REQUEST FOR EXPRESSION OF INTEREST supply of Plasma Derived Medicinal Product (PDMP) for clinical use, under Division of Blood Transfusion Services (BTS), division of Dept. of AIDS Control (DAC), MoHFW, GOI

(CONTRACT PLASMA FRACTIONATOR- FIRMS SELECTION)

Ref No.: DAC……

1. This notice follows the General Procurement Notice published in ……../… online.
2. The MoHFW, GoI is facilitating the availability of Plasma Derived Medicinal Product (PDMP) for clinical use, under fourth phase of National AIDS Control Project (NACP-IV). The MoHFW invites Expression of Interest (EOI) from reputed institutions/agencies/firms/global firms to produce plasma products viz. Human Albumin, Intra Venous Immunoglobulin and blood clotting factors (including FVIII & FIX) and others from human plasma provided by DAC supported govt. blood banks.
3. Approximately 50,000 L of screened recovered plasma is likely to be available for processing annually, however it is likely to scale over the years to come. GoI now invites eligible fractionators to indicate their interest in providing the plasma derived products prepared from unutilized human plasma collected from blood component separation units. The organization is required to collect plasma stock from DAC supported govt. blood bank, fractionate it, pack plasma derived proteins and distribute the finished goods appropriately into govt. sector hospitals. The drugs quality will be as per Indian pharmacopeia/ CDSCO approval in various concentrations and volumes.
4. Fractionator will be responsible for coordination of plasma stock collection, transportation, screening the samples (including Nucleic Acid Amplification testing), cGMP and total Quality as per WHO guidelines. The packed material (final products) for clinical use will be in accordance with the CDSCO requirements and current Indian Pharmacopeia. Fractionator will ensure the inspection and testing (third party) and supply chain management of the goods/supplies. The Fractionator will handle the procurement of goods and related services viz. quality assurance and supply chain management to meet clinical product requirements and DAC's requirements to achieve value for money, efficiency, transparency, probity and adherence to the current Quality Guidelines.
5. The contract will be initially for five years. This is extendable on the basis of performance and requirements.
6. The fractionator must have a substantial corporate structure and professional base in procurement, quality assurance, supply chain management; legal sanctions i.e. total operation management system and plasma fractionation. The EoI and capability will be assessed against evidence of skills and experience in providing services including, but not limited to, the above mentioned respective areas.
7. The EoI should be sent along with a Capability Statement including a profile of the lead fractionator and any collaborating organizations, covering relevant technical and geographical experience along with the financial turnover for the last five financial years. Experience in assisting organizations in procurement, quality assurance and supply chain management in general and in health sector projects may also be indicated in detail. Individual CVs are not required at this stage. Interested fractionator must also provide information indicating as to how that they are qualified to perform the services (brochures, description of similar assignments, experience in similar conditions, and availability of appropriate skills among staff, etc.). Fractionator may associate with other firms in the form of a joint venture or a sub-consultancy to enhance their qualifications. However subletting of fractionation process will not be permitted. Any EoI with inadequate information, those which do not meet the above criteria, or those received after the closing date may not be short listed. EoI should be as concise and focused as possible to give evidence of the above requirements, including the capability statement and organization profiles. The short listing will be done on the basis of the above information/documents only.
8. 'Request for Proposal' (RFP) will be issued only to shortlisted applicants only. DAC reserves the right to reject any or all the proposals without assigning any whatsoever reason. Detailed 'Expression of Interest' along with documents confirming compliance should reach the Section Officer, DAC, New Delhi 110 00 , within 21 days of publication of this notice in the newspaper (Dt: May, 2014).

9. Intellectual property rights (IPR) should be honored and managed by the fractionator. GOI will not be party to any of litigations/ concerns etc. arising from infringement of IPR.

10. For the product dossier the structure and format of the Common Technical Document (CTD), agreed within the framework of the International Conference on Harmonization (ICH, reference web site: http://www.ich.org) should be followed. Alternatively, a standard dossier in English, as prepared for the

Drug Regulatory Agency (DRA), can be submitted provided that it contains the information to the extent and detail as required by the WHO guidance documents, and is appropriately cross-referenced to the CTD format.

11. The initial submission of the documentation should contain

- A cover letter expressing interest as explained above,
- An appropriately filled out Quality Overall Summary - Product Dossier (QOS-PD) , QIS (Quality Information Summary) and BTIF (Bioequivalence Trial Information Form) or BW-BCS (Biowaiver Application Form: Biopharmaceutics Classification System) (where applicable) – i.e. the dossier according to CTD or cross-referenced to the CTD format.
- Annexure

Three copies in English are required. It should be well organized according to the CTD structure, bound and paginated, and should include a Table of Contents. No loose sheets should be provided for any information submitted.

Documents to be submitted

- In order to submit an expression of interest, the applicant must send documentation, arranged according to the information provided in the format.
- Covering letter, in English, expressing interest in participating in the DAC Prequalification Programe and confirming that the information submitted in the product dossiers is "true and correct".

Additional Information

- In case additional information is requested during the screening phase, this information should be provided as soon as possible before final submission.

Before completing this form, please re-read the 'Invitation to submit an expression of interest for contract plasma fractionator' **Full proposals must be submitted by -- -2014.** We will inform you if you have been shortlisted by **,2014.**If you have any queries relating to the tendering process or the nature of the service required please contact undersigned by email , in the first instance.

12. The undersigned officer may be contacted for any query is as follows.

13. The EoIs should be sent to the following address so as to arrive no later than ……. on ……... The shortlisted organizations shall be later invited to submit detailed proposals.

Deputy Secretary (Admin&Pros)
Department of AIDS Control
9th Floor, Chandralok Building
36, Janpath, New Delhi -110001
Tel: 011-43509964; Fax: 011-23731746
Website: www.naco.gov.in

Annexure

Response to:	**Invitation to submit expression of interest to join the list of preferred plasma fractionators.**
Lead applicant:	
Organization:	

1	Name of Organization	
2	Legal Status	
3	Address	
4	Contact Person	
5	Tel Fax Mobile E-Mail Website	
6	Organisation Vision and Objectives	
7	Primary business focus of Organization	
8	Geographical Areas of Operations (e.g. source of plasma, countries contributing plasma, countries being supplied finished products, etc.	
9	Organizational Infrastructure: • Organization size • Staff areas expertise • Facilities • Key relevant capabilities • Examples of your work • Management approach • About your organization • Specific area of expertise • Annual processing capacity for contract plasma fractionation	
10	Has your business ever had a contract terminated for default?	
11	Has your organization worked with GoI previously?	
12	Has any law enforcement agency stopped manufacturing / operation / ordered product recall (mention complete details, the reasons and how the issue was resolved) / black listed or suspended any license. If either is yes, provide details.	
10	Is there any additional information or critical factor about your organization that you feel we should be aware of which has not been requested in this document?	
11	Provide three references dealing with your services, related to contract manufacturing of plasma derived proteins.	