INTERNATIONAL CALL FOR TENDER

Tender Ref.: AD/ET/2011/814
Contract Title: “Rabies Vaccine Bank in Asia”

A pilot Rabies Regional Vaccine Bank managed by the OIE under the Highly Pathogenic, Emerging and Re-emerging Animal Diseases (HPED) Programme in Asia

Background:

Key facts1:
- Rabies occurs in more than 150 countries and territories;
- Worldwide, more than 55,000 people die of rabies every year;
- 40% of people who are bitten by suspect rabid animals are children under 15 years of age;
- Dogs are the source of 99% of human rabies deaths.

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.

The OIE provides science-based standards, guidelines and recommendations for the control of the disease in animals and to prevent the spread of the disease through trade, as well as standards 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 eradication of rabies.

Rabies is present on all continents with the exception of Antarctica, but more than 95% of human deaths occur in Asia and Africa. Preventing human rabies through elimination of domestic dog rabies is a realistic goal for large parts of Asia (and Africa), and is justified financially by the future savings of discontinuing post-exposure treatment for people.

Parenteral (injectable) vaccines for dogs

The World Organisation for Animal Health (OIE), with the 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 in Asia (HPED programme), will create a Regional Rabies Vaccine Bank in Asia.

The overall objective of the Regional Rabies Vaccine Bank is to rapidly provide eligible countries2, on a pilot basis, when eligibility criteria (conditions/situations) are met, with an emergency stock of rabies vaccines in order to vaccinate the animal population at risk within the framework of agreed national vaccination strategies.

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1 Extracts from the WHO website: http://www.who.int/mediacentre/factsheets/fs099/en/
2 For the EU, and for the implementation of this project, Asian countries eligible for funding of activities at country level under DCI Regulation (Development Cooperation Instrument) are as follows: Afghanistan, Bangladesh, Bhutan, Cambodia, People’s Republic of China, India, Indonesia, Democratic People’s Republic of Korea, Laos, Malaysia, Mongolia, Myanmar, Nepal, Pakistan, Philippines, Sri Lanka, Thailand and Vietnam.
The regional pilot Vaccine Bank is reliant on the supplier to deliver high quality vaccines upon request. The vaccine supplier will play a prominent role in ensuring the rapid and smooth transportation of the vaccines requested to the country of destination. 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 producer and supplier of rabies vaccines in order to set up a Regional Rabies Vaccine Bank in Asia, in accordance with the criteria set out below.

**Oral vaccination of dogs (pilot tests envisaged)**

In addition, the OIE takes the opportunity to invite vaccine manufacturers that might be interested to come forward with proposals for possible additional pilot projects (including field studies) which would use oral vaccination of dogs. The vaccine suppliers are invited to present their level of advancement (strains and baits/pharmaceutical form/galenics) in this field and possible proposals for field tests in a limited number of Asian countries (where possible).

At this stage, this does not constitute a commitment of the OIE to engage in the use of these vaccines.

Combined approaches including oral contraception of dogs could be envisaged and proposed if relevant and available.

**A - Parenteral (injectable) vaccines for dogs**

1 - The Vaccine Producer and Supplier:

The vaccine producer and supplier should have global references and experience in manufacturing, selling and delivering rabies vaccines. It must comply with relevant international standards such as the OIE international standards described in the latest English version of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 1.1.8: Principles of Veterinary Vaccine Production. The rabies vaccine production facility(ies) should meet the requirements for Containment group 3 pathogens as outlined in Chapter 1.1.2 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*.

The vaccine supplier 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 provided.

The vaccine supplier must comply with the relevant quality assurance control programmes and procedures based on international standards for all vaccines to be provided. 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 supplier will allow the OIE and/or the donor(s) supporting the project to a right-of-entry provision to inspect the corresponding production and storage facilities.

2 - The Rabies Vaccine Bank:

Within the framework of this programme and more specifically for this call for tender, the term “Vaccine Bank” refers to the service provided through a Vaccine Production, Storage (if necessary) and Supply Agreement between the supplier and the OIE.

The vaccine producers’ and suppliers’ offers should facilitate the setting up of a “virtual” Regional Rabies Vaccine Bank with as much flexibility as possible in order to effectively and efficiently deliver the products within the time allowed and manage certain variables such as rolling stocks and replenishment rules.

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

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3 [http://web.oie.int/eng/normes/MMANUAL/2008/pdf/1.1.08_VACCINE_PRODUCTION.pdf](http://web.oie.int/eng/normes/MMANUAL/2008/pdf/1.1.08_VACCINE_PRODUCTION.pdf)

4 [http://web.oie.int/eng/normes/MMANUAL/2008/pdf/1.1.02_BIOSAFETY.pdf](http://web.oie.int/eng/normes/MMANUAL/2008/pdf/1.1.02_BIOSAFETY.pdf)
The length of time between a formal delivery order of rabies vaccines from the OIE and the actual delivery of vaccines to beneficiary countries by the vaccine supplier is an important factor to consider. The OIE expects the delay 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”; “rapid delivery”; “planned delivery”).

3 - Location of the Vaccine Bank:
The vaccine producer and supplier is wholly responsible for producing on time or storing vaccines pertaining to the Vaccine Bank when relevant. The OIE will not engage in the provision of storage facilities at global or regional level.

4 - Rabies Vaccines:
In the context of the Rabies Vaccine Bank, the vaccine producer and supplier should have in stock and provide, or should be able to produce, on time, the vaccines within the short time period indicated in the Agreement.

The rabies vaccines produced should comply with OIE standards for the quality of veterinary vaccines referred to in -1- above as well as with the relevant parts of Chapter 2.1.13 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals5.2

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).

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

As live attenuated rabies vaccines are not accepted in some countries, for the Rabies Vaccine Bank (parenteral vaccination), the OIE will favour offers proposing other types of vaccines in order to ensure that the vaccines in the Rabies Vaccine Bank can be used in as many eligible countries as possible.

Vaccines should confer protective immunity for at least one year. Vaccines with demonstrated (internationally recognised justifications provided) longer protective immunity would be an additional asset.

The vaccine supplier will also provide evidence of the rabies vaccines: characteristics of the seed, method of culture, validation as a vaccine (e.g. efficacy, potency, safety, and stability), method of manufacture, on-process control, and batch control (e.g. sterility, safety, potency/biological activity, stability). Preservatives and boosters used should be indicated (if relevant).

The vaccine supplier offer will also foresee the submission of all relevant supporting documentation, as well as a full and detailed description of the protocols used.

The vaccine supplier is required to 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 possible secondary effects identified.

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

The type of packaging (number of doses per vial or bottle) proposed should be described. Different options and corresponding prices should be specified. Offers with prices covering both individual doses and multi-dose vials/bottles would be an additional asset.

5  http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.13_RABIES.pdf (under revision)
Offers including availability of ready to use individual doses of vaccines (kits with one-dose bottles and syringe, or individual syringes containing the vaccine) would be an additional asset. Other user-friendly solutions can be proposed (and described).

Advice (pros and cons) from the vaccine suppliers regarding the different type of packaging available would be welcome.

It is important to note that in the context of this Vaccine Bank, the OIE will order the delivery of these vaccines exclusively for the vaccination of carnivores (owned and restrained animals/pets (domestic) or un-owned, free roaming animals (feral) – through a "catch-and-release" strategy), i.e. mainly dogs, possibly some cats on a case by case need (on the spot). Vaccination of livestock (or of bats) is not envisaged in the context of this regional Vaccine Bank.

5 - Duration of the contract:

The anticipated completion date of the initial contract is foreseen in December 2013 (exact date to be confirmed when negotiating the final version of the contract).

6 - Shipment of Vaccines:

The vaccine supplier undertakes to assist the OIE in organising ground and air transportation for the vaccines to the airport of final destination.

It is anticipated that the delivery of vaccines to final destination will take place at the main commercial airport of the capital city or at one other main airport in the relevant eligible country of final destination (in any case, one airport per shipment and order of delivery).

The rabies 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 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 rabies vaccines must be shipped by the contractor 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:

- 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”; “rapid delivery”; “planned delivery”);
- Documents provided with the vaccines delivered (invoice, certificate of analysis, etc.).

Before any shipment takes place, the vaccine supplier will present a financial proposal to the OIE, regarding the proposed cost and the delivery time of the shipment. The delivery will only take place after validation and written approval by the OIE of the final cost and delivery time of the shipment.

The maximum delay between the OIE order and delivery to various countries in Asia should be as short as possible. The vaccine supplier’s offer should take into consideration the different possible delays and the corresponding prices. The vaccine supplier 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 will be applied.
B - Oral vaccination of dogs (pilot field studies envisaged)

The OIE takes the opportunity to invite vaccine manufacturers that might be interested to also come forward with proposals for possible additional pilot projects (including field studies) which would use oral vaccination campaign in dogs. The vaccine suppliers are invited to present their level of advancement (strains and baits/pharmaceutical form/galenics) in this field, and possible proposals for field tests in a limited number of Asian countries (where possible), as complementary strategies to parenteral vaccination of dogs.

The vaccine suppliers should present their experience in this field.

Possible production delays, volume constraints, regulatory constraints and barriers should be explained in detail (specific issues at country level included).

Price indications and possible variations over time (depending on volumes and bait formulation) should be provided.

The vaccines proposed should comply with OIE standards for the quality of veterinary vaccines referred to in -1- above as well as with the relevant parts of Chapter 2.1.13 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Possible limitations to the implementation of this requirement should be explained and specified.

For live vaccines that are prepared for oral vaccination of wild, feral (or domestic) animals, safety and efficacy in target animals and safety in non-target species, including humans, must be demonstrated.

The vaccine should not induce any adverse signs in target and non-target species. For vaccines used for dog immunisation, saliva should be checked for the absence of vaccinal virus because of possible contact with humans.

The attenuated rabies virus-based vaccines must achieve the lowest residual pathogenicity for target and non-target species (European Commission, 2002); this is of utmost importance in the case of oral vaccination of dogs as dogs are often in close contact with humans (WHO Expert Committee on Rabies, 2005).

The recombinant vaccines cannot induce any risk of rabies; therefore the safety controls concern only the possible residual pathogenicity of the recombined parenteral virus.

Keeping in mind possible follow-up actions for rabies control programmes, including with new donors, the OIE may envisage for rabies vaccination campaigns the use of a “pull-mechanism”6 which would consider the purchase of a certain quantity of such vaccines (for field tests), with certain conditions, while not financing the finalisation of the corresponding vaccine and bait.

Combined approaches including concomitant oral contraception of dogs could be envisaged and proposed if relevant and available.

All this information will be treated in a confidential manner.

C - General Information

7 - Miscellaneous:

Other services relating for example (not exhaustive) to:

(i) development of new vaccines;
(ii) scientific collaboration (e.g. availability free of charge of samples of antigens, of vaccines for in-vitro tests or tests on animals);
(iii) advice on, and reporting of, new vaccines/baits (in particular for oral vaccination of dogs) available; and
(iv) insurances (insurance of vaccine stocks, when relevant).

can be offered in the answer to this call for tender, and would be an additional asset.

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6 http://www.milkeninstitute.org/events/events.taf?cat=finlabs&id=362&function=detail (under revision)
8 - Financial Conditions:
The price of the service as described above and the payment conditions proposed will be important criteria in the selection of the vaccine supplier.

The vaccine supplier should make a proposal regarding the cost of the service and the payment conditions. The offers may be presented using different costing methods, e.g.
- cost of Vaccine Bank;
- vaccine cost per dose and/or per vial/bottle;
- price variations depending on quantities (total volume of the vaccine bank under the contract with the OIE for the duration of the contract).

The procedure used for calculation of cost of transportation and procurement should also be specified.

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 will be treated as confidential and will remain so. Pricing is also an important factor for the selection process.

9 - Financial Penalties:
Provisions for heavy financial penalties in case of late delivery will be foreseen in the contract.

Financial penalties will also be applied if the vaccines, 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 criteria:
The offer should be presented in two parts: (i) the technical part and (ii) the financial part (pricing). The first selection process will be made on the basis of the technical part. The financial part (pricing) will only be examined for the offers retained after the first selection.

This applies to both parenteral vaccines and oral vaccines (if available/offered).

The vaccine producer and supplier will be selected by an ad hoc Selection Commission which will examine all eligible offers officially received in due time at OIE Headquarters on the basis of (not exhaustive and not by order of importance):
- Global experience and supplier references;
- Nature and quality (compliance with OIE international standards), including packaging and number of doses per vial or bottle, of the vaccines offered given the conditions of use envisaged in Asia;
- Conditions proposed regarding the rolling system (replenishment of stock) and the length of time between a delivery order sent by the OIE and the expected time of delivery to beneficiary countries;
- Flexibility of the Vaccine Bank, and the service offered;
- Price of the service proposed;
- Payment conditions proposed.

Bidders are also invited to specify the list of countries where they already benefit from a market authorization for the vaccines proposed (all forms, both for parenteral and oral vaccines, if appropriate).

Bidders may need 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 - Content of the offer:
Offers should be submitted to the OIE Headquarters in the following manner:

(i) The Technical Offer should be placed and sealed in an envelope bearing the words "Envelope A - Technical offer" and then placed and sealed into another envelope bearing the words (as drafted below)
(ii) The Financial Offer should be placed and sealed in an envelope bearing the words "Envelope B - Financial offer" and then placed and sealed into another envelope bearing the words (as drafted below): Envelope B - Financial offer -

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

All parts of the offer other than the financial offer must be submitted in Envelope A.

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

The external envelope should state in large bold letters:

(iii)

- Envelope A - Technical offer -

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

and should be labelled as follows:

(iv)

Monsieur le Directeur Général
Organisation Mondiale de la Santé Animale (OIE)
12, rue de Prony
F-75017 Paris
France

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

12 – Procedure:

The contact person at the OIE Headquarters during the period of preparation of the offers: Dr. Alain Dehove (a.dehove@oie.int).

For the offer to be valid, it must be deposited and registered against receipt at the latest on Monday 14th November 2011 at 12:00 o'clock (Paris time) at OIE Headquarters (address specified under (iv) above).