



**PUBLIC EXPLORATORY NOTICE FOR EXPRESSIONS OF INTEREST IN THE
PRODUCTION AND MARKETING OF EHDV-8 INACTIVATED VACCINE**

Art. 1

Subject of the notice

With the present public notice, the Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale' (IZSAM), in its capacity as **National Reference Centre for Exotic Animal Diseases (CESME)**, announces that it has developed, on behalf of the Ministry of Health, an inactivated and adjuvanted vaccine against serotype 8 of the Epizootic Haemorrhagic Disease virus (EHDV-8). This vaccine was successfully tested on cattle inoculated with two subcutaneous administrations 21 days apart, obtaining the stimulation of an immune response capable not only of protecting the animals from the clinical form of the disease, but also of preventing viraemia. In this context, the IZSAM could make available to interested economic operators the *Master Seed Virus of EHDV-8* and, if of use, the production protocol and the data deriving from the production of the experimental vaccine. In this regard, it is intended to carry out a public tender procedure aimed at identifying a pharmaceutical company to which grant the exclusive right of use of the Master Seed Virus for the production and marketing, in Italy and abroad, of the inactivated vaccine against EHDV-8, so as to combat the spread of the virus and protect animals from infection, allowing the safe movement of animals from restricted areas. The minimum batch required to be constantly kept in stock, for the entire period of the grant of right, is 100,000 doses. The IZSAM reserves the right, at the time of the tender

procedure, to define the best commercial solutions for the concession of the right to use the Master Seed Virus, subject to the following conditions:

- **the right to use** the Master Seed Virus, which is the subject of the grant, for the purpose of producing and marketing the vaccine, is **to be considered exclusive**; such recognition will in fact be granted to the pharmaceutical company that will be selected - on the basis of technical/economic criteria and of opportunity - at the end of the procedure;
- the equitable payment to the Institute, as intellectual owner, of a percentage of the sale price (**royalties**), in Italy and abroad, of the vaccine marketed and sold by the licensee pharmaceutical companies;
- the provision, at the expense of each contractor, of a minimum quantity of vaccine stockpile to be held for the entire duration of the grant contract (100,000 doses) as well as the obligation to ensure the availability of the vaccine, in the event of a health emergency, in the necessary quantities and within the technical production timeframe, under penalty of termination of the contractual relationship with consequent application of appropriate penalties. In the event that the minimum stockpile quantity is used up or in the event that the stockpile is disposed of due to expiry of its validity, the contractor shall be paid the amount agreed upon in the concession contract.

Art. 2

Scope of application

Expressions of interest in participating in the procedure envisaged by this notice may be submitted by any pharmaceutical company that can demonstrate, **by means of an appropriate and substantiated technical report attached**, that it is capable of developing and marketing an inactivated vaccine against EHDV-8, based on the specifications outlined in art. 1 of the notice. In the event of epidemics caused by other viruses responsible for exotic diseases, for which the IZSAM has the relevant Master Seed Virus and production protocol, this concession may be extended, by means of another concession contract, to the production and marketing of the specific vaccines to be used for immunisation prophylaxis.

At the time of submitting the application, the companies concerned must not incur the causes of exclusion referred to in Articles 94, 95, 96, 97 and 98 of Legislative Decree 36/2023. There must be no grounds for prohibition, disqualification or suspension pursuant to Article 67 of Legislative Decree No. 159 of 6 September 2011. Economic operators must not find themselves in the condition referred to in Article 53, paragraph 16-ter, of Legislative Decree No. 165 of 2001, as well as in any other situation that determines the inability to contract with the Public Administration.

They must also meet the following special requirements:

- registration with the Chamber of Commerce, Industry, Handicrafts, Agriculture, for activities consistent with the object of this negotiated procedure (pharmaceutical companies);
- any other information relevant to the evaluation of the technical and economic capacity possessed, in terms of "*company reliability*";
- Possession of the technical, structural and organisational means adequate to meet, within the set timeframe, the services and obligations envisaged for the type of activity covered by this notice.

Art. 3

Submission of Expressions of Interest

Expressions of interest must be submitted to the certified electronic mail address: protocollo@pec.izs.it, using the attached form ("*Application for Participation*") by **the peremptory deadline of 5 February 2024 (18:00 hours)**, citing in the subject line "*Expression of interest for the granting of the right to use the Master Seed Virus for the production and marketing of an inactivated vaccine against serotype 8 of the Epizootic Haemorrhagic Disease virus*". **Applications received after the above deadline will not be considered.** The request to participate must be drawn up in Italian and signed by a person legally authorised to bind the applicant; a photocopy of a valid identity document of the signatory(s) must be attached.

Art. 4

Selection of Expressions of Interest

- The expressions of interest received will be examined by a special **technical committee of experts** who, after verifying the completeness and regularity of the declarations made regarding the possession of the requirements set out in Article 2 above, will draw up a list of pharmaceutical companies admitted to produce and market the vaccine owned by the Institute;
- the Institute, pursuant to Article 71 of Presidential Decree 445/2000, reserves the right to verify the truthfulness of the data indicated in the application and to request supporting documents at any time;
- the submission of expressions of interest does not entail any commitment of actual award on the part of the Contracting Authority, the award being subject exclusively to the Community and national regulations on public contracts.

Art. 5

Further information

It should be noted that expressions of interest will be declared inadmissible if they are incomplete in essential parts; therefore any documentary or other deficiency found in this first phase will automatically result in the exclusion of the application.

This procedure constitutes a preliminary selection of candidatures, aimed at the subsequent invitation for the awarding of the contract by negotiated procedure, pursuant to Article 50 of Legislative Decree 36/2023. It is established, as of now that, the submission of an application does not generate any right or automatism of participation in other awarding procedures, whether negotiated or public. **No economic offer must be attached to the application.**

Art. 6

Protection of privacy

This notice is inspired by the principles set out in Article 36 paragraph 1 of Legislative Decree no. 36/2023. Pursuant to Legislative Decree no. 196 of 30 June 2003, as integrated by the GDPR Privacy Regulation 2016/679, the data in the possession of the Administration will be treated with respect for confidentiality, secrecy and without any other purpose than that for which they are requested. The data controller is the Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise G. Caporale.

SINGLE PROJECT RESPONSIBLE (ART. 15 of Legislative Decree 36/2023): Dr. Angelo Mincione, Head of the Assets & Logistics Department (Tel: 0861/332313; e-mail: a.mincione@izs.it).

TECHNICAL REFEREE: Dr Mauro Di Ventura or his delegate (tel. 0861.332480; e-mail: m.diventura@izs.it).

Notice sent to the OJEC for publication on 19/01/2024

(Annex 1: application form)

Document produced as an electronic original, digitally signed pursuant to the Digital Administration Code (Legislative Decree no. 82/2005 as amended)