Government of West Bengal
Office of the Dy. Director of Health Services (E&S)
Directorate of Health Services
Central Medical Stores (CMS)
141, A.J.C. Bose Road, Kolkata – 700014

Memo no:HST/4M-08-2022/EOI-AVS/2022/186 Date:-16-03-2022

Section – 1

Notice inviting Expression of Interest from drug Manufacturers for supplying State specific Anti-snake Venom Serum (AVS) prepared with venom of snake specimens collected from snakes in West Bengal

Proposal issuing Authority: Directorate of Health Services, Government of West Bengal

Contact Details: Dy. Director of Health Services (E&S), Central Medical Stores (CMS)
141, A.J.C. Bose Road, Kolkata – 700014
Tel: 033-22654417-19 Email: cmswbhealth@gmail.com

Dy. Director of Health Services (E&S), Central Medical Stores, Government of West Bengal invites Expression of Interest (EOI) from eligible and qualified manufactures for supplying Anti-snake Venom Serum (AVS) prepared with venom of snake specimens collected from snakes in West Bengal.

1. Schedule

Sl.	Particulars	Date
1.	Date of publication of Notice inviting EOI (online)	16-03-2022
2.	Proposal / Suggestion regarding T&C (if any) may be submitted to email :cmswbhealth@gmail.com	21-03-2022
3.	EOI submission starting date and time (online)	24-03-2022 from 06:00 pm.
4.	EOI submission closing date and time (online)	11-04-2022 up to 12:00 noon
5.	Date of opening of EOI Documents (online)	11-04-2022 from 12:30 pm.

2. In the event, any of the specified dates as above being declared a holiday or if the office of CMS being closed on such date, the event of the specified date will be taken up on the next working day at the same time.

3. Intending applicants may download the EOI document from the e-tender portal of Govt. of West Bengal https://www.wbtenders.gov.in and the website of Department of Health & FW, Govt. of West Bengal https://www.wbhealth.gov.in/. Any subsequent notice regarding this notice inviting EOI shall be uploaded on these websites only. Applicants are requested to check these websites regularly for this purpose.

4. The EOI should be submitted online in the website https://www.wbtenders.gov.in before scheduled date and time.

Dy. Director of Health Services (E&S)
Government of West Bengal

16/3/22

Section – 2
Terms of Reference

Background

Around 20,000 cases of snake bites and approximately 300 deaths due to snake bites are recorded in the State per year. Most of the snake bite cases in the State are reported to be from Russell's viper (locally known as Chandrabora) followed by Monocled Cobra (Naja Kauothia), Spectacle Cobra (Naja Naja) and Common Krait (locally known as Kalaach).

Presently, polyvalent Anti-snake Venom Serum (AVS) are procured by Central Medical Stores (CMS) for treatment against snake bites. However, due to unavailability of State specific AVS (manufactured with venom of snake specimens collected from West Bengal), the presently supplied AVS which are manufactured with venom collected from snake specimens from other regions are found to be less effective in treating cases of snake bites in West Bengal. Therefore, AVS manufactured with venom extracted from local snakes are recommended for targeted treatment against snake bites and to minimize adverse reactions.

In this background, CMS intends to procure AVS manufactured with venom of snake specimens collected from snakes in West Bengal for the different health facilities across the State. The goal is to reduce the number of deaths due to snake bites with state specific AVS administration.

Request for EOI

With this objective CMS invites Expression of Interest (EOI) from eligible and qualified drug manufactures for supplying Anti-snake Venom Serum (AVS) with venom of snake specimens collected from the available species of snakes in West Bengal as per description below:

Sl	Item description	Cat. No.	Unit	Tentative annual requirement	Tentative supply commencement
1.	Anti-snake Venom Serum - **Lyophilised** Reconstituted (10ml/vial), neutralizing venoms of the following snake species of West Bengal: 1. Rusell's Viper 2. Monocled Cobra (Naja Kaouthia) 3. Spectacle Cobra (Naja Naja) 4. Common Krait (Kalaach)	AVS-01	Box of 10 nos. of vials with 10 nos. of matching diluents	20,000 boxes	Within 12 to 18 months from award of supply contract
2.	Anti-snake Venom Serum – **Liquid** (10ml/vial), neutralizing venoms of the following snake species of West Bengal: 1. Rusell's Viper 2. Monocled Cobra (Naja Kaouthia 3. Spectacle Cobra (Naja Naja) 4. Common Krait (Kalaach)	AVS-02	Box of 10 nos. of vials	12,000 boxes	

The tender duration will be 3 years. L2 may be allowed to match the rate with L1 and % share of business between L1 & L2 and more if so decided by the Tender issuing Authority which may be finalized at the time of the tender.

Eligibility criteria

To be eligible, the applicants shall have to meet the following criteria and demonstrate the same in their EOI submission document:

i. The applicant should be a company registered under any act in India with authorized license to manufacture Anti-snake Venom Serum (AVS). The manufacturer should have experience of sourcing venom through venom collector(s) in India.

ii. The applicants should have agreement with a prospective / authorized venom collector for collection of venom of snake specimens collected from snakes in West Bengal. In the EOI stage, the applicant may submit an undertaking to enter into an agreement with the any prospective venom collector for sourcing venom of snake specimens collected from snakes in West Bengal for manufacturing the State specific AVS.

   a. The prospective venom collector should be responsible to comply with necessary approvals/clearances/licenses/certification from competent authority(s) for collection of venom of snake specimens from the State.

   b. The manufacturer should be responsible to obtain drug testing certificate standardized by Central Research Institute (CRI), Kasauli to confirm that the manufactured AVS are stanrdised with State specific AVS requirements and approved for treatment of snake bites in the State.

iii. The applicants should not been barred/ blacklisted by Government of India or any State Government or any of its Departments or authorities.

iv. The applicants should fulfill other technical and financial eligibility criteria to be specified subsequently during notice inviting financial bid.

Role of the Department

Department of Health and Family Welfare, Govt of West Bengal shall be providing necessary facilitation for obtaining approval(s) of the competent authority(s) of the State for collection of venom from the snakes in West Bengal.

EOI Submission

Expression of Interest (EOI) shall be submitted with the following documents:

i. Details of the applicant in format attached in **Annexure – I**.

ii. Self-attested copies of following documents:
   a. Valid registration number and date of incorporation of entity
   b. PAN / TAN and GST registration certificate
   c. Valid AVS manufacturing license from competent authority in India or abroad
   d. Agreement with venom collector(s) in any State in India
   e. Quality Certification(s) obtained related to manufacturing of AVS
   f. Agreement/ Undertaking to enter into an agreement with authorized or prospective venom collector for collection of venom from snake specimens of snakes in West Bengal
   g. The bidder should submit the information of requirement of quantity of raw venom to supply the tendered quantity of Anti Snake Venom.

h. Undertaking stating that the applicant company has not been declared ineligible or blacklisted by central/ state government or any entity controlled by it which continues as on date
i. Any other documentary evidence in support of the credentials

iii. At this EOI stage no financial bid is required to be submitted

Criteria for short listing

A committee shall assess the eligibility of the applicants and shortlist qualified manufacturers. The shortlisted manufacturers shall be eligible to participate in the subsequent bidding process.

Final Selection

Final selection shall be done from the short listed bidders through subsequent competitive bids. Once final selection is done, the selected bidder should start supply within 12 (twelve) months which may be extended up to 18 months from award of supply contract in adherence to the observance/ fulfilling all the criteria mentioned in Annexure-II and Annexure-III.

Right to accept or reject and withdraw

Dy. Director of Health Services (E&S) reserves the right to withdraw from the EOI process or any part thereof, to accept or reject any/all EOI submission(s) at any stage of the process and/or modify the process or any part thereof or to amend any terms without assigning any reasons.

Communication & Contact Information

All communications and queries shall be addressed to -

Dy. Director of Health Services (E&S)
Central Medical Stores (CMS)
141, A.J.C. Bose Road, Kolkata – 700014

Annexure – I

Details of applicant

1. General
   a) Name:
   b) Country of incorporation:
   c) Address of the corporate headquarters and its branch office(s), if any, in India:
   d) Date of incorporation and/ or commencement of business:

2. Brief profile of the applicant:
   a) Main line of business:
   b) Manufacturing unit(s):
   c) Valid manufacturing license no.:
   d) Whether AVS certified by CRI:

3. Details of individual(s) who will serve as the point of contact/ communication for the applicant:
   a) Name:
   b) Designation:
   c) Company:
   d) Address:
   e) Telephone Number:
   f) E-Mail Address:

4. Particulars of the Authorized Signatory of the applicant:
   a) Name:
   b) Designation:
   c) Address:
   d) Phone Number:
   e) Fax Number:

5. Annual requirement of raw venom for supply tendered quantity Anti snake Venom:

6. Undertaking:
   I/ we hereby declare that our organization has not been declared ineligible or blacklisted by central/ state government or any entity controlled by it which continues as on date.

   I/ we hereby also declare that there are no pending Court cases against our organization in any Court of law.

   Place:
   Date:

(Signature and name of the authorized signatory of the applicant with seal)

Annexure-II

Proposed Strength of Snake Venom Antiserum as per provision of ***New Drugs and Clinical Trials Rules, 2019***

1. Proposed Strength :

Lyophilised (Reconstituted to 10 ml per Vial & ii) Liquid 10 ml Vial should have the neutralizing potency as follows:

1. 0.60 mg of Spectacled Cobra (Naja Naja) Venom
2. 0.45 mg of Common Krait (Banaarus Caeruleus) Venom.
3. 0.60 mg of Russel's Viper (Vipera Russelli) Venom
4. 0.60 mg of Monocled Cobra (Naja Kaouthia) Venom

2. Strength as per IP :

Snake Venom Antiserum is a sterile preparation containing equine immunoglobulin fragments F (ab') 2. Freeze dried powder is reconstituted in 10ml of sterile water for injection I.P. supplied along with the vial. Each ml has power to specifically neutralize the venoms of following species of snakes:

1. 0.60 mg of dried Indian Cobra (Naja naja) venom
2. 0.45 mg of dried Common Krait (Bangarus Caeruleus) venom
3. 0.60 mg of dried Russell's Viper (Vipera Russelli) venom
4. 0.45 mg of dried Saw scaled Viper (Echis Carinatus) venom

Reconstitution of Lyophilized Antivenom
The antivenom is supplied in liquid and freeze-dried form as well. The freeze-dried powder is reconstituted with 10ml of sterile water for injection IP supplied with the pack. The whole content of freeze-dried powder dissolves into a clear colorless or pale yellow liquid.

3. **Difference in composition** :

In place of 0.45mg of dried Saw scaled Viper (Echis Carinatus) venom, new proposed inclusion 0.60mg of Monocled Cobra (Naja Kaouthia) Venom;

Annexure-II

1. As per *Rule 2 (w) of New Drugs and Clinical Trials Rules, 2019.*

"new drug" means,— *(i) a drug, including active pharmaceutical ingredient or phyto-pharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made there under, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licensing Authority with respect to its claims; or*

(ii) a drug approved by the Central Licensing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

(iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority; or

(v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

Explanation.— The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licensing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs;

As per Rule 2(w) (ii) the proposed drugs will be <u>"New Drugs</u>"

2. <u>As per Rule 74.</u> of *New Drugs and Clinical Trials Rules, 2019* (CHAPTER X IMPORT OR MANUFACTURE OF NEW DRUG FOR SALE OR FOR DISTRIBUTION) :

<u>Regulation of new drug</u>.— No person shall import or manufacture for sale or for distribution any new drug in the form of active pharmaceutical ingredient or pharmaceutical formulation, as the case may be, except in accordance with the provisions of the Act and these rules.

3. Steps to be followed as per provision laid down under *New Drugs and Clinical Trials Rules, 2019.*

i) Step 1 : Application to Central Licensing Authority as per provision of New Drugs and Clinical trial Rules (in Form CT 10, CT 12 & CT 13).

ii) **Step 2 : Permission from Central Licensing Authority as per provision of New Drugs and Clinical trial Rules (in Form CT 11, CT 14 & CT 15).**

iii) **Step 3 : Test License as per provision of Drugs and Cosmetics Rules, 1945 (Rule 89).**

iv) **Step 4 : Clinical Trial as applicable.**

v) **Step 5 : Application for permission to manufacture new drug for sale or distribution in Form CT 21.**

vi) **Step 6 : Permission for manufacture of new drug for sale or distribution in Form CT 22 & CT 23.**

vii) **Step 7 : License to manufacture a new drug for sale or for distribution under Drugs and Cosmetics Rules, 1945.**