



# COVAC FACILITY

## Policy and allocation: update & next steps

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# Policy update

# WHO SAGE Policy development: steps and processes

- |   | <b>Status update</b>  |
|---|---|
| <b>1. Values Framework</b> for the allocation and prioritization of COVID-19 vaccination: Principles, objectives and target groups of a COVID-19 vaccination programme  | Endorsed by SAGE and published Sept 14 2020*  |
| <b>2. Guidance on prioritization of target populations</b> under supply constrained situations: development of use case scenarios of limited vaccine under different epidemiological settings                                       | Endorsed by SAGE at plenary meeting October 5-7 and published*  |
| <b>3. Policy recommendations on the use of COVID-19 vaccines</b> once authorized; under consideration of product-specific data and attributes, and with consideration of the regulatory status (emergency use or full registration) | Process iterative as products come along; takes place in parallel with WHO Emergency Use Listing/ prequalification by WHO |

(\*available on: <https://www.who.int/immunization/policy/sage/en/>)

# Main elements of the values framework

**Overarching goal:** “COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.”



**Core principles:** Human well-being; equal respect; global equity; national equity, reciprocity, legitimacy



**Objectives:** Eleven objectives for vaccination that correspond to the six core principles



**From values to priority groups:** Listing of (unranked) about 20 different priority groups in accordance with vaccination objectives and their relevance to core principles

# Roadmap towards prioritization of target populations:

To support country planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability in different epidemiologic settings

## Key assumptions:

- Vaccines are licensed and meet all minimum criteria of WHO TPP;
- Vaccines have at least minimal level efficacy in older age groups; idem for other subpopulations;
- NPI continue to be used;
- Vaccine effect on transmission less relevant for early scenarios, but information becomes available at some point;
- No account has been taken of seroprevalence and the possible degree of population protection already established.

	Community transmission	Cluster of cases/ sporadic transmission	No cases, risk of importation
Very limited supply (1-10%)			
Limited supply (11-20%)			
Moderate supply (21-50%)			

Contextualized and targeted public health strategies

# Roadmap towards prioritization of target populations: example for community transmission

## Community Transmission

**Strategy:** Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.

Stage I (1-10%)	Stage II (11-20%)	Stage III (21-50%)
<p><b>Stage Ia (initial launch)</b></p> <ul style="list-style-type: none"><li>- Health workers at <i>high to very high risk</i> of acquiring and transmitting infection</li></ul> <p><b>Stage Ib</b></p> <ul style="list-style-type: none"><li>- Older adults defined by age-based risk specific to country/region</li></ul>	<ul style="list-style-type: none"><li>- Older adults not covered in Stage I</li><li>- Individuals with comorbidities or health states determined to be at <i>significantly higher risk</i> of severe disease or death</li><li>- Sociodemographic groups at <i>significantly higher risk</i> of severe disease or death</li><li>- Health workers engaged in immunization delivery</li><li>- High priority teachers and school staff</li></ul>	<ul style="list-style-type: none"><li>- Remaining teachers and school staff</li><li>- Other essential workers outside health and education sectors</li><li>- Pregnant Women</li><li>- Health workers at <i>low to moderate risk</i> of acquiring and transmitting infection</li><li>- Personnel needed for vaccine production and other high-risk lab staff</li><li>- Social/employment groups at <i>elevated risk</i> of acquiring and transmitting infection because they are unable to effectively physically distance</li></ul>

# Allocation

# WHO Equitable Allocation Framework - overarching principles across COVID-19 health products



**Solidarity:** Joining forces to confront this unique challenge together and overcome this pandemic



**Accountability:** Clearly defined roles and responsibilities to ensure procedural justice



**Transparency:** To build and maintain trust



**Responsiveness to public health needs:** Health products are carefully selected and allocated to address the public health need



**Equity and fairness:** to inform the allocation process together with public health needs



**Affordability:** Consideration is given to pricing and procurement strategies to improve affordability of health products



**Collaboration:** Collaborative efforts amongst relevant global and national stakeholders is enhanced to accelerate and scale-up the response



**Regulatory and procurement efficiency:** Agile and comprehensive regulatory and procurement approaches are incorporated to improve timely access to safe, efficacious and quality health products for all countries in need



# Allocation Mechanism for Vaccines

## Phase 1: Proportional allocation up to 20% of population

Countries receive doses proportionally to their total population given the ubiquity of the threat

- Countries progressively receive doses until all countries reach 20% of their population (or less if they so requested).
- The pace at which countries receive vaccines depends on availability of doses and country readiness
- The allocation moves on to phase 2 once all countries have reached 20% coverage (or less if they so requested).
- Phase 2 may start ahead of this if available doses are unable to be allocated due to lack of readiness, funding or territory issues

**We will likely be in Phase 1 for most of 2021**



## Phase 2: Weighted allocation beyond 20% (if supply severely constrained)

Timing may be based on consideration of vulnerability and COVID-19 threat:

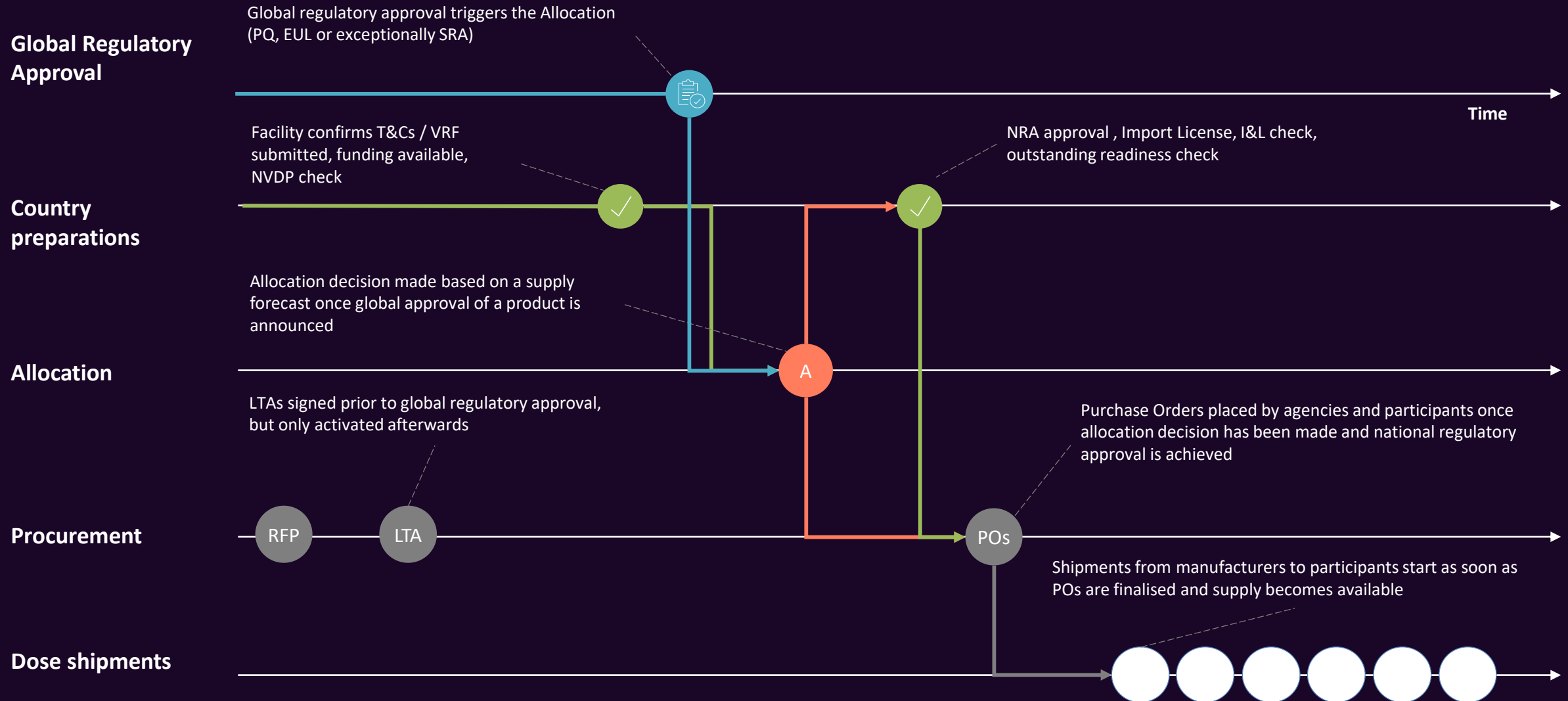
- In the case of a severely restricted supply, the timing of country shipments would be based on a risk assessment based on Threat and Vulnerability
- Countries with a higher risk would receive the doses they need faster than others, although all countries will receive some doses in each allocation round
- Threats and Vulnerabilities will be based on metrics defined closer to the end of phase 1, potentially related to the country's vulnerability to severe disease and its healthcare system.
- All countries will receive the total doses they have requested as rapidly as possible in phase 2.

# Objectives of the Phase 1 allocation

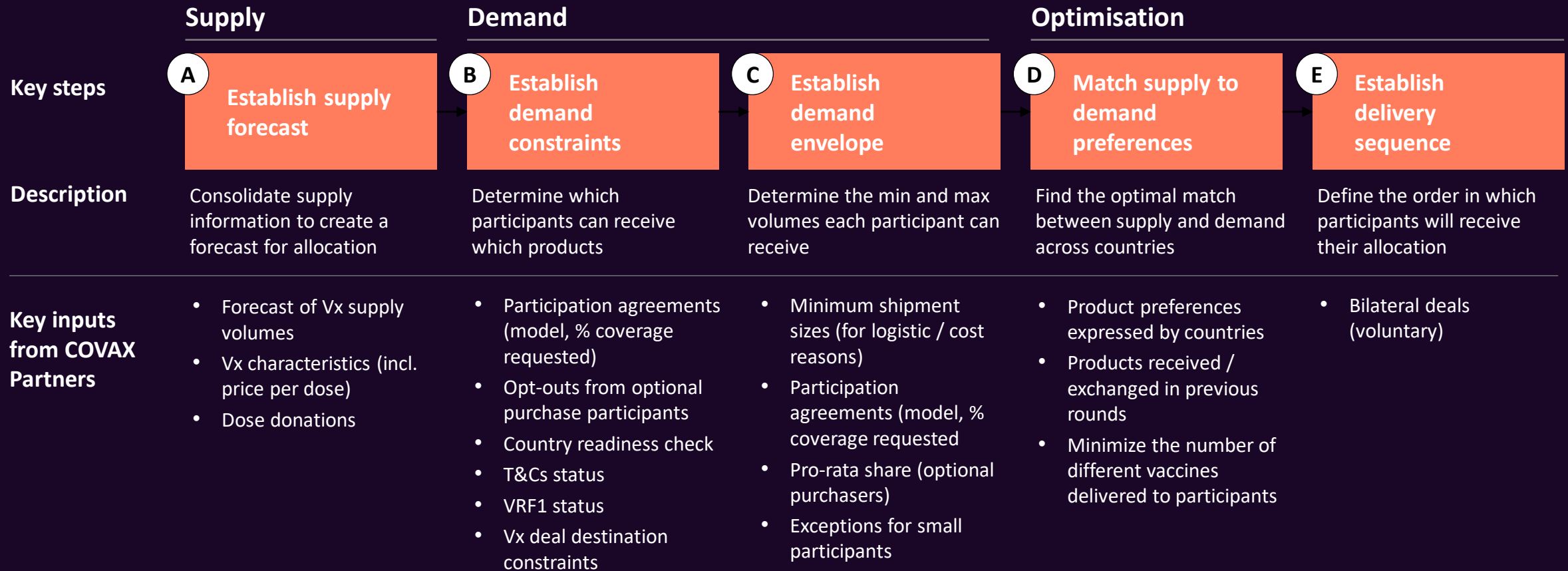
- ① **No doses should remain idle** – doses should not be ‘stockpiled’ before allocation
- ② **The allocation serves all participants able and willing to receive doses** – (excluding any limitations based on deals)
- ③ Only products that have **EUL, PQ** or in some cases **SRA approval** can be allocated
- ④ **Time gap between first and last participant** receiving COVAX doses should be **minimised**
- ⑤ The allocation aims to **give each participant doses for the same proportion of population over time** (with exceptions for small/large countries, and other operational reasons)
- ⑥ A **participant should receive a single product throughout** where possible<sup>1</sup>

# Allocations would be triggered by global regulatory approvals, followed with continuous shipments as supply is made available

ILLUSTRATIVE



# The allocation process will require information from COVAX Partners



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

→ Input

-> Implementation

Operations

Decision

## COVAX Facility

### Office of the COVAX Facility

Provides data relevant to the allocation  
Ensures Allocation Decision is implemented by COVAX Facility

### WHO Allocation Unit

Provides data relevant to the allocation and prepares the allocation model for the JAT

### Procurement agencies (UNICEF SD, PAHO RF)

Provides data relevant to the allocation  
Implement Vaccine Allocation decisions

### Self-procuring countries

Implement Vaccine Allocation Decisions

## Allocation Mechanism

### Joint Allocation Taskforce

Composed of staff from WHO and Gavi's Office of the COVAX Facility

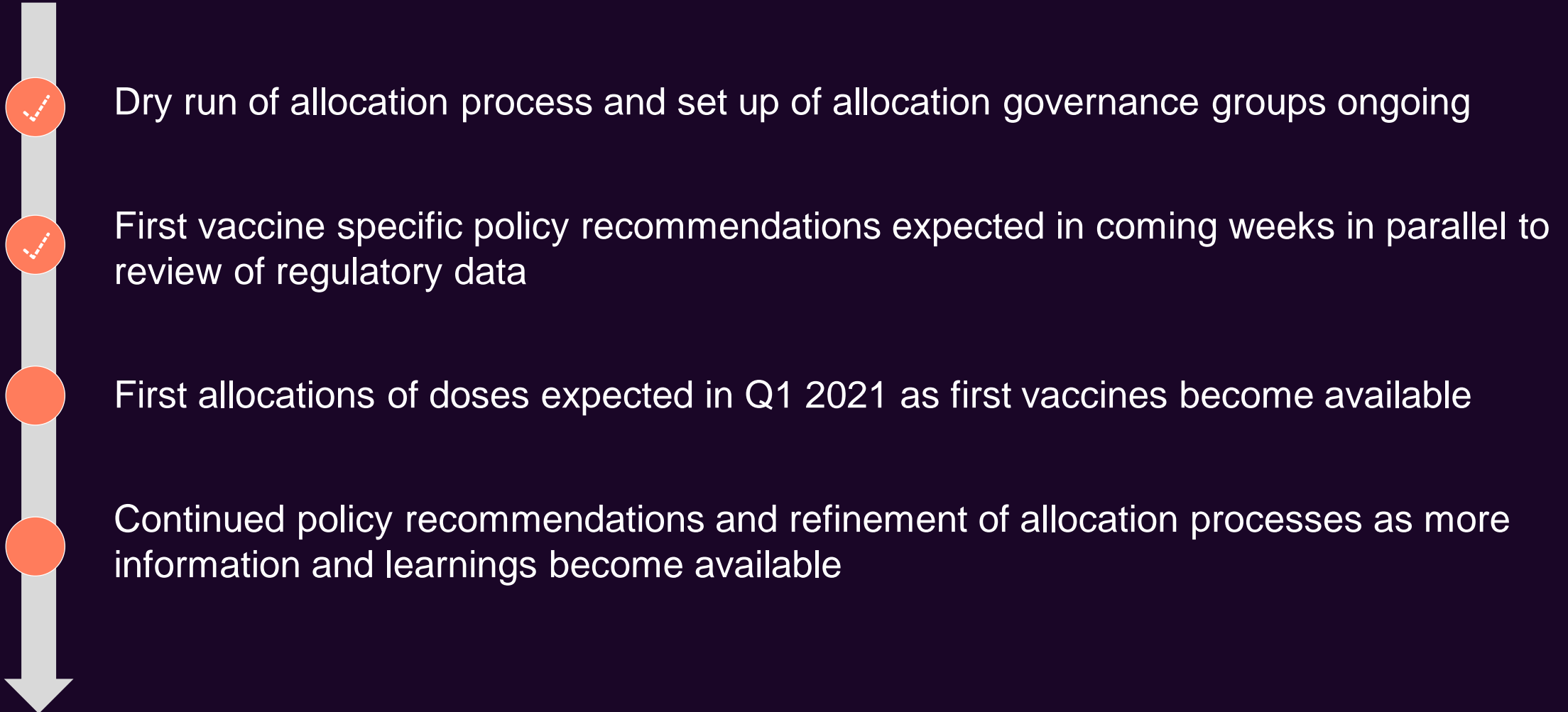
Prepares allocation proposal for the IAVG based on allocation model

### Independent Allocation Validation Group

Composed of independent Experts nominated by COVAX members and appointed by WHO

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

# Next steps



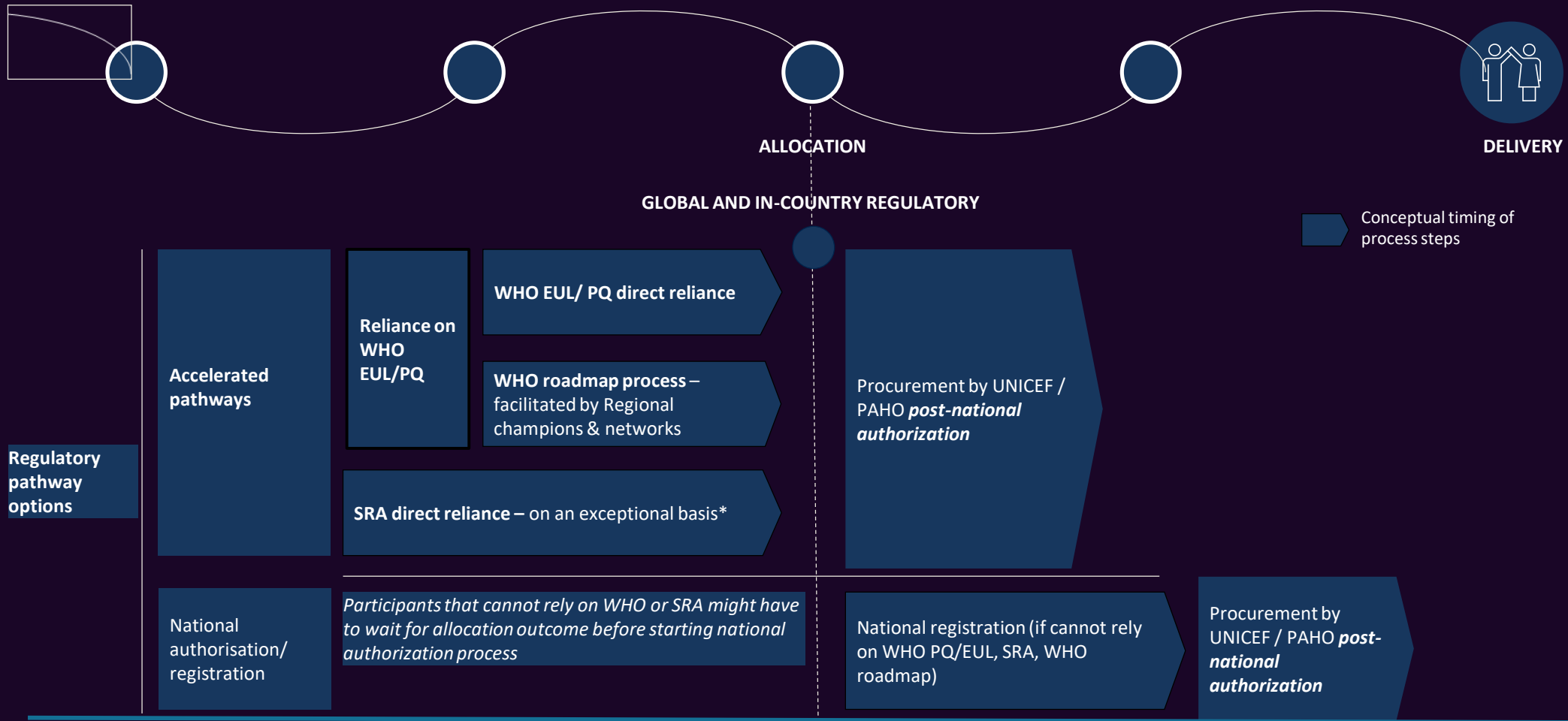
Thank you



COVAX

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# There are 4 regulatory pathways for country authorization



**Accelerated regulatory pathways crucial to avoid delay in procurement after allocation**