Government of West Bengal
Health and Family Welfare Department
Swasthya Bhawan
Salt Lake, Kolkata – 700 091.

"Call for Expression of Interest from NABL accredited drugs and pharmaceutical testing Laboratories for empanelment with the Department of Health & Family Welfare for analysis of Samples of Drugs/Pharmaceuticals and Chemicals procured by the Department".

1. The Department of Health and Family Welfare, Government of West Bengal procures a large number of drugs and chemicals for the supply and consumption of patients admitted in its hospitals. The Department has the mandate to supply quality drugs to all its patients.
2. The Department, through the Central Medical Stores, centrally selects through open tendering, the vendors for the supply of the drugs and medicines. The decentralized consuming units procure the drugs and chemicals directly from these selected vendors. Some drugs are also procured through local tenders by some of the consuming units.
3. Prior to the use of the drugs on patients, their quality testing is recommended from an independent laboratory.
4. The Department wishes to empanel NABL accredited drugs and pharmaceutical testing Laboratories for carrying out the independent testing of the drugs procured from the approved vendors by the consuming units.
5. The detailed EOI documents indicating the scope of work, qualifying requirements, forms and procedure for submission of proposal for EOI can be downloaded from Department's website at www.wbhealth.gov.in. The proposal may be submitted to Deputy Director of Health Services". (Equipment and Stores), Central Medical Stores, Kolkata – 700 014 on or before 19.08.2011 by 2.00 P.M. The Department of Health & Family Welfare reserves the right to accept or reject any or all the offers at any stage of the process without assigning any reasons thereof and no claim/dispute on this aspect shall be entertained.

INSTRUCTIONS TO THE APPLICANT

Background

Over the years, there has been a considerable increase in the procurement of drugs by the Department. These drugs are being supplied to patients attending the OPDs and IPDs of the Health Centres and Hospitals run by the Department along with use for Public Health Programmes. Considering the need for ensuring the supply of drugs conforming to set standards of qualify, the Department promotes the testing of the quality of the supplied drugs prior to its use on patients.

With the amendment of the Drugs and Cosmetics Act the GLP compliant pharmaceutical testing is mandatory for every pharmaceutical Company with effect from September, 2010. The Department therefore makes it a pre-requisite for its testing to be performed by GLP Compliant or NABL accredited laboratories for smooth and efficient functioning of the supply chain system.

2. Scope of work

The broad Scope of work is at **Annexure I.**

3. Applicant Status

The applicant should be a single entity and qualify the eligibility criteria.

The Laboratory should have a minimum of three years experience in analysis of drugs/chemicals and pharmaceuticals items. Documentary evidence and details are to be provided to support the claims for experience.

The laboratory should be NABL accredited.

A minimum annual turnover of Rs. 50 lakhs during the last three years.

Should have technically qualified and well experienced strong in-house resource base.

Should have sufficient in-house infrastructure and laboratory equipments to carry out the tests prescribed in the Drugs and Cosmetics Act.

The applicant should furnish an undertaking to the effect that the laboratory has not been black-listed in India or abroad.

4. Authorized Signatory

The ‘ Applicant’ mentioned in the EOI document shall mean the one who has signed the EOI documents forms. The applicant should be the duly Authorized Representative, for which a certificate of authority will be submitted. All certificates and documents (including any clarifications sought and any subsequent correspondence) received hereby, shall, as far as possible, be furnished and signed by the Authorized Representative.

5**. Availability of EOI**

The detailed EOI document indicating the scope of work, qualifying requirements, forms and procedure for submission of proposal for EOI can be downloaded from Department's website at www.wbhealth. Gov. in.

6. **Submission of Proposal**

The proposal complete in all respects shall be submitted in sealed envelope superscribed as "EOI for Empanelment for analysis of Drugs and Pharmaceuticals may be submitted to Deputy Director of Health Services (Equipment and Stores) Central Medical Stores, Kolkata – 700 014 on or before 19.08.2011 by 2.00 P.M.

The Department of Health & Family Welfare reserves the right to accept or reject any or all the offers at any stage of the process without assigning any reasons thereof and no claim/dispute on this aspect shall be entertained.

7. **Documents to accompany EOI**

7.1 The applications shall be complete with the following documents :

- Expression of Interest in Form – I.
- Details of experience in analysis of drugs/chemicals and pharmaceuticals items (at least for the last 3 years)
- Details of areas like Safety, Efficacy, Contaminants, Chemical, Microbiological, etc. and other parameters for which lab is NABL accredited and copy of valid NABL. Certificate.

  List of drugs and pharmaceuticals which can be tested in the laboratory for the parameters mentioned under Drugs and Cosmetic Act.
  Rate to be charged for the testing of each sample.

- Location map of the laboratory.
- Details of Financial status of the applicant in Form – II.
- Declaration in non judicial stamp paper regarding exclusion criteria strictly in the format as given at Annexure – III.
- Details of staff working in the laboratory along with Name, Educational qualification, experience and trainings etc.
- Details regarding Building, structure and layout of the building.
- Complete list of equipments available in the laboratory.
- Month-wise details of number of drugs/pharmaceuticals items tested during the last 2 years.
- Copy of other statutory approval documents like Registration Certificate/Trade Licence, Clearance from Pollution Control Board, IT Return (last 3 years) etc to carry out the activity in the area.
- Any other information required in support to the scope of work.

7.2 Every sheet and all forms complete in all respects shall be signed by the person/persons duly authorized to sign on behalf of the applicants with affixing the applicant's rubber stamp. The Power (s) of Attorney supporting/authorizing of the signatory shall be enclosed with the offer. Any/all corrections made in the proposal shall be duly authenticated by the signature of the Authorized Signatory.

8. **Amendment to EOI**

At any time prior to the last date for receipt of proposals, the Department of Heath & Family Welfare, may for any reason, whether at its own initiative or in response to a clarification requested by a prospective applicant, modify the EOI document by an amendment. In order to provide prospective applicants, reasonable time in which to take the amendment into account in preparing their proposals, the Department may, at its discretion, extend the last date for the receipt of proposals and/or make other changes in the requirements set out in the EOI.

All legal dispute which may occur under this scheme will be under the jurisdiction of Hon'ble High Court, Kolkata, West Bengal.

9. Evaluation.

The procedure of evaluation of the proposals is indicated at Annexure – II.

10. **Time Period**

The services of the empanelled laboratory will be engaged purely on ad-hoc basis and as per work requirement basis and could be discontinued by the Department without assigning any reason thereof. However, the empanelled laboratory should ensure the timely renewal of the NABL accreditation failing of which its empanelment could be discontinued.

11. **Technical Presentation**

Once the proposals are evaluated, if required, the short listed laboratories may be asked to make a presentation in the Department at a short notice. Further, a team of Department officials may also carry out physical inspection of the laboratory, wherever required to verify the facts.

12. **Rejection of EOI**

The application is liable to be rejected if

a) the application is not covered in proper sealed cover with superscription as indicated in para 6 above.
b) not in prescribed form and not containing all required details.
c) not properly signed.
d) received after the expiry of due date and time.
e) offer is received by fax, telegram or e-mail and not followed /supported by the prescribed documents within the stipulated date.

13. Disclaimer

13.1. The Department of Health & Family Welfare shall not be responsible for any late receipt for any reasons whatsoever. The applications received late will not be considered.

13.2. The Department of Health & Family Welfare reserves the right.

To reject any / all applications without assigning any reasons thereof.

To relax or waive any of the conditions stipulated in the document as deemed necessary in the best interest of the Department of Health & Family Welfare without assigning any reasons thereof.

To include any other item in the Scope of work at any time after consultation with applicants or otherwise.

To determine the number of laboratories to be empanelled taking into account the existing/likely workload.

To determine the proportion in which samples will be distributed among laboratories if more than one laboratory is empanelled.

PRE-QUALIFICATION CRITERIA

1. **Preliminary examination for the applications**

1.1 The Department of Health & Family Welfare shall examine the applications to determine whether they are complete, whether the documents have been signed as indicated in this document, whether all Forms as asked have been filled in properly, whether applications are generally in order and all information as indicated under various clauses have been furnished.

1.2 The Department of Health & Family Welfare reserves the right to waive minor deviations in the proposal application if they do not materially affect the capability of the applicant to perform the assignment.

1.3 Prior to detailed evaluation formalities, the Department of Health & Family Welfare shall determine the substantial responsiveness of each application to the invitation documents. A substantially responsive proposal is one which conforms to all the terms and conditions of the invitation document without any material deviation. A material deviation is one which limits in any way responsibilities and liabilities of the applicant as required in this document. The Department of Health & Family Welfare may waive any minor infirmity or non-conformity in an application which does not constitute material deviation. Non-responsiveness shall run the risk of rejection.

1.4 The evaluation shall be carried out on the basis of data available in the application documents received from the agency in the first instance. No Account will be taken of any further documents or clarifications or any such additional information furnished subsequently by the applicant. However, the Department of Health & Family Welfare reserves the right to call for such clarifications confined in scope to the contents of the application, should such a clarification become necessary for proper judgment in evaluation.

2. **Eligibility**

The proposals will be screened on the basis of the following essential eligibility criteria.

The applicant laboratory should have a minimum of three years experience in analysis of drugs/chemicals and Pharmaceutical items. Documentary evidence and details to be provided to support the experience.

The laboratory should be NABL accredited.

A minimum annual turnover of Rs.50 lakhs during the last three years.

Should have technically qualified and well – experienced strong in house resource base .

Should have sufficient in house infrastructure and laboratory equipment to carry out the tests as prescribed in the Drugs and Cosmetics Act.

3. **Criteria for exclusion from participation.**

Concerned Laboratories shall be excluded from participation in a procurement procedure if.

1. They are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matter, or are in any analogous situation arising from a similar procedure provided for in national legistation or regulations.

2. They have been convicted for an offence concerning their professional conduct by judgment which has the force of res judicata.

3. They have been guilty of grave professional misconduct proven by any means which the contracting authority can justify.

4. They have not fulfilled obligations in respect of payment of social security contribution or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the Republic of India.

5. They have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the communities financial interests.

6. Following another procurement procedure or grant award procedure financed by the community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

Annexure – 1

SCOPE OF WORK

The decentralized consuming units procure drugs, directly from the vendors selected through open tender by the Central Medical Stores. The consuming units then send the randomly selected samples from the supplied drugs to an independent laboratory for quality testing (non statutory). On receipt of the report that the supplied drug conforms to the required quality, the drugs is allowed to be distributed amongst patients and payment a made to the supplying vendor.

The interested NABL accredited Drug and pharmaceutical testing laboratories before submitting their proposal should satisfy themselves on the following points.

- Fulfillment of the eligibility criteria laid down under EOI.
- The services of the empanelled laboratory will be engaged purely on ad-hoc basis and as per work requirement basis and could be discontinued by the Department of Health & Family Welfare without assigning any reasons thereof . However, the empanelled laboratory should ensure the timely renewal of the NABL, accreditation failing of which its empanelment could be discontinued.
- The Laboratory will carry out the non - statutory analysis of samples of drugs and pharmaceuticals received from the Authorized Officer of the procuring units as per test procedures provided under Drugs & Cosmetic Act or as specified by Department of Health & Family Welfare from time to time. This shall include but not be limited to tests for the identity, purity, quality, strength and stability of the drugs and pharmaceuticals.
- The testing fee payable will be paid directly by the test requisitioning officer on submission of the bills.
  The samples will be packed and sent to the labs by the Authorized Officer of the procuring units and the cost for this will be bone by the procuring unit.
  The fees payable per test shall be at the rate agreed soon be upon between the Department and the testing laboratory.

* The Laboratory will send its report only to Authorized Officer of the procuring units within two weeks of receiving the samples and as per agreed procedure.
  The results may be sent by electronic means or uploaded on a secure website.
  The laboratory will not disclose any information including test results regarding the samples received from the procuring units, to any third party, without prior permission from Authorized Officer of the procuring units or the department of Health & Family Welfare.
* The Laboratory will be liable for sharing data related to testing of samples with Authorized Officer of the procuring units / or the Department for any further scientific analysis as and when required.

The details mentioned above are indicative only. Any other item not specifically indicated above, but required for the quality testing of the drugs and chemicals shall be deemed to have been incorporated within the scope

of the work. Omission of specific reference to any of the activities in the scope of work shall not relieve the laboratory, of its responsibility.

Annexure – II

EVALUATION PROCEDURE

- The proposals will be scrutinized on the basis of the eligibility criteria. Thereafter the short-listed labs may be required to make presentations and or written submissions to an Evaluation Committee for which they will be given 5 days notice. Along with the rates for testing of drugs, the capability of undertaking the tests, location of the lab within the state and the time taken for submission of reports shall be considered for the evaluation of the labs.

- The labs in descending order of merit so evaluated will be empanelled for analysis of samples of drugs and chemicals depending on their capability in performing the quality tests. The number of samples to be tested and the decentralized units from which samples shall be sent to a particular lab for testing shall be decided by the Evaluation Committee. The empanelled labs may be asked for taking the work of analysis as and when required.

Annexure III

APPLICANT'S DECLARATION REGARDING THE EXCLUSION CRITERIA

The D.D.H.S. (Equipment and Stores)
Dept. of Health & Family Welfare
Government of West Bengal
Central Medical Stores
141, A.J.C. Bose Road, Kolkata – 700 014.

Ref : Call for Expressions of Interest from NABL, accredited Drug and Pharmaceutical testing Laboratories for empanelment with Department of Health & Family Welfare for the non statutory analysis of drugs procured from vendors.

In response to your call for expression of interest. I/We hereby declare that I/We.

am./are not in any of the situations excluding we/us from participation contracts (and will produce the corresponding certificates if so requested)

agree to abide by the highest ethical standards in the profession and, in particular, have no potential conflict of interest.

will inform the Authority immediately if there is any change in the above circumstances at any stage during the tender procedure or during the implementation of the project.

fully recognize and accept that any inaccurate or incomplete information deliberately provided in this tender may result in my/our exclusion from this or other contracts funded by the Authority.

(Signature of the applicant or of authorized representation
along with Office seal)

FORM-1

EOI Letter Proforma

To
The D.D.H.S. (Equipment and Stores)
Dept. of Health & Family Welfare
Government of West Bengal
Central Medical Stores
141, A.J.C. Bose Road, Kolkata – 700 014.

Ref : Call for Expressions of Interest from NABL accredited/GLP Compliant Drug/Chemical and Pharmaceutical testing Laboratories for empanelment with Department of Health & Family Welfare for the non statutory analysis of drugs.

Sir,

The undersigned having read and examined in detail all the EOI documents pertaining to the proposals for Non Statutory Drug Testing, do hereby express the interest to do the work as specified in the scope of work.

2. Details

Sl. No.	Criteria	Particulars
1.	Name of the Laboratory	
2.	Type of organisation	Ownership/Partnership/Pvt. Limited Company/ Public Limited.
3.	Address (in full) PIN Code Telephone No. Fax Email id Website (if available)	
4.	Date of Establishment	
5.	Whether part of a pharmaceutical/drug manufacturing unit	No/Yes – Details of association
6.	Whether testing samples for pharmaceutical/drug manufacturing unit.	No/Yes Details of the pharmaceutical/ drug manufacturing unit/s
7.	Name of authorized person with designation and contact number	
8.	NABL accreditation Number and validity date : (Please enclose valid certificate)	
9.	Capability of Maximum number of samples to be tested daily	

10.	Whether capable of despatch of reports within 14 days from receipt of samples	
Sl. No.	**Criteria**	**Particulars**
11.	Sample Collection Points available in West Bengal (mention places presently available or proposed set up if offered empanelment)	
12.	Maximum number of samples that can be tested per month if empanelled	
13.	Minimum number of samples expected for testing per month if empanelled.	
14.	Whether performing non statutory testing of drugs/pharmaceuticals for other state governments/central government/PSUs.	No/Yes Details
15.	List of drugs/chemical/pharmaceuticals for which testing capability is available is enclosed in Form III	Yes/No
16.	Rate to be charged for the testing of each sample	
17.	Any other details wish to be submitted.	

3. Documents forming part of EOI
We have enclosed the followings:

4. I/We hereby declare that my/our EOI is make in good faith and the information contained is true and correct to the best of my/our knowledge and belief.

Thanking you,

Yours faithfully,

(Signature of the Applicant)

Name

Designation :

Seal :

Date :

Place

FORM-II

FINANCIAL STATUS OF THE APPLICANT

Fill in the blanks for each of the last three fiscal years, duly certified by Chartered or Public Account or Chamber of Commerce or Banks.

	2008-2009	2009-2010	2010-2011
1. Share Capital (INR)			
2. Paid up Capital (INR)			
3. Free Reserve (Gross) (INR)			
4. Unallocated Balance Surplus (INR)			
5. Expenses not written-off (INR)			
6. Total assets (INR)			
7. Total liabilities (INR)			
8. Current credit resources (INR)			
9. Contingent Liability (INR) (give in details)			
10. Total profit before tax (INR)			
11. Turnover from contracting during the financial year (INR)			
12. Bank References and address			

(Place & Date) (Name & Signature)

Form – III

List of drugs/chemicals/pharmaceuticals for which testing capability available.

Sl.No.	Name of the Drug/Chemical/ Pharmaceutical	Packing (Tablet/ capsule/liquid/ infusion/ powder/ granules/etc)	Testing parameters available (identity, purity, quality, strength, stability etc.) as per Drugs & Cosmetic Act.	Maximum time for delivery of test results	Rate for testing of the sample (if single uniform rate not applicable)
1.					
2.					
3.					