requirements, end January 2021

WHO PQ/EUL assessment timeline for COVID-19 Vaccines

(details at 7 January 2021)

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.		BNT162b2/COMIRNATY	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.		AZD1222	Core – EMA Non-COVAX	recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein	✓	✓	✓	In progress Core data Non-Covax. Covax data to be reviewed as EMA post approval change	Earliest by EMA Feb 2021 (non-Covax) Additional nodes in March/ April for Covax
5.		AZD1222	MFDS KOREA	=	✓	✓	Tentative 18 and 29 Jan 2021 (CMC for SK Bio)	Core data (non-covax) in progress	Earliest end of Feb 2021
6.		Ad26.COVID.S	EMA	recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Rolling data to EMA – Dec, Feb, April (critical data), May	Not yet started. Use abridged procedure relying on EMA	Earliest May – June 2021

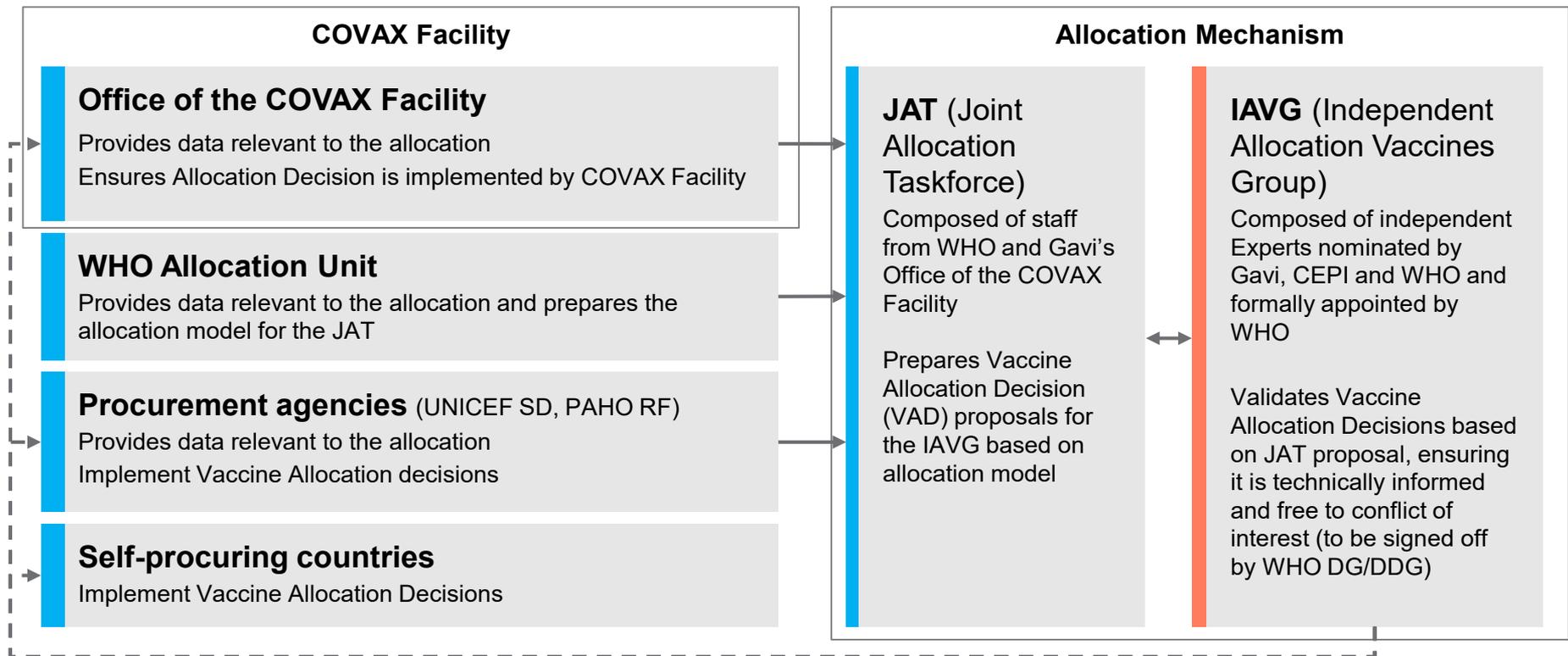
WHO PQ/EUL assessment timeline for COVID-19 Vaccines (cont'd)

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.	 Sinopharm / BIBP ²	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	End of Dec 2020		Earliest March
2.	 sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	Tentative early Jan 2021		Earliest March
3.	 THE GAMALEYA NATIONAL CENTER	Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	Under screening – Non CTD.		
4.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
5.	 康希诺生物 CanSinoBIO	Ad5-nCoV		Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested				
6.	 moderna	mRNA-1273	EMA	mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)	Expected in Jan 2021				Estimated end of Feb 2021
7.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	EOI Under assessment	08 Jan 2021			
8.	 Sinopharm / WIBP ¹		NMPA	No pre-submission meeting yet					
9.	 NOVAVAX		EMA	No pre-submission meeting yet					

Establishing the Independent Allocation Working Group (IAVG) for the COVAX Facility

Context: The IAVG contributes to the validation of Vaccine Allocation Decisions for COVAX Facility

→ Input → Implementation **Operations** **Validation**



Priority: establish the Independent Allocation of Vaccines Group (IAVG) to support the allocation of COVAX Facility Vaccines

Role

Validates Vaccine Allocation Decisions based on *Joint Allocation Taskforce* (JAT) proposal, ensuring it is technically informed and free to conflict of interest (to be signed off by WHO DG)



Composition

12 multidisciplinary members appointed by WHO with expertise in the following areas:

Access to medicines and health products	Global immunization (incl. program delivery) and/or infectious disease epidemiology
Emergency public health response	International health diplomacy, law and policy

Due consideration will be given to the principles of equitable geographical representation and gender balance



Status



Expressions of Interest to be sent by **Friday Jan 8th** on IAVGnominations@gavi.org

More information: <https://www.who.int/news-room/articles-detail/covax-independent-allocation-of-vaccines-group>

Backup

State of Vaccines (data at 6 January)

COVID-19 vaccination doses administered, Jan 6, 2021



Total number of vaccination doses administered. This is counted as a single dose, and may not equal the total number of people vaccinated, depending on the specific dose regime (e.g. people receive multiple doses).

