RFP/RABIESVB/2021

B. TERMS OF REFERENCE

RABIES VACCINE BANK

WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

FEBRUARY 2021

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 320 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

Rabies is a highly fatal viral disease of humans and all other warm-blooded animals. The virus is present in the saliva of infected animals and is generally transmitted by the bite of diseased animals – most commonly dogs and other carnivores.

Rabies is present on all continents with the exception of Antarctica. More than 95% of human deaths caused by rabies occur in Asia and Africa. End human rabies deaths by 2030 is the goal of the Global Strategic Plan to end human deaths caused by dog-mediated rabies.

The World Organisation for Animal Health (OIE) provides intergovernmental science-based standards and guidelines to mitigate the risk to the public and animal health posed by infection with rabies virus and to prevent the international spread of rabies virus which include recommendations for the diagnosis of the disease and the quality of vaccines for use in animals. Through its network of Reference Laboratories and Collaborating Centres, the OIE provides policy advice, strategy design and technical assistance for the diagnosis, control and elimination of rabies. The OIE does not manage a prequalification procedure of vaccines / vaccine suppliers.

In 2012, the OIE established a pilot Regional Rabies Vaccine Bank (2012-2015), initially for Asia, co-funded by the European Union (under the regional cooperation programme on Highly Pathogenic and Emerging and Re-emerging Diseases in Asia - HPED programme). With additional financial support from Australia, France and Germany, the pilot Regional Rabies Vaccine Bank was progressively expanded to Africa.

This OIE pilot mechanism has shown that this is a viable, scalable, practical approach suitable to the needs of many countries.

Based on the success of the first rabies Vaccine Bank, the OIE has 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 2012, this mechanism has facilitated deliveries of rabies vaccines for dog parenteral 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[1] on Vaccine Banks. 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 rabies vaccines delivered through the OIE Vaccine Bank mechanism since 2012 amounts almost 26 million doses.

Orders placed through the OIE Rabies Vaccine Bank were initially funded predominantly by donors to the OIE World Animal Health and Welfare Fund and have reached a total of **8 367 200 doses** between 2012 and 2020 (Afghanistan, Algeria, Angola, Bangladesh, Benin, Bhutan, Cambodia, Côte d'Ivoire, Eritrea, Gambia, Haiti, Indonesia, Kenya, Lao PDR, Lesotho, Liberia, Madagascar, Mali, Myanmar, Namibia, Nepal, Nigeria, Philippines, Senegal, Sri Lanka, Togo, Tunisia, Vietnam, Zimbabwe).

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

Thus, since 2014 and to date, several countries have purchased rabies vaccines directly from the OIE Rabies 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 **1 253 000 doses** of rabies vaccines have been ordered or purchased directly by countries (Burkina Faso, Ghana, Malaysia, Singapore) or implementing partners operating in countries like the

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

Swiss Tropical and Public Health Institute (Chad, Mali), the US Center for Disease Control and Prevention (Bangladesh) or Four Paws (Myanmar).

Partner international organisations such as WHO or FAO have also procured vaccines through the OIE Vaccine Bank for a country in need.

It is noted that for human health, WHO procures only WHO pre-qualified vaccines. In exceptional circumstances, WHO may procure vaccines which are not pre-qualified but are recommended for use by WHO technical unit.

As part of its work on human health, the World Health Organization (WHO) jointly with Other UN agencies (such as WHO PAHO[2], UNICEF[3], UNDP[4] & UNFPA[5]) undertakes a variety of health projects for which equipment and supplies are procured for implementation. Purchase of these products are non-commercial and international in character, as the products in question are for use in health programmes mainly in developing countries or in the offices / programmes of these Organisations.

For rabies vaccines for dog vaccination, WHO (Supply HQ) has agreed to use the OIE procurement procedure through an international call for tender and negotiated contract procedure with selected suppliers, in order to benefit from the OIE's expertise in the area of rabies vaccines for dogs. This has enabled the purchase of **16 338 750 doses** of rabies vaccines. WHO has called upon the OIE Rabies vaccine bank to deliver vaccines to Central African Republic Pakistan, South Africa, Tanzania and the Philippines since 2014. Other international organisations such as FAO have also started to show interest in drawing on the OIE Vaccine Bank mechanism in order to arrange for delivery of vaccines to countries requiring immediate vaccination with an initial purchase of **33 700 doses** for Tanzania.

The global rabies community, and the Tripartite (WHO, FAO, OIE) in particular, is strongly committed to fight against rabies. In 2015, the world called for action on rabies and set the goal of **zero human dog-mediated rabies deaths worldwide by 2030**.[6] In September 2017 the global anti-rabies initiative was launched, and the WHO, the OIE, the FAO and the Global Alliance for Rabies Control (GARC) unveiled an ambitious plan to end human deaths from dog-transmitted rabies by 2030. The plan 'Zero by 30: The Strategic Plan'[7] – centres on a One Health approach and addresses the disease in a holistic and cross-sectoral manner while highlighting the important role that veterinary, health and educational services play in rabies prevention and control. In 2020, a new step of international collaboration and coordination has been met with the launch of the United Against Rabies Forum[8] gathering the Tripartite (FAO, OIE and WHO) and a range of international stakeholders to create an enabling environment so that members and countries can focus on activities that efficiently contribute to Zero by 30, while also sharing of knowledge, experience, ideas, and information.

The OIE rabies Vaccine Bank is considered a strategic tool that could support the achievement of the elimination of human rabies deaths by 2030.

2.2 PROJECT OBJECTIVES

In 2022, the OIE and WHO will continue to work together using this new international call for tender to deliver rabies vaccines for dog vaccination around the world.

The OIE will establish a new global Rabies Vaccine Bank 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 WHO, FAO and NGOs.

The overall objectives of the Rabies Vaccine Bank are to rapidly provide requesting countries[9], when eligibility criteria (conditions/situations) are met, either with (i) an emergency stock of high quality rabies vaccines in order to vaccinate the animal population at risk within the framework of agreed national

[2] Pan American Health Organization
[3] United Nations Children's Fund
[4] United Nations Development Programme
[5] United Nations Population Fund
[6] http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Rabies_portal/EN_RabiesConfReport.pdf
[7] https://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Rabies_portal/Zero_by_30_Final_130618.pdf
[8] https://uarforum.org/
[9] While the OIE rabies Vaccine Bank is global and doesn't focus on a specific region, it is expected that requests and deliveries will predominantly be in the regions Africa and Asia

vaccination strategies; or (ii) as part of a stimulus package that to kick off vaccination campaigns and facilitate collaboration between national human health and animal health services on rabies control and/or to leverage larger governmental commitments deploying large scale national vaccination campaigns.

The Rabies 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 Rabies 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 Parenteral (injectable) rabies vaccines for dogs in order to set up a global Rabies 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 rabies vaccines. The vaccine manufacturer(s) must comply with relevant international standards described in the latest English version of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.*[10].

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.

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) shall allow the OIE, its nominated experts and/or the donor(s) supporting the project a right-of-entry to inspect the corresponding production and storage facilities. The vaccine manufacturer(s) shall permit the OIE and WHO or their representatives further to previous notice to the supplier, 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 assessment 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.

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

3.2 THE RABIES VACCINE BANK

For 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.[11]

The vaccine manufacturers' offers shall facilitate the setting up of a "virtual" Rabies 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.

Vaccines can be purchased by the OIE (using funds provided by donors), by WHO or 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 will be signed between the vaccine manufacturer(s) and the OIE. The contract(s) authorises the OIE and WHO to purchase vaccines through the Rabies Vaccine Bank. Third party clauses provide the possibility to authorise eligible countries (including country programmes), and possibly some international organisations or duly authorised non-governmental organisations to purchase vaccines through the Rabies 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 Rabies 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. It is understood that dog rabies vaccines are rarely used in situations of true emergency and that Early Release Certificates would rarely need to be used (when possible).

The lead time between a formal order of rabies vaccines from the OIE or from WHO (or from a country or a duly authorised international organisation) and the actual delivery of vaccines to beneficiary countries by the vaccine supplier is an important factor to consider. The OIE and WHO expect the lead time to be as short as possible and the vaccine supplier to respect the length of time indicated in the contract. Several options may be proposed (e.g. (non-exhaustive) "emergency delivery"; "planned delivery").

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.

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

3.3 LOCATION OF THE VACCINE BANK

The vaccine manufacturer(s) are wholly responsible for producing on time and/or storing vaccines pertaining to the Rabies Vaccine Bank when relevant. The OIE and WHO shall not engage in the provision of storage facilities at global or regional level.

3.4 RABIES VACCINES

The vaccine expected is an inactivated Parenteral (injectable) vaccine for dogs.

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

The rabies vaccines produced shall comply with OIE intergovernmental standards of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and in particular with the relevant part of Chapter 3.1.17. 'Rabies (infection with rabies virus and other lyssaviruses). Conformity of the rabies vaccines with VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) guidelines will be considered.

In particular, it is underlined that the potency of inactivated virus vaccines is established and controlled using tests formulated by the United States Department of Agriculture (USDA) in the United States of America or the European Pharmacopoeia (the potency of the vaccine is established in the USA by the National Institutes of Health (NIH) test; elsewhere, the European Pharmacopoeia test is widely adopted).

Vaccine main characteristics

Vaccines shall confer protective immunity for at least one year (duration of immunity). Vaccines with demonstrated (internationally recognised justifications provided) longer protective immunity would be an additional advantage.

The vaccine manufacturer(s) shall describe the characteristics of the vaccine in full detail including the method of inactivation, the kind of adjuvant used, the administration procedures, the volume per dose and the possible secondary effects identified.

The vaccine manufacturer(s) shall also provide evidence (i) of the characteristics of the seed: biological characteristics, quality criteria, validation as a vaccine strain (in particular in accordance with of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 1.1.9 Tests for sterility and freedom from contamination of biological materials intended for veterinary use, and (ii) of the method of manufacture: procedure, requirements for media and substrates, in-process control, final product batch/serial tests (sterility, safety, residual live virus, batch/serial potency).

If present, preservatives and boosters used shall be indicated.

The final products are subjected to tests for innocuity and absence of toxicity.

The guaranteed shelf-life of the vaccines shall be specified (upon release from the factory). The vaccines shall have at least one year or 80% of remaining shelf-life when they are delivered to the beneficiary countries, more if possible (to be specified).

The vaccine manufacturer(s)' 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.

Labelling and packaging procedures

The type of packaging proposed shall be described, including number of doses per vial or bottle. In order to obtain low prices, it is anticipated 10 dose vials to be proposed.

Guidance from the vaccine manufacturer(s) regarding the pros and cons of packaging options available are welcome.

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). Information shall be provided on the different languages than can be provided for the labels and Directions For Use (DFU) (on the labels or translated separately). The OIE and WHO expects the provision of labels and DFU in English and French (with translation of label and DFU provided separately). Provision of labels and DFU in other additional language are considered an advantage.

The vaccine manufacturer(s) are encouraged to specify in their offers if there are constraints regarding the minimum number of doses that can be provided for one delivery, or the maximum size of a consignment for transportation (maximum number of doses that can be shipped at one time for one delivery).

The storage conditions of the vaccines must be specified (temperature ranges in °C). Possible measures proposed to monitor the temperature during transportation and storage would be an additional advantage.

Vaccines shall be used exclusively for the vaccination of dog and cats.

Existing market authorisations from Regulatory Authorities

Evidence should be supplied of existing market authorisations from Regulatory Authorities for the vaccine. 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.

3.5 CONTRACT - DURATION OF THE CONTRACT(S)

OIE wishes to enter into non-exclusive “Long Term Arrangements” (LTAs) for the procurement of rabies vaccines for dog 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 vaccine manufacturer(s) are encouraged to specify (i) the lists 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 rabies 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 rabies vaccines must be properly stored and packaged before shipment and ready to use upon delivery. Shipping shall only take place upon receipt of a delivery order from OIE Headquarters or WHO Supply HQ. This order shall specify the beneficiary country (including the relevant beneficiary authority), the airport of destination, the requested number of doses (and of vials/bottles) and the vaccine type to be shipped. The rabies vaccines must be shipped by the contractor to the airport of the country of destination designated by the OIE (or by WHO) and stored in the cold chain facility indicated by the recipient country.

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

- 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 vaccines 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.
- In order to monitor the cold-chain during international transit to Government central stores of vaccines manufacturers may be requested to include WHO Performance, Quality and Safety (PQS) prequalified electronic shipping indicators (E06 category) in each and every shipping carton (or as required upon request). The references of the devices meeting WHO requirements for international shipments can be found at the following site[12].
- 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 supplier shall present a financial proposal to the OIE, WHO or any third party, regarding the proposed cost and the delivery time of the shipment. The delivery shall only take place after validation and written approval by the OIE or by WHO of the final cost and delivery time of the shipment.

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 supplier(s) or its freight forwarder/ forwarding agent. It is to be noted that WHO may request FCA incoterms for their orders. 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 supplier(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 or WHO order and delivery to various eligible countries shall be as short as possible. The vaccine manufacturers' offer shall take into consideration the different possible speeds of delivery and the corresponding prices. The vaccine manufacturer(s) must comply with the time schedule as outlined and agreed upon in the contract(s); should a breach of contract occur without prior approval of the OIE or WHO, financial penalties shall be applied.

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, for example:
    - Supporting the design of the vaccination campaign;
    - Conducting dog census;
    - Dog vaccination identification;
    - Scientific collaboration to support the national rabies elimination programme;
    - Non-branded communication/education campaign support or materials;
- Provision of other size of vials (in particular one dose vial) in complement to the requested 10 doses vial vaccines.

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:

[12] https://www.who.int/immunization/documents/financing/who_ivb_15.04/en/

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 rabies 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 intergovernmental relevant standards and, if applicable, VICH guidelines, for the quality, safety and efficacy of veterinary vaccines as well 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, predominantly Africa and Asia);
- characteristics of the vaccine in full detail including the method of inactivation, purity, the kind of adjuvant 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);
- 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 third parties (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 (predominantly Africa and Asia);
- 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 WHO, countries, international organisations or any other third party that have been given access to the rabies Vaccine Bank by the OIE;
- selected vaccine supplier(s) shall take account of the additional volumes purchased by WHO, countries, international organisations or any other third party to further reduce the prices for OIE, WHO 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;
- 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 Rabies 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.

4.2.1 Options for payment

The OIE official accounts are in Euros (EUR), WHO official accounts are in USD. Depending on the vaccine manufacturer(s) selected, the contract(s) shall be established in EUR or in USD (preference in EURO for the OIE). 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).