

ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

Contract title: Supply of vaccines for eradication of rabies in wildlife population and against Classical Swine Fever

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Lot 2: Supply of vaccines for combating classical swine fever

Publication reference: EuropeAid/135620/IH/SUP/RS

**Column 1-2 should be completed by the Contracting Authority
Column 3-4 should be completed by the tenderer
Column 5 is reserved for the evaluation committee**

Annex III - the Contractor's technical offer

The tenderers are requested to complete the template on the next pages:

- Column 2 is completed by the Contracting Authority shows the required specifications (not to be modified by the tenderer),
- Column 3 is to be filled in by the tenderer and must detail what is offered (for example the words "compliant" or "yes" are not sufficient)
- Column 4 allows the tenderer to make comments on its proposed supply and to make eventual references to the documentation

The documentation supplied should clearly indicate (highlight, mark) the models offered and the options included, if any, so that the evaluators can see the exact configuration. Offers that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

The offer must be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offered specifications.

1.1. Description of the Supply

The subject of the contract is the supply by the Contractor of the following goods in given quantities according to the distribution list defined in this Technical Specifications, DDP (Delivery Duty Paid) within the periods or dates specified.

Delivery of vaccines to the Beneficiary as per section 1.2.1 below		
Item n°	Item	Quantity (doses)
1.1	Vaccines for vaccinations of domestic pigs against classical swine fever with delivery within 120 days from the commencement date	400,000

1.) The ratio of bottle sizes under 1.1 above should follow that described under 1.1 k.) below

1.2. Technical requirements

The technical specifications are requirements based on the respective item's projected function or purpose.

Items non compliant with technical specifications will be rejected.

1.2.1 Delivery of the vaccines

Following completion of the import procedures by the supplier, the vaccines shall be delivered in the storage of the Beneficiary in Belgrade at the following address:

National Reference Laboratories Complex
Batajnicki drum bb
Belgrade (Zemun)

The Contracting Authority reserves the right to modify or change the details of the delivery point (within Belgrade) through specific administrative orders.

1.2.2 Transport and Storage of the vaccines

From the manufacture, until the delivery and putting of the vaccines in the storage of the Beneficiary, the supplier must ensure that the vaccines are stored (in any interim storage as the case may be) and transported in compliance with the conditions prescribed by the vaccine manufacturer including (but not limited to) maintenance of the cold chain. As a condition for issuance of the provisional acceptance, for each phase of delivery as described above in Section 1.1 the supplier will provide a report to the Contracting Authority with copy to the Beneficiary, in form of a comparison table between the conditions set by the vaccine manufacturer and those recorded during transport and interim storage together with relevant supporting documents (e.g. records from data loggers). The supplies therefore at all times must be accompanied by (officially certified) data loggers to record the temperatures in transport and storage.

Remark: The Contractor will be responsible for interim storage of the supplies until the delivery to the Beneficiary. This may include interim storage within Serbia during customs clearance, procedure for issuance of the import permits, and certificate(s) of analysis for vaccines batches by the competent authorities in the Beneficiary Country including the Agency for Medicines and Medical Devices (ALIMS)ⁱ. It will be the responsibility of the Contractor to ensure that any interim storage in Serbia complies with the relevant national legislation.

The supplier will ensure, in cooperation with the Beneficiary, that the vaccines stored in storage of the Beneficiary are equipped with data logger(s).

1.2.3 Control of quality before realization in the field

Please refer to relevant Articles of Special Conditions.

1.2.4 Contractors human resources

The supplier is responsible to provide presence of the responsible and competent person ("Contact person") in Serbia during implementation of the Contract activities. Person to be nominated by the supplier will be responsible for day to day contacts with the Contracting Authority / Beneficiary.

1.3. Technical specifications

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
1.1	a.)Vaccine for vaccination of domestic pigs against classical swine fever (C strain). The vaccine must be freeze-dried.			
	b.)The vaccine must be registered by either the European Medicines Agency (EMA), or competent authority of any European Member State at least in one member state of the EU, or competent authority in the Republic of Serbia.			
	c.)In case that the vaccine is not registered or licensed or authorised for use in Serbia by the Agency for Medicines and Medical Devices (ALIMS) it must comply with the requirements stipulated in the Rule Book "RULES OF CONDITIONS FOR THE IMPORT OF MEDICINES AND MEDICAL DEVICES WHICH DO NOT HAVE THE MARKETING AUTHORIZATION" RULES BOOK; "Official Gazette of RS", Nos. 37/08 and 45/08.			
	d.)The producer company of the vaccine must meet GMPs (Good Manufacturing Practices) in the plant facilities. Relevant documentary proof issued by a competent authority in this relation should be attached to the offer			

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	<p>e.)On each bottle of the vaccine must be label with the name and the composition of the product as well as name and address of the producer.</p> <p>f.)Moreover, the label has to include batch number, expiry date of batch, proper storage conditions, vaccine doses per bottle, minimum quantity of vaccinal virus per dose, route of administration and reference to user instructions for further information (e.g. dosage and application).</p> <p>g.)In addition, the label must clearly indicate that the vaccine is intended for veterinary use only.</p>			
	<p>h.)On the label of the vaccine has to be printed the period within which the vaccine is to be used after reconstitution.</p>			

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	<p>i.)With each bottle, there must be directions provided for use of the vaccine including the method of application. The user instruction must be in Serbian language and must be provided with each package of bottle. The user instruction leaflet must contain the following information:</p> <ul style="list-style-type: none"> • name, registration number, description and indication of vaccine • composition and content of vaccine. • period within which the vaccine is to be administered after reconstitution. • storage conditions • information about age groups for vaccination, dosage and applications • contraindications • potential interactions or side effects • producing company 			

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	j.)Each vaccine bottle is provided with appropriate diluents. The bottle of diluents must indicate the name or composition and the volume of the reconstituting liquid.			
	k.) 200.000 doses of vaccine will be furnished in 10 doses bottle and 200.000 doses in 20 or 25 dose bottles			
	l.)The period of validity of the vaccine must not be less than 8 months after the date of delivery the vaccines to the premises of the Beneficiary.			

1.4 Visibility

All supplies must comply with the generic Visibility policies in force within the scope of external aid contracts financed from the EU general budget; tenderers will thus be aware that certain visibility rules apply and that the guidelines and manuals concerned may be found in the EUROPEAID website, at: https://ec.europa.eu/europeaid/communication-and-visibility-manual-eu-external-actions_en.

The Contractor shall ensure the highest visibility to the financial contribution of the European Union. To ensure such publicity the Contractor shall implement among other actions the specific activities described in the Special Conditions. All measures must comply with the rules in the Communication and Visibility Manual for EU External Actions published by the European Commission.

i The ALIMS is performing the control according to the (Republic of Serbia's) Law on Medicines and Medical Devices, published in the OG RS No 30/10, 107/12, Article 147-152 and by Rulebook on the Quality Control of Medicines and Medical Devices, OG RS 64/11