

## WHO Target Product Profiles for COVID-19 Vaccines

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### **Purpose of the document**

Selected disease areas are identified as WHO priorities for research and product development. In the case of COVID-19, target product profile development followed the COVID-19 Global research and innovation forum: towards a research roadmap. The target audience includes vaccine scientists, product developers, manufacturers and funding agencies.

All the requirements contained in WHO guidelines for WHO policy recommendation and prequalification will also apply. The criteria below lay out some of the considerations that will be relevant in WHO's case-by-case assessments of COVID-19 vaccines in the future.

Therefore, should a vaccine's profile be sufficiently superior to the critical characteristics under one or more categories, this may outweigh failure to meet another specific critical characteristic. Vaccines which fail to meet multiple critical characteristics are unlikely to achieve favourable outcomes from WHO's processes.

A generic description of WHO's Vaccine Prequalification process can be found at the end of this document.

Modelling of the potential impact of COVID-19 vaccines with different efficacy profiles, administered using different immunization strategies, at different stages of the epidemic is a high priority to further refine desired characteristics. For certain vaccine characteristics, additional footnotes are provided on the rationale and assumptions made.

### **Acknowledgement**

WHO gratefully acknowledges the many individuals and institutions that provided comments to the draft at the public consultation stage.

## **I. Background**

On April, 2020, WHO released its initial Target Product Profile for COVID vaccines, to help inform the development of these vaccines. Now that vaccines are available and there is more information both about feasibility and likely use of vaccines, as well as potential limitations posed by variants, the TPP is being revised to reflect more current information.

As before, this document describes the preferred and minimally acceptable profiles for human vaccines for COVID-19. In general, the minimally acceptable profiles are aligned with expectations for emergency use authorization listing or licensure of new vaccines. Licensed or pre-qualified vaccines would likely have more of the attributes of the preferred profile.

This Target Product Profile (TPP) was developed through a consultation process with key stakeholders in human and animal health, scientific, funding and manufacturing communities. It is intended that it will guide and prioritize the development of vaccines and decisions about need for boosters, based on the available data. As new scientific evidence is generated, this TPP may again require further review and revision.

## II. Target Product Profiles

*Roadmap strategic goal:* Develop and make vaccines available under Emergency Use Authorization Listing or Licensure that will protect people around the world from adverse health consequences caused by COVID-19, particularly hospitalization and death.

<b>Vaccine characteristic</b>	<b>Preferred</b>	<b>Critical or Minimal<sup>1</sup></b>
Indication for use	For active immunization of at-risk persons to prevent COVID-19. Activity against other coronaviruses or expected future variants is highly preferred.	For active immunization of at-risk persons to prevent COVID-19
Contraindication	None	Some contraindications may be acceptable
Target population	All ages, including pediatrics (with appropriate dosing). Data should support administration to important groups <sup>2</sup>	Adults, including elderly
Safety/Reactogenicity	Substantial evidence of safety and efficacy, with a highly favourable benefit/risk <sup>3</sup> profile in the context of observed vaccine efficacy.	Safety and reactogenicity whereby vaccine benefits outweigh safety risks.
Measures of Efficacy	For initial vaccination series: Efficacy <sup>4</sup> against symptomatic disease with ~70% point estimate and	For initial vaccination series:  Efficacy against symptomatic disease with ~50% point estimate and lower 95% confidence interval ≥30% OR

<sup>1</sup> Generally aligned with Emergency Use Authorization Listing of Vaccines

<sup>2</sup> Important groups include pregnant and lactating women and the immunocompromised

<sup>3</sup> Benefit/risk may depend on age and other factors, including those predisposing to more severe covid or to greater incidence of adverse events. Benefit/risk assessment should take potential for enhanced disease into account. Benefit/risk assessment may change as information becomes available about rare adverse events.

<sup>4</sup> Efficacy or Effectiveness. Should be assessed against variants of concern.

	lower 95% confidence interval $\geq 50\%$ OR	
	Efficacy against severe disease <sup>5,6</sup> with 90% point estimate and 70% lower bound.	Efficacy against severe disease with 70%-80% point estimate and 30% lower bound <sup>7</sup> .
	For additional doses (doses after primary schedule): Additional doses (whether of the same or different vaccines) should be considered when vaccines no longer meet the severe disease criterion, and additional doses must reach the severe disease criterion	For additional doses (doses after primary schedule): Additional doses (whether of the same or different vaccines) should be considered when vaccines no longer meet the severe disease criterion, and additional doses must reach the severe disease criterion
Dose regimen	Single-dose primary series <sup>8</sup> . Lower frequency (Yearly or less) of booster doses is preferred	Two-dose regimen <sup>9</sup> but Regimes requiring booster doses in order to retain protection against severe disease are permitted
Durability of protection	Confers protection against severe disease for at least 1 year in healthy adults.	
Deployability		
Route of Administration	Non-parenteral (syringe/needle or other adjunct equipment-avoiding) is preferred for ease of rapid administration and other logistical issues.	Any route of administration is acceptable, if vaccine is safe and effective.

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<sup>5</sup> Severe disease endpoints may include long COVID, but are not required to.

<sup>6</sup> Immunobridging, based on standardized and validated assays, and with appropriate regulatory concurrence, can be used to predict that vaccines will meet specific efficacy criteria.

<sup>7</sup> Lower bound may be 0% if vaccine meets criteria for efficacy against symptomatic disease

<sup>8</sup> Note strong preference for single-dose, but do not desire to discourage development of 2-dose vaccines if that is what is feasible

<sup>9</sup> note cholera is 2 dose, and many 2 dose vaccines confer partial protection after a single dose. For two-dose vaccines, protection after single dose should be assessed

Product Stability and Storage	Higher storage temperatures and higher thermostability will greatly enhance vaccine distribution and availability, and are thus strongly preferred.	Demonstration of at least 2-week stability at 2-8°C.
Co-administration with other vaccines	Potential for coadministration with other vaccines (e.g., flu, polio, measles, pneumococcal) preferred	Stand-alone product
Presentation	Multi-dose presentation <sup>10</sup> is preferred for ease of use in campaigns. Lack of need for reconstitution.	Multi- or mono- dose presentations are acceptable.
Registration and Prequalification	WHO pre-qualified <sup>1112</sup>	Meets criteria for WHO EUL
Availability	Capability and firm developer commitment to make vaccine available to LMICs (as in minimal criteria) on an acceptable timeline, either directly or via technology transfer.	Capability to rapidly scale-up production <sup>13</sup> at cost/dose that allows broad use, including in LMIC, with availability of sufficient doses at cost/dose that allows broad use, including in LMICs

### III. Considerations on Programmatic suitability

<sup>10</sup> Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy. If feasible, vaccines consistent with an "open vial" policy may have additional advantages

<sup>11</sup> Prequalification process is described here:

<http://apps.who.int/medicinedocs/documents/s21095en/s21095en.pdf>.

<sup>12</sup> Programmatic suitability considerations for pre-qualified vaccines are described here:

[http://apps.who.int/iris/bitstream/10665/76537/1/WHO\\_IVB\\_12.10\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/76537/1/WHO_IVB_12.10_eng.pdf)

<sup>13</sup> Includes ancillary supplies, e.g., syringes, diluent, etc.

## **Vaccine for human use**

### **WHO Prequalification**

The prequalification procedure is described in detail in the document Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies (WHO TRS 978) available here: <http://apps.who.int/medicinedocs/documents/s21095en/s21095en.pdf>. The WHO PQ process which assesses vaccine quality, safety, efficacy and suitability for use in low and middle-income countries has developed criteria called Programmatic Suitability for Prequalification (PSPQ) criteria to review vaccines submitted for prequalification. ([http://apps.who.int/iris/bitstream/10665/76537/1/WHO\\_IVB\\_12.10\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/76537/1/WHO_IVB_12.10_eng.pdf)).