Report of the meeting of the *ad hoc* Group on the development of a Target Product Profile (TPP) template

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1. 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.

In response, the Director General convened this *ad hoc* Group (the Group) to develop a harmonised template for veterinary vaccines and associated guidance aligned with WOAH's mandate and standard standards.

2. Appointment of the Chair and Rapporteur

Dr Baptiste Dungu and Dr Meritxell Donadeu were appointed as co-chairs and Dr Rachel Tidman acted as rapporteur. The ToR and list of participants are provided as Annexes I and II, respectively.

3. TPPs and WOAH Standards

The Group discussed the relationship between TPPs and existing WOAH standards and agreed that TPPs should be developed as guidance tools, in total alignment with but distinct from WOAH standards, that support their implementation.

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.

The Group agreed that minimum attributes included in a TPP should reflect existing WOAH standards, when available and applicable to the intended use. Where gaps, limitations or inconsistencies in current standards are identified through the TPP development process, these should be clearly flagged to the relevant Specialist Commission as potential inputs for future revisions of the standards. Ideal attributes may vary according to intended use, and multiple intended uses will necessitate multiple TPPs for one disease.

The Group noted that some existing *Terrestrial Manual* chapters describe vaccines primarily on the basis of currently available products. In this context, TPPs may help to articulate forward-looking expectations for future vaccines, and where relevant, identify gaps or limitations in existing standards.

4. TPP Development Process

The Group discussed how the development of TPPs could be integrated into WOAH's existing technical governance and consultation mechanisms. This will include convening of a disease- or topic-specific Group under the authority of the Director General, development of a draft TPP using the agreed template, review by the relevant Specialist Commission(s) and availability of finalised TPPs in the Commission meeting reports and in the WOAH website for the use of WOAH Delegates and stakeholders.

The Group noted that engagement with manufacturers, regulators and end users will be required to ensure that TPPs are feasible, relevant, and fit for purpose.

5. TPP Template

The Group produced a TPP template and accompanying user guidance, informed by existing TPP examples. The Group agreed that the template should be concise, practical and driven by the intended use, and supported by clear instructions to facilitate consistent interpretation and use.

The Group agreed that the intended use must be clearly stated at the beginning of each TPP. The intended use defines the scope of the TPP and guides the selection and interpretation of all attributes. The Group noted that, for a single disease, different intended uses may require separate TPPs, and that clarity on this point is important to avoid confusion for users. The Group recommended aligning intended uses with disease progressive pathways where available (e.g. foot and mouth disease, peste des petits ruminants).

The Group agreed on the overarching categories under which attributes should be structured, covering: (i) product use summary; (ii) design; (iii) performance; (iv) product specifications; and (v) regulatory aspects and further considerations.

The Group agreed that the template should include separate columns describing the attributes of the minimum acceptable product and of the ideal product for a given intended use. The minimum attributes describe the essential attributes required to meet the intended use, while the ideal attributes describe characteristics that are desirable but not essential. For some TPPs, the attributes of the minimum and ideal products may be the same.

In developing the template, the Group discussed how to capture information relevant to vaccine design without limiting future vaccine technologies. It was agreed that the template should not prescribe specific technologies. Instead, vaccine attributes should describe the requirements that the product must meet to fulfil the intended use, recognising that different technologies may be capable of meeting those requirements. The Group included guidance in the TPP template, noting that certain TPPs may conclude that specific technologies are appropriate in order to comply with the TPP minimum or ideal attributes.

The Group discussed target price for the end user and product lead time as attributes, noting that these may not be applicable or feasible to specify for all TPPs. However, it was agreed that reflection on affordability and lead time for deployment of vaccines may be critical for some diseases and contexts. The template therefore includes these attributes as optional, enabling disease- or context-specific groups to determine whether and how they should be addressed.

Finally, the Group noted that this TPP template has been developed for vaccines, but recommended WOAH consider similar processes for development of TPPs for other veterinary products and diagnostics.

6. Next steps

The Group report and TPP template will be considered by the WOAH Aquatic Animal Health Standards Commission and Biological Standard Commission in the February 2026 meetings.

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…/Annexes

Annex 1. Terms of Reference

MEETING OF THE AD HOC GROUP ON THE DEVELOPMENT OF A TARGET PRODUCT PROFILE (TPP) TEMPLATE

Virtual, 14 January 2026

Purpose

The purpose of this *ad hoc* group (AHG) is to develop a harmonised template for a Target Product Profile (TPP) for veterinary vaccines aligned with the objectives and standard-setting processes of the World Organisation for Animal Health (WOAH).

The AHG will:

- Develop an agreed TPP template to implement existing WOAH vaccine standards.
- Ensure the TPP template is in line with WOAH standards and supports Resolution No. 29 (2025) on vaccines and vaccination.
- Provide an accompanying explanation/justification in the AHG report.

The consultation is convened under the authority of the WOAH Director General and reports through the Biological Standards Commission (BSC) and Aquatic Animal Health Standards Commission (AAC).

Background

WOAH Members and other stakeholders have expressed the need to clarify the purpose, format, and content of TPPs within the WOAH context. Stakeholders have highlighted that while current WOAH standards establish minimum requirements for vaccines, they often lack detailed guidance on desired vaccine performance and operational characteristics in support of different disease control or prevention needs.

Section 2.1 of the **Animal Health Forum Technical Item on Vaccines and Vaccination (2025)** recognised TPPs as practical tools for aligning expectations among research, regulatory, and end-user communities. It recommended that WOAH develop a standardised template to help stimulate innovation and support consistent and transparent communication with product developers including researchers, regulatory agencies and funders. Recognising this need, WOAH has initiated the development of a TPP template through this AHG.

Actions to deliver

The AHG will:

1. Review existing TPP examples from relevant initiatives.
2. Identify and agree on the key elements and parameters to be included in a WOAH TPP template.
3. Develop a draft TPP template, aligned with WOAH's mandate and standard-setting frameworks (e.g. Manuals and Codes).
4. Draft an explanatory note providing guidance for users on how to populate and interpret the template).
5. Prepare recommendations for presentation to the Biological Standards Commission (BSC) and Aquatic Animal Health Commission (AAC) in February 2026.

Expectations

Experts are expected to:

- Review all working materials circulated prior to the meeting.
- Contribute actively to technical discussions, progress on the work offline and provide written inputs as requested.
- Agree collectively on the structure and essential parameters of the TPP template.
- Review and comment on the draft report and final outputs after the meeting.

Experts should:

- Sign the WOAH Undertaking on Confidentiality.
- Complete the WOAH Declaration of Interest form.
- Read and acknowledge the WOAH personal data management policy.

Deliverables

Deliverables of this expert consultation include:

- Draft WOAH Target Product Profile (TPP) Template.
- Explanatory Note, describing the purpose, scope, and guidance for completing the template.
- Meeting Report summarising the discussion, conclusions, and recommendations for submission to the BSC and AAC.

Timeline

- January 2026 – Virtual consultation meeting (2 hours) to review and agree on the purpose and minimum elements to be included in the TPP template.
- January 2026 – circulation of the draft template and explanatory note for expert review and written feedback.
- February 2026 – submission of the agreed template and explanatory note to the Biological Standards Commission (BSC) for consideration.

Annex 2 List of Participants

MEETING OF THE AD HOC GROUP ON THE DEVELOPMENT OF A TARGET PRODUCT PROFILE (TPP) TEMPLATE

Virtual, 14 January 2026

MEMBERS

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