World Health Organization

Member States Briefing – Allocation Mechanism for Vaccines

February 11th 2021

Agenda

1 **Recap of the Allocation Mechanism for COVAX Facility Vaccines and latest activities**

2 Governance of the Allocation Process

3 Allocation Logic for COVAX Facility Vaccines

1 Back in May 2020 - Why was an allocation mechanism conceptualized?

Goal

Protect public health and minimize societal and economic impact by reducing COVID-19 mortality

Rationale for an allocation mechanism

- Availability of a limited number of vaccines doses to be supplied to the COVAX Facility
- Many candidates, uncertainties if any would be successful
- The Allocation Framework (and resulting Mechanisms) would ensure equitable access to COVAX vaccines, adapted to be pragmatic so participants could have access to vaccines as soon as possible

1 From May 2020 to February 2021 – what has and has not changed?

What has changed?

- The Facility is facing **global competition and constraints over supply**, with bilateral agreements between countries and manufacturers for considerable amounts of doses
- Out of COVAX vaccine candidates, some **clinical trials ended** and some vaccines were **authorized for emergency use** (Globally: Pfizer, and soon for AZ and SII, with many countries approving earlier for national emergency use)
- **Vaccination has started in 75 economies as of Feb 10th**
  - incl. 52 HICs, 13 UMICs, 9 LMIC and 1 LIC
  - 134 million vaccine doses have been administered (~86% of these doses have been administered in 10 countries)

What has not changed?

- The **need to ensure countries have access** to doses, without having to go into individual agreement with different manufacturers, regardless of income level

1 Where we are now – Latest developments and next steps

- A communication was sent from the facility on Jan 29th to participants indicating expected AZ and SII supply until June 2021 – this was an indicative information and not an official allocation
- EUL is expected mid-February for SII and AZ (SK Bio site)
- The first allocation round will allocated those 3 products: Pfizer, SII and AZ (SK Bio site) after EUL and **announced before end of February**
- In addition, to avoid idle doses and speed up operations to distribute vaccines, **a small amount of early doses will be made available** upon EUL to serve ready participants as soon as possible
- Those doses will be a part of the allocation communicated and be deducted from future purchase orders

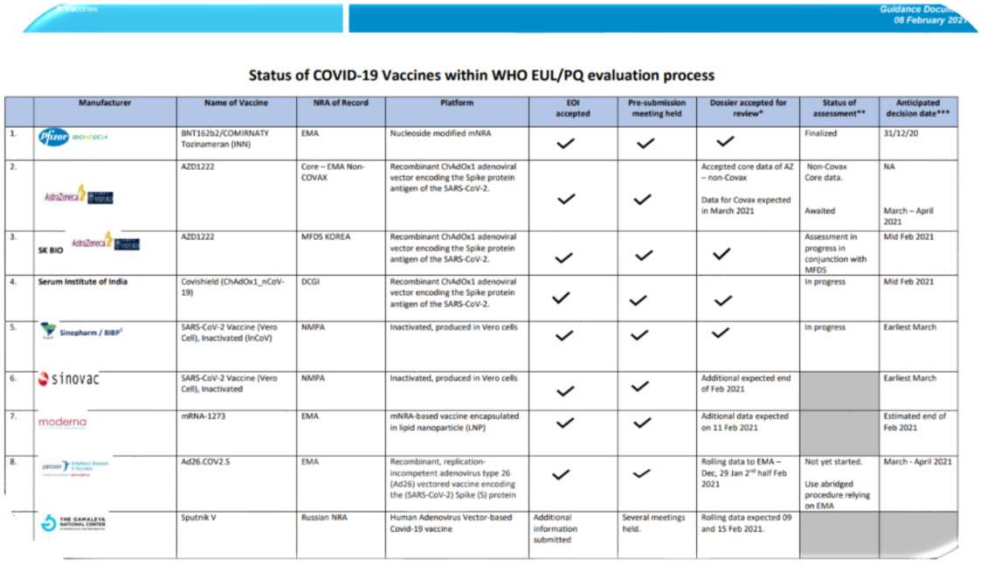
1 WHO Emergency Use Listing (EUL) – indicative review timelines

December: Pfizer/BioNTech (30 Dec)

mid-February: AZ/Serum Institute of India
AZ/SK Bio, Korea

early March: Sinopharm
Sinovac

In discussion: Moderna
J&J
Novavax
Gamaleya



Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	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 Tozinameran (INN)	EMA	Nucleoside modified mNRA	✓	✓	✓	Finalized	31/12/20
2.		AZD1222	Core – EMA Non-COVAX	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	Accepted core data of AZ – non-Covax Data for Covax expected in March 2021	Non-Covax Core data. Awaited	NA March – April 2021
3.	SK BIO	AZD1222	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Assessment in progress in conjunction with MFDS	Mid Feb 2021
4.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	In progress	Mid Feb 2021
5.	Sinopharm / BIBP	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Earliest March
6.	sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	Additional expected end of Feb 2021		Earliest March
7.	moderna	mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	Aditional data expected on 11 Feb 2021		Estimated end of Feb 2021
8.		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, 29 Jan 2nd half Feb 2021	Not yet started. Use abridged procedure relying on EMA	March - April 2021
		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted	Several meetings held.	Rolling data expected 09 and 15 Feb 2021.		

https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08Feb2021.pdf

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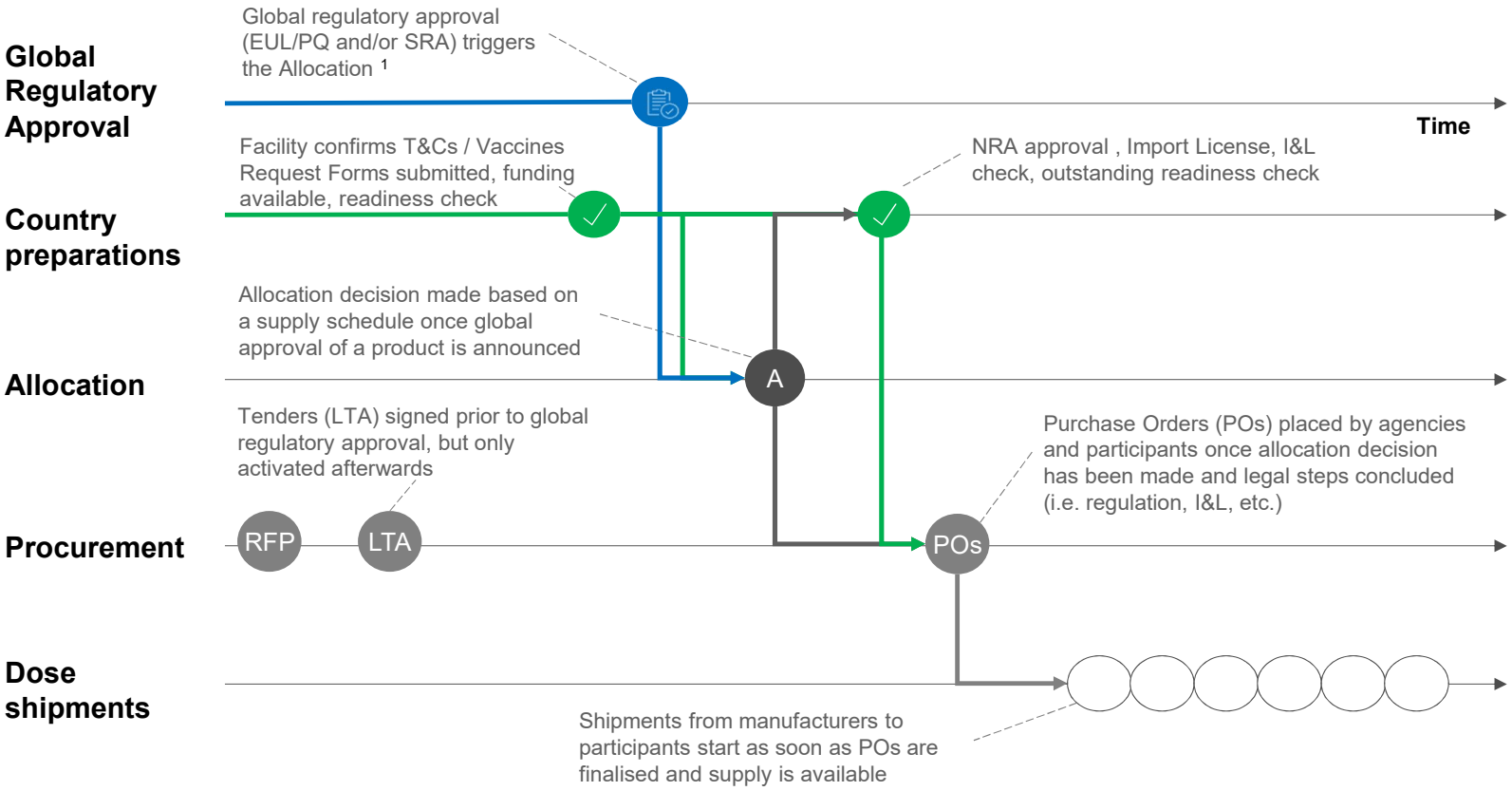
2 Governance of the Allocation Process

3 Allocation Logic for COVAX Facility Vaccines

2 Allocations are triggered by global regulatory approvals[1], followed with continuous shipments as supply is made available

ILLUSTRATIVE

SIMPLFIED FOR A SINGLE PRODUCT

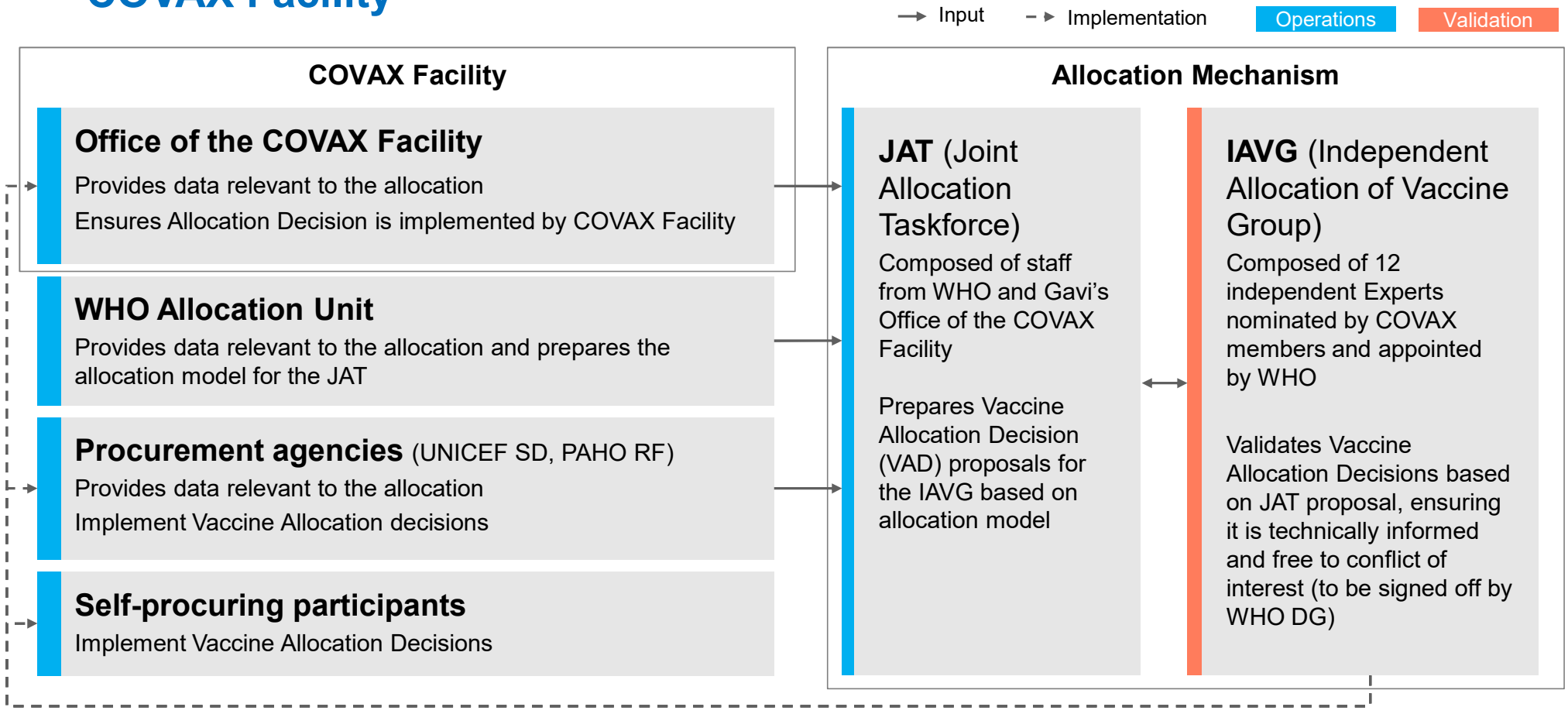


Changes in supply and demand may require updated Allocation decisions (e.g., new products being made available)

Those processes are happening in parallel when possible to speed up delivery of doses

1. Plus SAGE policy recommendation and favourable supply prospects for COVAX Facility

2 The Allocation Mechanism for Vaccines interacts directly with the COVAX Facility



2 Composition of the Independent Allocation of Vaccine Group (IAVG)*

Professor Anna Mia Ekström >

Dr Arlene King >

Christopher Maher >

Hachiya Masahiko >

Dr Narendra Kumar Arora >

Dr Bruce G. Gellin >

Dr Dafrossa Cyrily Lyimo >

Professor Tjandra Aditama >

Doctor Alejandro Cravioto >

Maria Guevara >

Dr Manica Balasegaram >

Poh Lian Lim >

- The 12 IAVG members have been selected
- The terms of reference as well as their profiles are available at: https://www.who.int/groups/iavg

* As of 11 February 2021

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3 Allocation Logic for COVAX Facility Vaccines

3 Why are we using an Algorithm to allocate the COVAX vaccines among participants?

Context

- Phase 1 – coverage proportional to population
- All participants should, to the extent possible get coverage at the same time, up to 20%.
- Additionally, participants have expressed their product preferences, and their desire for consistency between allocated products.

Role of the algorithm

- Objective and transparent tool for allocation
- Optimize for three competing objectives:
  - Equality, Vaccine Preference and Vaccine Consistency
- Speed to provide an allocation after an EUL
- The amount of data to be processed for the ~190 participants and the portfolio of vaccine

This role increases in importance as more vaccines in the COVAX portfolio become available for allocation

3 The Allocation logic optimises the proposed allocation based on three of the 7 Phase 1 objectives

1. Only products that have **EUL, PQ or SRA approval** [4] can be allocated
2. **Time gap** between first and last participant receiving doses **should be minimised** in each round
3. **No doses should remain idle** – doses should not be 'stockpiled' before allocation
4. The allocation should **serve all participants able and willing** to receive doses
5. Participant should receive doses for the **same proportion of population** over time[3]
6. Participants should **receive a single product** throughout where possible[1,2]
7. Participants receive products **in line with their preferences** where possible[2]

The allocation logic optimises the proposed allocation based on **three of the core objectives** [5]**:**

- Ensure equality in population covered
- Ensure product consistency
- Match participant preferences

These objectives need to be weighted as they tend to compete against each other

1. With the exception of the Pfizer vaccine which has specific characteristics and is not likely to be used to cover the full request for any one participant
2. For AMC Participants and Committed Purchase participants
3. With exceptions for small participants
4. Once WHO EUL is granted, a global policy recommendation will be issued by WHO. If supply prospects are favourable, the allocation is triggered
5. The allocation algorithm doesn't track funding availability for AMC participants

3 The allocation logic consists of 5 key simple steps

NOT EXHAUSTIVE

Under discussion

	Supply		Demand		Optimisation	
Key steps	A Establish supply forecast	→	B Establish demand constraints	→ C Establish demand envelope	→ D Match supply to demand preferences	→ E Establish delivery sequence
Description	Consolidate supply information to create a forecast for allocation		Determine which participants can receive which products	Determine the min and max volumes each participant can receive in the allocation round	Find the optimal match between supply and demand across participants	Define the order in which participants will receive their allocation
Key inputs from COVAX Partners	• Forecast of Vx supply volumes • Vx characteristics (incl. price per dose) • Dose donations		• Participation agreements (model) • Opt-outs from optional purchase participants • Country readiness assessment • T&Cs status • VRF[1] status • Vx deal destination constraints	• Minimum shipment sizes (for logistic / cost reasons) • Participation agreements (model, % coverage requested) • Pro-rata share (optional purchasers)	• Product preferences expressed by participants • Products received / exchanged in previous rounds	

Source: COVAX Facility WHO UNICEF SD / PAHO RF

1. Vaccine Request Form (AMC)

3 D

Match supply and demand preferences

The allocation is optimized through an algorithm towards three objectives: Equality, Product consistency and Product preference

Three optimisation objectives[1]

Objectives	Explanation
Minimise inequality	Minimise differences in % population covered between participants
Maximise product preference match [2]	Ensure each participant receives the product with the closest match to their preferences
Maximise product consistency [3]	Ensure participants do not receive a mix of different products (where possible)

The three objectives are weighted in the algorithm, with most weight given to equality

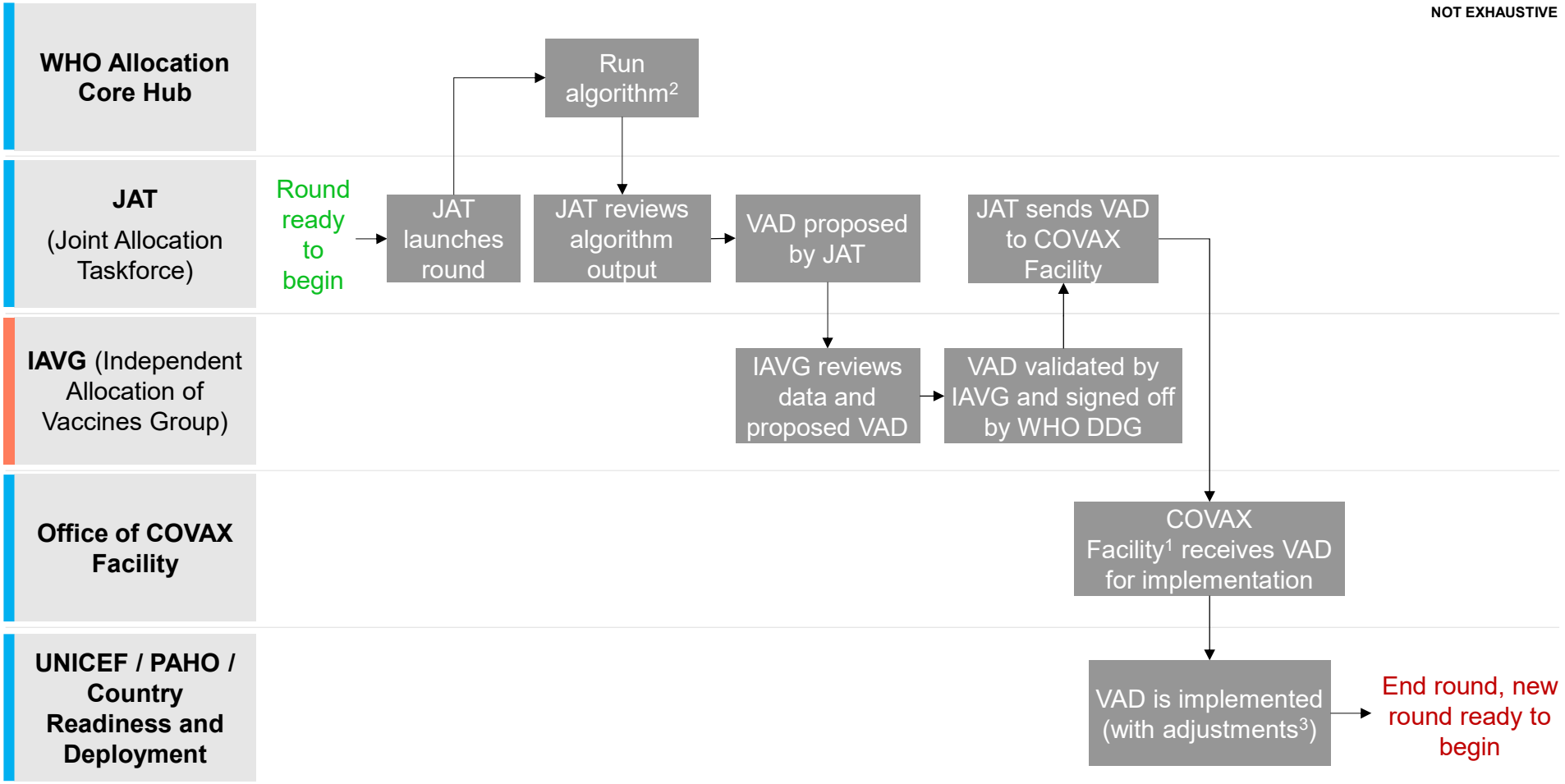
1. Objectives are weighted
2. Does not apply to optional participants, since they don't provide preferences but chose which product to receive
3. Will be relaxed for participants that indicate in their VRF / VIF that they would prefer to receive product quickly rather than wait to obtain a single product

PRELIMINARY

3 The JAT and IAVG formulate a Vaccine Allocation Decision, passed on to COVAX Facility for implementation

Operations | Validation

NOT EXHAUSTIVE



1. The allocation would then be passed to UNICEF SD as supply coordinator, and PAHO RF and self-procuring participants
2. Algorithm can be checked/modified by JAT if required
3. Exceptional operational adjustments by UNCEF SD and PAHO RF based on rules formulated by the JAT

WHO/OCF Joint Allocation Taskforce

For more information please contact WHO at the following address:

JAT@who.int

Backup

3 Objectives of the Phase 1 allocation

1. **No doses should remain idle** – doses should not be 'stockpiled' before allocation
2. The **allocation serves all participants able and willing to receive doses** – (excluding any limitations based on deals)
3. Only products that have **EUL, PQ** or in some cases **SRA approval** can be allocated[4]
4. **Time gap between first and last participant** receiving COVAX doses within a round should be **minimised**
5. Participant should receive doses for the **same proportion of population** over time[3]
6. Participants should **receive a single product** throughout where possible[1,2]
7. Participants receive products **in line with their preferences** where possible[2]

1. With the exception of the Pfizer vaccine which has specific characteristics and is not likely to be used to cover the full request for any one participant
2. For AMC Participants and Committed Purchase participants
3. With exceptions for small participants
4. Once WHO EUL is granted, a global policy recommendation will be issued by WHO. If supply prospects are favourable (APA or LTA), the allocation is triggered

3 A

Establish supply forecast

UNICEF Supply Division as procurement coordinator will provide the JAT with a forecast of which product can be allocated during the round as well as the product's key characteristics

Illustrative example

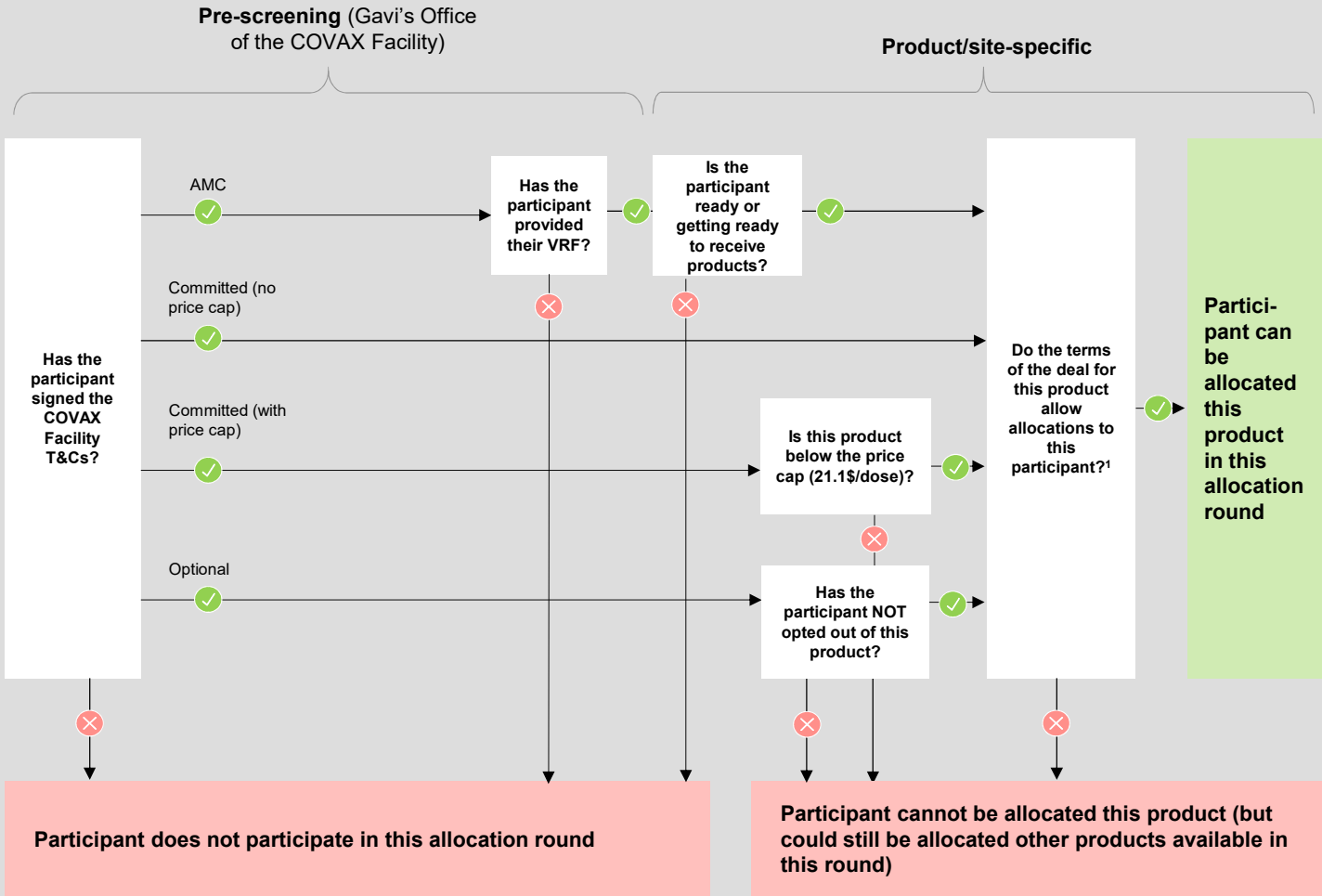
	Product A		Product B
	Site A1	**Site A2**	**Site B1**
	10M within 8 weeks by Q1 2021	**10M** within 8 weeks (by April 2021)	**20M** in March 2021
Platform	✓ mRNA ❑ Inactivated ❑ Viral Vector	✓ mRNA ❑ Inactivated ❑ Viral Vector	❑ mRNA ✓ Inactivated ❑ Viral Vector
Regulatory status	✓ PQ ✓ EUL ✓ SRA	✓ PQ ✓ EUL ✓ SRA	✓ PQ ✓ EUL ✓ SRA
Cold chain	❑ 2-8 C ❑ -20 C ✓ -70 C	❑ 2-8 C ❑ -20 C ✓ -70 C	✓ 2-8 C ❑ -20 C ❑ -70 C
Other	**5** Doses / vial **2** Doses / regimen **10$** Price / dose	**10** Doses / vial **2** Doses / regimen **10$** Price / dose	**10** Doses / vial **2** Doses / regimen **5$** Price / dose

3 B

Establish demand constraints

The eligibility of participants for each products would be checked before the allocation round

Illustrative example - approach



1. Will be impacted by whether or not SFPs have met financial commitments to be included in each deal

Note: The algorithm may also exclude participants from early rounds if they have indicated they would prefer to wait in order to receive a single product throughout

3 C

Establish demand envelope

Based on the two previous steps, a range of maximum and minimum allocation limits is determined by participants, based on constraints such as the minimum shipment quantity or the pro-rata share that optional participants can receive for each deal with manufacturers

Illustrative approach and output

- The minimum allocation for each participant would be the minimum shipment quantity (tbd)
- The maximum allocation allowable for each participant is based on how many doses they have requested in Phase 1 (subtracting previous allocations)
- For optional purchase participants, a correction is to be applied to ensure that they obtain their full pro-rata share by the end of each deal to which they participate

	Product A		**Product B**	…
	Site A1	**Site A2**	**Site B1**	…
Participant A	⊗	Min: 50k Max: 50M	Min: 50k Max: 50M	
Participant B	Min: 50k Max: 15M	Min: 50k Max: 15M	⊗	
Participant C	Min: 50k Max: 200M	Min: 50k Max: 200M	Min: 50k Max: 200M	

For some participants, some products cannot be allocated (as per demand or supply constraints)

3 D

Match supply and demand preferences

Based on the optimization algorithm, each participant is allocated an amount of doses per product

Illustrative output

The algorithm determines how many doses each participant should receive from each site to match supply and demand

	Product A		Product B	…
	Site A1	Site A2	Site B1	…
Participant A	⊗	0M	0.2M	
Participant B	0	0.005M	⊗	
Participant C	1M	1M		
(Other participants)	9M	9M	19.8M	
Total	**10M**	**10M**	**20M**	

The model will automatically adjust the allocation based on batch size (i.e., round up or down so that the allocation can be shipped)

All supply available in a round will be allocated

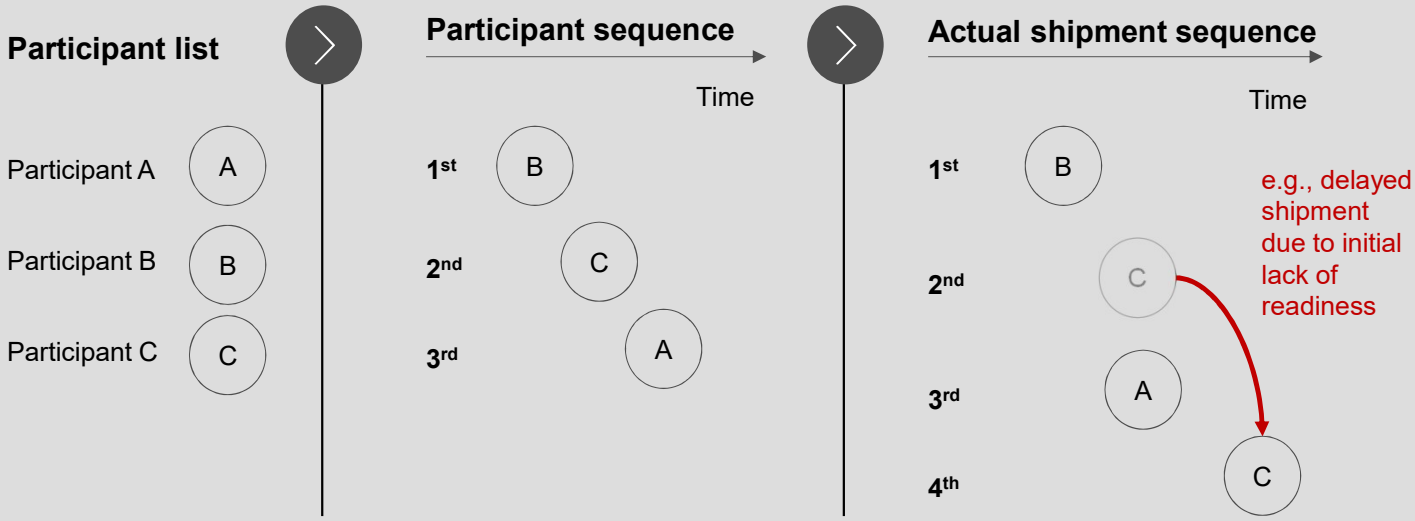
3 E

Establish participant delivery sequence

The sequence of deliveries will be affected by the timing of I&L approvals, national regulatory approvals, country readiness, shipping limitations etc.

In case of competition for capacity, prioritisation of delivery will be given according to a set sequence for the allocation round

Illustrative approach



PRELIMINARY

3 Less populous participants may be allocated a larger coverage of doses early on to account for logistics constraints

As the allocation framework mentions, exceptions can be made for less populous participants

"Exceptions on quantity per allocation round can be made for small States where it may be cost effective to provide in one shipment more than the percentage of the tranche and/or tier under consideration, because of small overall populations (the minimum threshold remains to be determined)"

– WHO Allocation Framework

Approach considered: Minimum allocation quantity

- Each participant would be allocated a minimum quantity threshold (being determined - capped to 20% of their population)
- This avoids less populous participants to be allocated a very small number of doses per round
- It takes into account challenges on logistics and costs of supplying and shipping such small batches to some small participants (e.g. islands), especially in case of UCC requirements