
CENTRAL PURCHASING OPERATOR

Date: 23.04.2025

MINUTES - CONTRACT TYPE - GOODS

**ON THE ARGUMENTATION AND APPROVAL OF TECHNICAL SPECIFICATIONS
AND QUALIFICATION CRITERIA**

Object of the procedure : "Purchase of vaccines against bubonic plague" and "Purchase of bovine and avian tuberculin allergens", divided into 2 (two) lots:

Lot 1: “Purchase of vaccines against distemper disease” .

Lot 2: “Purchase of bovine and avian tuberculin allergens”.

Relevant code in the Common Procurement Vocabulary (CPV): 33651600-4 Vaccine.

Limit fund value : 33,184,700 (thirty-three million one hundred eighty-four thousand seven hundred) lek excluding VAT and 336,354.15 (three hundred thirty-six thousand three hundred fifty-four point fifteen) Euro excluding VAT , divided into lots:

Lot 1: “ Purchase of vaccines against distemper disease” with a limit fund: 1 1,490,400 (eleven million four hundred ninety thousand four hundred) lek excluding VAT and 116,464.63 (one hundred sixteen thousand four hundred sixty four point sixty three) Euro excluding VAT

Lot 2: " Purchase of bovine and avian tuberculin allergens", with a limited fund: 21,694,300 (twenty-one million six hundred ninety-four thousand three hundred) lek excluding VAT and 219,889.52 (two hundred nineteen thousand eight hundred eighty-nine point fifty-two) Euros excluding VAT

The exchange rate according to the Bank of Albania on 22.04.2025 is 98.66 (ninety-eight points sixty-six) euros.

Based on Article 21, point 2, of Law No. 162/2020 "On Public Procurement", as amended, Article 2, point 2/c and Article 78, point 2, of the Council of Ministers No. 285, dated 19.05.2021 "On the approval of the public procurement rules", as amended, the contracting authority/entity, the Centralized Purchasing Operator sh.a, has drafted the minutes for the argumentation and approval of the technical specifications and qualification criteria for the above-mentioned procedure, with the following content:

Lot 1: “ Purchase of vaccine against distemper disease”

2. SPECIAL QUALIFICATION CRITERIA

1. The bidder must submit:

- a. *Summary Self-Declaration Form , according to Annex 9;*
- b. *Bid Security, according to Annex 4;*

2. The bidder must submit :

2.1 Professional capacity of economic operators:

The Bidder must declare that it meets the general eligibility/qualification criteria. These criteria must be met by submitting a written self-declaration of the entity, on the day of bid opening, according to Annex 9.

2.2 Economic and financial capacity:

1. operators must submit a certificate of annual turnover for the financial years (2022, 2023, 2024), where the turnover value for at least one of the years of the required period must be **no less than the calculated value of the lot limit fund**. *The criterion is considered fulfilled if economic operators reach the minimum turnover value in at least 1 (one) year of the required period of financial years .*

Argument: The above request is based on Article 77, point 3, of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and on Article 43, point 2/ae of the Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended. The determination of the years required for the submission of the annual turnover certificate is based on point 2, of Article 61, of Law No. 29/2023 “On Income Tax”, as amended, which stipulates that: “ *The annual tax return shall be submitted to the tax authority no later than March 31 of the year following the tax year for which the return is submitted* ”. The establishment of this criterion is done with the aim of creating confidence in the Contracting Authority, regarding the economic and financial situation of the bidding EO, by proving through the requested documents , that they possess the necessary economic and financial capacities to successfully implement the contract as foreseen by the CA.

As regards the determination of the required value, *not less than the estimated value of the lot limit fund* is within the limit set out in Article 43, point 2/a of the Council of Ministers No. 285, dated 19.05.2021 “On the approval of public procurement rules”, as amended, which provides that “ *The value of the minimum annual turnover required of economic operators cannot exceed: a) twice the estimated value of the contract or lot, in procurement procedures above the upper monetary limit;* ”.

2. operators must submit certified copies of the balance sheets for the years: (2022, 2023, 2024) submitted to the relevant tax authorities. If the economic operator is in the conditions of the definitions of Article 41 of Law No. 10091, dated 05.03.2009, then the balance sheets must also be accompanied by *the legal audit reports of the annual financial statements, carried out by legal auditors or auditing companies.*

The criterion is considered fulfilled if in the two consecutive required balance sheets there is no negative ratio between assets and liabilities .

Argument: The above request is determined based on Article 77, point 3, of Law No. 162, dated 23.12.2020 "On Public Procurement" as amended; Article 43, point 4, of Council Decision No. 285, dated 19.05.2021 "On the approval of public procurement rules", which stipulates that: "*If assessed, the contracting authority/entity may require economic operators to provide information in their annual balance sheets, for a maximum period of the last three financial years, to show the ratios between assets and liabilities . If one or two balance sheets are required, the requirement is considered fulfilled if there is no negative ratio between assets and liabilities in the required balance sheet(s)*", as well as in point 5 of Article 61, of Law No. 29/2023 "On Income Tax", as amended, which stipulates that: "*Taxpayers who keep accounting according to the requirements of the relevant law, submit the annual declaration together with the financial statements, as well as other data specified in the instruction of the minister responsible for finance for the implementation of this law.* ", as well as the requirements of Law No. 25/2018 "On accounting and financial statements", as amended. Through this criterion , for the presentation of the balance sheets, it has been decided, taking into account the object of the contract, its nature and volume, to serve the contracting authority to recognize the situation and capacities of the economic operator, who must prove that they possess the necessary economic and financial capacities, all in function of the successful implementation of the contract.

2.3 Technical capacity:

1. operator must provide evidence of previous similar supplies carried out during the last 3 (three) years from the date of publication of the contract notice, in the amount of **not less than 40% of the value of the lot limit fund**. These previous, similar supplies must be certified by the following documentation:

a. When similar supplies have been made with public entities, the economic operator must present the certificate issued by the public entity for the successful fulfillment of the contract and/or tax sales invoices completed according to the requirements of the legislation in force and declared to the tax authorities, indicating the dates, amounts and quantities of goods supplied.

b. When similar supplies are made to private entities, the economic operator must submit the relevant tax sales invoice completed according to the requirements of the legislation in force and declared to the tax authorities, indicating the dates, amounts and quantities of goods supplied .

Argument : The above requirement is based on Article 77, point 4 of Law No. 162, dated 23.12.2020 "On Public Procurement", as amended, and Article 40, point 4, of the Council of Ministers No. 285, dated 19.05.2021 "On the Approval of Public Procurement Rules", as amended. This criterion requires economic operators to prove that they have the experience necessary to implement the contract, therefore it is required that previous similar supplies be worth no less than 40% of the value of the limit fund, which is within the threshold value set out in the aforementioned article. The required percentage is considered necessary to prove the reliability and experience of the bidding economic operators, in providing goods similar to the procurement object, for the successful implementation of the contract. Similar experience is considered an essential criterion and therefore economic operators must present evidence such as references/tax invoices, etc., to prove their performance with both the private and public sectors .

2. The economic operator, for the vaccines offered, may be their Manufacturer. If it is not the manufacturer, it must present an Authorization from the Manufacturer or from the Distributor Authorized by the Manufacturer. In the case of the latter, a document must be presented that proves the relationship between the Distributor and the Manufacturer .

Justification: The above request is based on Article 77 of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and on Article 40 of Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended.

This criterion requires economic operators to prove that they are the manufacturer or have the opportunity to obtain the vaccine provided by the manufacturer or the distributor authorized by the manufacturer. Also, through this criterion, economic operators prove that they offer an original product produced according to the requirements of the State Commission for Veterinary Medicines, based on Law No. 10465, dated 29.09.2011 “On the Veterinary Service in the Republic of Albania” as amended.

3. operator must submit a detailed declaration with the relevant data of the manufacturing company such as trade name, place of business, email, etc., as well as documentation confirming the legal status/registration certificate of the manufacturer, specifying that the marketing certificate, for the doses of the vaccine offered, has been issued by the European Medicines Agency (EMA) or in one of the EU countries, according to the provisions of Law No. 10465, dated 29.09.2011 “ *On the veterinary service in the Republic of Albania* ”, Article 85, point 3.

Justification : The above request is based on Article 77 of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, Law No. 10465, dated 29.09.2011 “On the Veterinary Service in the Republic of Albania”, Chapter VII “Veterinary Medical Products”, Section 1 “Authorization for the Marketing of Veterinary Medical Products”, Article 85 “Marketing of Veterinary Medical Products”, point 3, which stipulates:

"The State Commission for Medicinal Products recognizes and accepts the marketing certificate for medicinal products, issued by the European Medicines Agency (EMA) or in one of the EU countries."

This criterion requires economic operators to prove that they will offer a vaccine that is recognized and permitted to be marketed in the Republic of Albania by the State Commission for Vaccines.

4. To prove that the vaccines offered meet the required technical specifications, the economic operator must submit a technical sheet/catalogue or any equivalent product document reflecting the technical specifications of the relevant dose .

Justification: The above request is based on Article 77 of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and on Article 40 of Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended.

The establishment of this criterion, also referring to the legislation in force, serves the contracting authority to assess whether an economic operator has the capacity to provide the required product and to compare the compliance of the technical specifications and standards required by the CA with the technical specifications for the goods offered by the economic operator.

5. The economic operator must have a license to trade in veterinary medicinal products under the name " *Wholesale of medicines (for animals)* ", code II.7.B.2 , issued by the Ministry of Health.

Justification : Based on point 4, article 77, of law no. 162, dated 23.12.2020 “ *On public procurement* ”, as amended, law no. 10465, dated 29.09.2011 “ *On the veterinary service in the Republic of Albania* ”, as amended, point 5/a of article 40, of Council of Ministers no. 285, dated 19.05.2021, “On the approval of the Public Procurement Rules”, as amended, and Council of Ministers no. 538, dated 26.5.2009 “ *On licenses and permits handled by or through the National Business Center and some other joint sub-legal regulations* ”, as amended .

This criterion requires economic operators to prove that they are licensed for the wholesale trade of veterinary medicines .

6. The participating economic operator must have at least 1 (one) refrigerated transport vehicle for the transport of vaccines according to the conditions set out in the technical specifications, which it must own/rent/use.

The following documents must be submitted for the requested means:

- a) If owned, the vehicle ownership certificate, valid registration certificate, valid technical inspection certificate, and valid compulsory vehicle insurance policy must be available.
- b) If it is rented/loaned, the rental/loan contract, registration certificate, valid technical inspection certificate, as well as a valid compulsory vehicle insurance policy and photos of the vehicle clearly visible for use in transporting the doses subject to procurement must be available.

Note. *This criterion is considered fulfilled by completing the form according to Appendix 9 of the DT. The supporting documents required above will be submitted by the successful qualified bidders, before the publication of the winner announcement and the start of the appeal deadlines, or if clarifications are requested by the Contracting Authority.*

Justification : The above request is determined based on Article 40, point 5/ç of the Council of Ministers' Decision no. 285, dated 19.05.2021 "On the approval of the Public Procurement Rules", as amended.

This criterion requires economic operators to prove that they have the necessary means to transport vaccines according to the provisions of the technical specifications.

All documents must be originals or notarized copies.

Cases of failure to submit a document, or documents with false or inaccurate data, are considered conditions for disqualification.

Lot 2: “Purchase of bovine and avian tuberculin allergens”

2. SPECIAL QUALIFICATION CRITERIA

1. The bidder must submit:

- a. *Summary Self-Declaration Form , according to Annex 9;*
- b. *Bid Security, according to Annex 4;*

2. The tenderer must submit:

2.1 Professional capacity of economic operators:

The Bidder must declare that it meets the general eligibility/qualification criteria. These criteria must be met by submitting a written self-declaration of the entity, on the day of bid opening, according to Annex 9.

2.2 Economic and financial capacity:

1. Economic operators must submit a certificate of annual turnover for the financial years (2022, 2023, 2024), where the turnover value for at least one of the years of the required period must be **no less than the calculated value of the lot limit fund**. *The criterion is considered fulfilled if economic operators reach the minimum turnover value in at least 1 (one) year of the required period of financial years .*

Argument: The above request is based on Article 77, point 3, of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and on Article 43, point 2/ae of the Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended. The determination of the years required for the submission of the annual turnover certificate is based on point 2, of Article 61, of Law No. 29/2023 “On Income Tax”, as amended, which stipulates that: “ *The annual tax return shall be submitted to the tax authority no later than March 31 of the year following the tax year for which the return is submitted* ”. The establishment of this criterion is done with the aim of creating confidence in the Contracting Authority, regarding the economic and financial situation of the bidding EO, by proving through the requested documents , that they possess the necessary economic and financial capacities to successfully implement the contract as foreseen by the CA.

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also be accompanied by *the legal audit reports of the annual financial statements, carried out by legal auditors or auditing companies.*

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2. The economic operator may be their Producer, if not the producer, must present an Authorization from the Producer or from the Distributor Authorized by the Producer. In the case of the latter, a document must be presented that proves the relationship between the Distributor and the Producer.

Justification: The above request is based on Article 77 of Law No. 162, dated 23.12.2020 “On Public Procurement”, as amended, and on Article 40 of Council of Ministers No. 285, dated 19.05.2021 “On the Approval of Public Procurement Rules”, as amended.

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3. The economic operator must submit a detailed declaration with the relevant data of the manufacturing company such as trade name, place of business, email, etc., as well as documentation confirming the legal status/registration certificate of the manufacturer, specifying that the marketing certificate, for the doses of the vaccine offered, has been issued by the European Medicines Agency (EMA) or in one of the EU countries, according to the provisions of Law No. 10465, dated 29.09.2011 “ *On the veterinary service in the Republic of Albania* ”, Article 85, point 3.

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6. The participating economic operator must have at least 1 (one) refrigerated transport vehicle for the transport of vaccines according to the conditions set out in the technical specifications, which it must own/rent/use.

The following documents must be submitted for the requested means:

- a) If owned, the vehicle ownership certificate, valid registration certificate, valid technical inspection certificate, and valid compulsory vehicle insurance policy must be available.
- b) If it is rented/loaned, the rental/loan contract, registration certificate, valid technical inspection certificate, as well as a valid compulsory vehicle insurance policy and photos of the vehicle clearly visible for use in transporting the doses subject to procurement must be available.

Note. *This criterion is considered fulfilled by completing the form according to Appendix 9 of the DT. The supporting documents required above will be submitted by the successful qualified bidders, before the publication of the winner announcement and the start of the appeal deadlines, or if clarifications are requested by the Contracting Authority.*

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This criterion requires economic operators to prove that they have the necessary means to transport vaccines according to the provisions of the technical specifications.

All documents must be originals or notarized copies.

Cases of failure to submit a document, or documents with false or inaccurate data, are considered conditions for disqualification.

II. Justification of technical specifications

The technical specifications have been drafted according to international standards, by a working group composed of experts in the field.

The drafting of the technical specifications was carried out based on Law No. 10465, dated 29.9.2011 “On the Veterinary Service in the Republic of Albania” as amended, the “Distemper Disease Control Program”, Regulation No. 370, dated 29.7.2014, “On the approval of the Regulation “On Veterinary Medicinal Products”, Regulation No. 429/2016 of the European Parliament and of the Council regarding the management and conservation of antigen reserves”, and the diagnostic manual of tests and vaccines No. 12/2023, of the World Organization for Animal Health.

PROCUREMENT UNIT