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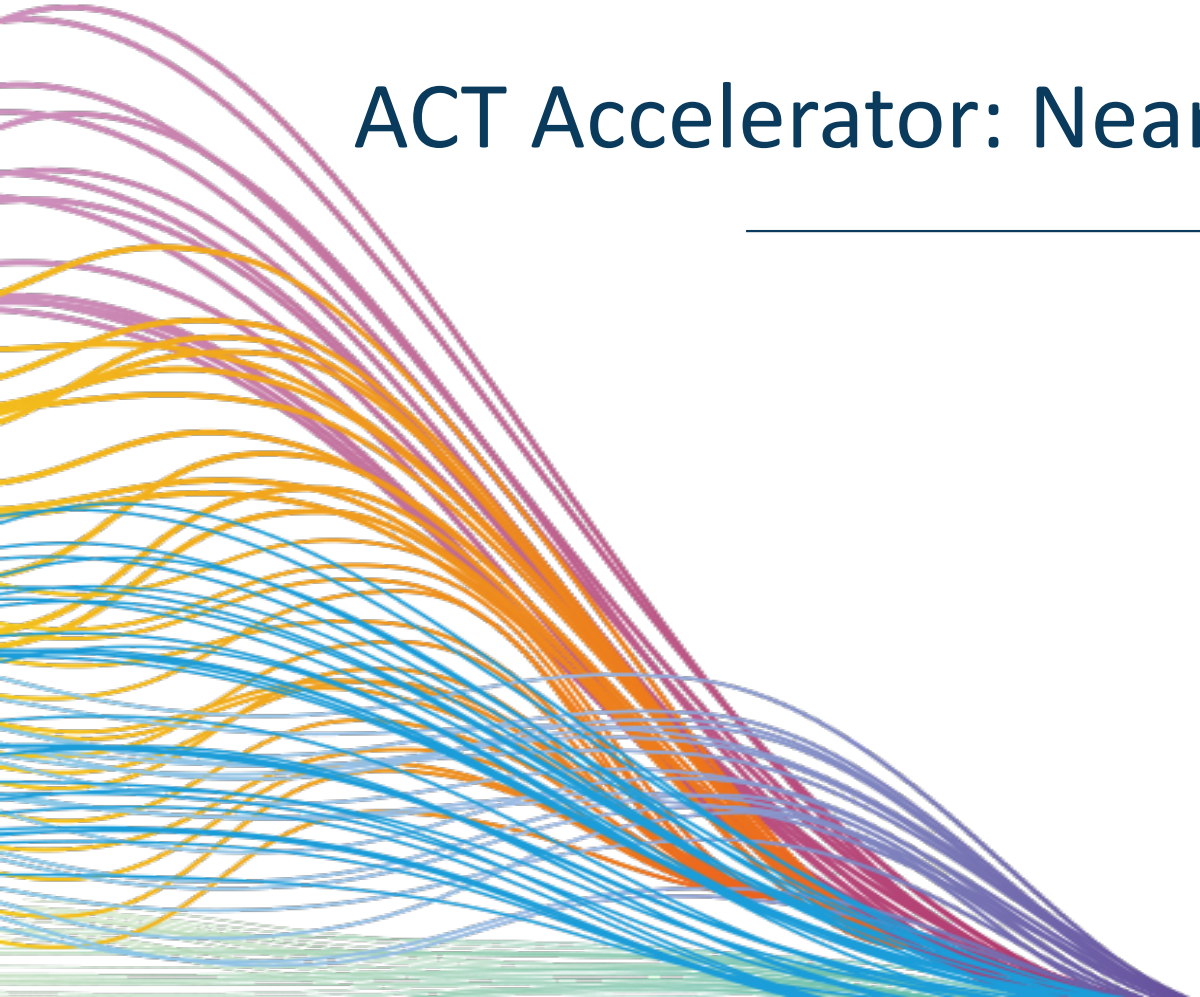


ACT Accelerator: Near Term Priorities

MS COVID-19 Briefing
7 January 2021

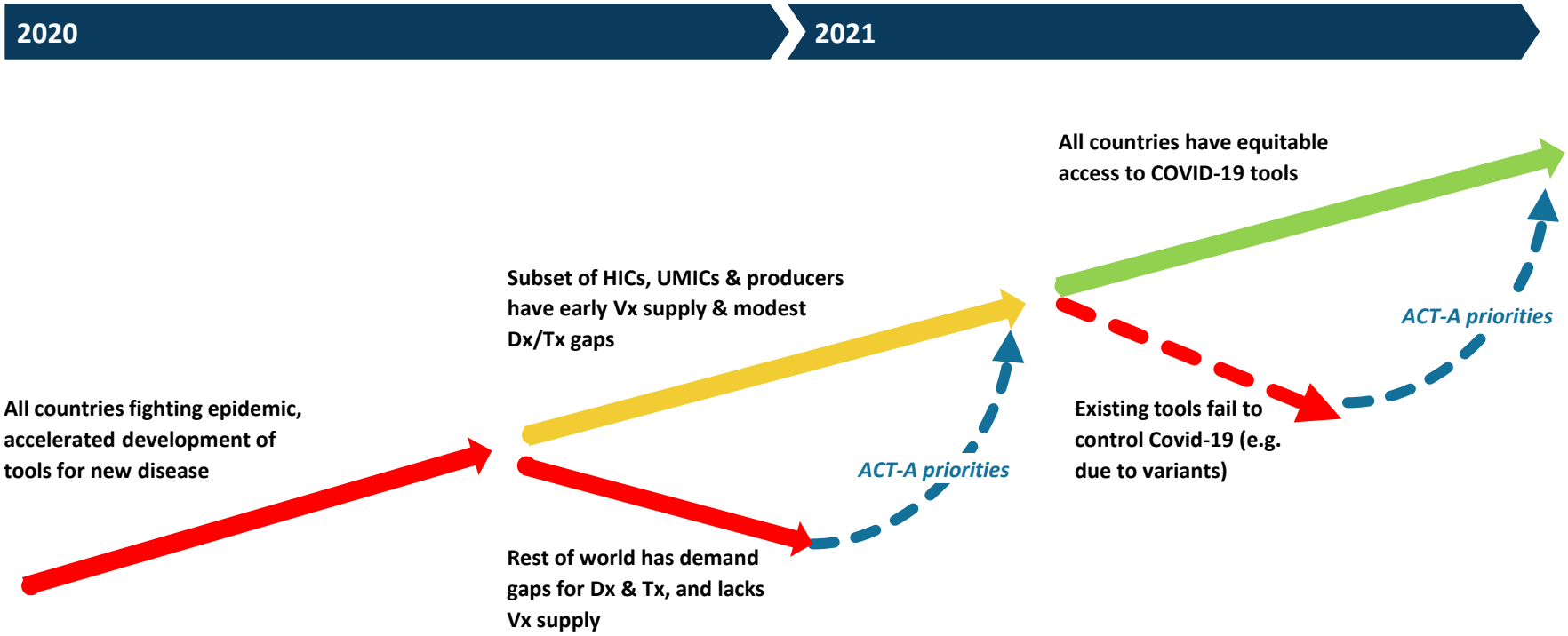
Near term ACT-A Priorities

1. Refreshed & Prioritized **Strategy & Budget** (28 Jan briefing)

2. Operationalized **Allocation Mechanism** (14 Jan briefing)

3. Accelerated **Vaccine Rollout** (today)

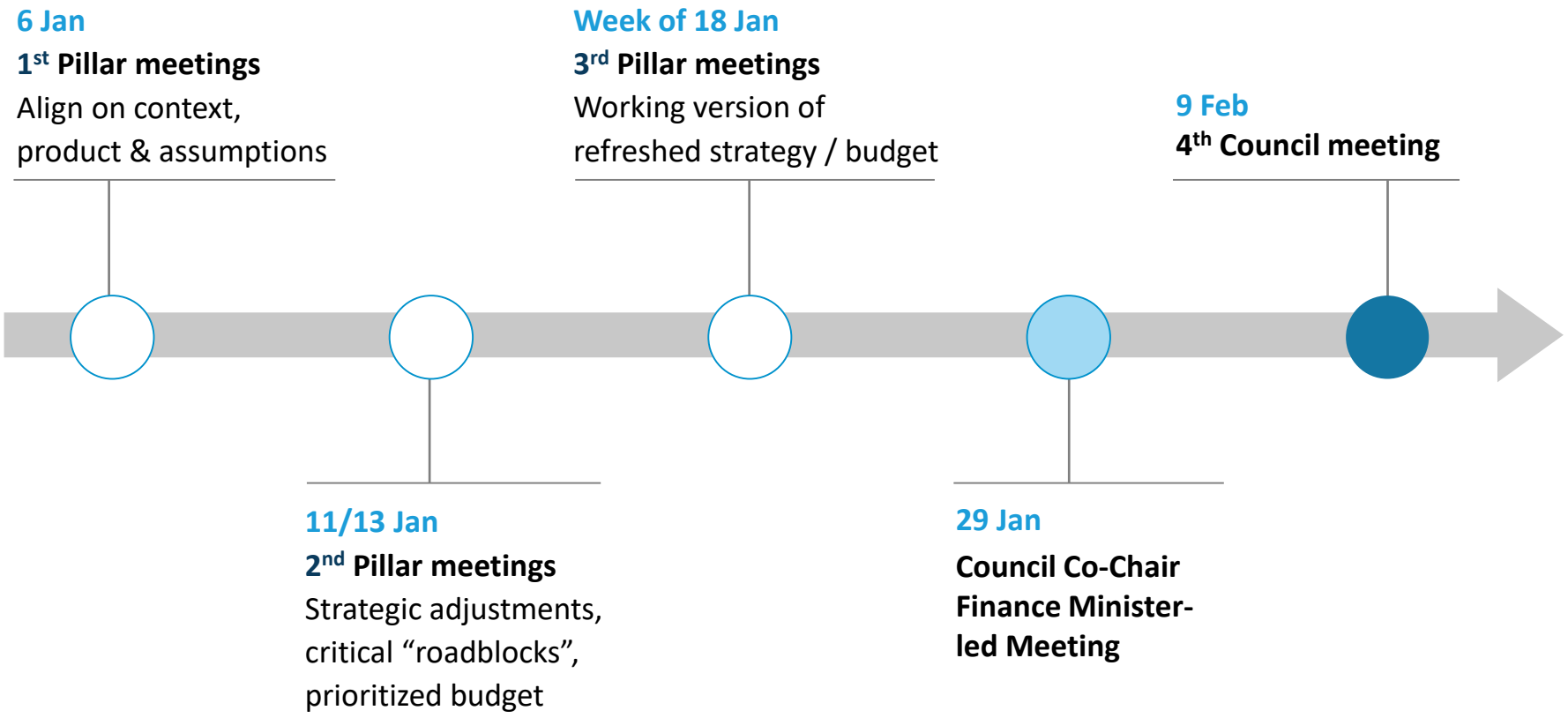
The **refreshed ACT-A strategy & priorities** will be framed in terms of known and emerging risks to equitable access to Covid-19 tools



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



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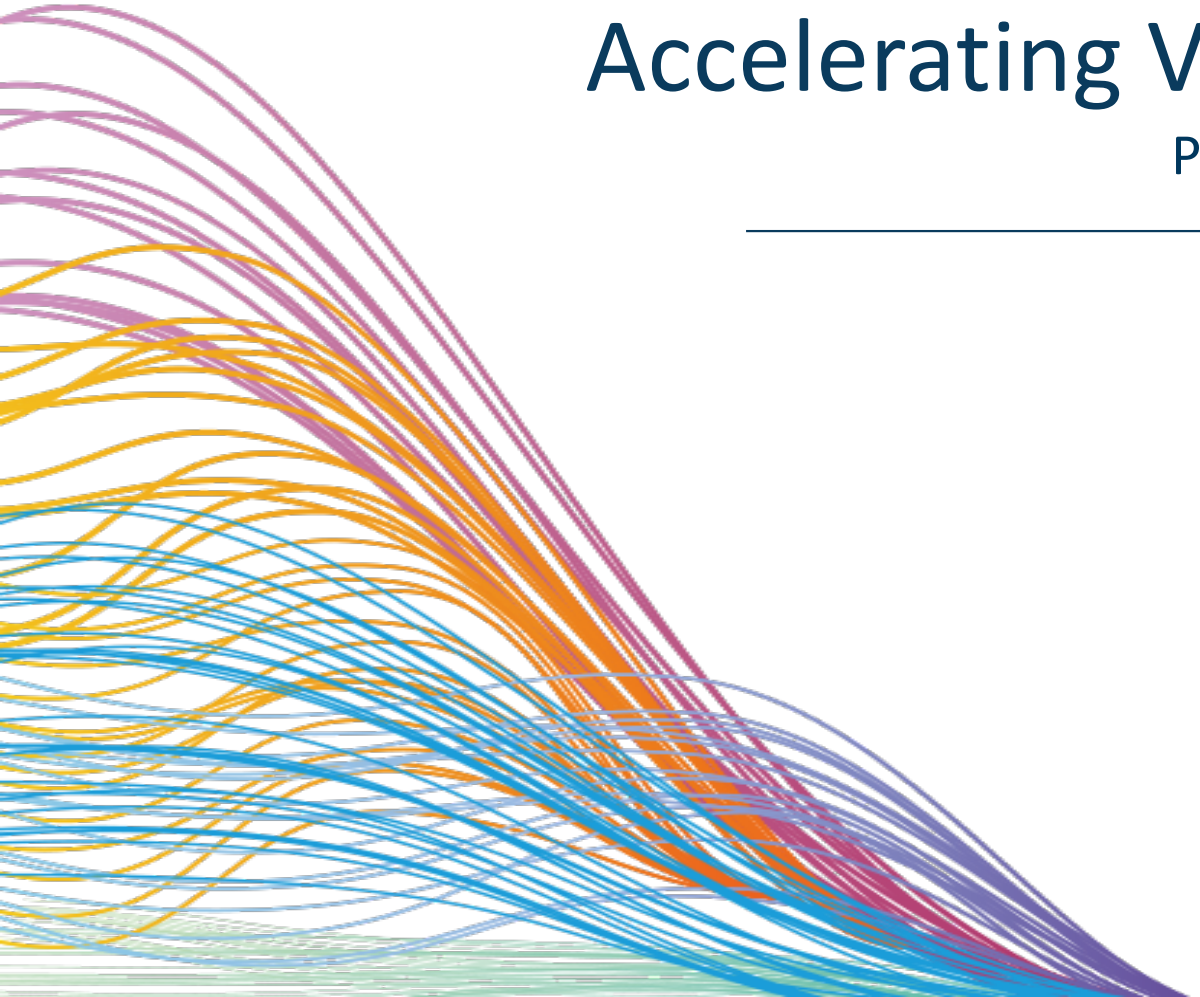

Accelerating Vaccine Rollout

Priorities at 7 January 2021

MS COVID-19 Briefing

State of Vaccines (data at 6 January 2021)

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State of Vaccines: campaigns have started in 42 countries

(data as of 6 January 2021)

Legend
Ongoing vaccination campaign

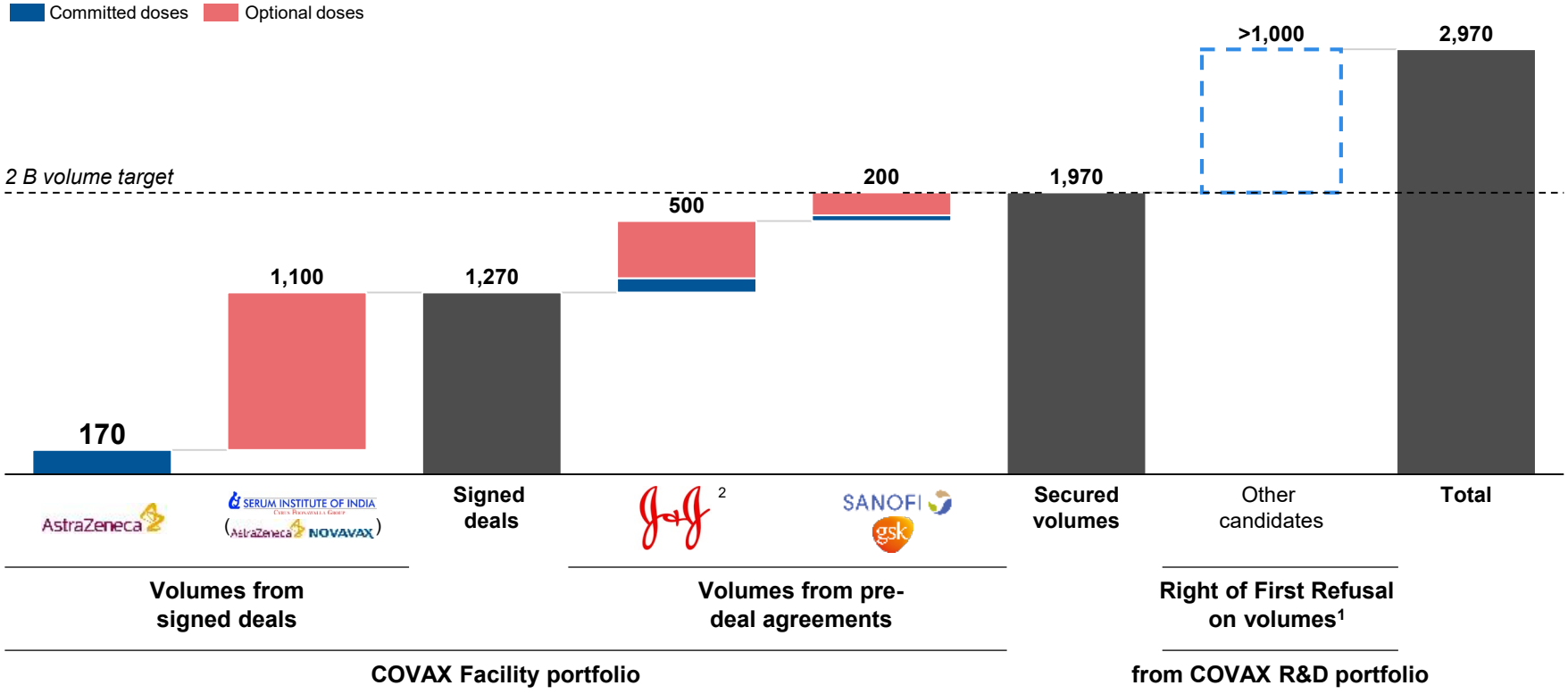
Country classification by income level[1]	# of countries per income group	# of countries where vaccination has started	% of countries where vaccination has started	List of countries where vaccination has started
HIC	83	36	43%	Austria, Bahrain, Belgium, Canada, Chile, Croatia, Cyprus, Czech Republic, 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)

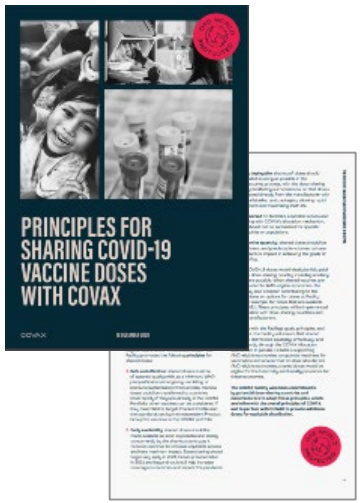
COVAX secured volume, in M doses (2021 and 2022)



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."

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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

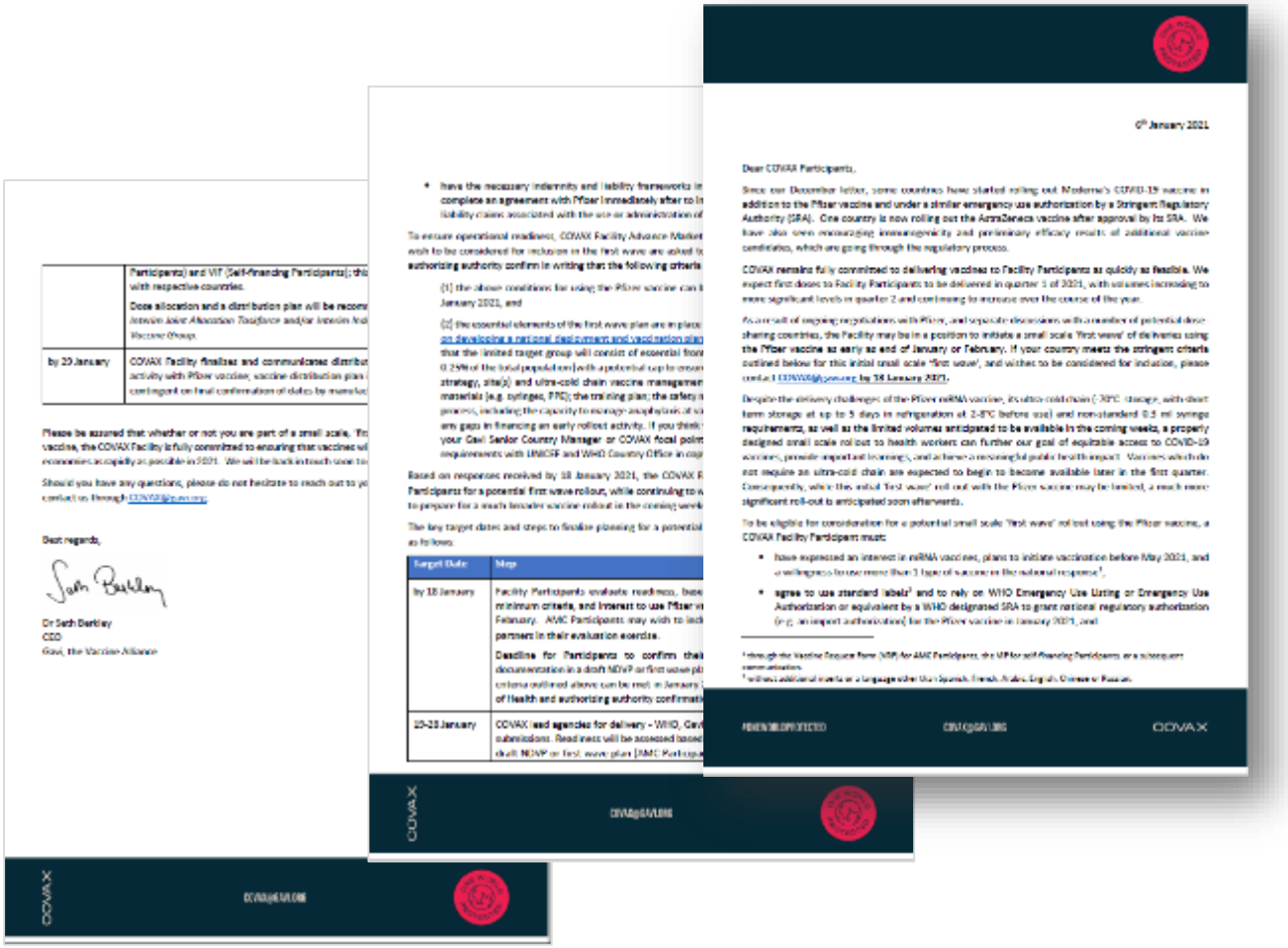
Meaningful public health impact with limited doses
(e.g. target centralized HCWs)

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)



Main country requirements for early, 1st wave activity

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 response[1]
- 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

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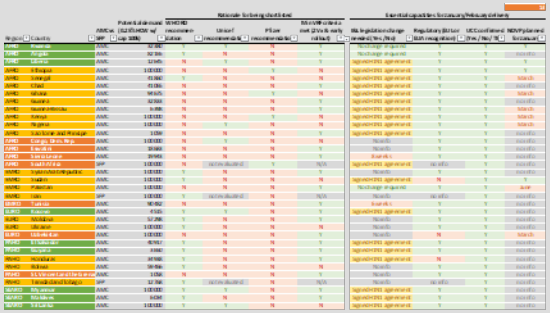
Identifying potential 'early rollout countries'

(e.g. Pfizer activity)

Steps involving Countries/Economies	Date	Steps involving Regions
Letter sent out	Jan 6	Regional engagement cross-agencies - general update (demand, supply) and cross-agency alignment
Participants to **confirm interest** with verification that minimum criteria can be met (incl. AMC MoH or equivalent)	Jan 18	
COVAX establishes a **short list of participants** that are **confirmed ready**	Jan 19-28	
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	Jan 29	

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)

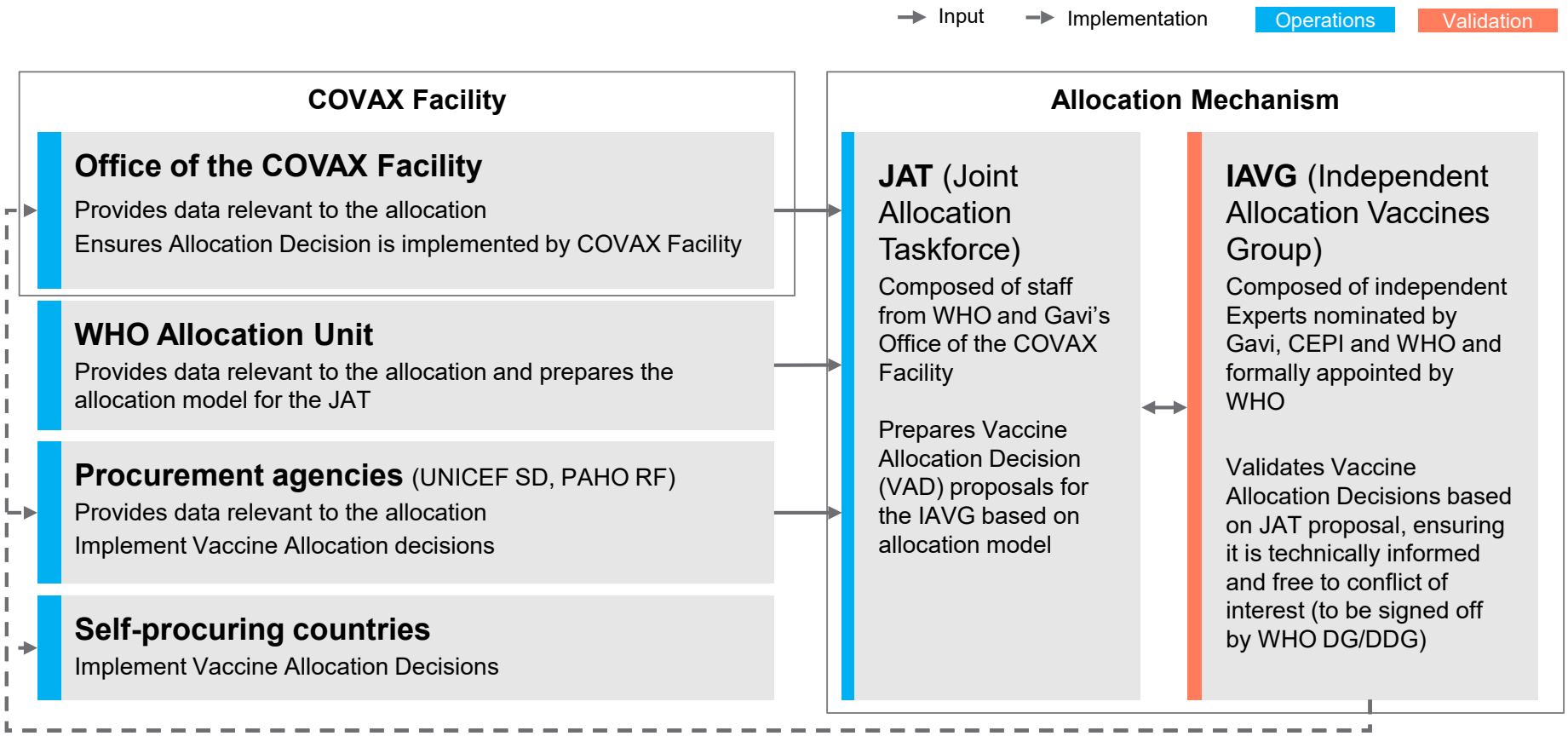
	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.	Pfizer BIONTECH	BNT162b2/COMIRNATY	EMA	Nucleoside modified mNRA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine（CHO Cell）	NMPA	Recombinant protein subunit	Not accepted Product in Phase I/II				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.	AstraZeneca OXFORD	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.	SK BIO AstraZeneca OXFORD	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.	janssen Infectious Diseases & Vaccines	Ad26.COV2.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 OF EPIDEMIOLOGY AND MICROBIOLOGY	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 Viralogy 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



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

- Open call launched on Dec 18
- Deadline for nominations on Jan 8th
- Members appointed by WHO in January

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)

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