EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for Food Safety

CALL FOR TENDERS

N° SANTE/2016/G2/030

Purchase, storage and delivery of live attenuated vaccine against lumpy skin disease

TENDER SPECIFICATIONS

TABLE OF CONTENTS

1. INFORMATION ON TENDERING

1.1. Participation

Participation in this procurement procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.

It is also open to all natural and legal persons established in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the plurilateral Agreement on Government Procurement1 concluded within the World Trade Organisation applies, the participation to this procedure is also open to all natural and legal persons established in the countries that have ratified this Agreement, on the conditions it lays down.

1.2. Contractual conditions

The tenderer should bear in mind the provisions of the draft contract which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

1.3. Compliance with applicable law

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU[2].

1.4. Joint tenders

A joint tender is a situation where a tender is submitted by a group of economic operators (natural or legal persons). Joint tenders may include subcontractors in addition to the members of the group.

In case of joint tender, all members of the group assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole, i.e. both financial and operational liability. Nevertheless, tenderers must designate one of the economic operators as a single point of contact (the leader) for the Contracting Authority for administrative and financial aspects as well as operational management of the contract.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the leader on behalf of all members of the group, authorised by the other members via powers of attorney.

1.5. Subcontracting

Subcontracting is permitted but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole.

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[1] See http://www.wto.org/english/tratop_E/gproc_e/gp_gpa_e.htm

[2] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

Tenderers are required to identify subcontractors whose share of the contract is above *20* % and whose capacity is necessary to fulfil the selection criteria.

During contract performance, the change of any subcontractor identified in the tender or additional subcontracting will be subject to prior written approval of the Contracting Authority.

1.6. Structure and content of the tender

The tenders must be presented as follows:

Part A: Identification of the tenderer (see section 1.7)

Part B: Non-exclusion (see section 4.1)

Part C: Selection (see section 4.2)

Part D: Technical offer

The technical offer must cover all aspects and tasks required in the technical specifications and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be rejected on the basis of non-compliance with the tender specifications and will not be evaluated.

Part E: Financial offer

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

The quoted price must be a fixed amount which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

The price must be submitted on the basis of Annex V.

The following prices must be quoted :

- Price of vaccine purchase (price per dose)
- Price of vaccine storage (price per 10.000 doses of vaccine per year)
- Maximum price of vaccine consignment delivery to any of the destinations listed in point 2.3 (5) (to be given per 100.000 doses and to be applied regardless quantity or destination and on the basis of 10 deliveries throughout the contract duration) .
- Price for destruction and disposal of any unused vaccine doses coming to the end of the shelf life

1.7. Identification of the tenderer

The tender must include a **tender submission form (Annex I)** signed by an authorised representative presenting the name of the tenderer (including all entities in case of joint tender) and identified subcontractors if applicable, and the name of the single contact point (leader) in relation to this procedure.

In case of joint tender, this tender submission form must be signed either by an authorised representative for each member, or by the leader authorised by the other members with powers of attorney. The signed powers of attorney must be included in the tender as well. Subcontractors that are identified in the tender must provide a letter of intent signed by an authorised representative stating their willingness to provide the services presented in the tender and in line with the present tender specifications.

All tenderers (including all members of the group in case of joint tender) must provide a signed Legal Entity Form with its supporting evidence. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

The tenderer (or the leader in case of joint tender) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on: http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm

The tenderer (and each member of the group in case of joint tender) must declare whether it is a Small or Medium Size Enterprise in accordance with Commission Recommendation 2003/361/EC. This information is used for statistical purposes only.

2. TECHNICAL SPECIFICATIONS

2.1. Title of contract

Purchase, storage and delivery of live attenuated vaccine against lumpy skin disease

2.2. Purpose and context of contract

Context

The Commission has to maintain a stock of at least **175.000 d**oses of live attenuated LSD vaccine in storage in order to make it rapidly available in case it is needed.

In addition, this stock **of 175.000 doses** of live attenuated vaccine should be replaced quickly, within 4 weeks, when depleted, in order to maintain the Union's capability to respond to an emergency.

Purpose

The purpose of the contract is:

- the purchase and storage of **175.000 doses** of live attenuated vaccine against LSD;
- the replacement of the above **175.000** doses of LSD vaccine, if depleted (due to the vaccine shelf life expiry or its delivery to any place referred to in point 3.5), for up to (2) two times during a period of 4 years after the contract signature;
- to ensure a rapid delivery of additional stock to replace the quantities used from the above in case of emergency vaccination of cattle;
- the storage of any vaccines in stock until the end of the contract (4 years + remaining shelf life);
- proper destruction and disposal of any unused vaccine doses coming to the end of the shelf life.

2.3. Specific technical requirements

1. The live attenuated, homologous, vaccine against LSD should be based on an attenuated lumpy skin disease virus strain.

2. Requirements for the production of vaccine

   The live attenuated vaccine must be produced according to the principles of the last existing update of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE).

3. Requirements for the storage of the vaccine

   The manufacturer shall store the vaccine according to the principles the last existing update of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) and provide detailed information on:

   - the place and conditions under which the vaccine will be stored;
   - the expiry of the vaccine under such conditions; and
   - the guarantees offered as regards safety of storage;

   The **vaccine should be stored in vials of maximum 25 doses each**. The manufacturer must label the vials with information on the volume of the bottles and the number of doses per bottle.

   The manufacturer shall guarantee that the vaccine is tested on efficacy, safety, innocuity and sterility in case any changing condition in storage may alter these characteristics. See section 15.3 for the requirements.

4. Requirements for the production and supply of the vaccine

The vaccine shall be produced in either one batch or sequential batches provided and should be supplied by the tenderer as soon as possible, no later than the deadlines specified in point 5.

The total volume of **175.000** doses to be kept in store in case the need should arise for emergency vaccination against LSD must be readily available within 4 weeks following signature of the contract .

Replacement of the vaccine doses in case of depletion of the above stock should take place as soon as possible, and must not take longer than 4 weeks following partial or total depletion or vaccine expiry.

5. Requirements for the delivery of the vaccine

The manufacturer shall be prepared to deliver part or all the vaccine in stock within the delays specified hereafeter to any Member State of the EU and:

- Member countries of the European Economic Area (EEA) other than EU Member States, and

- Armenia, Azerbaijan, Belarus, Georgia, Moldova, Russia, Ukraine, Serbia, Montenegro, Bosnia-Herzegovina, Albania, the former Yugoslav Republic of Macedonia, Kosovo as defined by United Nations Security Council Resolution 1244 of 10 June 1999 - Egypt, Israel, Jordan, Lebanon, Turkey,

In accordance to the following rules:

Delivery of the **175.000 doses of** the vaccine to the storage site (to be stored) must be carried out within 4 weeks following signing of the contract.

Delivery of up to **175.000 doses** from the stock, after its initial establishment as above, within 5 working days following notice by the Commission to any of the destinations listed in point 3.5 .

In order to monitor the execution of the contract and Technical Specifications in particular, appropriate monitoring, assessment, supervisory and reporting procedures shall be set up.

In cases of emergency, where the quantity of vaccines in stock would not cover the need and where a shipment of vaccines to one of the above listed destinations is needed as soon as possible, the Commission reserves the right to negotiate directly with the manufacturer the specific terms and conditions of such a shipment using vaccines from the manufacturer's own reserves which may not have a maximum shelf life anymore. In that case the relevant purchase and consignment costs may in any case not be higher than the prices already quoted for this contract.

6. Requirements for the replacement of the vaccine stock

Guarantee of a quick replacement of 175.000 doses of the LSD vaccine, if depleted (due to the vaccine shelf life expiry or its delivery to any place referred

to in point 3.5), no later than 4 weeks for a **maximum of 2 times during a period of 4 years after contract signature.**

2.4. Documentation for tenderers

The last existing update of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) is available on the organisation's website (English version):

http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

2.5. Volume of the contract

The estimated maximum total budget for this contract is EUR 600.000.

The duration of the contract is **48 months** after the signature of the contract by the last contracting party, **extended with the remaining shelf life of the vaccines in stock at the end of this initial contract duration**.

Only the produced, supplied and delivered quantity of the vaccine shall be paid by the contacting authority.

3. REPORTS AND DOCUMENTS TO BE SUBMITTED

The work carried out by the Contractor under the contract will be the subject of the following reports, which must be sent to the Commission by the Contractor.

- **Technical report**: 3 copies

  Upon production of each batch of vaccines purchased in the framework of the contract a report should be submitted including information on the procedure used for the production of the live attenuated vaccine, results of efficacy, safety innocuity and sterility tests carried out as well as the system put in place to ensure a correct and secure storage.

  It must be sent to the Commission no later than 2 weeks after the production of the live attenuated vaccine.

  This report includes information on:

  - the efficacy, safety, innocuity and sterility tests carried out;
  - the storage equipment used;
  - the security system in place (temperature control, anti-theft measures)
  - insurance arrangements (fire, accidents)
  - procedures in place to ensure a rapid delivery of the vaccine.

  Upon delivery of vaccines to any place listed in point 3.5. the Contractor must sent to the Commission a report including :

- Date of shipment
- Date of reception
- Quantities delivered including batch details
- Place of delivery
- Proof of receipt of the vaccines by the recipient
- Conditions under which the vaccines were delivered

In case any of the vaccines in stock are approaching expiry date the contractor must send the Commission a report, no earlier than 3 months and no later than 2 months before the actual expiry date (or dates), including the quantities of the vaccine placed in stock that is close to expiry including batch details and expiry date (or dates) thereof.

Upon partial or total replacement of the vaccine stock due to vaccine use or expiry the Contractor must sent to the Commission a report including :

- Date of replacement
- Quantities of vaccine placed in stock including batch details

After the end of each calendar year and after the end of the contract (no later than 30 days after the end of the calendar year and after the end of the contract) the Commission must receive a cumulative report detailing in chronological order all quantities of vaccine produced and delivered as well as the quantities of the vaccine stored with at least the following information related to the calendar year in question:

Production of vaccines

Numbers of doses of vaccines produced/purchased in the framework of the contract complete with batch details

Storage of vaccines

- Full description of the vaccine stock at the beginning of the calendar year (number of doses, batch details , dates of entry in the stock
- Full list of all changes in the vaccine stock throughout the calendar year (for each change numbers of doses of vaccines that were inserted or removed from the stock each time complete with batch details, dates of entry or exit , reason for this movement and vaccines remaining in store following each withdraw from the stock or replenishment thereof)
- Full description of the vaccine stock at the end of the calendar year (number of doses, batch details , dates of entry in the stock)

After the end of the contract the report must also contain information on the total number of destroyed and disposed of vaccines.

Delivery of vaccines

Full list of all deliveries throughout the calendar year (for each delivery numbers of doses of vaccines that were delivered complete with batch details, destination and dates of delivery)

- **Financial report**

  Upon production of each batch the invoice mentioning quantities and batch details and accompanied by the above described technical report should be sent to the Commission.

  After the end of each calendar year (no later than 30 days after the end of the calendar year) an invoice for the storage costs accompanied by the above mentioned technical report must be sent to the Commission.

  Upon delivery of vaccines an invoice accompanied by the above mentioned technical report.

  After the end of the contract :

  - an invoice with any storage costs of vaccines kept in stock after the end of the contract's 4 year period for their remaining self life
  - an invoice with any destruction and disposal costs as mentioned in point 3 , accompanied by the above mentioned report to be sent to the Commission (report after the end of the contract).

4. EVALUATION AND AWARD

The evaluation is based solely on the information provided in the submitted tender. It involves the following:

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria
- Selection of tenderers on the basis of selection criteria
- Verification of compliance with the minimum requirements set out in these tender specifications
- Evaluation of tenders on the basis of the award criteria

The contracting authority may reject abnormally low tenders, in particular if it established that the tenderer or a subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

The Contracting Authority will assess these criteria in no particular order. The successful tenderer must pass all criteria to be awarded the contract.

4.1. Verification of non-exclusion

All tenderers must provide a declaration on honour (see Annex IV), signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in that declaration on honour.

In case of joint tender, each member of the group must provide a declaration on honour signed by an authorised representative.

In case of subcontracting, subcontractors whose share of the contract is above *20* % must provide a declaration on honour signed by an authorised representative.

The Contracting Authority reserves the right to verify whether the successful tenderer is in one of the situations of exclusion by requiring the supporting documents listed in the declaration of honour.

The successful tenderer must provide the documents mentioned as supporting evidence in the declaration on honour before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose share of the contract is above *20* %.

The obligation to submit supporting evidence does not apply to international organisations.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

4.2. Selection criteria

Tenderers must prove their legal, regulatory, economic, financial, technical and professional capacity to carry out the work subject to this procurement procedure.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Contracting Authority that it will have at its disposal the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.

The tender must include the proportion of the contract that the tenderer intends to subcontract.

4.2.1. Declaration and evidence

The tenderers (and each member of the group in case of joint tender) and subcontractors whose capacity is necessary to fulfil the selection criteria must provide the declaration on honour (see Annex IV), signed and dated by an authorised representative, stating that they fulfil the selection criteria applicable to them. In case of joint tender or

subcontracting, the criteria applicable to the tenderer as a whole will be verified by combining the various declarations for a consolidated assessment.

This declaration is part of the declaration used for exclusion criteria (see section 4.1) so only one declaration covering both aspects should be provided by each concerned entity.

The Contracting Authority will evaluate selection criteria on the basis of the declarations on honour **save as otherwise specified in annex VIII**. Nevertheless, it reserves the right to require evidence of the legal and regulatory, financial and economic and technical and professional capacity of the tenderers at any time during the procurement procedure and contract performance. In such case the tenderer must provide the requested evidence without delay. The Contracting Authority may reject the tender if the requested evidence is not provided in due time.

After contract award, the successful tenderer will be required to provide the evidence mentioned below before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose capacity is necessary to fulfil the selection criteria].

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

4.2.2. Legal and regulatory capacity

Tenderers must prove that they are allowed to pursue the professional activity necessary to carry out the work subject to this call for tenders. The tenderer (including each member of the group in case of joint tender) must provide the following information in its tender if it has not been provided with the Legal Entity Form:

- For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation applicable to the legal person requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, if required under applicable law, a proof of registration on a professional or trade register or any other official document showing the registration number.

4.3. Economic and financial capacity criteria

The tenderer must have the necessary economic and financial capacity to perform this contract until its end. In order to prove their capacity, the tenderer must comply with the selection criteria stated below.

For contracts with a value of 135,000 EUR or more, tenderers (and in case of a consortium, the consortium leader and the consortium members) are also requested to fill in the 'simplified balance sheet' and the 'simplified profit and loss accounts' enclosed in the 'Simplified Presentation' form in Annex VI for the last year for which accounts have been closed. Alternatively, the tenderers may fill in only the fields marked in bold and the ones marked in italics. All amounts must be expressed in Euro using the conversion rate as per section 9 (Price) of these tender specifications.

On the basis of the data from the 'Simplified Presentation' form in Annex VI, a number of values and ratios will be calculated in order to evaluate the economic and financial capacity of the tenderers.

The following values will be calculated:

Value	Formula/source	Unfavourable if:
own funds	from the balance sheet	negative
	own funds - paid-up capital	negative
working capital	permanent capital - fixed assets	negative
gross operating surplus	from the P&L accounts	negative
net result	from the P&L accounts	negative
self-financing capacity (SFC)	net result after tax + amortization – capitalized production	negative

Following ratios are calculated:

Ratio	Formula	Unfavourable if	Average if	Favourable if
general liquidity	current assets/short-term debts	below 1	between 1 and 1.25	Above 1.25
financial independence	own funds/total liabilities	below 0.20	between 0.20 and 0.40	above 0.40
indebtedness	own funds/medium & long-term debts (MLT)	below 0.30	between 0.30 and 0.60	above 0.60
coverage of deposits and borrowed funds by the SFC	SFC / MLT debts	below 0.25	between 0.25 and 0.50	above 0.50
profitability	gross operating surplus / turnover	below 0.10	between 0.10 and 0.20	above 0.20

Each type of evaluation has a corresponding scoring (number of points) as follows:

Scoring	
Unfavourable value/ratio	0 points
Favourable value	1 point
Average ratio	1 point
Favourable ratio	2 points

In order to meet the financial capacity criterion, the tenderer must obtain a score of at least 8 points (out of a total of 16 points), which corresponds to 50% of the maximum number of points.

Evidence (to be provided on request):

- Copy of the profit and loss accounts and balance sheets for the last two years for which accounts have been closed from each concerned legal entity;

If, for some exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, it may prove its economic and financial capacity by any other document which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of the exceptional reason and its justification. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

- **Technical and professional capacity criteria and evidence**

A. Criteria relating to tenderers

Tenderers (in case of a joint tender the combined capacity of all members of the group and identified subcontractors) must comply with the criteria listed below. The evidence must be provided on request.

The project references indicated below consist in a list of relevant services provided in the past three years, with the sums, dates and clients, public or private, accompanied by statements issued by the clients.

- **Criterion A1**: The tender must hold a marketing authorisation, licence or certificate of free sale relating to the vaccine issued in accordance with national law of the country of manufacture.

Evidence A1: Copy of marketing authorisation, licence or certificate of free sale relating to the vaccine

- **Criterion A2**: The tenderer must hold a permission to export the vaccine (e.g. export licence from the country of manufacture).

Evidence A2: Certificate, export licence or equivalent

- **Criterion A3:** The tenderer must demonstrate the safety, non-transmissibility, irreversibility of attenuation and immunogenic properties of the vaccine strain and vaccine.

Evidence A3: Certificate of analysis, quality control testing certificate.

- **Criterion A4:** The tenderer must prove the fact that the vaccine is manufactured and stored according to the principles of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (2016 edition) of the World Organisation for Animal Health (OIE).

Evidence A4: any relevant documents (SOP, etc.)

- **Criterion A5:** The vaccines should have a minimum shelf life of 2 years.

Evidence A4: Certificate

B. Criteria relating to the team delivering the service:

Not applicable.

4.4. Award criteria

The contract will be awarded to the tenderer who submits the lowest price.

Annexes :

Annex I - Tender submission form

Annex II - Financial Identification form

http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm

Annex III - Legal identification :

Privacy Statement
Legal Entity form - Private Company
Legal Entity form - Public Company

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

Annex IV - Certification with respect to the exclusion criteria

Annex V - Budget

Annex VI - Simplified financial statements

Annex VII - Draft Contract

Annex VIII: Document check list

Annex IX : Template power of attorney