INTERNATIONAL CALL FOR TENDER

Tender Ref.: AD/SR/2016/177

Contract Title: “Production, Storage and Supply of Foot and mouth disease (FMD) Vaccines in South-East Asia and neighbouring countries”

Background:

Foot and mouth disease (FMD) is recognised worldwide as one of the most serious livestock diseases. FMD incursions, including those leading to animal deaths and/or purposeful elimination directly result in severe economic losses and a reduced pool of valuable genetic resources. It also has the potential to disrupt regional and international trade of animals and animal products. FMD exerts a chronic socio-economic burden and poses a threat to the livelihood and security of smallholder farmers and their immediate community. The annual economic impact in endemic regions, from production losses and vaccination costs alone, has been estimated between 6.5 and 21 billion USD.

The Second Global Conference on Foot and Mouth Disease Control organised by the FAO and OIE, held from 27-29 June 2012 in Bangkok (Thailand) drew up a series of recommendations for countries, regional and global technical partners, the OIE and FAO and other development partners; these recommendations are available on the OIE website. In particular, priority activities at regional and global level include supporting the development of regional roadmaps for FMD and the use of regional vaccine banks.

FMD is enzootic in large parts of South-East Asia and adjacent countries. In an effort to tackle the disease, the South-East Asia Foot and Mouth Disease Campaign (SEAFMD) was launched in 1997, and was renamed the SEACFMD in 2010, when the People's Republic of China formally joined the programme, followed by Brunei and Singapore. Its aim is to coordinate and facilitate regional FMD control activities and, in doing so, harmonise and drive action into national plans and encourage governments and donors to align their activities in order to achieve the goals envisioned by the SEACFMD Roadmap, a Roadmap to prevent, control and eradicate FMD (by 2020) in South-East Asia and China. The 21st Meeting of the OIE Sub-Commission for FMD in South-East Asia and China held in Manila in March 2015 endorsed the Strategic Framework for the next Phase of the SEACFMD 2020 Roadmap covering 2016-2020. The first four Phases of the Campaign have been completed.

In order to successfully control FMD and improve the socioeconomic conditions in South-East Asia, there is a need to increase the number of zones and countries that are FMD-free. International donors and national governments are working collectively to improve the existing surveillance, vaccination and control strategies, and monitoring their impact.

The World Organisation for Animal Health (OIE), with the initial financial support of the European Union (represented by the European Commission), and under the framework of the regional cooperation programme on highly pathogenic and emerging and re-emerging diseases (HPED) in Asia, created a regional Vaccine Bank for FMD, which was launched on 30 November 2011. This mechanism has allowed further deliveries of FMD vaccines to beneficiary countries with additional financial support from Australia, China, Korea and New Zealand. This call for tender will select the manufacturer(s) of

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the new OIE Regional FMD Vaccine Bank for South-East Asia and neighbouring countries (for the period 2016-2020) replacing the initial mechanism (2011-2015).

A five-year project, “Strengthening Foot and Mouth Disease Control in South-East Asia,” has been signed by the OIE with the Ministry of Foreign Affairs and Trade of New Zealand in 2015. This project seeks to increase the number of zones and countries that are FMD-free in South-East Asia, primarily focusing on Myanmar and Lao PDR, through activities including vaccination in target areas and support for the procurement of FMD vaccines.

The rapid implementation of strategic vaccinations of a suppressive, ring or targeted nature to control the disease, reduce the potential spread of FMD, safeguard “free-zone” status, and minimize costs arising from the potential loss of “free-zone” status is crucial during an early stage of epizootics.

The overall objective of the FMD vaccine bank is to rapidly provide countries, when eligibility criteria (conditions / situations) are met, with FMD vaccines in order to vaccinate the relevant animal population within the framework of agreed vaccination strategies. This allows for the procurement of high quality FMD vaccines complying with OIE intergovernmental standards for eligible countries, at a price negotiated through an international call for tender.

The regional vaccine bank is reliant on the manufacturer(s) to produce and deliver high quality vaccines upon request. The vaccine manufacturer(s) will play a prominent role in ensuring the rapid and smooth transportation to the country of destination, of vaccines formulated on the basis of the virus strains requested. This includes maintenance of the cold chain until delivery within 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 authority 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 vaccine manufacturer(s) of FMD vaccines in order to set up a Regional FMD Vaccine Bank for South-East Asia and neighbouring countries, in accordance with the criteria set out below. It is understood that the services required include both an antigen bank and a vaccine bank (referred to as “vaccine bank” in short).

1 - The Vaccine manufacturer(s)

The vaccine manufacturer(s) shall have global references and experience in manufacturing, quality control, selling and delivering FMD vaccines (international trade); it must comply with relevant international standards such as the OIE intergovernmental standards described in the English version of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.6: Principles of Veterinary Vaccine Production2 and Chapter 1.1.7.: Tests for sterility and freedom from contamination of biological materials3.

The vaccine manufacturer(s) must be in possession of a valid official certificate of Good Manufacturing Practices provided by relevant official national authorities for all plants producing the vaccines to be delivered.

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, as well as a full and detailed description of the protocols used.

The vaccine manufacturer(s) selected shall allow the OIE 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.

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2 Chapter 1.1.6.- Principles of veterinary vaccine production (NB: Version adopted in May 2015) http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VACCINE_PRODUCTION.pdf
3 http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.07_TESTS_FOR_STERILITY.pdf
2 - The FMD Vaccine Bank

Within the framework of this programme and more specifically 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, in accordance with Chapter 1.1.10. - Vaccine banks, of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals\(^4\).

**Indicative definitions:**

- **Core Strains:** the core strains of the Vaccine Bank are the strains that are likely to be requested by Countries on a regular basis. Core strains are high priority FMD strains for South-East Asia that must be readily available in the Vaccine Bank for the production of FMD vaccines.

- **Optional Strains:** the optional strains of the Vaccine Bank are strains that may occasionally be requested by Countries. Optional strains are lower priority FMD strains for South-East Asia that should be available in the Vaccine Bank and that may be used for the production of FMD vaccines.

- **Production Order:** A production order is an official request submitted by the OIE Headquarters, signed by the Director General of the OIE, to the vaccine manufacturer(s) for the production of vaccines. It includes detailed information on the strains, quantities, size of vials and speed of production requested.

- **Delivery Order:** A delivery order is an official request submitted by the OIE Headquarters, signed by the Director General of the OIE, to the vaccine manufacturer(s) for the delivery of vaccines to a beneficiary country. It includes detailed information on the strains, quantities, size of vials, speed of delivery and country of destination.

- **Production and Delivery Order:** An order of production and delivery is an official request submitted by the OIE Headquarters, signed by the Director General of the OIE, to the vaccine manufacturer(s) for the production and delivery of vaccines to a beneficiary country. It includes detailed information on the strains, quantities, size of vials, speed of production and country of destination.

- **Replenishment:** Mechanism (contractual arrangement or through specific orders) by which new stocks of one or more FMD strains and/or FMD vaccines are added to the FMD Antigen/Vaccine Bank, to modify the balance between FMD strains stored, or to modify the quantity of pre-formulated vaccines in stock, depending on deliveries made.

The vaccine manufacturers’ offers shall facilitate the setting up of a “virtual” Regional FMD 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: (i) stocks of antigens (core and optional strains); (ii) planned production of vaccines; (iii) rolling stocks/replenishment rules; (iv) use of additional optional strains; (v) number of valences/vaccines possible (cattle equivalent); (vi) number of doses per vial/bottle; (vii) quantity of different vaccines (cattle equivalent); (viii) transfer of quantity of strains/vaccines from one strain/vaccine to another without financial penalties.

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 through country programmes or projects), and possibly some international organisations or duly authorised non-governmental organisations to purchase vaccines through the FMD Vaccine Bank, on a case-by-case approach (see Section 8.2 below).

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. A step-wise approach can be proposed by the vaccine manufacturer(s) (different commitments depending on volumes).

- 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

\(^4\) [http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.10_VACCINE_BANKS.pdf](http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.10_VACCINE_BANKS.pdf)  (NB: Version adopted in May 2016)
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 (to be signed by beneficiary countries when appropriate) can be considered and if so, the relevant procedure.

The lead time between a formal delivery order of FMD vaccines from the OIE and the actual delivery of vaccines to beneficiary countries by the vaccine manufacturer(s) is an important factor to consider. In the case of emergency vaccinations, 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”; “rapid delivery”; “planned production and delivery”).

The bidders are encouraged to specify the different possible thresholds for the sizing of the antigen bank and the possible constraints with regard to the size of the production lots (possible production constraints and possible economies of scale depending on the size of the production / delivery orders).

A buy-back mechanism for strains/vaccines which are not used may be proposed to the OIE in order to facilitate flexibility in the use of the Vaccine Bank.

3 - Location of the Vaccine Bank

The vaccine manufacturer(s) are wholly responsible for producing on time or storing antigens and vaccines pertaining to the vaccine bank. The OIE shall not engage in the provision of storage facilities at global or regional level. Proposing different locations for storage in order to reduce the logistical risks would be an asset. Solutions that would facilitate the management of the vaccine bank under a tax free regime (prices and OIE payments without VAT) would be an additional asset.

4 - FMD Vaccines

In the context of the FMD 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.

4.1 – Strains (Antigen Bank):

- (i) at least the following strains (not by order of importance):

<table>
<thead>
<tr>
<th>Core strains requested</th>
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<tbody>
<tr>
<td>O1 Manisa</td>
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The availability of additional optional FMD strains (both pre-determined and not determined in advance) would be an additional asset. Bidders are expected to recommend or to propose possible additional strains that would be most compatible to combat the prevalent strains circulating in SEACFMD countries such as (not by order of importance):

O Myanmar 98; O Panasia; O Cathay; and the new A SE-Asia.

This could include other strains suitable to the prevalent strains.

- (ii) furthermore, one additional optional (not yet determined) strain should be made available in the offer.

Price and time constraints associated with optional strains (both determined and not determined in advance) should be clearly specified in the offer.

The number of doses for the different strains in the antigen bank requested in the contract will depend on the prices, as well as the total number of vaccine doses purchased through this vaccine bank mechanism.

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5 The so called "A Lopburi-Thai" and "A Gen2-China" strains (local names) present an antigenicity similar to "A Malaysia 97" and "A22 Iraq" strains
4.2 – Vaccines (pre-formulated vaccines on the shelf):

- Doses of inactivated vaccines against FMD for cattle for the valences: [O1 Manisa + A Malaysia 97] (bivalent). The number of doses of this bivalent inactivated vaccine for cattle against FMD requested in the agreement is dependent on the price.

The FMD vaccines produced shall comply with OIE standards for the quality of veterinary vaccines referred to in Part 1 above and with the OIE standards on the quality of FMD vaccines (OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 2.1.5.: Foot and mouth disease)\(^6\).

The vaccine manufacturer(s) offer shall foresee the submission of all relevant supporting documentation as well as a full and detailed description of the protocols used.

The vaccine manufacturer(s) shall also provide evidence of the FMD vaccine’s potency, sterility, freedom from extraneous agents, purity, activity, efficacy, safety, stability and duration of immunity.

The FMD vaccines proposed should be of high potency. The requirement is of at least 6 PD\(_{50}\) (6 times the 50% protective dose in cattle) per dose; the vaccine manufacturer(s) will need to demonstrate proof of compliance by providing relevant documentation.

The FMD vaccines proposed should allow differentiating infected animals from vaccinated animals (DIVA strategy). FMD vaccines must be purified to reduce the Non Structural Protein (NSP) content such that DIVA strategies can be implemented to differentiate infection from vaccines and the absence of circulating FMD virus. The absence of circulation of the virus may be demonstrated by showing that vaccinated animals are free from the antibody to Non Structural Proteins (NSP) arising as a result of infection. FMD antigens used to formulate vaccines should therefore be purified, to reduce the NSP content. In this regard, the vaccine manufacturer(s) will need to demonstrate proof of compliance.

The vaccine manufacturer(s) is/are required to describe the characteristics of the vaccine in full detail including the type of antigen used, the characteristics of the seed virus, the method of culture, the method of inactivation, the validation as a vaccine strain, the method of manufacture, the inactivation control, the kind of adjuvant used, the administration procedures, the volume per dose and possible secondary effects or precautions (hazards) identified.

The vaccines should have at least one year of remaining shelf-life guaranteed when they are delivered to the beneficiary countries.

In the context of this Vaccine Bank, the OIE may request the production of FMD vaccines for cattle, pigs or small ruminants or for several of these categories.

The possibility of producing or delivering lots of 100,000; 200,000; 250,000; 300,000 or 500,000 (cattle equivalent) vaccine doses (or different quantities) should be included in the offer.

Storage conditions of antigens (facilities, containment of stored antigens and labelling of stored antigens) shall be described.

The procedure for possible emergency release of vaccines prepared from concentrated antigens shall be specified (possible use of early release certificates).

**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.

The type of packaging proposed should be described (number of doses per vial or bottle). Different options and corresponding prices should be specified. The availability of a small number of doses per vial or bottle is considered important. Guidance from the vaccine manufacturer(s) regarding the pros and cons of packaging options available are welcome.

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\(^6\) [http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.05_FMD.pdf](http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.05_FMD.pdf)
5 - Duration of the contract

The anticipated completion date of the initial contract is foreseen in December 2020 (exact date to be confirmed when negotiating the final version of the contract). Provisions for possible annual extensions of the contract will be foreseen in the contract.

6 - Shipment of Vaccines

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

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

The FMD vaccines must be properly stored and packaged before shipment and ready to use upon delivery. Shipping will only take place upon receipt of a delivery order from the Director General of the OIE sent by OIE Headquarters. This order will specify the beneficiary country (including the relevant beneficiary authority), the airport (or port) of destination, the requested number of doses (or of vials / bottles), the requested speed of delivery (e.g. planned, rapid, urgent) and the vaccine type (strains, valence) to be shipped. The FMD vaccines must be shipped by the vaccine supplier to the airport (or port) of the country of destination designated by the OIE and stored in the cold chain facility indicated by the recipient country.

Tenders must specify the following terms and conditions relating to the shipment of vaccines:

(i) Strains offered;
(ii) Number of bottles or vials in a shipment lot;
(iii) Information required to complete a delivery order (number of vaccine doses or number of bottles or vials);
(iv) Type of packaging;
(v) Minimum and maximum size of the delivery lots. The minimum and maximum of shipment lots (packaging constraints) should be specified;
(vi) Different delivery options (e.g. (non-exhaustive) “emergency delivery”; “rapid delivery”; “planned delivery”); etc.;
(vii) List of documents provided with the vaccines delivered (invoice, certificate of analysis, etc.);
(viii) Tenders should also specify the information that will be needed in order to complete a delivery order: number of vaccine doses or number of bottles or vials.
(ix) Precise chronology and timeline between each specific step and documents (when each document becomes available, timeline between the availability of each document).
(x) All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.
(xi) 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.
(xii) The INCOTERM conditions shall be detailed in the terms and conditions of shipment proposed.

Before any shipment takes place, the vaccine manufacturer(s) shall present a financial quotation to the OIE, including the proposed cost and the delivery time of the shipment. The delivery will only take place after validation and written approval of the final cost and delivery time of the shipment by the OIE.

It must be noted that from experience beneficiary countries may indicate preferred flights, air carriers or arrival dates/times when requesting deliveries of vaccines to the OIE. The OIE will indicate such special conditions on a case-by-case basis before deliveries are organised.
Once the transport is organised, 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). The cost of transportation will not be included in the Contract.

The bidders are invited to specify the countries where they can deliver easily, countries where they have local shipping agents, countries that would require specific arrangements, and countries for which they may have specific difficulties or logistics challenges.

The lead time between the OIE order and the delivery to countries in South-East Asia should be as short as possible. 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 vaccine manufacturer(s)’ 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; should a breach of contract occur, financial penalties shall be applied.

The OIE considers that this vaccine bank is established as a priority for SEACFMD Member Countries with possible extension to the entire Asia region7. Considering that the delivery of FMD vaccines (cost of vaccine and transportation) is funded through a multi-donor trust fund (the OIE World Animal Health and Welfare Fund), the procurement of FMD vaccines will follow the availability of funds (depending on donor priorities and earmarking of funds).

7 - Miscellaneous

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

(i) advice on the management of the balance between the strains (core strains and optional strains);
(ii) advice on the management of the replenishment mechanisms;
(iii) advice on, and reporting of, new antigen strains;
(iv) development of new antigen strains;
(v) scientific collaboration (e.g. availability free of charge of samples of each antigen, of monovalent vaccines for each of the antigens for in-vitro tests or tests on animals);
(vi) insurance (insurance of antigen and/or vaccine stocks);
(vii) advice on the preferred design of any packaging;
(viii) vaccine manufacturers’ commitment and services such as possible (non-branded) support to communication / awareness campaigns.

8 - Financial Conditions

8.1 - Procurement of vaccines by the OIE (with donor support)

The OIE will not divulge the amount of funding available for this vaccine bank during the selection process as it is managed in the context of a multi-donor trust fund and significant additional funding may become available during the life of the vaccine bank.

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7 The South-East Asia and China Foot and Mouth Disease (SEACFMD) Campaign: SEAFMD was formally established in 1997 by the following founding member countries: Cambodia, Lao PDR, Malaysia, Myanmar, the Philippines, Thailand and Vietnam. Although free of FMD, Indonesia recognised the importance of working with the campaign to maintain its FMD-free status. It therefore became a member in 1999. Two other FMD-free countries - Brunei Darussalam and Singapore - as well as the People’s Republic of China (PRC) joined the campaign in 2010. Consequently, SEAFMD has been renamed the South-East Asia and China FMD campaign (SEACFMD).
The price of the service as described above and the payment conditions proposed shall be important criteria in the selection of the vaccine manufacturer(s). The vaccine manufacturers shall submit a proposal regarding the cost of the service and the payment conditions (see in particular Parts 2 – 4 and 6 above). The offers may be presented using different costing methods and price structures, e.g.:

(i) including (or not) the cost of an antigen bank (with or without a fixed cost);
(ii) vaccine cost per dose (monovalent, bivalent, etc.) and/or per strain;
(iii) cost per bottle or vial, etc.;
(iv) variation of vaccine cost per dose and/or per vial/bottle, depending on the different size of vials (and number of doses) proposed;
(ix) method used for calculation of cost of transportation and procurement.

The OIE would favour a mechanism with no fixed costs for the vaccine bank. The vaccines could be paid for when ordered (part of the payment when production is requested, final payment when the vaccines are delivered) or when delivered.

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

The OIE expects very detailed and precise information on the price-quantity relation (price grid depending on quantities for the different strains requested, for different quantities produced or for different vial sizes).

8.2 - Direct purchase by countries or by international organisations through the OIE Vaccine Bank

When negotiating the contract with the selected manufacturer(s), the OIE will explore the possibility of creating provisions for possible third party clauses. These provisions would allow eligible countries in South-East Asia to purchase FMD vaccines directly through the OIE Vaccine bank (same vaccines, same prices) when authorised by the OIE.

This mechanism would also potentially need to be opened to relevant global or regional organisations.

The bidders are encouraged to specify the terms and conditions they would envisage for such third party clauses.

9 - Financial Penalties

If the vaccine manufacturer(s) does/do not respect the conditions mentioned in the contract, the vaccine manufacturer(s) will be submitted to financial penalties.

Provisions for heavy financial penalties in case of non-delivery or late delivery will be foreseen in the contract.

Financial penalties shall also be applied if the vaccine(s), strain(s), vials/bottles, number of doses, or the valence requested in accordance with terms and conditions of the contract are not available in due time.

10 - Selection process and criteria

The offer shall be presented in two parts (i) the technical part and (ii) the financial part (pricing) – see also Part 12 below. The initial selection process shall be made on the basis of the technical part. The financial part (pricing) will only be examined for the offers retained after the initial selection – see also Part 13 below.

The contract award criteria remain unchanged throughout the procedure to ensure equality of treatment for all tenderers.

The vaccine manufacturer(s) will be selected by an ad hoc tender selection committee composed of renowned international experts, representatives from OIE Reference Centres on FMD and relevant OIE staff members, who will examine all eligible offers officially received in due time at OIE Headquarters on the basis of the following criteria (not exhaustive and not by order of importance):
(i) the financial, economic and professional (i.e. experience) capacity of the tenderers, including global experience in international trade and supplier(s) references;

(ii) quality, including technical merit, functional characteristics, accessibility, design suitable for all users, innovative characteristics, marketing and related conditions;

(iii) the organisation, qualifications and experience of the personnel assigned to perform the contract;

(iv) customer service, technical assistance and delivery conditions;

(v) nature and quality (compliance with OIE intergovernmental standards), including packaging, strains proposed and number of doses per vial or bottle, size of production lots;

(vi) conditions proposed regarding the rolling system (replenishment of stock) and the lead time between a production order or a delivery order sent by the OIE and the expected lead time of delivery to beneficiary countries;

(vii) possible logistics constraints announced by the vaccine supplier(s);

(viii) flexibility of the vaccine bank, and the services offered;

(ix) other services proposed (see Part 7);

(x) price of the service proposed, in EUR or in USD;

(xi) options for payment: OIE official accounts are in Euros (EUR) but third parties may request invoices and payments to be made in USD.

Tenderers are also invited to specify the list of countries particularly in Asia, where they already benefit from a market authorisation for the vaccine proposed. They should provide the list of countries where they have already provided FMD vaccines and the list of countries where they are unable to deliver FMD vaccines or may have restrictions for vaccine delivery (or indicative reservations / logistical concerns from experience of for legal reasons).

Tenderers may be requested to provide additional information during the selection process if required.

Please note that all documents relating to the offer should be prepared in English.

11 - Notification of the award of the grant

The OIE shall inform each unsuccessful candidate, either in paper or electronically, that their tender has been rejected. Upon written request by the party in question, the OIE shall send the candidate having submitted an eligible tender, within six days of receiving the request, all information relating to the rejection.

The successful candidate(s) will be notified and invited to sign a contract with the OIE reiterating the terms and conditions for implementing the contract, based on the final negotiation with the selected service provider(s).

The contract shall include a copy of the main part of the technical offer and of the financial offer received from the corresponding successful candidate as annexes to the contract.

12 - Content of the offer:

Offers shall be submitted to the OIE Headquarters in the following manner:

(i) Seven copies and one original of the Technical Offer shall each be placed and sealed in an individual envelope bearing the words "Envelope A - Technical offer" and then all placed and sealed into another external envelope bearing the words (as drafted below)⁸:

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- Envelope A - Technical offer -
NE PAS OUVRIR A LA RECEPTION - CONFIDENTIEL - Appel d'offres
Ref: AD/SR/2016/177
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⁸ « NE PAS OUVRIR À LA RÉCEPTION » (in French) means: "Do not open (this mail) at the front desk / reception desk / when received"; "CONFIDENTIEL" (in French) means: “Confidential”; and “Appel d’offres” (in French) means: “Call for tender”. This should be written in French because OIE Headquarters is located in Paris, France and some OIE reception desk staff handling incoming mail is French speaking.
(ii) Seven copies and one original Financial Offer should be placed and sealed in other separate envelopes bearing the words "Envelope B - Financial offer" and then placed and sealed into another external envelope bearing the words:

- Envelope B - Financial offer –

   NE PAS OUVRIR A LA RECEPTION - CONFIDENTIEL - Appel d'offres

   Ref: AD/SR/2016/177

All parts of the offer other than the Financial Offer shall be submitted in Envelope A.

These two envelopes containing the Technical Offer and the Financial Offer shall be put into an external envelope and sealed.

The external envelope shall state in large bold letters:

(iii)

| NE PAS OUVRIR A LA RECEPTION |
| CONFIDENTIEL - Appel d'offres – |
| Ref: AD/SR/2016/177 |

and shall be labelled as follows for shipment to the OIE Headquarters:

(iv)

Madame la Directrice Générale
Organisation Mondiale de la Santé Animale (OIE)
12, rue de Prony
F-75017 Paris
France

The wording (iii) on the envelopes shall also appear on the outside of the (plastic) wrapper if the offers are sent through commercial couriers or quick mail delivery services.

13 - Procedure:

A tender opening committee, composed of at least five persons designated by the OIE Director General or persons she has empowered for that purpose, receives the tenders, and meets at OIE Headquarters following the deadline for the transmission of the offers. For the decisions of the tender opening committee to be valid, at least three members of the committee must be present.

The committee is responsible for verifying that the tenders received have complied with the procedures for the receipt and presentation of tenders described in the tendering documentation, and for preparing the list of tenders deemed eligible.

Tenders received after the deadline shall be deemed ineligible.

An international tender selection committee then proceeds to award the contract(s). The OIE Director General specifies the composition of the tender selection committee and its operating rules. The committee has at least seven members, designated by the OIE Director General or persons she has empowered for that purpose (see Section 10). For the decisions of the tender selection committee to be valid, at least four members of the committee must be present.

The International Selection Committee is composed of representatives from relevant OIE Reference Laboratories, OIE staff members, external persons and possibly Donor representatives (as observers, depending on their requests).
The tender selection committee checks the tenderers’ technical and financial qualifications to ensure that tenderers have the capacity to meet the specific needs of the proposed contract. The committee checks that the tenders meet the eligibility requirements specified in the tendering documentation.

The tender selection committee makes its initial pre-selection solely in terms of the items presented in the technical offers. Technical proposals deemed non-compliant or inadequate are eliminated at this stage.

Following this initial phase, the tender selection committee reviews the financial offers. The tender selection committee recommends the tender:

(i) whose tender substantially complies with the requirements, criteria and conditions stated in the tendering documentation;

(ii) whose tender is seen to be the most technically and economically advantageous in light of the evaluation criteria stated in the tendering documentation.

The contact person at the OIE Headquarters during the period of preparation of the offers is:

Dr. Alain Dehove, DVM, MS
Director of Finance
World Organisation for Animal Heath (OIE)
12, rue de Prony
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France
alain.dehove@oie.int
Telephone: (+33) 1 44 15 18 75

For the offer to be valid, it must be deposited and registered against receipt at the latest on 5 August 2016 at 12:00 o’clock (Paris time) at OIE Headquarters (address specified under above).

14 - Appeals

Candidates believing that they have been harmed by an error or irregularity during the award procedure may lodge a complaint with the OIE. The OIE will address the candidate a reply within five days after receipt of the complaint. If the OIE fails to address the complaint, the unsuccessful tenderer may request arbitration by the Permanent Court of Arbitration (PCA) at The Hague, governed by the PCA arbitration rules 2012 and the PCA Optional Rules for Arbitration between International Organisations and third Parties.

(End) - 11 pages -