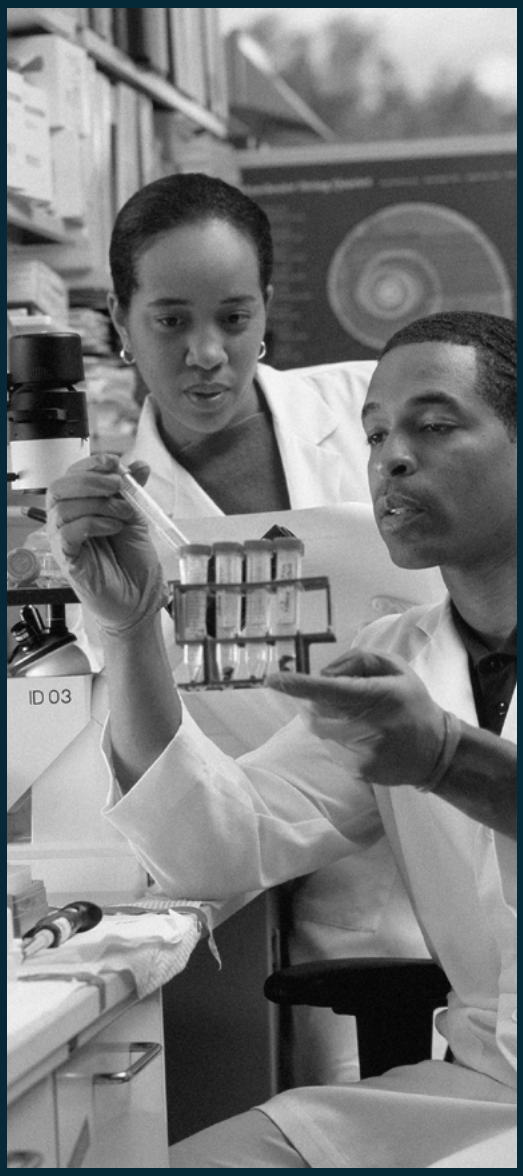

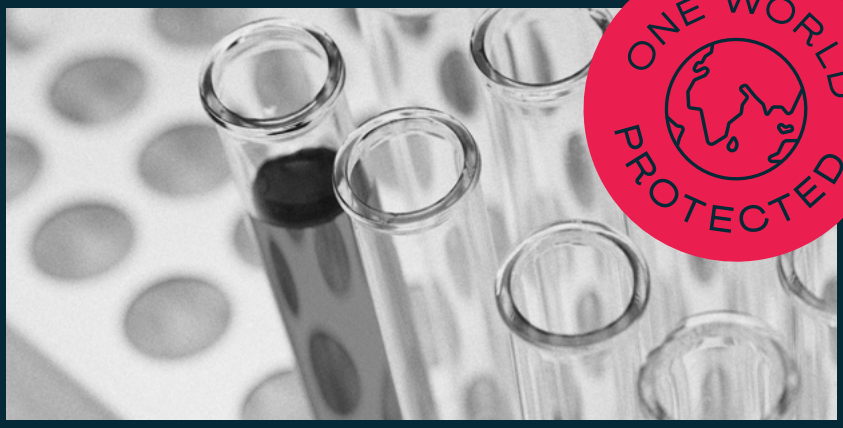

ONE WORLD PROTECTED

PORTFOLIO PRINCIPLES FOR NEW CANDIDATES

COVAX

NOVEMBER 2021

PRINCIPLES FOR THE INCLUSION OF NEW CANDIDATES IN THE COVAX PORTFOLIO: CONTEXT

- COVAX now has a portfolio of eleven products, currently the largest of any stakeholder in the eco-system
- Several other candidates are going through clinical trials and / or are waiting for regulatory approval, some of which could potentially be added to the COVAX portfolio
- The One Deal Team developed a **set of principles for evaluating the inclusion of new candidates in the COVAX portfolio**
- They are structured in two sections:

1. **Benefits of the vaccine candidate** (clinical differentiation; breadth of indication; and ease of implementation)
2. **Suitability to the COVAX portfolio** (price/affordability; geographic distribution; supplier readiness to scale and country preference)

- Over time COVAX will move towards **simplification** of its portfolio, when it is possible to do so to ensure achievement of the countries' objectives for timely and sufficient supply. However with supply/ demand challenges remaining, diversification of the portfolio will remain important
- The principles were **shared widely for consultation and socialisation** with 12+ technical bodies in the COVAX eco-system

1. BENEFITS OF THE VACCINE CANDIDATES

Principle	Description	Metric A (TPP preferred) [1]	Metric B (TPP critical / minimal) [1]
Clinical Differentiation 	Combines indicators for **Safety, Efficacy and Duration of protection.** Considers published data and starting/ongoing studies on efficacy against new variants, as well as potential of technology platform for rapid adaptation	**Safety:** Safety and reactogenicity sufficient to provide a highly favourable benefit/risk profile in the context of observed vaccine efficacy **Efficacy:** At least 70% efficacy (on population basis, with consistent results in the elderly) [2] **Duration of protection:** Confers protection for at least 1 year	**Safety:** (a) Outbreak - Safety and reactogenicity whereby vaccine benefits outweigh safety risks. (b) Long-Term (LT) - Safety and reactogenicity sufficient to provide a highly favourable benefit/risk profile in the context of observed vaccine efficacy; with only mild, transient adverse events related to vaccination **Efficacy:** Clear demonstration of efficacy (on population basis) ideally with **~50%** point estimate. Endpoint may be assessed vs. disease, severe disease, and/ or shedding/transmission [2] **Duration** of protection: Confers protection for at **least 6 months**
Breadth of indication 	Optimal Target Product Profile (TPP)	Optimal TPP across age groups and type of population	
Ease of implementation 	Product stability and storage, including cold-chain requirements and dose regimen characteristics *Option for purchase in trays/boxes with varying numbers of doses; 0.5 ml for any dose, whether primary or booster; and Vaccine Vial Monitors (VVM) = Preferred, but not mandatory principles*	Higher storage temperatures and higher thermostability will greatly enhance vaccine distribution and availability and are thus strongly preferred Vaccine vial monitor (VVM): Proof of feasibility and intent to apply a VVM to the primary container [3]	Outbreak: Shelf life of at least 12 months as low as – 60-70°C, and demonstration of at least 2- week stability at 2-8°C LT: Storage at -20°C or higher; Vaccine vial monitor (VVM): Proof of feasibility and intent to apply a VVM to the primary container

[1] *Metrics refer to preferred and critical/minimal scenarios in* **WHO Target Product Profile** *(TPP); https://www.who.int/blueprint/priority-diseases/key-action/WHO_Target_Product_Profiles_for_COVID-19_web.pdf*

[2] *Vaccines currently under development may not be able to demonstrate efficacy pre-EUL and will use immunogenicity data compared to vaccines with EUL. The level of immune response should give reasonable likelihood to predict a level of efficacy of 70 or 50% efficacy.*

[3] *cf. Preferred characteristics in WHO Target Product Profile*

2. SUITABILITY TO THE COVAX PORTFOLIO

Principle	Description	Metric A (TPP preferred) [1]	Metric B (TPP critical / minimal) [1]
Price/ Affordability*	Achieving "Total system effectiveness" (as per Healthy Market Framework), taking into consideration total cost of delivery [4]	Weighted average price per dose accounting for AMC pricing system in selected candidates NB: we will take into consideration total system effectiveness, however consider delivery costs as part of the "Ease of Implementation" criteria to avoid double counting	
Geographic distribution*	Diversification of supplier/ manufacturing base	Location of supplier/manufacturer	
Supplier Readiness to Scale	Supplier's willingness and ability to supply at large scale to AMC countries. COVAX will assess robustness of plans in place, availability of adjuvants, etc.	Metrics to assess **Supplier Performance** may include: • Track record of the supplier (e.g. performance history supplying UNICEF) • Vaccine policy Metrics to assess **Supply Robustness** (internal & external) may include: • Domestic manufacturing constraints imposed by country governments which impact supply • Supplier capacity: bilateral commitments by the supplier • Robustness of manufacturing, capacity, etc. • Supplier's access to materials and reagents • Constraints on adjuvants	
Country Product Preference	Countries' expressed interest in a product. This however may be less relevant for new candidates that may not have had a chance to develop a track record yet	Country preference as expressed in Covax Collaboration Platform (CCP)	

[4] *Healthy Market Framework: https://www.gavi.org/sites/default/files/document/healthy-markets-framework--public-overviewpdf.pdf*

(*) These are more relevant for Covax from a pillar perspective, rather than individual participants