Prequalification Documents for Procurement of Drugs by Procuring Agencies in Sindh

Sindh Public Procurement Regulatory Authority, Government of Sindh

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Preface

Prequalification is a formal procedure for the screening of potential bidders prior to invitation to bid. Prequalification is not a device intended to reduce competition, but a process to ensure that invitations to bid are extended only to those who have adequate capabilities and resources.

The prequalification process may be of benefit to both bidders and Procuring Agencies alike, in that:

(a) the process enables prospective bidders, who may be insufficiently qualified on their own, to avoid the expense of bidding, or to form a joint venture that may give a better chance of success;

(b) with prequalification, well-qualified firms will price their bids with the knowledge that they are competing against other similarly qualified bidders;

(c) it reduces the amount of work and time involved by purchasers in evaluating bids from unqualified suppliers; and

(d) it significantly reduces, if not eliminates, problems associated with low-priced bids submitted by bidders of doubtful capability.

The scope of the contract and a clear statement of the requirements for qualification are sent to those who responded to the invitation.

Contents of Pre qualification Documents

Instruction to Applicant:

1. Eligibility:

All interested bidders, national or international, firms and individuals, shall be allowed to bid for any project where international competitive bidding is adopted;

(i) Competition may be restricted only in the following cases;
   (a) as a matter of law or official regulations, commercial relations are prohibited with the bidder's country by the federal government; or
   (b) a firm is blacklisted or debarred by the procuring agency, and the matter has been reported to the Authority, subject to Rule 35.

(ii) Government owned enterprises or institutions may participate only if they can establish that they are;
   (a) legally and financially autonomous; and
   (b) operate under commercial law;

Provided that where government owned universities or research centers in the country are of a unique and exceptional nature, and their participation is critical to project implementation, they may be allowed to participate; and

(iii) For the purposes of Part II of the Rules, bidders shall include all those contractors or suppliers and providers of services related thereto or consultants that are registered or incorporated in Pakistan, irrespective of the nationality of their owners and of their professional staff;

2. Source of Funds:

Procuring Agency shall reveal the nature of funds, regular budget, grant, etc.

3. Language:

(i) All communications and documentation related to procurements of Government shall be in English, Urdu or Sindhi:

Provided that notice inviting tenders, notices for pre-qualifications and request for expressions of interest shall be issued in aforementioned three languages.

(ii) In case of any dispute reference shall be made to the original documentation retained on record and decision shall be made in accordance with such original documentation.

4. Cost of Application:

Applicant shall bear all costs associated with preparation and submission of its application and the Procuring Agency shall in no case be responsible for those costs, regardless of the conduct or out come of the prequalification process.

5. Documents Establishing Qualification of the applicant:

To establish its qualification to perform the contract, the applicant shall provide the information requested in the respective annexure.

a. Manufacturer shall only provide annexure "A"
b. Whole seller/Authorized Distributors shall provide their business information in annexure "B" as well as information of their Principal in annexure "A".

6. Signing of the Application and Number of Copies:

Application shall be signed by the person duly authorized by the applicant on original (Procuring Agency can obtain copies as required by them)

Application submitted by existing or intending joint venture shall be signed by the all partners, stating that all partners shall be jointly and severally liable.

7. Sealing and marking of applications;

Applicant shall enclose original and required copies in sealed envelope which shall;

a. bear name and address of the applicant
b. bear specific identification of this prequalification process as mentioned in the Notice for Prequalification or in the instructions.
c. If the envelope is not sealed and marked as required the PA will assume no responsibility for misplacement of application.

8. Dead line for submission of application:

Application shall be received by the Procuring Agency at the address not later than date mentioned in the Notice for prequalification or in the instructions to applicant.

9. Late Application:

Procuring Agency reserves the right to accept or reject the late application.

10. Opening of application:

Procuring Agency shall announce the opening date of application and shall record the minutes of opening meeting.

Qualification Criteria

Required average annual turnover
The amount of Annual Sales Value required should be *at least five times* the estimated contract value.]

Required production capacity
[The Annual Production required should be at least *three times the quantities* specified under the contract.]

Required number of similar contracts completed
[The range should be not *less than three and not more than five*, depending on the size and complexity of the subject contract within the last five years.]

Required Quality Assurance
[In the case of an applicant who manufactures the goods, the applicant should provide (i) a valid license issued by the regulatory authority in the country of manufacture to supply the goods and (ii) evidence that it has received a satisfactory GMP inspection certificate in line with the Drug Act. and has demonstrated compliance with the quality standards during the past two years.

In the case of an applicant who does not manufacture the goods, the applicant should provide evidence of being duly authorized by the manufacturer, meeting the criteria under this document to supply the goods

Required number of years of manufacturing experience
[The applicant should have manufactured and marketed the specific goods subject of bidding for at *least two years*, and for similar goods *for at least five years*. Applicants wishing to prequalify for products that they do not manufacture must submit the information corresponding to the primary manufacturer of the goods who shall comply with these manufacturing requirements.]

Required experience on packaging, distribution, and transportation
[The applicant should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of pharmaceuticals, under logistical and climatic conditions.

Scope of Contract:

Brief Description (Generic name) of drugs/Hospital supplies
Estimated Quantity and place of requirement.
Delivery Time/ Schedule of Requirement
Method of Procurement
Mode of Payment.

Annexure "A"

Manufacturer's Qualification

I. Company Profile.

1. Name of company : _____

Year established : _____

Form of company : [ ] Individual

[ ] Partnership

[ ] Corporation

[ ] Other (specify)

Legal status : _____

Trade registers number : _____

NTN & Sales Tax number (If applicable):

_____

License Number : _____

(attach copy)

2. Address : _____

Country (For ICB) :

_____

Telephone : _____ Telefax: _____

Telex : _____ E-mail: _____

Please attach the company organizational chart

II. Product Information

1. Total number of drugs manufactured: _____
   (Provide list of manufactured products)
2. Are all manufacturing operations (processing, packaging, labelling) carried out internally?

[ ] YES [ ] NO

If "No," attach a list of pharmaceuticals and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

Product	Manufacturer	Address
1)		
2)		
3)		

3. Provide details if pharmaceutical products and/or raw materials manufactured by your company are exported to other countries

Pharmaceutical product/raw material	Country	Generic Name	Trade Name
1)			
2)			
3)			

4. Does your company have Good Manufacturing Practices certification?
   [ ] Yes (attach a copy of the GMP certificate if any)
   Certified by: _____
   [ ] No

5. Has your company been inspected by other governments, organizations or clients?

Inspected by	Year	Outcome

6. Have products manufactured by your company been exported to other countries?
   [ ] YES [ ] NO
   If "Yes", supply details:
   [ ] Country or (countries): _____
   [ ] By public procurement organization
   [ ] By private Exporter(s)

7. A. Date, number and expiry date of manufacturing license or permit.
   Date : _____
   Number : _____
   Expiry Date : _____

   Manufacturer : _____
   Address : _____

   B. Are the products in the product list produced routinely by the company?
   [ ] YES [ ] NO

   C. Or only occasionally on request?
   [ ] YES [ ] NO

   D. Number of specialized personnel involved in the manufacture of pharmaceuticals (exclude administrative personnel).
   Pharmacists : _____
   Chemists : _____
   Others : _____

8. A. Are the products manufactured by your company, manufactured under contract by other companies or repackaged?

[ ] Manufactured

[ ] Repackaged

[ ] Manufactured under contract

B. If any products are manufactured under contract, attach a list of such products with the name and address of the manufacturer for each product.

Product	Manufacturer	Address
1)		
2)		
3)		

C. If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product.

Product	Manufacturer	Address
1)		
2)		
3)		

III. QUALITY INFORMATION

1. Do you maintain your own quality control laboratory?

[ ] YES [ ] NO

2. Number of specialized personnel working in your quality control laboratory (excluding administrative personnel).

Pharmacists : _____

Chemists : _____

Others : _____

3. List names and addresses of quality control laboratories used in addition to or in lieu of your own laboratory.

_____

_____

4. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?

[ ] YES [ ] NO [ ] Certificate of Analysis

5. Quality standards

[ ] BP Edition [ ] USP Edition [ ] EP Edition [ ] IP Edition [ ] Other:

Are all recommended tests carried out?

[ ] YES [ ] NO

If "No," state reason why not:

_____

_____

6. Are control samples of each batch retained?

[ ] YES [ ] NO

7. Do you have written cleaning procedures?

[ ] YES [ ] NO

8. Do you record the training of your employees according to a training programme?

[ ] YES [ ] NO

9. Do you have a written recall procedure?

[ ] YES [ ] NO

10. Do you have a written procedure on how to deal with complaints?

[ ] YES [ ] NO

11. Name and title of the authorized person (s) responsible for batch release:

Name:_____

Title: _____

Experience in pharmaceuticals: _____ years

12. Name and qualification of the head of the Quality Control department:

Name: _____

Qualification: _____

Experience in pharmaceuticals:_____ years

13. Indicate if you perform quality tests conducted routinely:

[ ] active starting materials

[ ] non-active starting materials

[ ] packaging materials

[ ] intermediate products

[ ] bulk products

[ ] finished products

14. Are all quality control tests performed internally?

[ ] YES [ ] NO

If "No," list tests performed by external laboratories:

Tests	Laboratories	Address

15. Explain process of approving sources for starting materials and describe basis for approving specifications of starting materials.

_____

_____

_____

_____

16. Do you conduct tests on each container of the active starting material?

[ ] YES [ ] NO

If not, explain your way of sampling: _____

_____

17. Do you test each container of non-active starting materials?

[ ] YES [ ] NO

If “No,” describe method of sampling: _____

_____

18. Are you willing to reveal the sources of starting material? (Information will be deemed confidential)

[ ] YES [ ] NO

19. Are stability tests routinely conducted for every product?

[ ] YES c [ ] NO

If “No,” state reason why not: _____

_____

20. For each batch, check the procedures that are routinely done:

[ ] Batch numbers and control numbers of each component
[ ] Weighed quantities double checked and signed off for each component
[ ] Acceptance record of each component
[ ] Date and time of each stage of production
[ ] Identification of equipment used
[ ] Name of persons in charge at each stage
[ ] In-process control results
[ ] Environment control results
[ ] Remarks on production incidents
[ ] Comments on not following the master formula
[ ] Yield and reconciliation
[ ] Packaging material batch numbers
[ ] Line clearance sign off
[ ] Result of QC of end product
[ ] Inspection checks and test results, dates and signatures of inspecting

21. Explain procedure for releasing batches of finished products:

c _____
c _____
c _____

22. Do you keep samples of each batch?

[ ] YES [ ] NO

Indicate how long do you keep the samples:_____ years

23. Are these kept in the original containers?

[ ] YES [ ] NO

24. Attach a detailed account of the current quality assurance system in your company.

A Quality Assurance manual or handbook may be submitted.

25. Do you carry out inspections or quality audits of your own suppliers?

[ ] YES [ ] NO

If "Yes," describe audits in detail:

_____

_____

_____

_____

26. Describe your storage facilities:

Indicate % of annual turnover:

Pharmaceutical formulations : _____%

Bulk drugs : _____ %

Medical Supplies : _____ %

[ ] Products sold Public Sector

[ ] Sold only to the local market

[ ] Both

* 27. Annual sales turnover in the previous three years. Mention Private Sector and Public Sector sales separately (in Pak Rupees)

(In Million)

Annual turnover	Open market sales	Public Sector Sale	Year

* PA may fix minimum threshold in light of Guidance mention in qualification criteria.

Annexure "B"

Supplier's Qualification

I. Company Profile.

1. Name of company : _____

Year established : _____

Form of company : [ ] Individual
[ ] Partnership
[ ] Corporation
[ ] Other (specify)

Legal status : _____

Trade registers number : _____

NTN & Sales Tax number (If applicable):

_____

License Number : _____
(attach copy)

2. Address : _____

Country (For ICB) :

_____

Telephone : _____ Telefax: _____

Telex : _____ E-mail: _____

Please attach the company organizational chart

3. Type of activity carried out by the company(tick the appropriate catogry/ies)

[ ]	Manufacturer	[ ]	Wholesaler
[ ]	Branded products	[ ]	Branded products
[ ]	Generic products	[ ]	Generic products
[ ]	Medical supplies	[ ]	Medical supplies
[ ]	Laboratory reagents	[ ]	Laboratory reagents
[ ]	Other products (specify below)	[ ]	Other products (specify below)
	_____		_____

*Indicate % of annual turnover:

Pharmaceutical formulations : _____%

Bulk drugs : _____ %

Medical Supplies : _____ %

[ ] Products sold Public Sector

[ ] Sold only to the local market

[ ] Both

4. Names and addresses of international pharmaceutical companies, parent companies and/or subsidiaries and associated companies with whom there is collaboration or joint venture, if any:

Company	Address

5. Employees:

Total:	
Management:	
R&D	
Sales	
Administrative	
Others (specify):	

6. Capital value of the company (specify currency)

(a) Authorized capital: _____

(b) Paid up capital: _____

(c) Administration: _____

* 7. Annual sales turnover in the previous three years. Mention Private Sector and Public Sector sales separately (in Pak Rupees)

(In Million)

Annual turnover	Open market sales	Public Sector Sale	Year

* PA may fix minimum threshold in light of Guidance mention in qualification criteria.