

# Practical Guidelines for National Procurement of Veterinary Vaccines

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# Foreword

Good quality veterinary vaccines are key tools to prevent, control and eradicate animal diseases. However, WOAHP Members face challenges in the procurement of good quality vaccines: some countries do not have clear national procurement processes; some others have national processes which are not appropriate for veterinary products (e.g. national process based on prices with limited/no consideration to quality), and some others struggle to import vaccines for systematic or emergency vaccination.

These guidelines contribute to WOAHP's answer to recurrent expressed needs. They should be considered in association with other WOAHP tools or recommendations: standards have been developed and are included in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, as well as in the *Terrestrial Animal Health Code*; the PVS Pathway includes a specific legislative support named *PVS Veterinary Legislation Support Programme* (VLSP); WOAHP Collaborating Centres have been accredited for vaccine (or veterinary products) quality control; vaccine banks have been established for some diseases and countries, but are not meant to replace national procurement. Other international organisations also propose some supportive processes or mechanisms to improve access to quality vaccines, such as the EuFMD's pre-qualification procedure for vaccines against FAST diseases or the WHO Operational principles for good pharmaceutical procurement.

Acknowledging the existing tools and mechanisms, and the remaining need expressed by its Members, WOAHP has developed these short and practical guidelines. This document presents key pre-requisites to consider before any vaccine procurement and describes the different steps of the procurement process. It also provides useful templates and proposes selection criteria.

I trust these guidelines will prove useful to Veterinary Services and contribute to improving their access to good quality vaccines.



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February 2024

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## Abbreviations and acronyms

<b>CfT</b>	Call for Tender
<b>GMP</b>	Good Manufacturing Practices
<b>SPC</b>	Summary of the Products Characteristics
<b>WOAH</b>	World Organisation for Animal Health



# 1. Introduction

## 1.1. Why are guidelines needed for the procurement of veterinary vaccines?

Veterinary vaccines, when associated with other measures, have proven to be powerful tools to prevent, control and eradicate animal diseases. An effective procurement process ensures that safe and effective vaccines that meet internationally recognised quality standards are available, at the right time, in the right quantities and at a fair price. Establishing effective procurement procedures can be quite challenging, especially during disease emergencies. Many countries have realised that their national procurement processes regarding veterinary products were unclear, inefficient or simply non-existent.

In this context, the World Organisation for Animal Health (WOAH, founded as OIE), as the international organisation responsible for improving animal health worldwide, has developed these practical guidelines to support its Members in the process of identifying and procuring quality assured veterinary vaccines, as well as to provide clear guidance on the information regarding the vaccines and the manufacturers required for the procurement process.

**Note:** These guidelines have been developed to support WOAH Members in their procurement of quality-assured veterinary vaccines. While using these guidelines, gaps may be identified in national legislation related to the veterinary domain. The WOAH Performance of Veterinary Services (PVS) Pathway can support countries in the revision of their veterinary legislation through the [Veterinary Legislation Support Programme](#).

## 1.2. What is special about veterinary vaccines?

Vaccines differ from other veterinary products in many ways and must be given special consideration during their purchase. For example, most vaccines are temperature-sensitive, which means that the reliability and adequacy of cold chain capacity is critical throughout the supply chain to ensure that the vaccines are effective in the field. Assessing the robustness of the cold chain procedure is important during the procurement process.

Selection must be done carefully and should be based on the circulating pathogen strains and on the objectives set by the vaccination strategy to ensure a successful campaign. For a given disease there may be a range of vaccines such as live attenuated formulations, inactivated products and/or recombinant or new generation products offering various advantages depending on their use and objectives.

Compliance with internationally recognised standards for manufacturing quality, safety and efficacy is critical; in addition, other selection criteria, such as price, delivery time, and vial size, are also relevant for the procurement process. **Vaccine ‘quality’, as demonstrated by meeting WOAH standards as defined in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* should always be the first criteria to be considered and is more important than attractive low prices. Hence, in a successful procurement process, a technical evaluation is undertaken before any assessment of the financial proposal.**

## 1.3. Who are the guidelines for?

These guidelines provide practical guidance on the essential steps for an efficient and transparent procurement process of quality-assured veterinary vaccines.

They target primarily the **persons in charge of managing vaccine procurement** in the Veterinary Services, Aquatic Animal Health Services or relevant governmental agencies, in order to accompany them through each stage of the process by proposing clear and practical guidance.

However, these guidelines can also be useful for the following stakeholders:

- **WOAH Delegates or Chief Veterinary Officers**, to inform decision makers of the specifics of veterinary vaccine procurement and the importance and benefits of a transparent process that prioritises vaccine quality over price.
- **Vaccine manufacturers and distributors**, to better understand countries' requirements when purchasing veterinary vaccines and provide clear, comprehensive responses to the Call for Tender (CfT).

## 1.4. How should the guidelines be used?

Chapter 2 of these guidelines offers a short summary of the prerequisites to any procurement process. It provides key information to successfully select the right vaccines, as well as references to relevant international standards and other references to support decision-making.

Chapter 3 focuses on the procurement phase. It is structured around the following **five main steps** (see Figure 1) **designed** to provide countries with practical guidance on how to conduct their purchasing process.

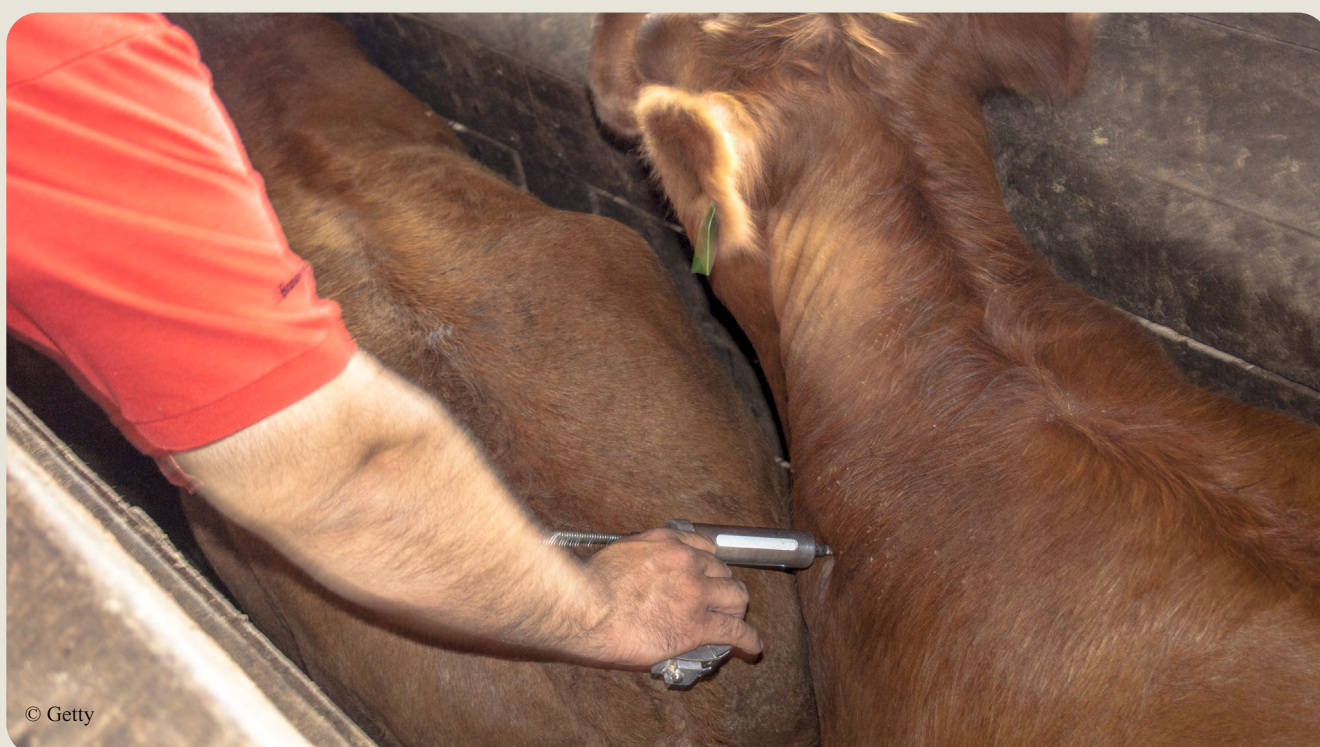
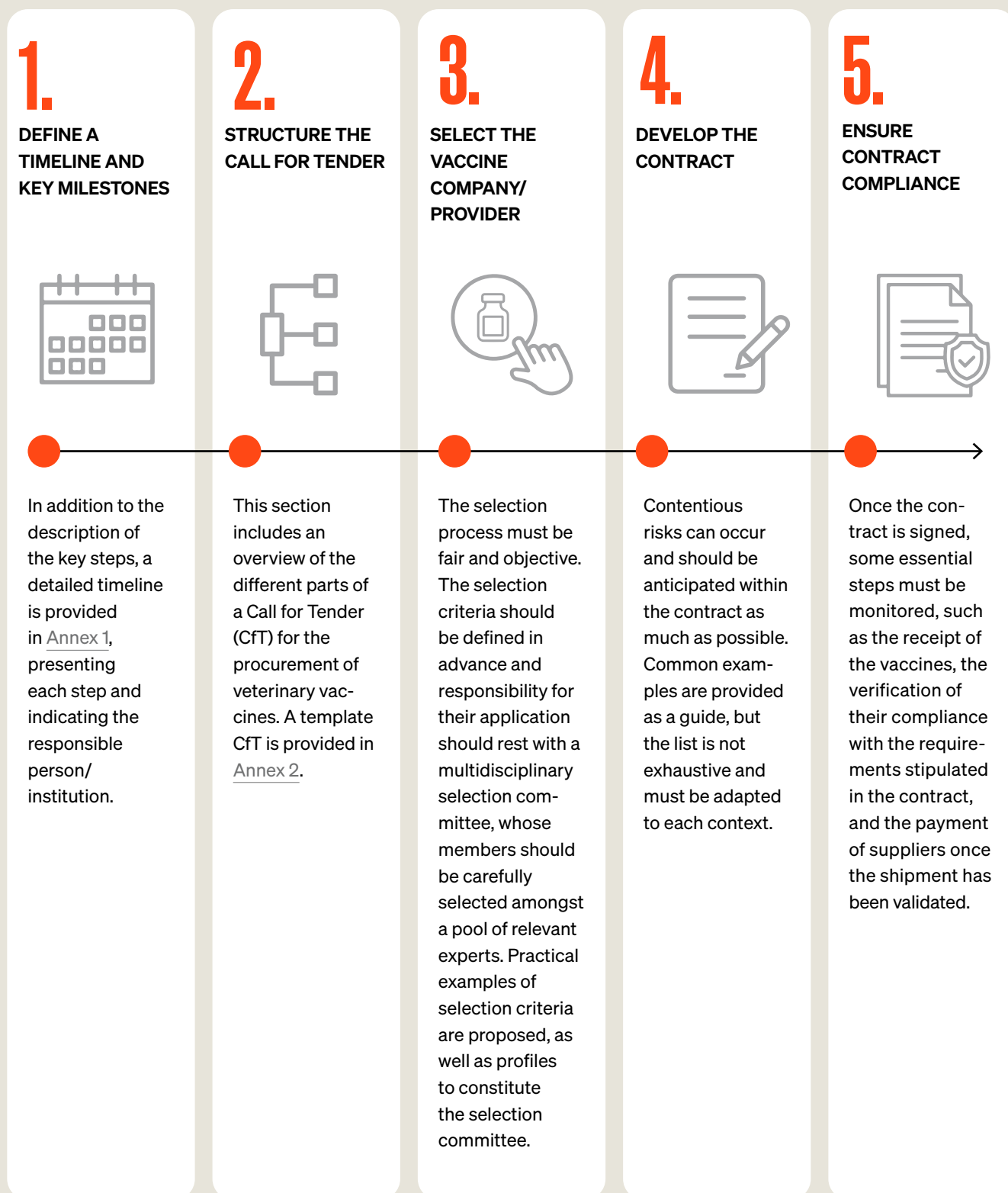


Figure 1. Five main steps of the vaccine procurement phase



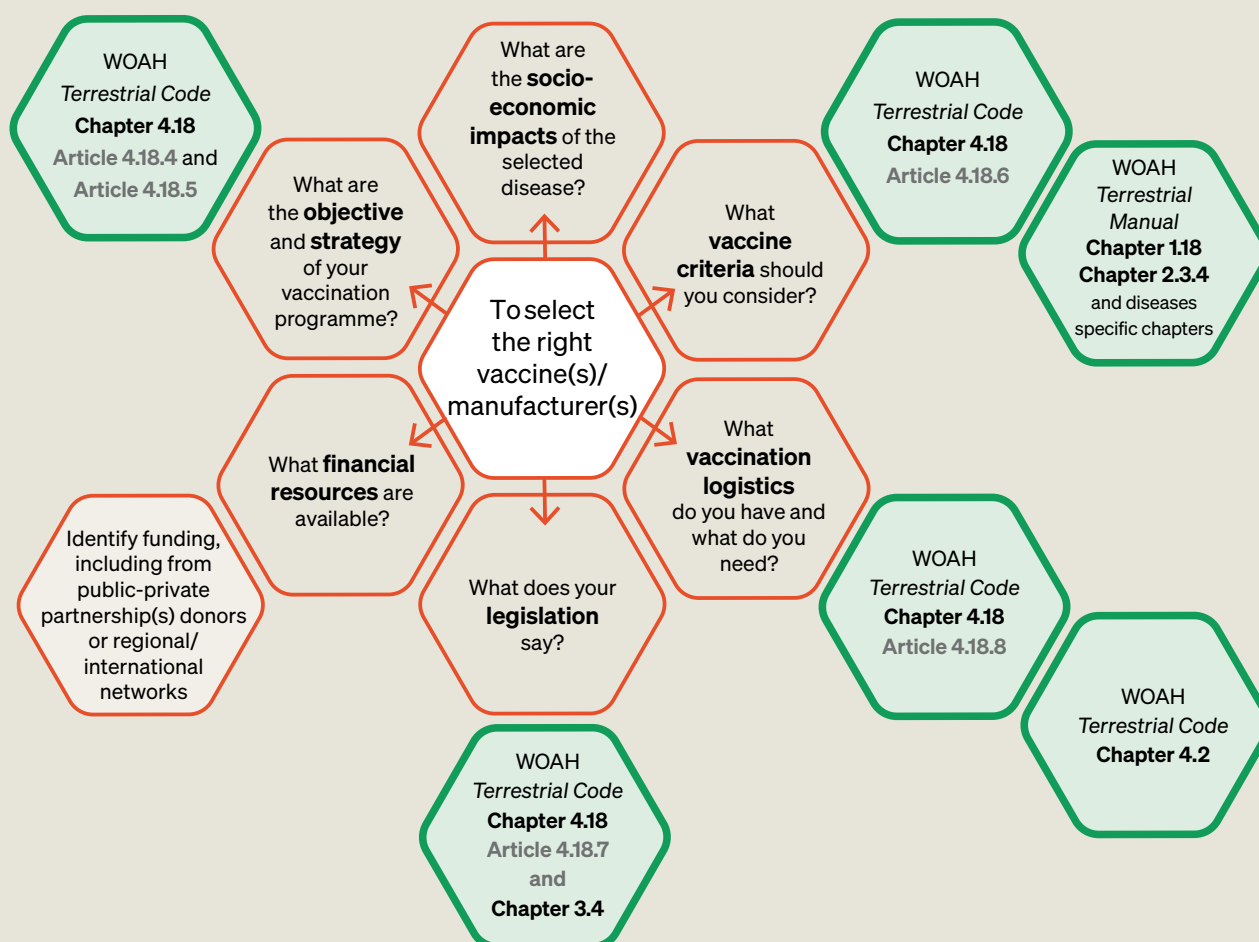


# 2. Prerequisites for the procurement phase

Before considering the procurement phase for quality-assured veterinary vaccines, the national vaccination strategy should be clearly described. The following key questions will help countries to define the vaccination programme and the best vaccine option(s)<sup>1</sup>. They will also support the drafting of the CfT.

Figure 2 summarises key questions to be answered for the selection of appropriate vaccines. For each question, references to the appropriate WOA standards are indicated to guide countries in the process.

Figure 2: Six key questions surrounding the selection of a vaccine



<sup>1</sup> Countries may wish to consider several vaccine options, even multivalent vaccines, for their vaccination programme.

### Main WOAH Standards to be considered:

- **In the WOAH *Terrestrial Code***
  - Chapter 4.18 Vaccination
  - Chapter 3.4 Veterinary Legislation
  - Chapter 4.2 General principles on identification and traceability of live animals
- **In the WOAH *Terrestrial Manual***
  - Chapter 1.1.8 Principles of Veterinary Vaccine Production
  - Chapter 2.3.4 Minimum requirements for the production and quality control of vaccines
  - Disease-specific chapters

Addressing these key questions prior to the procurement phase is essential to ensure that the procedure goes smoothly and effectively, which will improve the overall efficiency of the vaccination programme. It will help vaccine procurement teams to better define the selection criteria to be included in the CfT, which is a critical step in choosing the most suitable provider.



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# 3. The procurement process

## 3.1. How to establish the timeline and determine key milestones



The procurement process can be complex and requires countries to clearly identify all the steps of the process and who will oversee them. Listing the steps in chronological order and establishing responsibilities will ensure better preparation and a more efficient process. Setting up this calendar can also help to anticipate potential issues and to better manage them.

The key steps to consider are provided below:

- 1. Preparation of the CfT:**
  - Define the selection criteria.
  - Draft the CfT.
  - Identify the members of the selection committee.
  - Set up an administrative system to receive the tenders.
  - Ensure that it works effectively.
- 2. Publication of the CfT:**
  - Publish the CfT online on the institutional website, other professional digital platforms and on any relevant national newspapers/ platforms and publications.
  - Advertise the CfT proactively and widely, and inform known producers of suitable vaccines.
- 3. During the publication of the CfT:**
  - Monitor the receipt of tenders and ensure that a sufficient number are received.
  - If none are received, check the administrative system for possible errors.
  - Plan for an extension and additional advocacy if the number of tenders received is insufficient.
  - Plan a session or system to answer questions that tenderers may have during the preparation of the tender.
- 4. Closing date for submission of tenders:**
  - Determine the final deadline (date and time) for receipt of the tenders.
- 5. Opening of tenders:**
  - Verification phase<sup>2</sup> of the eligibility of the received tenders: deadline, validity, completeness.
  - Ask for additional documents if required.
  - Inform tenderers of their eligibility – or non-eligibility – to the CfT.

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<sup>2</sup> Sufficient time should be allowed to request additional documents from potential suppliers.

## 6. Assessment phase:

- Gather the selection committee to assess the technical proposals.
- List and score/rank the technically valid proposals that will undergo the financial assessment; list the tenderers that are not technically valid and that will not undergo the financial assessment.
- Assess the financial proposal of the tenders for which the technical proposal has been validated.
- Pre-select supplier(s) and set up a negotiation phase<sup>3</sup> (in case several suppliers have been selected) to discuss price, quantities, duration of the contract, delivery conditions, payment process, etc.
- Finalise the assessment based on the negotiation.
- Once the contracting process has been finalised, communicate to all tenderers their status (selected or non-selected).

## 7. Contract:

- Draft the contract.
- Negotiate with the selected supplier(s) to adjust remaining items, as necessary.
- Finalise and sign the contract.

## 8. Contract implementation and compliance:

- Track vaccine orders (as stated per contract).
- Track the delivery plan (as stated per contract).
- For the receipt of vaccines:
  - Verify shipment (verification of documents; inspection as per tender specifications; when relevant, conduct a quality check of each vaccine batch).
  - Validate or reject the consignment based on the agreed contract criteria.
- Ensure all payments are made in alignment with the conditions defined in the contract.

## 9. Post-contract evaluation:

- Evaluate the service provided: product quality, compliance with the contract and delivery conditions (quantity, packaging, deadline, etc.).
- Issue any final payment(s).
- Conduct a review meeting to identify areas of improvement for any future tenders.

**The list above is indicative but not exhaustive and should be adapted to a country's national context.** [Annex 1](#) provides a sample timeline to be completed, with the above-mentioned key steps and the corresponding deadline and institution/person responsible for each step.

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<sup>3</sup> This sub-step depends on the country's national regulations.

## 3.2. How to structure the call for tender



A CfT should consist of at least four sections.

The first section should be an **introduction** to provide some general information about the CfT. The second section should provide **background and context** to the applicants and explain the main objectives of the country's vaccination programme. The third section should cover the **scope of services** and can be divided into three main topics:

1. What the manufacturer/supplier should comply with.
2. The characteristics of the requested vaccine.
3. The details of the contract (duration, terms of delivery and payment).

The fourth section should provide information on the **expected structure** of the tenders, for example:

- the required format<sup>4</sup> (hard copy, Word, PDF) and maximum number of pages;
- requirement to provide two separate documents: technical proposal and financial proposal;
- deadline for proposal submission;
- mailing address and/or email address, or link to which the tender should be sent, or tender portal for secure submissions;
- name and contact details of the person in charge of the CfT process;
- and the description of the selection process.

For more information and guidance on this process, please consult the template CfT in [Annex 2](#).

## 3.3. How to select the vaccine provider



The selection process should be fair, objective and as transparent as possible to avoid any problems later in the process. All requested documents must be duly provided by the tenderers and then thoroughly verified by the selection committee. Therefore, prior to the selection process, the selection criteria need to be agreed upon and the members of the selection committee must be carefully selected.

### 3.3.1. Definition of selection criteria



The selection criteria must be defined at the very beginning of the process, even before the CfT is drafted, as they will need to be included in this document. Article 4.18.6 'Choice of vaccine' of [Chapter 4.18](#) of the *Terrestrial Code* provides a useful summary of vaccine characteristics that may need to be considered for the CfT.

Once the list of criteria has been established, they should be prioritised – and even ranked – according to the objective of the vaccination programme and the country context ([Annex 3](#)).

<sup>4</sup> A user-friendly format (such as Word or PDF) should be requested to ease the review and assessment process. A maximum number of pages for the technical proposal can also be established.



Some of the criteria to be considered are listed below.

### Regarding the vaccines:

#### Vaccine characteristics

- Preferred type of vaccine.
- Preferred administration route(s) (oral, intradermal, subcutaneous, intramuscular).
- Number/preferred pathogen strain(s) to be used (if relevant).
- Evidence of safety for the target species (relevant studies must be available).
- Evidence of vaccine efficacy.
- Duration of protective immunity.
- Storage, transport, and shelf-life characteristics.
- Proof of compliance<sup>5</sup> with international standards concerning quality production, as described in the *Terrestrial Manual*<sup>6</sup> (indicate relevant chapter depending on the targeted disease).

#### Labelling options and packaging conditions

- Vials or bottles, doses per vial, number of vials per box, number of boxes, etc.
- Information concerning available language(s) for the vaccine label, product information for the vaccine's 'Directions for Use' and for the summary of product characteristics (SPC) (or indicate clearly if one specific language is required).
- Production capacities.
- Delivery conditions (e.g. shipping under cold chain conditions, delivery in one or several batches).

#### Market authorisation from regulatory authorities

- Certificate of marketing authorisation/registration/licensing in the corresponding country (including the number of the marketing authorisation and holder).
- Statement of marketing authorisation/licensing/registration status in other countries (regional and/or international level).

### Regarding the manufacturer/supplier:

- Proof of compliance with WOAHA international standards described in the latest English version of the WOAHA *Terrestrial Manual* (see [Annex 4](#)) (for example certification of the manufacturer/supplier from the national competent authority).
- Copy of most recent valid, official good manufacturing practices (GMP) certification provided by the relevant authority (in the corresponding country or region).
- Proof of compliance with relevant quality assurance programmes and procedures based on international standards for all vaccines to be delivered.
- Supplier access to its manufacturing (and warehousing) facilities for inspection at all reasonable times.
- Statement of licensing status in other countries (from region) if/when needed.

### Regarding the financial proposal:

- The service included (service offered).
- Price.

<sup>5</sup> Prequalification processes for the vaccines sought may have been carried out already (e.g. EuFMD's prequalification vaccines list, other regional prequalification vaccines lists). It can be useful and time-saving to search for this information in the corresponding region.

<sup>6</sup> WOAHA *Terrestrial Manual* and Chapter 1.18. Principles of Veterinary Vaccine Production, and Chapter 2.3.4. Minimum Requirements for the Production and Quality Control of Vaccines: <https://www.woaha.org/en/what-we-do/standards/codes-and-manuals/#ui-id-2>.

Once the selection criteria are identified, they should be prioritised and/or weighted. This includes the identification of the criteria that are essential, such as compliance with quality assurance standards (the tender will be rejected if not compliant with these standards).

**Please note that while the price is an important criterion, it should not be the central focus when deciding on a supplier.** Most of the time, the vaccines *per se* are a relatively marginal cost compared to the full cost of the vaccination programme. The main expenses are the human resources and equipment for storing, transporting and administering the vaccine, which are vital for a successful vaccination programme. Therefore, the price of the vaccine should be considered once essential technical criteria have been met.

### 3.3.2. Appointment of a selection committee

The veterinary procurement process is complex and requires the involvement of experts from different backgrounds (e.g. procurement, finance, law, related technical field, veterinary services, policy). Thus, the selection committee must be multifunctional. It can also be divided into two teams: one for the assessment of the technical proposal and another for the assessment of the financial proposal. However, a core team should be present in both committees.

The proposed composition of each team is provided below.

#### **Core team of the selection committee:**

- Technical official in charge of implementing the vaccination campaign.
- Procurement official in charge of the procurement procedure within the organisation/institution.
- Persons with legal expertise (to support the drafting of the contract).

#### **Selection committee for the technical proposal:**

- Veterinary vaccinology experts and technical experts on the relevant disease.
- Regulatory experts<sup>7</sup> (to assess the suitability of the application).
- Logistics expert to assess the shipment, delivery, cold chain distribution, etc.

#### **Selection committee for the financial proposal:**

- Financial officers.

If the Veterinary Services have the sole responsibility of the selection of tenderers, they must ensure they gather all the required expertise to conduct the selection.

Separating the selection committee into two teams (one to assess the technical proposal and another to assess the financial proposal) will allow the members to focus on their respective domain of expertise or experience, without spending time on other matters. It will also prevent the financial assessment of proposals that are not technically valid.

<sup>7</sup> The regulatory expert is a person specialised in the regulation of the import of products of a biological and/or medical nature into the country.

### 3.3.3. Organising a discussion or negotiation session with preselected candidates



Once the preselection is done, there may be several eligible candidates. Individual sessions can then be scheduled for the various candidates to answer questions regarding their proposal and to possibly negotiate better deals or conditions. However, as mentioned above, those responsible for the procurement process should first ensure that the country's national regulations permit negotiation sessions with potential suppliers.

## 3.4. What to consider when drafting the contract



When drafting the contract, potential contentious risks should be anticipated and clauses should be included in the contract to protect the contracting institution from such risks.

Common examples of contentious risks include the following:

- delay in vaccine delivery;
- lack of clarity on the respective responsibilities of the contract parties (e.g. for obtaining any export license or other official authorisation required for export and for carrying out the customs formalities, shipment insurance coverage, who will cover the risk of loss or damage during export and when will that risk pass from one contract party to the other);
- inadequate shelf-life for the vaccination campaign;
- quality issues or the vaccine supplied is not as described in the contract (e.g. different sized vials, different place of manufacturing, different formulation or vaccine strains, or evidence that the safety or efficacy is not as claimed in the contract);
- cold chain issues (e.g. vaccine supplied does not meet the recommended storage temperature, usually of +2°C to 8°C).

To prevent the abovementioned risks, it is important to identify them in advance and to include clauses in the contract that will allow these conflicts to be managed. To this end, the contracting institution/organisation should take time to brainstorm potential risks, including ones specific to the national context. The support of a legal expert will be required for drafting the contract.



## 3.5. How to ensure contract compliance



Once a shipment arrives, it is important to verify and document the compliance of the vaccine with requirements stipulated in the contract (e.g. quality<sup>8</sup>, quantity, shelf-life, temperature control during shipment). Any discrepancy should be reported immediately. Whenever possible, it is recommended to control the quality of each vaccine batch, in accordance with [Chapter 2.3.4.](#) of the *Terrestrial Manual*.

Regular communication (e.g. quarterly) with the vaccine provider helps to maintain good relations with the supplier and to ensure rigorous compliance with the contract by both contract parties. This is particularly important in the case of a long-term contract.

Once delivery has been confirmed, it is also important to ensure that payment to the supplier is made in accordance with the terms of the contract. On-time payment helps to establish trust with the supplier.

If a dispute arises that is not covered by the contract, the parties can refer to national/international regulations to resolve it. However, it is always better to anticipate potential conflicts as much as possible and to include protective clauses in the contract.



<sup>8</sup> International recommendations are to systematically test all batches. As this might be complicated to implement, one recommendation would be to ensure that the vaccines have all the necessary international certifications up-to-date. In addition, it is recommended to identify a reference laboratory in the region that could support the testing process.

# Annexes

## Annex 1 – Timeline template with key steps

	Description of the task	Institution in charge	Deadline	Contact person and details
<b>1</b>	<b>Preparation of the call for tender (CfT)</b>			
	<ul style="list-style-type: none"> <li>Define the selection criteria</li> <li>Draft the CfT</li> <li>Identify the selection committee members</li> <li>Set up an administrative system to receive tenders; ensure that it works effectively</li> </ul>			
<b>2</b>	<b>Publication of the CfT</b>			
	<ul style="list-style-type: none"> <li>Publish the CfT online and on professional digital platforms, national newspapers, and other official national platforms</li> <li>Advertise the CfT, including by informing known producers with potential interest in applying</li> </ul>			
<b>3</b>	<b>During the publication of the CfT</b>			
	<ul style="list-style-type: none"> <li>Monitor the reception of tenders; ensure a sufficient number of proposals is received</li> <li>Plan for an extension period in case an insufficient number of tenders is received</li> <li>Plan a session or system to answer question from applicants regarding the preparation of the dossier</li> </ul>			
<b>4</b>	<b>Closing date for submission of tenders</b>			
	<ul style="list-style-type: none"> <li>Determine the deadline (date and time) for receipt of the tenders</li> </ul>			
<b>5</b>	<b>Opening of tenders</b>			
	<ul style="list-style-type: none"> <li>Verification phase (of all requested documents concerning Q&amp;A of vaccines, manufacturers, registration/licensing of the products, etc.)</li> <li>Ask for additional documents if required</li> <li>Inform tenderers of their eligibility – or non-eligibility – to the CfT</li> </ul>			
<b>6</b>	<b>Assessment phase</b>			
	<ul style="list-style-type: none"> <li>Assess the technical proposals</li> <li>Assess the financial proposal of tenders for which the technical proposal has been validated</li> <li>Pre-select supplier(s) and set up a negotiation phase<sup>9</sup> (in case several suppliers have been selected)</li> <li>Communicate to all tenderers their status (selected or non-selected)</li> </ul>			
<b>7</b>	<b>Contract</b>			
	<ul style="list-style-type: none"> <li>Draft the contract</li> <li>Set up a second negotiation phase (price, quantities, duration of the contract, delivery conditions, payment process)</li> <li>Finalise and sign the contract</li> </ul>			
<b>8</b>	<b>Contract implementation and compliance</b>			
	<ul style="list-style-type: none"> <li>Track the vaccine orders (as stated in the contract)</li> <li>Track the delivery plan (as stated in the contract)</li> <li>When receiving the vaccines: <ul style="list-style-type: none"> <li>Verify the shipment (verification of documents and quality check: inspection as per tender specifications)</li> <li>Validate or reject the consignment based on the pre-established criteria</li> </ul> </li> <li>Ensure payment is executed respecting conditions defined in the contract</li> </ul>			
<b>9</b>	<b>Post-contract follow-up</b>			
	<ul style="list-style-type: none"> <li>Evaluate the service provided: product quality, compliance with the contract and delivery conditions (quantity, packaging, deadline, etc.)</li> <li>Payment process</li> </ul>			

<sup>9</sup> This sub-step depends on corresponding national regulations.



# Annex 2 – Call for Tender template

## Contents

### Section 1: Introduction

### Section 2: Background and context

### Section 3: Scope of services

#### A- Information on vaccine manufacturer/supplier compliance

#### B- Information concerning the requested vaccine

1. Vaccine strain(s) and main characteristics
2. Labelling and packaging procedures
3. Production and delivery capacities
4. Market authorisation from regulatory authorities

#### C- Contract details

1. Duration of the contract
2. Delivery process of the vaccines

### Section 4: Response structure

#### A-Technical proposal

#### B-Financial proposal

### Conclusion

## Section 1: Introduction

*(Short introduction on the country)*

## Section 2: Background and context

*(Description of background and context, including description of the vaccination program the country is intending to implement: objectives, duration of the vaccination campaign, estimated start date and duration, estimate of quantities of vaccines needed for the duration of the campaign, etc.)*

## Section 3: Scope of services

*(This section should be a description of what the country is expecting in the technical proposals of the applicants/tenderers and what they should include). Here are some suggestions:*

### A- Information on vaccine manufacturer/supplier<sup>10</sup> compliance

Global references and experience in manufacturing, quality control, selling, exporting and delivering similar vaccines, such as:

- proof of compliance with international standards on minimum requirements for vaccines production facilities and quality control of vaccines (see Annex 4);
- proof of compliance with WOAH intergovernmental standards described in the latest English version of the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*;<sup>11</sup>
- copy of most recent valid, official good manufacturing practices (GMP) certification provided by the relevant authority (in country or region);

<sup>10</sup> The points provided in this list are in addition to the standard government terms and conditions for veterinary product contracts.

<sup>11</sup> <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/#ui-id-2>

- proof of compliance with relevant quality assurance programmes and procedures based on international standards for all vaccines to be delivered;
- supplier allows access to its manufacturing (and warehousing) facilities for inspection at all reasonable times;
- statement of licensing status in other countries (from the region) if/when needed.

Ensure a note is added saying that the manufacturer/supplier must notify the buyer of any critical issues which could interfere with the production and distribution of products.

## B- Information concerning the requested vaccine

*(This section should describe all information relative to the vaccines matching the country's selection criteria)*

### 1- Vaccine strain(s) and main characteristics

*Description of specific expected characteristics according to vaccination programme strategy and context, such as:*

- preferred strain to be used (if relevant);
- preferred vaccines (e.g. live inactivated or biotechnology-derived vaccines, Differentiating Infected from Vaccinated Animals [DIVA]);
- evidence of safety in the target species, users, consumers of products derived from vaccinated animals and for the environment (relevant studies must be available);
- evidence of vaccine efficacy and effectiveness supportive of the label claims;
- duration of protective immunity (if relevant);
- storage, transport, and shelf-life characteristics;
- proof of compliance with international standards concerning quality production described in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (indicate relevant chapter depending on the disease targeted).

### 2- Labelling and packaging procedures

*Indicate the packaging options that should be included in the proposal, such as:*

- vials or bottles, doses per vial, number of vials per box, number of boxes, etc.;
- information concerning available language for the labelling and for the vaccines' 'Directions for Use', for the Summary of Products Characteristics (SPC) (or indicate clearly if one specific language is required).

### 3- Production and delivery capacities

*Describe the requirements in terms of production capacity and delivery conditions, such as:*

- production capacities and lead times;
- delivery conditions (e.g. shipping under cold chain conditions, delivery in one or several batches).

### 4- Market authorisation from regulatory authorities

*Indicate the authorisations to be provided in the tender, including:*

- certificate of marketing authorisation/registration/licensing in the country if relevant (including the number of the marketing authorisation number and holder);
- statement of marketing authorisation/licensing/registration status in other countries if relevant (regional and/or international level).

## C- Contract details

### 1- Duration of the contract

The duration of the contract should align with the duration of the vaccination campaign.

### 2- Delivery process of the vaccines

All relevant information concerning the delivery process should be included, such as:

- packaging and shipping of vaccines<sup>12</sup>
- delivery terms: as per Incoterms;<sup>13</sup>
  - for instance, for international delivery via airfreight, prefer CIP;
  - for national suppliers, prefer DDU (delivery and duty unpaid);
  - when applicable, trans-shipment points should be indicated (including availability of cold chain at all trans-shipment points);
- delivery date and conditions (partial delivery, complete, frequency)
  - labelling on packages (language, expiry dates of the vaccines and appropriate storage temperatures);
- delivery information before shipment, such as:
  - number of vials and doses per vial
  - type of vaccine (strains/type)
  - number of boxes
  - gross weight/volume
  - temperature indicator strips in boxes.

## Section 4: Response structure

The tender should include two separate parts: a technical proposal and a financial proposal.

### A- Technical proposal

This section should refer to [Section 3: Scope of services](#) and serve as a reminder of what is needed in the technical proposal, including the following:

- general company information
- nature and quality of the vaccines
- service proposed (service offered).

The following can also be included/requested:

- a section concerning estimated risk factors that could interfere with the execution of the service
- additional information the tenderer considers important to communicate.

### B- Financial proposal

This section should define the currency to be used for the proposal, details of the pricing (vaccines, shipment/delivery process and other services), as well as conditions for payment options.

## Conclusion

In this section, clearly indicate the requirements for responding to the tender, such as:

- the required format (hard copy, Word, PDF), deadline, or other requirements;
- mailing address and/or email address to which the tender should be sent;
- name and contact details of the person in charge of the Call for Tender process.

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<sup>12</sup> [https://www.ema.europa.eu/en/documents/scientific-guideline/vich-gl43-target-animal-safety-veterinary-pharmaceutical-products-step-7\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/vich-gl43-target-animal-safety-veterinary-pharmaceutical-products-step-7_en.pdf)

<sup>13</sup> <https://iccwbo.org/resources-for-business/incoterms-rules/>

# Annex 3 – Ranking of selection criteria

The list of criteria below is not exhaustive and additional selection criteria may need to added according to the national context.

REGARDING:		MUST have	GOOD to have	
the vaccines	<b>Vaccine strains and main characteristics</b>			
	• Preferred strain to be used (if relevant)			
	• Evidence of safety in the target species (relevant studies must be available)			
	• Evidence of vaccine efficacy			
	• Duration of protective immunity (if relevant)			
	• Storage, transport and shelf-life characteristics			
	• Proof of compliance with international standards concerning quality production described in the <i>Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</i> <sup>14</sup> (indicate relevant chapter depending on the targeted disease)			
	<b>Labelling and packaging procedures</b>			
	• Vials or bottles, doses per vial, number of vials per box, number of boxes, etc.			
	• Information concerning available language for the labelling and for the vaccines' 'Directions for Use', for the Summary of Products Characteristics (SPC) (or indicate clearly if one specific language is required)			
	<b>Production and delivery capacities</b>			
	• Production capacities			
	• Delivery conditions (e.g. shipping under cold chain conditions, delivery in one or several batches)			
the manufacturer/supplier	<b>Market authorisation from regulatory authorities</b>			
	• Certificate of marketing authorisation /registration/licensing in the country			
	• Statement of marketing authorisation/licensing/registration status in other countries (regional and/or international level)			
	• Proof of compliance with international standards on minimum requirements for vaccine production facilities and quality control of vaccines			
	• Proof of compliance with WOAH intergovernmental standards described in the latest English version of the WOAH <i>Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</i>			
	• Copy of most recent valid, official GMP certification provided by the relevant authority (in country or region)			
	• Proof of compliance with relevant quality assurance programmes and procedures based on international standards for all vaccines to be delivered			
	• Supplier allows access to its manufacturing (and warehousing) facilities for inspection at all reasonable times			
	• Statement of licensing status in other countries (from region) if/when needed			
	the financial proposal	• The service included (service offered)		
		• Price		

<sup>14</sup> <https://www.woah.org/en/what-we-do/standards/codes-and-manuals/#ui-id-2>

## Annex 4 – WOAH standards for the manufacture of veterinary vaccines

In the World Organisation for Animal Health (WOAH) *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*, section 2.3 (Veterinary vaccines) describes the minimum requirements expected for quality assured veterinary vaccine production according to WOAH international standards.

It is highly recommended that any applicants to the Call for Tender respect these standards as a minimum.

In 2019, WOAH published a technical document, *Technical standards for manufacturing and quality control of veterinary vaccines*, compiling selected vaccine-related chapters from the *Terrestrial Manual* and the *Terrestrial Animal Health Code*.

This technical support is available online through the following link:  
<https://bulletin.woah.org/?panorama=5-1-3-standards-vaccines-en>.



# Practical Guidelines for National Procurement of Veterinary Vaccines

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