RFP/PPRVB/2021

B. TERMS OF REFERENCE

PPR VACCINE BANK

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

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Contracting authority

World Organisation for Animal Health (OIE)

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1. INTRODUCTION

1.1 OIE MANDATE

The World Organisation for Animal Health (OIE) is an international organisation mandated by its 182 Members to improve animal health and welfare worldwide.

Founded in 1924, the OIE was established further to the collective awareness for countries to work together to control animal diseases threatening livestock as well as human health and well-being, at a time where the increased trade of animal products enhanced the risk of spreading animal diseases across boundaries. The International Agreement signed by the founding countries led to the creation of the Office International des Epizooties – which in 2003 adopted the common name of "World Organisation for Animal Health" yet kept its historical acronym "OIE". The creation of the OIE signals the first global commitment to fighting animal diseases collectively.

Since this date, the OIE's missions have expanded to comprehensively respond to the challenges facing animal health and welfare worldwide.

A key OIE mission is to ensure the transparency of the animal health situation worldwide, including diseases transmissible to humans. The OIE collects, analyses and disseminates in real-time information on the sanitary situation of animal diseases, and offers its Members the possibility to be certified of their official diseases status for a number of diseases important for trade.

The OIE is also historically responsible for the development and publication of animal health standards supporting disease prevention and control methods while safeguarding the sanitary safety of world trade in animals and animal products. These international standards are developed by elected experts that participate in the OIE Specialist Commissions, Working Groups and ad hoc Groups. The OIE is recognised by the World Trade Organization (WTO) as the reference standard-setting international organisation in the field of animal health.

The OIE is supported through 300 Reference Laboratories and Collaborating Centres. These internationally renowned research centres provide a solid scientific foundation to the work of the OIE and enables the organisation to provide its Members with international standards which are scientifically-based and up-to-date as well as high-quality expertise on disease control and eradication methods.

Furthermore, the OIE provides support to its Members in the implementation of its standards and guidelines, through activities aimed at strengthening national Veterinary Services. The OIE actively works with major international, regional and national financial organisations to target effective investments in animal health systems.

1.2 ADDITIONAL INFORMATION

The OIE is placed under the authority of the World Assembly of National Delegates, which meets annually in May in Paris (France).

The day-to-day activities of the OIE are placed under the responsibility of the Director General and managed by the Headquarters, located in Paris, with the support of 13 Regional and Sub-Regional Representations (RR and SRR) worldwide. The goal of these regional offices is to provide regionally adapted services to OIE Members in order to achieve the OIE mandate of improving animal health and welfare.

In addition, the OIE has set up five Regional Commissions (Africa, Americas, Asia, Far East and Oceania, Europe and the Middle East) to address specific problems in the different regions of the world. These Commissions are fully-fledged regional institutional bodies. They organise a Conference every two years and focus on addressing technical issues and enhancing regional cooperation.

Overall, the OIE is an intermediate-sized organisation with approximately 160 staff operating in Paris and 70 in the RR and SRR.

The culture of the organisation is also largely shaped by the distinctive qualifications of its workforce, encompassing scientific profiles (veterinarians, epidemiologists, biologists…), policy experts (international trade, public health…) as well as highly versatile staff in support functions.

2. EXECUTIVE SUMMARY

2.1 PROJECT BACKGROUND

Peste des Petits Ruminants (PPR) is a viral infectious disease with acute symptoms mainly affecting sheep and goats and occasionally wild small ruminants, and which often causes animal death and serious secondary infections.

In goats and sheep it has, in some cases, a mortality and morbidity rate close to 100%. The severity of the symptoms depends on the age, the species (usually more severe in goats than in sheep), and also the breed. In addition, cattle, camels, buffaloes and some wildlife species are prone to the PPR virus although their potential role in the maintenance and circulation of PPR virus (PPRV) has not been formally established. The virus is transmitted by direct or indirect (i.e. fomite) contact with infective excretions, including aerosols, between animals in close contact.

PPR has a widespread distribution spanning Western, Eastern and Central Africa, the Arabian Peninsula, the Middle East and Central, Southern and Eastern Asia. PPR is not a zoonosis but when enzootic, it has major economic consequences for animal production and trade in animals, especially with the intensification of livestock trade and production. Therefore, considering the distribution of the disease, prevalently in developing countries with under resourced animal health services, it presents a real threat for the development of these areas and for countries free of the disease.

The OIE provides science-based standards, guidelines and recommendations to control the disease in animals and to prevent the spread of the disease through trade; the OIE also provides intergovernmental standards for the diagnosis of the disease and the quality of vaccines for use in animals. Through its global network of Reference Laboratories and Collaborating Centres, the OIE provides policy advice, strategy design and technical assistance for the prevention, diagnosis, control, reduction and progressive eradication of PPR.

As a viral disease, no specific treatment exists for PPR; therefore, the vaccination of small ruminants is the only effective means of controlling PPR in an infected population.

This disease is estimated to cause over $2 billion in losses each year, and its elimination will improve food and nutritional security for billions of consumers and especially the more than 300 million vulnerable households who keep sheep and goats in the affected regions.

In light of the recommendation made during the GF-TADs Global Steering Committee (GSC) held in Paris in October 2012 requesting that the Global GF-TADs Working Group activities be extended to PPR, with the task of developing an OIE-FAO Global Strategy for the Control and Eradication of PPR[1], an International Conference for the Control and Eradication of PPR was organised by the OIE and FAO and took place in Abidjan (Côte d'Ivoire) on 31 March to 2 April 2015. Ministerial delegations, representatives of regional bodies and international organisations accounting to more than 300 participants from across the continents participated in the conference. A global eradication programme was launched one year later (October 2016).[2]

Both organisations, OIE and FAO, affirm that PPR can be eradicated in half the time it took to eradicate rinderpest if the global strategy devised by FAO and OIE is adequately resourced and well-coordinated at all levels, with strong political commitment from national authorities and effective engagement with Veterinary Services and rural communities.

The OIE first established a PPR Vaccine Bank for Africa in February 2013, after selecting a vaccine manufacturer through an international call for tender. This Vaccine Bank was supported by the Bill & Melinda Gates Foundation project entitled "Vaccine Standards and Pilot Approach to PPR Control in Africa (VSPA)", which was implemented from October 2012 to September 2014. The prime objective of this project was to implement a coordinated strategy which included the strengthening of capacities of regional actors such as the Africa Union's PANVAC as well as national Veterinary Services, in order to control and possibly eradicate PPR in several pilot countries in Western Africa. Through this project, 10 million doses of PPR vaccines were delivered to three countries: Burkina Faso, Ghana and Mali. The

[1] https://www.oie.int/eng/ppr2015/doc/PPR-Global-Strategy-2015-03-28.pdf

[2] https://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/PortailPPR/EN_GEP_PPR_Finalweb.pdf

Vaccine Bank set up for the project also enabled the delivery of 4 million doses of PPR vaccines to Togo, with financial support from the World Bank.

In 2015, the OIE signed a new contract for the implementation of the World Bank PRAPS[3] project, which, amongst other activities, targets the control and elimination of PPR in 6 countries of the Sahel region: Burkina Faso, Chad, Mali, Mauritania, Niger and Senegal. These countries have launched widespread vaccination campaigns over the past five years.

Based on the success of the first PPR Vaccine Bank, and the launch of the PRAPS, the OIE launched a new call for tender in 2016 which resulted in the signature of supply agreements with 2 vaccine manufacturers which have been awarded to supply the OIE vaccine Bank until December 2021 (after signature of an extension).

Since 2013, this mechanism has facilitated deliveries of PPR vaccines for sheep and goat vaccination using different funding procedures: (i) purchase by the OIE (using donor funds), (ii) direct purchase by countries or government agencies, and (iii) direct purchase by international organisations or implementing partners.

The OIE published in October 2018 the OIE Policy Paper on Vaccine Banks[4]. It clarifies the role and positioning of the OIE with regard to its Vaccine Banks. In particular, it defines principles for the implementation of the OIE Vaccine Banks in accordance with the OIE's mandate, its Strategic Plan, as well as other activities and procedures undertaken by the organisation.

The total number of PPR vaccines delivered through the OIE Vaccine Bank mechanism since 2013 amounts almost 77 million doses.

Orders placed through the OIE PPR Vaccine Bank were initially funded predominantly by donors (World Bank) to the OIE World Animal Health and Welfare Fund and have reached a total of **10 000 000 doses** between 2012 and 2020 (Burkina Faso, Ghana, Mali).

However, the OIE Vaccine Bank mechanism progressively became also appealing to countries, implementing partners and international organisations wishing to purchase PPR vaccines for their national needs.

Thus, since 2013 and to date, several countries have purchased PPR vaccines directly from the OIE PPR Vaccine Bank with the authorisation of the OIE. Through this mechanism, the country finances all associated costs linked to the purchase of vaccines, including transportation and insurance. In this case, the Vaccine Bank provides a solid guarantee in terms of quality of vaccines and cost efficiency. A total of **64 900 000 doses** of PPR vaccines have been ordered or purchased directly by countries (Burkina Faso, Chad, Mauritania, Niger, Togo) which was possible in particular thanks to the national funding provided by the World Bank PRAPS.

Partner international organisations such as FAO or the World Bank have also procured vaccines through the OIE Vaccine Bank for a country in need. This has enabled the purchase of **1 710 000 doses** of PPR vaccines (Burundi, Togo).

The advocacy and commitment of the international community against PPR have continued in the most recent years. On 7 September 2018, over 45 countries renewed in Brussels their commitment to globally eradicate PPR by 2030. At the same time, countries urged resource partners and the international community to contribute in bridging the PPR Global Eradication Programme's US$340 million funding gap. As of beginning 2021, the World Bank is in the last phase of validation of a phase 2 of the PRAPS which would be implemented from 2022 to 2027.

Lessons learned from the Global Rinderpest Eradication Programme demonstrate that the use of a highly efficacious vaccine capable of immunising animals against all rinderpest virus strains was a vital contributor to the campaign's success. Similarly, efficient PPR vaccines are available and can induce life-long protective immunity in vaccinated animals.

The OIE PPR Vaccine Bank is one of the tools, among many others, that could support the achievement of the global PPR eradication.

[3] Regional Sahel Pastoralism Support Project for Africa

[4] https://www.oie.int/fileadmin/Home/eng/Links/docs/pdf/Policy-Paper-VB-final-EN_Oct-2018_01.pdf

2.2 PROJECT OBJECTIVES

The overall objective of this OIE PPR Vaccine Bank is to rapidly provide requesting countries[5] with PPR vaccines in order to vaccinate the animal population at risk with high quality vaccines complying with OIE intergovernmental standards. The long term aim will be to control and progressively eradicate PPR through vaccination, in line with the Global Strategy devised by FAO and the OIE.

The OIE will establish a new PPR Vaccine Bank starting in 2022 which will allow (i) purchase by the OIE (donor funding), (ii) direct purchase by countries or government agencies, and (iii) direct purchase by international organisations and implementing partners, such as FAO, the World Bank and NGOs.

The overall objectives of the PPR Vaccine Bank are to rapidly provide requesting countries, when eligibility criteria (conditions/situations) are met, either with (i) an emergency stock of high quality PPR vaccines in order to vaccinate the animal population at risk within the framework of agreed national vaccination strategies; or (ii) with a stimulus package that can typically include between tens of thousands and hundreds of thousands of high quality vaccine doses to support animal health services on PPR control and eradication and to leverage larger governmental commitments deploying large scale national vaccination campaigns.

The PPR Vaccine Bank can also be used by countries or by international organisations to purchase larger quantities of high-quality vaccines for planned vaccination campaigns (planned production and deliveries). This limits the number of procurement procedures at national level, while facilitating the delivery of high-quality vaccines at a price negotiated at global level through an international call for tender.

The PPR Vaccine Bank relies on the supplier to deliver high-quality vaccines upon request. The vaccine supplier will play a prominent role in ensuring the rapid and smooth transport of the vaccines requested to the country of destination. This may include maintenance of the cold chain until delivery to a cold store at the airport of destination (or a cold store close to the airport of destination), until official acknowledgement of receipt by the relevant authorities of the beneficiary country, as well as guaranteeing the quality of the vaccines delivered.

The purpose of this international call for tender is to select the most suitable manufacturer(s) of PPR vaccines for sheep and goats in order to set up a PPR Vaccine Bank, in accordance with the criteria set out below. The Vaccine Bank is expected to be operational starting 1 January 2022 for a period of 4 years.

3. SCOPE OF THE SERVICES

The OIE expects offers which respond/comply to the following elements:

3.1 THE VACCINE MANUFACTURER(S)

The vaccine manufacturer(s) shall have global references and experience in manufacturing, quality control, selling, exporting and delivering PPR vaccines. The vaccine manufacturer(s) must comply with relevant international standards including the OIE intergovernmental standards described in the latest English version of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*[6] as well as relevant international standards on Minimum requirements for vaccine production facilities and Quality control of vaccines.

The vaccine manufacturer(s) must be in possession of a valid official certificate of Good Manufacturing Practices provided by relevant and reputable official national authorities for all plants producing the vaccines to be delivered. Evidence of current certification and the outcomes of the most recent independent Good Manufacturing Practices (GMP) inspection by the regulatory body must be supplied with the tender documentation.

[5] While the OIE PPR Vaccine Bank is global and doesn't focus on a specific region, it is expected that requests and deliveries will be predominantly in the region of Africa, in particular West Africa

[6] https://www.oie.int/en/standard-setting/terrestrial-manual/access-online/

The vaccine manufacturer(s) must comply with the relevant quality assurance control programmes and procedures based on international standards for all vaccines to be delivered. Proof of compliance must be provided by supplying relevant supporting documentation.

The vaccine manufacturer(s) selected shall allow the OIE, its nominated experts and/or the donor(s) supporting the project to a right-of-entry to inspect the corresponding production and storage facilities. The vaccine manufacturer(s) shall permit the OIE or its representatives further to previous notice to the manufacturer, to have access to their manufacturing and warehouse facilities at all reasonable times to assess (or periodically reassess) the production and capacity, testing, packaging and storage of the goods, and shall provide reasonable assistance for such assessments including the provision of copies of manufacturing protocols, lot production records, test results or quality control reports.

The vaccine manufacturer must commit to immediately notifying OIE of any critical issues relevant to production, storage and distribution of products covered by the contract identified during internal control procedures or GMP inspections.

3.2 THE PPR VACCINE BANK

Within the framework of this call for tender, the term “Vaccine Bank” refers to the provision of the following services: Vaccine Production, Quality Control, Storage, Supply and Delivery formalised through a signed Agreement (commercial contract) between the vaccine manufacturer(s) and the OIE.[7]

The vaccine manufacturers’ offers shall facilitate the setting up of a “virtual” PPR Vaccine Bank with as much flexibility as possible, in order to effectively and efficiently deliver the products within the timeframe allowed and manage certain variables such as rolling stocks and replenishment rules, the number of doses per vial or bottle, and the capacity to manage the production and to supply additional types of vaccines (if developed and compliant).

Vaccines can be purchased by the OIE (using funds provided by donors), by Countries (or country programmes) or possibly other international organisations duly authorised, or duly authorised non-governmental organisations in some cases.

The contract(s) negotiated after the selection process in the framework of this call for tender would be signed between the vaccine manufacturer(s) and the OIE. Third party clauses provide the possibility to authorise eligible countries (including country programmes), and possibly some international organisations or non-governmental organisations to purchase vaccines through the PPR Vaccine Bank, on a case-by-case approach.

The vaccine manufacturers are encouraged to specify in their offers:

- the maximum volume (number of doses) they would be able to provide through this Vaccine Bank, both on an annual basis (indicative) and in total.
- the minimum and maximum size of a production batch (how many doses can be produced at one time) and the corresponding lead time (between the order of production and the availability of the vaccines at the gate of the factory), with or without the use of Early Release Certificates (quality control fully completed or not);
- if specific volumes (number of doses) need to be considered when ordering production or delivery of vaccines (size of shipments);
- if the use of Early Release Certificates can be considered.

The lead time between a formal order of PPR vaccines from the OIE to the vaccine manufacturer and the actual delivery of vaccines to beneficiary countries by the vaccine manufacturer is an important factor to consider. The OIE expects the lead time to be as short as possible and the vaccine manufacturer(s) to respect the timeframes indicated in the contract. Several options may be proposed (e.g. (non-exhaustive) “emergency delivery” “planned delivery”).

[7] More generic information on Vaccine Banks in the Chapter 1.1.10 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

It is to be noted that, upon receipt of a request for vaccines by the OIE (from a country or from a duly authorised international organisation or non-governmental organisation), the OIE will use the following criteria listed by order of importance to attribute the Order to the manufacturer.

- Preference indicated by the country;
- Price (vaccine cost) ;
- Lead time;
- Market authorisation in the country of delivery.

As it is an on-demand mechanism, the OIE will not be responsible of un-used vaccines at the manufacturer premises at the end of the contract.

3.3 LOCATION OF THE VACCINE BANK

The vaccine manufacturer(s) is/are wholly responsible for producing on time or storing the vaccines pertaining to the Vaccine Bank. The OIE shall not engage in the provision of storage facilities at global, regional or national level. Proposing different locations for storage (that will be detailed in the offer) in order to reduce the logistic risks might be considered as an additional advantage (management of logistic risks so that vaccine delivery is not disrupted).

3.4 PPR VACCINES

In the context of the PPR Vaccine Bank, the vaccine manufacturer(s) shall have in stock and provide, or shall be able to produce on time, the vaccines within the time period indicated in the Contract.

The PPR vaccines produced shall meet the requirements for PPR vaccines and comply with OIE intergovernmental standards for the quality of veterinary vaccine production referred to in Part 1 above as well as with the relevant parts of Chapter 3.7.9 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (requirements for PPR vaccines), adopted in May 2019. Conformity of the PPR vaccines with VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) guidelines will be considered.

Vaccine strain and main characteristics

Considering that all current PPR vaccines with authorisation for field use are conventional vaccines based on attenuated virus strains, the OIE assumes such vaccines will be offered in this tender process and has drafted requirements accordingly. This should not necessarily be considered as excluding offers of vaccines based on biotechnologies, but any such offer will need to demonstrate compliance with the relevant chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* as well as appropriate authorisations from reputable regulatory agencies have been achieved.

The two most commonly used vaccine strains (Nigeria/75/1 and Sungri/96) have both been shown in experimental trials to protect animals against PPRV isolates of all lineages. The vaccine can be based on the Nigeria 75/1 strain of PPRV or on another well-known attenuated strain such as Sungri/96.

The history of the vaccine received and stored in the laboratory as master seed should be well known and registered: origin, number of passages in cell culture, the range of the number of passages of the vaccine in cell culture that has been tested and shown to be effective in providing protection in animals against PPR with the recommended dose for vaccination for at least 3 years. This PPR virus vaccine strain should not be able to be excreted by inoculated animals and spread to in-contact animals. It should be proven that the vaccine strain has not reverted to virulence following at least three back passages in sheep and goats.

The seed should be controlled and tested free from bacterial, fungus and mycoplasma contamination. It should be tested free from pestivirus and any other potentially contaminating virus. Only live attenuated PPR virus should be present. The seed should have passed an innocuity test in animals (rodents, sheep and goats) and have demonstrated its efficacy to protect sheep and goats against PPR with the recommended dose.

The vaccine should be safe for use in all species of targeted animals, including young and pregnant recipients.

Information should be available to indicate that studies have been carried out and have demonstrated that the vaccine strain which has been used has not reverted to virulence after at least three back passages.

Field or other tests should have proven that the attenuated PPR vaccine is efficacious for use in all sheep and goats species, including young and pregnant animals.

Duration of protective immunity should be determined for each vaccine strain in animal trials. For the Nigeria 75/1 and Sungri/96 vaccines, this has been shown to be at least three years. Therefore, the vaccine shall confer immunity protection for at least three years. Vaccines with demonstrated (internationally recognised justifications provided) longer protective immunity would be an additional advantage.

The vaccine shall have at least 2 years of remaining shelf-life between 2°C and 8°C, stored under vacuum and protected from light. PPR vaccine freeze-dried in the Weybridge medium can be kept for at least 2 years at 2°C to 8°C (although storage at –20°C is better), provided it is stored under vacuum and protected from light. If the vaccine is described as a "thermotolerant vaccine" (ability to retain protective immunogenicity after exposure to temperatures above the storage temperature required according to the manufacturer's recommendations), the appropriate published data will be made available, and evidence of independent validation by a reputable agency supplied.

The supply of thermotolerant vaccines is an important advantage. Tenderers may propose thermotolerant and non-thermotolerant vaccines in their offer. It may be relevant to propose both options if the price proposed for the 2 vaccines differs as prices will be one of the criteria of the selection between the tenderers.

The supply of Differentiating Infected from Vaccinated Animals (DIVA) vaccines would represent an advantage. Tenderers may propose DIVA and non-DIVA vaccines in their offer. For DIVA vaccines, the associated diagnostic assay should be specified (without incorporating it in the price offer) including information on its availability on target regions. It may be relevant to propose both options (DIVA and non-DIVA) if the price proposed for the 2 vaccines differs as prices will be one of the criteria of the selection between the tenderers.

The vaccine manufacturer(s) shall provide evidence of the biological characteristics of the vaccine, its quality criteria (sterility, purity, freedom from extraneous agents), the method of manufacture (procedure, requirements for substrates and media, in-process controls, final product batch tests (sterility and purity, safety and efficacy, batch potency).

The vaccine manufacturer will need to demonstrate proof of compliance via the supply of relevant documentation. The vaccine manufacturers' offer shall also foresee the submission upon request of all relevant supporting documentation, as well as a full and detailed description of the protocols used: a full and detailed description of the vaccine's characteristics including method of manufacture, the kind of diluent and adjuvant used, administration procedures, volume per dose and possible secondary effects identified.

The vaccine manufacturer(s) shall specify the safety requirements (target and non-target animal safety, reversion-to-virulence for attenuated/live vaccines), environmental consideration, efficacy requirements (for animal production and for control and eradication), stability, and duration of immunity.

Labelling and packaging procedures

Detailed labelling procedures shall be specified in the offer, i.e. such as information on the content, form and quality of the labels used, as well as details on the timing of the labelling in the production chain (or on any related constraints).

The languages available for the labelling and the languages available for the vaccine Directions For Use (DFU) shall also be specified. Since it is anticipated that this PPR Vaccine Bank will largely be used in West Africa, the vaccine manufacturer(s) shall be able to provide the labels and the vaccine Directions For Use (DFU) in French. Provision of labels and DFU in English is also expected while other additional languages are considered an advantage.

The whole description of the packaging (number of doses per vial or bottle, number of bottles per box, number of boxes per pallet, diluent vials included, etc.) proposed shall be detailed in the offer. Different options and corresponding prices shall be specified. Offers with different prices covering different multi-dose vials/bottles is possible. The number of doses of vaccine will depend on the price. The capacity to supply different sizes of vaccine vials (and number of doses per vial) and matching sizes of diluent vials

would be an additional advantage. Experience has indicated that 100ml vials (100 doses) may sometimes raise concerns among users (wastage, cost/benefit and environmental issues) when no other size of vial is available (notably when vaccinating small herds in remote areas).

Other user-friendly solutions can be proposed (and described).

Guidance from the vaccine manufacturer(s) regarding the pros and cons of packaging options available are welcome. It is important to note that in the context of this PPR Vaccine Bank, the OIE will request the delivery of these vaccines exclusively for small ruminants (goats and sheep), with emphasis on countries of the Sahel region engaged in the PRAPS project (but not exclusively).

The vaccination of camels and cattle is not envisaged in the context of this Vaccine Bank.

Existing market authorisations from Regulatory Authorities

Evidence should be supplied of existing market authorisations from Regulatory Authorities for the vaccine. As it is envisaged that this PPR Vaccine Bank is used by some of the countries of the PRAPS, a market authorisation in the West African Economic and Monetary Union would represent a strong advantage (if not registered in this region, the submission of an application will be needed after selection). Existing authorisations from Regulatory Authorities in countries that are Members or Observers to VICH will be an advantage. A commitment to supply information for use authorisation in geographies where an existing market authorisation has not yet been achieved should be provided. All of the above information will be treated in a confidential manner.

3.5 CONTRACT - DURATION OF THE CONTRACT(S)

OIE wishes to enter into non-exclusive “Long Term Arrangements” (LTAs) for the procurement of PPR vaccines for sheep and goats for the period 2022-2025 (four years). Although the actual duration of the contract(s) shall be subject to negotiation with the vaccine supplier(s) when finalising the contracts, the duration of the initial contract shall not exceed 4 years (expected end date December 2025).

3.6 SHIPMENT OF VACCINES

The vaccine manufacturer(s) shall be responsible for organising ground and air transportation for the vaccines to the airport of final destination.

The final destination of vaccines shall be the main commercial airport of the capital city or another main commercial airport in the country of final destination (in any case, one airport per shipment and order of delivery).

The tenderer will have to provide detailed evidence of experience in delivering PPR vaccines, (experience of delivery in Western African countries is an important advantage).

The vaccine manufacturer(s) are encouraged to specify (i) the list of countries where they can deliver easily (using commercial flights and their local agents), (ii) the list of countries where they may have some constraints based on their experience (approach on a case-by-case basis depending on the lack of availability of cold storage or on difficult flight connections for example) and (iii) possible countries where they consider it might be very difficult or almost impossible to deliver PPR vaccines by plane (to a main commercial airport). A discussion on other possible means of transportation (by road or by sea) could be an additional advantage (either for some specific cases / countries or for certain (large) volumes – to be indicated). In the case of large quantities to be transported by sea, information on indicative price conditions, lead times and quantitative thresholds shall be provided.

The PPR vaccines must be properly stored and packaged before shipment and ready to use upon delivery. Shipping will only take place upon the receipt of a delivery order from OIE Headquarters. This order will specify the beneficiary country (including the relevant beneficiary authority), the airport of destination, the requested number of doses (or of vials/bottles) and the vaccine type to be shipped. The PPR vaccine must be shipped by the contractor(s) to the airport of the country of destination designated by the OIE and stored in the cold chain facility indicated by the recipient country.

The proposed detailed terms and conditions of shipment must be described as regards:

- Type of vaccine (strain/type);
- Number of bottles or vials in a shipment lot;

- Information required to complete a delivery order (number of vaccine doses or number of bottles or vials);
- Type of packaging;
- Minimum size of the delivery lots;
- Different delivery options (e.g. (non-exhaustive): “emergency delivery”, “planned delivery”);
- Documents provided with the vaccine delivered (invoice, certificate of analysis, packing list, airway bill (AWB), etc.);
- The vaccine manufacturer(s) shall explain the precise chronology and timeline between each specific step and documents (when each document becomes available, timeline between the availability of each document).
- All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.
- The cost of packaging, packing and all temperature monitoring devices must be included in the offered price. Bidders are requested to specify the price implications of temperature monitoring devices on the packing details sheet.

Before any shipment takes place, the vaccine manufacturer(s) shall present a financial proposal to the OIE or any third party, regarding the proposed cost and the delivery time of the shipment. The cost of transportation will not be included in the Contract. The delivery shall only take place after validation and written approval of the final cost and delivery time of the shipment by the OIE.

Once the transportation has been organised, overall the OIE expects compliance with the CIP Incoterms® (Carriage and Insurance Paid to; “CIP (insert named place of destination) Incoterms® 2010”) with the transportation services organised by the vaccine manufacturer(s) or its freight forwarder/ forwarding agent. The OIE (or the country, or the international organisation purchasing through the OIE Vaccine Bank) would pay for the cost of the vaccines, the cost of transportation to the airport of destination and the corresponding insurance. The OIE considers that delivery is most efficient when the vaccine manufacturer(s) (or its freight forwarder/ forwarding agent) is responsible for organising the transport of the vaccines (considering that the cost of transportation is relatively marginal compared to the total cost of the vaccines).

To avoid complications caused by flight connections and with maintaining the cold chain, the OIE favours direct flights as often as possible (or a limited number of connecting flights).

The maximum lead time between the OIE order and delivery to countries should be as short as possible. The vaccine manufacturer(s)’s offer shall take into consideration the different possible speeds of delivery and the corresponding times. The vaccine supplier(s) must comply with the time schedule as outlined and agreed upon in the contract; should a breach of contract occur without prior approval of the OIE, financial penalties shall be applied.

Since it is anticipated that this PPR Vaccine Bank will mainly be used in West Africa, the vaccine manufacturer(s) should have relevant French speaking staff available in order to facilitate communications with French speaking countries when necessary (organisation of deliveries, negotiation with countries for direct purchases authorised by the OIE).

The vaccine manufacturer(s) should be ready to go through quality controls of their vaccines by an independent institution. In the case of the PRAPS related deliveries, this institution will be the Pan African Veterinary Vaccine Centre (AU-PANVAC).

3.7 OTHER POSSIBLE SERVICES

Other possible services can be offered in the tenders and would constitute additional advantages, relating for example to (not exhaustive):

- Technical support to recipient countries:
    - Scientific collaboration to support the national PPR eradication programme;
    - Support in post vaccination monitoring campaign.

- Provision of new types of vaccine and advice on those new vaccines (in particular DIVA vaccines).

The aptitude of the manufacturer(s) to produce (within the duration of the Contract) new vaccines such as thermotolerant vaccines, dual vaccines allowing the protection against another livestock disease (e.g. recombinant capripox-based PPR vaccines that can protect against both capripox and PPR); DIVA vaccines or any other type of vaccines complying with international standards will be an additional advantage. If the manufacturer(s) has/have a programme for developing new types of vaccines in progress, the OIE would be interested in receiving information on the progress of the programme.

Price and time constraints associated with those extra types of vaccines or services should be clearly specified in the offer, as well as relevant guarantees with regard to the vaccine's compliance with international standards. This includes the validation as a vaccine; the method of manufacture; the in-process controls; and the final product batch tests for sterility and purity, safety and efficacy, and batch potency.

4. RESPONSE STRUCTURE

Responses to the call for tender should cover the following elements to provide sufficient background to the evaluation of the offers and ensure homogenous assessment:

The offer shall be presented in two parts: (i) the technical response and (ii) the financial response (pricing).

Please note that the tenders and all documents relating to the tender should be in English.

4.1 TECHNICAL RESPONSE

The tender response should be provided in a Word or PDF document, with a table of contents and in the most succinct format possible for efficient evaluation. The OIE states its preference to receive only the information requested to specifically demonstrate compliance of the manufacturer and vaccine with technical requirements, along with evidence of certification/validation by reputable Regulatory Authorities or GMP certifiers, thereby avoiding unnecessary and unhelpful additional documentation. Responses padded with unnecessary and unhelpful additional documentation that complicate the evaluation process will be taken as evidence of a supplier's inability to efficiently comply with supply requirements.

4.1.1 General company information

This section should include information on your organisation and its activities, including:

1. General information

- Company name (and name of group if applicable);
- Structure (location and number of employees in the headquarters as well as manufacture sites or regional offices);
- Contact point name, phone number and email address;
- Financial capacity, please fill in and include the document in annex in your response.

2. Activities

- Company background review;
- Description of major activities;
- Description of where the company is supplying PPR vaccines in the World.

3. Experience and references

Specify in particular experiences and references in:

- Winning call for tenders to deliver vaccines;
- Managing Vaccine Bank or a supply agreement for countries or international organisations;

4.1.2 Nature and quality of the vaccines

This section should include information on the vaccine proposed to respond to the requirements set in the section 3 (scope of services) in particular but not exhaustively:

- compliance with OIE relevant intergovernmental standards and, if applicable, VICH guidelines, for the quality, safety and efficacy of veterinary vaccines as well as for vaccine production facilities and quality control of vaccines;
- valid official certificate of Good Manufacturing Practices and report arising from the most recent independent GMP inspection by the certifying body;
- list of countries where the manufacturer already benefits from a market authorisation for the vaccines proposed (all forms, if appropriate), in particular in West Africa;
- characteristics of the vaccine in full detail including the method of attenuation, risk of reversion to virulence, purity, the kind of adjuvant and diluent used, the administration procedures, the volume per dose and the possible secondary effects identified;
- duration of immunity;
- characteristics of the seed;
- presence of preservatives and boosters;
- storage conditions of the vaccines (temperature ranges in °C);
- evidence of independent evaluation of any claim for thermotolerance;
- guaranteed shelf-life of the vaccines;
- number of doses per vial or bottle;
- packaging;
- characteristics of the label and Directions For Use (DFU).

4.1.3 Service proposed (services offered)

This section should include information on the service proposed to respond to the requirements set in the section 3 (scope of services) in particular but not exhaustively:

- Conditions proposed regarding the rolling system (replenishment of stock);
- lead time between a delivery order sent and the expected time of delivery to beneficiary countries;
- the maximum volume (number of doses) the manufacturer would be able to provide for the duration of the contract, annually and per order;
- possibility to use an Early Release Certificates;
- possibility for countries and international organisations to purchase vaccines through the OIE vaccine Bank at the same conditions;
- possibility to supply information in support of an emergency use authorisation in any country where an existing market authorisation is not held and which have such legislative requirements prior to use;
- list of countries where the manufacturer is able to deliver, in particular in West Africa;
- terms and conditions of shipment;
- other possible services.

4.1.4 Success – risk factors

This section should provide a review of major constraints identified at this stage, potential risks to the execution of the service and requirements to ensure its successful completion.

4.1.5 Additional information

This section should include any additional information not provided for elsewhere that you deem important for us to know.

4.2 FINANCIAL OFFER

The price of the service as described above and the payment conditions proposed shall be important criteria in the selection of the vaccine supplier.

The OIE requests vaccine manufacturers to consider the following requirements which will be reflected in the supply agreement to be concluded between OIE and the selected vaccine manufacturer(s):

- selected vaccine supplier(s) shall offer the same prices as those agreed with OIE to countries, international organisations or any other third party that have been given access to the PPR Vaccine Bank by the OIE;
- selected vaccine supplier(s) shall take account of the additional volumes purchased by countries, international organisations or any other third party to further reduce the prices for OIE and such other organisations.

The financial offer should be provided in EURO or in USD (preference in EURO) and quoted free of all duties, taxes and other charges, excluding VAT.

The vaccine supplier shall submit a proposal regarding the cost of the service and the payment conditions. The offers may be presented using different costing methods, e.g.:

- vaccine cost per dose and/or per vial/bottle;
- type of vaccine (thermotolerant or not, DIVA or not)
- variation of vaccine cost per dose and/or per vial/bottle, depending on the different size of vials and number of doses proposed;
- Possible economies of scale would be an additional advantage (lower price after a certain quantity ordered).

The OIE expects a mechanism with no fixed costs for the Vaccine Bank. The vaccines should be paid when delivered.

The method used for calculation of cost of transportation (insurance included, in accordance with CIP Incoterms®) and procurement should also be specified.

To facilitate the use of the PPR Vaccine Bank by different partners, especially if several vaccine manufacturers are selected, the OIE expects a direct unit cost per dose of vaccine purchased (with cost of transportation to be added for each delivery).

The OIE expects as much transparency and detailed information as possible regarding the price structure (cost of vaccine production, storage cost, cost of packaging, cost of labelling, cost of insurance, etc.). This information shall be treated as confidential and will remain so.

In all cases, the prices shall include the price of the diluent. The vaccine manufacturers shall deliver both the vaccine and the corresponding quantity of diluent (ready for use) at the same time for each and all deliveries.

4.2.1 Options for payment

The OIE official accounts are in Euros (EUR). Depending on the vaccine manufacturer(s) selected, the contract(s) shall be established in EUR or in USD (preference in EURO). It must be noted that in order to facilitate customs clearance, some beneficiary countries may require invoices in a currency differing from the currency of the contract signed (e.g. contract signed in EUR and invoice in USD on a case-by-case basis for some countries).