1. CHARACTERISTICS OF THE SUPPLY OBJECT OF THE MARKET SURVEY

1.1. Place of execution: Piedmont Region

1.2. Short description of the supply: Supply of Covid-19 vaccines, to be used for active immunisation for the prevention of COVID-19, a disease caused by the SARS-CoV-2 virus, of citizens residing in the Piedmont Region, and related transport and delivery services to the premises of the ordering parties. Below are the estimated quantities:

DESCRIPTION	PHARMACEUTICAL FORM	QUANTITY MAX	UNIT OF MEASURE
Covid-19 vaccine	Suspension/solution for injection	3,000,000	Dose

1.3. Technical requirements for the products: The vaccine offered must comply with the applicable state and/or EU directives on production authorisation, importation, marketing and quality control of medicinal products with particular reference to the requirements of the current Official Pharmacopoeia or any other relevant provisions in force.

It is preferable to propose vaccines for which, at the time of participation, a formal application for marketing authorisation has been submitted to the EMA (European Medicines Agency) or, at least, an application requesting the "rolling review" procedure has been submitted to the EMA. In any case, given the existence of new active immunisation medicinal products for the prevention of COVID-19 outside the European market, the proposal of products which have not yet undergone EMA validation will also be admitted: for such products, the participant in the expression of interest must indicate the certifications/validations possessed and the estimated timeframe for the acquisition of authorisation from the European Medicines Agency.

Each package must clearly indicate the name of the medicinal product, its composition, date of preparation, expiry date, batch number and indications relating to the performance of State controls, and must contain all the information required by current national and supranational regulations.

1.4. Packaging: The information on the label and on the packaging systems must be in Italian or English. All products must be packaged in material that is resistant to loading, transport and unloading, as well as suitable for guaranteeing correct storage, the temperature conditions envisaged by the relative technical data sheet, the "vaccines" monograph of the current edition of the Official Pharmacopoeia and an effective barrier against humidity and dust.

All products must be perfectly identifiable both on the outer packaging (secondary packaging) and on the inner packaging (primary packaging).

In particular, the primary and secondary packaging must bear the following indications, by way of example and without limitation - the supplier's mark; - the symbols required for correct product preservation (e.g. preservation temperature); - the product name; - the production batch number; - the preparation date; - the expiry date.

Any special warnings or precautions to be observed when storing the products must be clearly legible.

1.5. Related services: The transport and delivery of the products to be supplied shall be carried out at the Supplier's care, risk and expense at the premises indicated by the requesting parties in the relevant delivery requests.

The vaccine must be transported, until delivery, in vehicles equipped with the necessary insulation and refrigeration and in suitable thermal containers, in order to ensure the temperature conditions provided for in the monograph of the product and the monograph "vaccines" of the Official Pharmacopoeia edition in force and must comply with the provisions of Legislative Decree no. 219 of 24 April 2006 and subsequent amendments and additions.

At the time of delivery, the vaccine must have a residual shelf life of not less than two-thirds of the maximum validity declared by the manufacturer for that product category.

The Supplier must provide a demonstrable guarantee that the specialised couriers appointed to deliver the vaccines will carry out the transport under controlled conditions such as to comply with the preservation specifications of the product; compliance with the preservation temperature envisaged for the vaccine to be supplied shall therefore be demonstrated by means of appropriate documentation to be attached to the transport document and by the compulsory presence of the temperature indicator, under penalty of rejection of the supply.

1.6. Duration of the supply: the supply should cover the period March 2021 - October 2021.

1.7. Methods and terms of payment

The invoices will be issued by the Supplier after the positive conformity check, after the issuing of the conformity check report containing the date of acceptance of the supply.

The payment of the fees shall be made in favour of the Supplier on the basis of the invoices issued by the latter upon receipt thereof or, in any case, within a maximum period of 30 days from receipt.

2. PROCEDURE FOR PARTICIPATING IN THE MARKET SURVEY

Interested economic operators should send the following documents by e-mail to emergenza.covid@scr.piemonte.it by Friday 26 February.

1) **TECHNICAL DATA SHEET**

A copy of the Summary of Product Characteristics (RCP) must be sent, concerning the product offered, corresponding to the latest update approved by AIFA, with evidence of the reference numbers of the Marketing Authorisation (A.I.C.) for all the packages offered.

In the case of vaccines for which the authorisation procedure is still pending at the European Medicines Agency (EMA), a copy of the marketing authorisation application or a copy of the application, in Italian or English, requesting the "Rolling review" procedure submitted to the EMA must be sent.

In the absence of such documentation, it is requested that the product's technical data sheet be sent, in Italian or English, with the indication of the Body/Authority that authorised its marketing.

2) **MODEL B**

Using the facsimile form entitled "**Model B – Technical Economic data sheet**", available in the documentation attached to this notice, **the indicative unit amount** relating to the maximum quantities available must be sent, expressed in Euros, excluding VAT. This value does not in any way represent the economic offer. It will be used exclusively for the purpose of benchmarking market prices. In the same form, the operator must include a timetable of the expected delivery times in relation to the maximum available quantities during the supply period.

It is not mandatory to dispose of the total quantities covered by this market survey. All documentation must be signed digitally (or with a holographic signature in the case of a non Italian operator) by the owner or legal representative or procurator of the economic operator participating in the present market survey and must be accompanied by a copy of the valid identity document of the signatory.

3. CLARIFICATIONS AND COMMUNICATIONS

Any requests for information or clarifications on the subject matter, participation in the present market survey and the conduct of the procedure must be submitted in Italian or English and sent to the contracting authority by e-mail to emergenza.covid@scr.piemonte.it.

4. PROCESSING OF PERSONAL DATA

The data controller is S.C.R. Piemonte S.p.A., with the role of contracting authority, which may be contacted at the following addresses: telephone 011/6548300 - e-mail presidenza@scr.piemonte.it - pec presidenza@cert.piemonte.it;
The data are processed by the Data Controller, the authorised parties, the designated managers and the public and private entities involved in the procedure, for purposes solely connected to the present procedure as well as to fulfil the legal obligations to which the Data Controller is subject, pursuant to art. 6 par. 1 letters b) and c) of EU Regulation 2016/679.
The data may possibly be processed by private and public entities for activities instrumental to the purposes indicated, which the owners may use as data processors, as well as by public entities if necessary to comply with any legal obligations, always in compliance with current legislation on the protection of personal data.
It is not foreseen the transfer of data in third countries, except for possible communications by mail with subjects operating in EU territory that guarantee the respect of the regulations in force through the adhesion to the EU-US Privacy Shield agreement.
The processing of data does not involve the activation of any automated decision-making process, including profiling, as per art. 22, paragraphs 1 and 4, of EU Regulation 679/2016.
The data will be kept for the duration of the procedure within the terms established by the sector regulations.
The data subject has the right to ask the Data Controller for access to personal data and the rectification or cancellation of the same or the limitation of the processing of personal data concerning him/her and to object to their processing, as well as the right to lodge a complaint with a Supervisory Authority.
The person responsible for the protection of personal data of the contracting authority can be contacted at the following email address: rpd@scr.piemonte.it.

5. FURTHER INFORMATION

The sole purpose of this notice is to acquire documentation to provide SCR Piemonte with the best possible knowledge and information in order to identify the technical solutions available on the market that are capable of satisfying the indicated need.

The contribution requested from the operators is free of charge, with no right to reimbursement of expenses.

This notice therefore constitutes a market survey, implementing the principle of prior publicity as well as the principles of non-discrimination, equal treatment, proportionality and transparency provided for in Article 36, paragraph 1, which refers to Article 30, paragraph 1, of Legislative Decree 50/2016 as amended.

This notice does not call for any competitive or quasi-competitive awarding procedure and does not provide for ranking lists or the awarding of scores.

The use of this market survey procedure does not give rise to any obligations on the part of the contracting authority, nor to any expectations, in law or in fact, on the part of the market participants concerning the conduct of the selection procedure.

The contracting authority reserves the right to interrupt, modify, extend or suspend the procedure, allowing, at the request of the parties involved, the return of any documentation submitted, without this constituting, in any way, any right or claim to compensation or indemnity.