WHO target product profiles

A target product profile (TPP) outlines the desired ‘profile’ or characteristics of a target product that is aimed at a particular disease or diseases. Such profiles can guide product research and development (R&D):

- In industry, in-house target product profiles (TPPs) are used as planning tools that guide development towards desired characteristics.
- In the regulatory context, TPPs are considered as tools to frame development in relation to submission of product dossiers.
- In the context of public health, TPPs set R&D targets for funders and developers.
- Over the last decade public health-oriented funders have increasingly developed their own TPPs. It is not always clear how these TPPs relate to WHO’s preferences, creating the possibility that not-for-profit product development programmes are not always well aligned with WHO’s identified needs.
Features of a WHO TPP document

WHO TPPs recognize that **access, equity and affordability are integral parts of the innovation process** and need to be considered at all stages, not just after a product is developed.

The WHO TPP documents aim to inform product developers, regulatory agencies, procurement agencies and funders on R&D and public health priorities.

They describe

(1) the preferred and (2) the minimally acceptable profiles for vaccines, therapeutics, diagnostics or medical devices criteria.

TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics.

They also provide information for funders and developers on the performance and operational characteristics expected of products if they are to meet WHO’s needs.
Overview

This Target Product Profile (TPP) describes the preferred and minimally acceptable profiles for human vaccines for long term protection of persons at high ongoing risk of COVID-19 such as healthcare workers and for reactive use in outbreak settings with rapid onset of immunity.
In early 2020 there was general agreement on appropriate success criteria

>50% point estimate with >30% LB
(on alpha-adjusted confidence interval) endorsed by WHO, USFDA, India, China, HC

This was proposed to assure that weakly effective vaccines will not meet criteria for wide distribution, potentially doing more harm than good

This was also proposed to assure studies of sufficient size to evaluate safety and other important endpoints

### Vaccine characteristics (draft criteria)
#### Measures of efficacy

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Critical or minimal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For initial vaccination series:</strong></td>
<td><strong>For initial vaccination series:</strong></td>
</tr>
<tr>
<td>Efficacy (or effectiveness) against <strong>symptomatic disease</strong> with ~70% point estimate and lower 95% confidence interval ≥50%</td>
<td>Efficacy against <strong>symptomatic disease</strong> with ~50% point estimate and lower 95% confidence interval ≥30%</td>
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<tr>
<td><strong>OR</strong></td>
<td><strong>OR</strong></td>
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<tr>
<td>Efficacy against <strong>severe disease</strong> with 90% point estimate and 70% lower bound.</td>
<td>Efficacy against <strong>severe disease</strong> with 70%-80% point estimate and 30% lower bound.***</td>
</tr>
</tbody>
</table>

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* Severe disease endpoints may include long COVID, but are not required to.
** Immunobridging, based on standardized and validated assays, and with appropriate
*** Lower bound may be 0% if vaccine meets criteria for efficacy against symptomatic disease
## Vaccine characteristics
### Measures of efficacy

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<td>For additional doses (doses after primary schedule):</td>
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<tr>
<td>Additional doses (whether of the same or different vaccines) should be</td>
<td>Additional doses (whether of the same or different vaccines) should be considered</td>
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<tr>
<td>considered <strong>when vaccines no longer meet the severe disease criterion</strong>, and additional doses must reach the severe disease criterion</td>
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Some final reflections

- All the requirements contained in WHO guidelines for WHO policy recommendation and prequalification will also apply.
- The criteria 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.
- Likewise, preferred characteristics should not be considered as the maximum desirable characteristics; vaccines that exceed these characteristics may find advantages in WHO’s processes.
Process leading to publication of a revised WHO TPP for COVID vaccines

1. Independent Expert group developed revised draft
2. Open consultation process completed
3. Independent Expert group will develop final version (after considering the suggestions received)
4. Publication of FINAL TPP in WHO website