



WOAH Target Product Profile – Template for animal vaccines

Background

WOAH Members and partners have highlighted the need to clarify the purpose, format and use of Target Product Profiles (TPPs) within the WOAH framework. While WOAH standards establish minimum requirements for veterinary vaccines, they do not always provide sufficient guidance on desired product attributes to support disease prevention, control, or elimination objectives for a given epidemiological context or intended use.

The 2025 Animal Health Forum [Technical Item on Vaccines and Vaccination](#) recognised TPPs as practical tools to align expectations among researchers, manufacturers, regulators, funders and end-users, and recommended the development of a standardised WOAH TPP template.

A TPP outlines ideal and minimal performance characteristics of the product's attributes, in this case vaccines. It is usually developed in a collaborative and consultative exercise by R&D teams, disease specific experts, commercial teams, and end users. It helps to set a goal and vision for the teams and ensures the product remains commercially viable. A TPP can be updated based on technical progress and can provide a framework for stop-go decisions if minimum performance criteria are not met. Meeting regulatory and intellectual property rights requirements are important considerations in product development.

Notes to develop a TPP

- When developing a TPP, the first attribute to be defined is the '**Intended use**', as this guides all subsequent attributes. The intended use defines the purpose of the product, target population or farming system. Multiple TPPs may be developed for the same disease to cover different use scenarios. For example, one TPP could be developed for a vaccine in which the intended use is prevention of clinical signs of a particular disease in endemic countries, while another TPP could be developed for a vaccine in which the intended use is breaking transmission and/or elimination of the same disease or prevention of disease in free countries. The Intended use therefore provides guidance on attributes such as target population, target immunogen, performance, etc. When developing a TPP, it is important that consideration is given to identifying and prioritising the intended uses, as this will define how many TPPs are needed for a given disease.
- Where available, the intended use should be aligned with the relevant disease progressive control pathway.
- A TPP includes a column describing the ideal attributes of the product, and another column with minimum acceptable attributes for the product. The ideal and minimum attributes of product may be the same or different.
- TPPs and WOAH standards, where available, must be aligned. Minimum attributes included in a TPP should reflect existing WOAH standards when available and applicable to the intended use. TPPs can be used to identify gaps and inform feedback to inform future revisions of standards.
- The 'Comments' column has been included in this template to provide guidance on completing TPPs where the characteristics are not self-explanatory. This column should be deleted once the TPP has been developed.
- If detailed specifications are needed for a specific attribute, it is recommended that superscripts and notes are used at the bottom of the TPP table.

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- TPPs do not prescribe specific technologies, provided that the final product complies with the defined attributes. However, as a conclusion, the most appropriate technologies to comply with the minimum or ideal attributes could be inferred in a TPP.
 - TPPs are 'live documents' that may need periodic updates (approximately every 5 years, although this may depend on disease-specific needs) as needs, knowledge, and technologies evolve.

This TPP template is structured into five sections, each one including several characteristics:

1. Product use summary,
2. Design,
3. Performance,
4. Product specifications,
5. Regulatory aspects and further considerations.

WOAH TPP for a [disease name] vaccine			
Attributes	Ideal	Minimum	Comments
1. Product use summary			
1.1. Intended use			Indication of use: prevention, control, elimination, eradication, emergency use, etc. Include geography and epidemiology as applicable.
1.2. Target population			Species, age, sex. Include age at first vaccination. Include reproductive status.
1.3. Further comments			
2. Design			
2.1. Target immunogen			Pathogen species, genotypes, serotypes, variants, or immunogens as applicable.
2.2. Vaccination regime			Single or multiple doses, booster requirements.
2.3. Maximum volume, route of administration			Include optimal routes of administration if applicable.
2.4. Co-administration with other vaccines or medicines			Consideration of interference. Feasibility of co-administration with other vaccines (combination vaccines).
2.5. Differentiation of infected and vaccinated animals			If applicable
2.6. Dissemination, shedding and carrier status after vaccination			
2.7. Further comments			
3. Performance			
3.1. Efficacy			Expected efficacy to different strains/variants, epidemiological relevance, prevention of clinical signs, prevention of transmission, prevention of carrier status.
3.2. Efficacy evaluation			Tests and standards to be used to evaluate vaccine performance, including correlation of immune response and protection when appropriate.
3.3. Onset of immunity			
3.4. Duration of immunity (DoI)			If relevant, include test to measure DoI, especially if different from 3.2.
3.5. Safety, including adverse reactions			Safety in vaccinated animals, by species and physiological status such as pregnancy, lactation, or semen production. Include risk of reversion to virulence if applicable. Type and frequency of adverse reactions
3.6. Withdrawal period			For the different species and types of animals (e.g. beef or dairy cattle)

WOAH TPP for a [disease name] vaccine

Attributes	Ideal	Minimum	Comments
3.7. Non-target animal safety and environmental impact			impact of in non-target animals and vaccine strain to be inadvertently released into the environment to cause infection of non-vaccinated animals (i.e., from attenuated vaccines or improperly inactivated killed vaccines)
3.8. Further comments			
4. Product specifications			
4.1. Physical presentation			To be included if this impacts the intended use: liquid, freeze-dried, tablet, spray. If not, any presentation that is fit for purpose.
4.2. Vial and pack size			For the settings specified in the intended use.
4.3. Vaccine stability			Shelf-life at different temperatures and storage requirements of the vaccine (formulated product). Thermotolerance of the vaccine.
4.4. In-use stability			Once the vial has been opened.
4.5. Formulation			Use of adjuvants and stabilizers.
4.6. Storage as bulk antigen			Stability of the antigen.
4.7. Supplies requirement			Including diluent.
4.8. Further comments			
5. Regulatory aspects and further considerations			
5.1. Product registration			Specific regulatory requirements that will need to be met. May have regional implications
5.2. Vaccino-vigilance			Feedback from the end-users and the field
5.3. Target price end user			Optional. To be completed when relevant and useful. Range of maximum prices that might be acceptable in different settings. The end user may be private owners/farmers, governments, etc.
5.4. Product lead times			Optional. Time between ordering the vaccine and final product. Can be important, for example, for emergency vaccines.
5.5. Further comments			
FINAL TPP COMMENTS			Optional: These final comments can be used to outline the most likely/pragmatic type of vaccine or technology that is most likely to meet the TPP, based on what is available at the time or envisaged for the near future.