

Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies



World Health Organization
Regional Office for the Western Pacific
Manila, Philippines
2002

WHO Library Cataloguing in Publication Data

Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies

1. Pharmaceutical preparations - supply and distribution
2. Guidelines.

ISBN 92 9061 014 X

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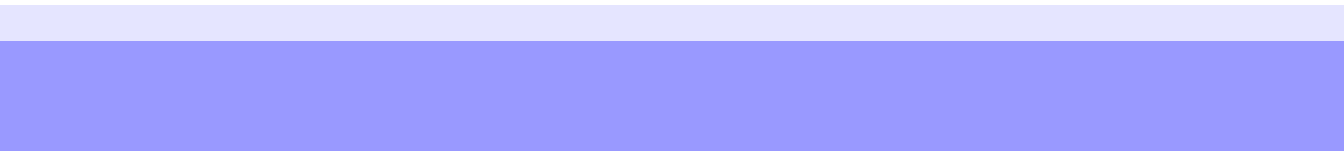
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Foreword

Procurement is an important step for efficient drug management and supply, and has become a routine procedure in the existing drug management system in many countries. An effective procurement process ensures the availability of the right drugs in the right quantities, at reasonable prices, and at recognizable standards of quality. Problems can often be encountered if procurement is carried out without such a systematic process, for instance the needed medicines are out of stock, overstocks and wastage of resources, and purchase of low quality products.

Given the impact of procurement activities on the operation and effectiveness of health services, it is essential that these activities be performed by trained staff using sound procedures. Effective procurement is a collaborative process between the procurement office, with needs of trained staff and an appropriate management system, and committees which make decisions as to which drugs to buy, in what quantities and from which suppliers.

This booklet is especially intended for countries with small procurement agencies. It is intended to provide practical guidelines for the procurement process. Pre-qualification of suppliers receives special attention as a means of ensuring the purchase of products of good quality. An effective procurement process will make an important contribution to the establishment of a reliable and good quality health service.

WHO's work in essential drugs is designed to support Member States to ensure the accessibility of good quality essential medicines that are affordable and are rationally used. I hope this booklet will help the users to improve the efficiency of their drug supply systems through effective procurement.

Shigeru Omi, M.D., Ph.D
Regional Director
WHO Regional Office for the Western Pacific

Summary

As a substantial part of the health budget in many countries is used to purchase pharmaceutical products, procurement of drugs is obviously a crucial function. Various types of tender mechanisms as well as direct procurement are described and discussed. A good way for small procurement agencies to ensure product quality is to conduct restricted tenders to which only prequalified suppliers are invited. The prequalification and tender procedures are described. Model questionnaires for prequalification of suppliers, a model tender invitation and an inspection checklist for drug receipts are enclosed. These can be modified to suit local conditions and legal requirements.

1. Objectives of this booklet

As good publications on the procurement of pharmaceutical products already exist and provide the partial basis of this booklet (1, 2), the purpose of this document is to provide countries with practical and simple guidelines in the procurement of pharmaceutical products. It includes the basic requirements that ensure quality, safety and efficacy of imported pharmaceutical products especially for countries with no local pharmaceutical industry and no drug registration system. For more in-depth information on procurement, the reader may refer to the above-mentioned references.

While this publication does not cover all aspects of the drug management cycle, it describes the core principles of procurement and various methods of tendering for drug procurement. It discusses the advantages and disadvantages of these methods as well as the tender process itself. The prequalification of suppliers is also discussed.

Selection of drugs and quantification of drug needs are not covered in this document. For these two issues, the reader may refer to *The Use of Essential Drugs, WHO Technical Report Series No. 895, Geneva 2000* (4) and *Estimating Drug Requirements, A Practical Manual, WHO/DAP/88.2* (5). Procurement of drugs by the public sector normally includes drugs on the essential drugs list.

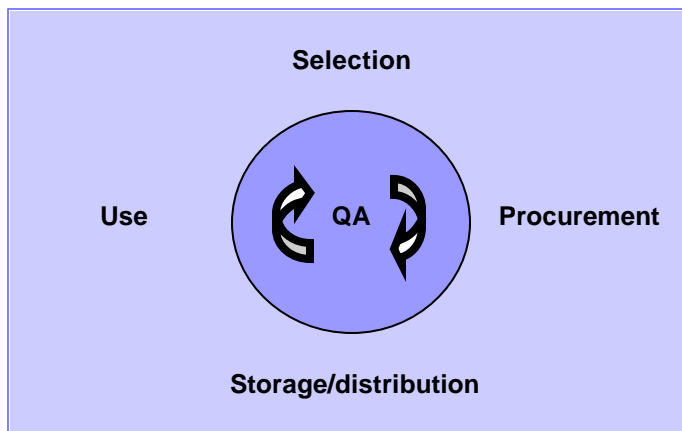
The Attachments are ready-to-use documents that can be modified and extended to meet local requirements. They are suitable for relatively small procurement agencies with limited capacity. More elaborate questionnaires and tender invitation/contracts can be developed in line with the development of the drug regulatory system and the capacity of the procurement agency.

2. Introduction

Procurement is only one of several elements of the drug management cycle, but can be the function that takes up much of the time of pharmacists in small countries.

The Drug Management Cycle

The supply and management of drugs is a continuous process that is illustrated below:



Selection of drugs Selection of drugs for procurement by the public sector should be based on the national essential drugs list. The methodology for selection of essential drugs can be found in *The Use of Essential drugs, WHO Technical Report Series No. 895, Geneva 2000 (4)*.

Quantification of drug needs To avoid wastage through over-stocking or stock-outs of pharmaceuticals, a reliable system of quantification of drug needs is required. *Estimating Drug Requirements, A Practical Manual, WHO/DAP/88.2 (5)* is a useful guide for quantification of needs.

Procurement Procurement is being done through various methods such as tenders, competitive negotiations or direct procurement. The aim is to provide quality drugs at the lowest possible cost when needed.

**Storage/
distribution**

Correct storage of drugs to avoid deterioration and waste is essential, as is a proper stock inventory control system that can be computerized. Drugs should be available when needed. A system that enables coordination between drug needs and supply will ensure adequate distribution of drugs from the central source to the health facilities.

Use

In addition to being available in the required quantities when needed, drugs have to be used rationally. If not, drugs can be useless and even harmful. In addition to serious health consequences, irrational drug use leads to waste, thus increasing the cost of running a drug supply system. The adoption of the essential drugs concept, use of standard treatment guidelines, monitoring of drug use and interventions for improvements are all important tools that should be actively used.

**Monitoring and
improving the
Drug Management
Cycle**

The Drug Management Cycle is a continuous process that needs to be monitored with the aim of improving all its elements.

**Quality assurance
in the Drug
Management Cycle**

In each of the above-mentioned steps of the cycle, quality assurance measures should be included. The following issues should be addressed:

- Selection of well documented quality products from reliable manufacturers.
- Certificate of Analysis of delivered products.
- Use of the WHO certification scheme,
- Quality assessment of drugs upon receipt.
- Inspection of shipments.
- Laboratory testing.
- Appropriate storage and transport
- Appropriate dispensing and use
- Monitoring of product quality/
reporting system

The pharmaceutical staff usually performs a variety of tasks in smaller countries while bigger countries require several departments to handle the following duties:

- Selection of drugs
- Management of the essential drugs programme
- Estimation of drug needs
- Procurement
- Distribution and storage
- Rational use of drugs
- Drug control

The extent to which these duties are carried out may vary according to the capacity of the handling agency.

Most small countries generally base their drug requirements on past consumption as data on drug utilization and morbidity are usually lacking. Procurement is carried out through a tender system that is either restricted or open. Ideally, before marketing approval is granted in a country, pharmaceutical products undergo initial evaluation for safety, efficacy and quality by the national drug regulatory authority (DRA) through a drug registration process which is described together with the functions of the DRA in the publication entitled *Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products. A Manual for a Drug Regulatory Authority. Regulatory Support Series No. 5, World Health Organization, Geneva, 1999* (6).

In small countries whereby the DRA lacks the capability to evaluate pharmaceutical products, one department may carry out both drug control and procurement. Ideally, such functions should be separated.

For pharmaceutical products with proper drug registrations and marketing approvals, the procurement agency concentrates mainly on the commercial aspects of procurement. However, it must ensure that such products have complied with quality standards.

In countries that have no drug registration system, quality assurance measures must be built into the procurement process to ensure safety, efficacy and quality of pharmaceutical products. In addition, a system for monitoring and maintaining product quality throughout the product's shelf life is important.

3. Core principles of pharmaceutical procurement

Selection of drugs for optimal drug use is important not only from a medical point of view but also to optimize use of funds for pharmaceuticals. Purchase of substandard products from unknown or dubious suppliers represents a health hazard as well as a waste of funds. Drugs should be available at the right quantity when and where they are needed. If drug estimates are too high leading to overstocking, products may expire before the stock is used. Purchase of substandard drugs and wastage due to overstocking increase the total cost of drugs. Suppliers who deliver the goods according to the agreed schedules should be endorsed.

Based on the above considerations, the core principles of pharmaceutical procurements are:

1. Procurement of the most cost-effective drugs in the right quantities.
2. Selection of reliable suppliers of quality products.
3. Assurance of timely delivery.
4. Use of the lowest possible cost.

Common problems in drug procurement

1. Pharmaceutical procurement based on open international tenders results in a large number of offers, some of which may be reasonably priced but suffer from low quality.
2. Sometimes, products delivered are not in compliance with international standards of efficacy, quality and safety.
3. It is difficult to get compensation for substandard imported products that have been already paid for.
4. Delays in deliveries are often encountered when dealing with new and unknown suppliers through open tenders.

4. Determining the tender format

In some countries, existing laws and regulations need to be amended to more adequately address important issues that include the following: (1) whether the tender should be open or restricted to prequalified suppliers, (2) the tender period, and (3) how the quantities to be purchased are estimated.

The following procurement methods are being used in actual practice:

A. Open tender

An open tender is a formal procedure whereby quotations are invited from a potential manufacturer or supplier. Experience shows that contrary to expectations, pharmaceutical companies generally respond to tenders even for relatively small quantities. As a result, too many offers are submitted that overload the limited capacity of procurement agencies in small countries and hence, the proper evaluation of the bidders, as well as the bids, cannot be undertaken within the schedule of the tender process.

B. Restricted tender

A restricted tender, open only to prequalified suppliers, seems to work best in small countries. Although initial evaluation of suppliers is time consuming, when a core of prequalified suppliers has already been established, the recurring work for the procurement agency and the overall workload is significantly lower than that in an open tender. Product quality may be more easily assured through a restricted tender.

C. Competitive negotiations

Competitive negotiations means approaching a few selected companies and requesting price quotations. Usually, this method results in higher prices.

D. Direct procurement

This is the simplest but perhaps the most expensive procurement method of all as it involves direct purchase from a single supplier either at quoted prices or negotiated prices. This method is well suited for emergency situations, but is not the preferred choice for routine orders.

A restricted tender open for only pre-qualified suppliers could provide a better system for quality assurance than an open tender. In a restricted tender, the pre-qualification of suppliers is done independently of the evaluation of prices of the products. Therefore, the supplier assessment can be done more objectively. With a restricted tender, pre-qualification can be done continuously as prospective suppliers express their interests and before tenders are conducted.

Assessment of suppliers in an open tender can be time consuming because of the large number of bids. The period of evaluation of bids is a very busy one and assessment of suppliers may not get done as thoroughly as it should.

Procurement method	Advantages	Disadvantages
Open tender	Many bids, some with low prices New suppliers can be identified	High workload required in evaluating bids and selected suppliers
Restricted tender	Fewer bids, prequalified suppliers, Quality easier to ensure	Fewer bids, more limited options A system for prequalification of suppliers must be in place
Competitive negotiations	Suppliers generally well-known, less evaluation work	Generally higher prices
Direct procurement	Easy and quick	High prices

A restricted tender, open only to prequalified suppliers, should be the method of choice.

**PROCUREMENT METHODS PRACTISED BY SOME MEMBER COUNTRIES/
AREAS IN THE WESTERN PACIFIC REGION**

Country	Estimation methods	Procurement methods
Fiji	Consumption-based	Open tender
Papua New Guinea	Consumption-based	Open tender, direct procurement
Solomon Islands	Consumption-based,	Open tender, direct service-based, procurement
Vanuatu	Population-based	Restricted tender
Marshall Islands	Service and	Direct and negotiated consumption-based, procurement
Northern Mariana Islands	Consumption-based	Direct procurement
Palau	Consumption-based	Negotiated and direct procurement, restricted tender
American Samoa	Service and consumption-based	Direct procurement
Cook Islands	Consumption-based	Negotiated and direct procurement
Kiribati	Consumption-based	Open tender, direct procurement
Tokelau	Consumption-based	Negotiated procurement
Tonga	Consumption-based	Open tender (negotiated and direct)
Tuvalu	Population/ Consumption-based	Restricted tender negotiated procurement
Western Samoa	Consumption-based	Restricted tender

5. Estimated or fixed tender quantities

The two most commonly used options are “Fixed-quantity, scheduled delivery purchasing contract” and “Estimated quantity, periodic-order contract.”

A. Fixed-quantity, scheduled delivery purchasing contract

This type of contract specifies fixed quantities (allowing for small variations from time to time) and delivery is either in one shipment or several smaller shipments over the life of the contract. The purchaser accepts the risk of overstocking if the quantity far exceeds actual requirements. If the quantity ordered is less than the actual need, the purchaser risks paying higher prices for additional orders. In some developing countries where access to funds and foreign exchange is sporadic and uncertain, it may be necessary to tender periodically as funds become available. This requires a fixed quantity, scheduled delivery tender contract. This will also apply if products imported have a long lead-time.

B. Estimated quantity, periodic-order contract

The tender quantity is based on an estimate and the contract price is negotiated for each drug. Orders are then placed periodically. In this method, the supplier faces the risk that the amount actually purchased may differ from the estimate.

6. Split or single awards

To avoid being dependent on one supplier, contract awards are split between two or three suppliers. This method enables procurement agencies to maintain links with several suppliers. The use of this mechanism, however, may result in higher prices.

7. Required/optional use of local agents in international tenders

In some countries only local agents can import pharmaceuticals from foreign companies. In other countries this is only an option. Generally, in developing countries, it is not advisable to use local agents especially if they lack the technical competence that is necessary to avoid confusion and other problems arising from technical issues. Dealing with local agents could delay the procurement process and prices end up being higher when dealing through a local agent.

8. Annual or biannual tenders versus multiple tenders during the year

The tender cycle depends on the capacity of the procurement agency to:

- Select the drugs for tender
- Quantify drug requirements
- Prequalify suppliers
- Prepare tender documents
- Evaluate tenders

Distance to the suppliers is a factor for consideration and suppliers need ample time to prepare their bids.

9. Prequalification of suppliers to be invited for restricted tenders

Pharmaceutical products are supplied by:

- Manufacturers
- Trading houses/wholesalers
- Local agents

Prequalification of suppliers establishes the profile of pharmaceutical companies. For companies who do not engage in the manufacture of drugs, information regarding the actual manufacturer(s) of the drugs is required. In some countries drugs can only be purchased from local agents. Other countries purchase drugs directly from the manufacturer. This method is preferred inasmuch as dealing through middlemen/agents/wholesalers result in generally higher prices as well as more complicated negotiations. There are some countries that encourage local participation in the distribution of drugs and laws exist that require local companies to handle imports.

Type of supplier	Advantages	Disadvantages
Local agent	Easy and fast communication.	Higher prices, more difficult communication on technical issues.
Wholesaler	Easy and fast communication, stocks on hand.	Higher prices, more difficult communication on technical issues.
Manufacturer	Lower prices, easy communication on technical issues.	

Before invitations for bids are requested, a system for prequalification of suppliers and monitoring of their performance should be established. Prequalification is usually open to any interested supplier. The purpose of the prequalification is to ensure that the company in question is a registered company, that the products offered are manufactured in compliance with Good Manufacturing Practices (GMP) and that marketing authorization in the country of origin has been obtained for the products offered. If the supplier is known to the procurement agency, evaluation of past performance is part of the prequalification. Also part of the prequalification which should be requested for products intended for bidding is the Products Certificates based on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in

International Commerce otherwise known as the WHO Certification Scheme(3). These certificates confirm that the products have been manufactured according to current GMP standards and that the manufacturer has been inspected by the national DRA and the products are approved for marketing in the country of origin. It further certifies that all written product information has been approved by the national DRA. For products not approved for marketing in the country of origin, the reason(s) must be given.

It is important to be aware of the fact that some companies in industrialized countries take advantage of the lack of regulatory control in developing countries and export pharmaceutical products that have not been approved in the country of origin. In spite of this, the drug regulatory authority sometimes issue Product Certificates according to the WHO Certification Scheme, confirming that the product is not registered because there is no need for the product in the country of origin or that there is no market for the product in the country of origin. Such reasons tend to give rise to further doubts. When using the WHO Certification Scheme, it is important to be aware of its weaknesses. One must keep in mind that certificates are only as good as the certifying authority and in the WHO Certification Scheme relies mainly on the honesty and competence of the issuing authorities.

Tools for prequalification of suppliers

- Obtain supplier information through the use of questionnaires
- Use the WHO Certification Scheme
- Seek information from the drug regulatory authority of the exporting country
- Use existing networks for information exchange between drug regulatory authorities: WHO Electronic Discussion Group for Drug Regulatory Authority (WHODRA), Drug Information Exchange for Pacific Island Countries (DIEFPIC)
- Evaluate product samples
- Monitor and record the performance of the suppliers

To obtain the information necessary to evaluate manufacturers/ suppliers, a suitable questionnaire should be used. Attachment 1 is an example of a questionnaire for the prequalification of suppliers, which can be used as it is or modified to meet local requirements. This simple questionnaire indicates whether products offered are manufactured according to GMP standards as well as provides useful business information. Another mechanism for obtaining supplier information is formal or informal information exchange between drug regulatory authorities and procurement agencies.

The *Model Questionnaire for Prequalification of Suppliers* (Attachment 1) consists of four main sections: Business Information, Manufacturing Information Quality and Product Information.

Business Information

This section establishes if the company is a manufacturer or a wholesaler. It contains data to assess the size of the business in terms of staff, categories of staff, capital value, sales turnover and if the company is engaged only in export trading. Companies that do not appear viable must be avoided. It is also important to know the countries the company have been exporting its products to. If a company has exports to countries with sophisticated drug regulatory systems, this indicates that its products comply with stringent quality standards. However, if the products are exported only to developing countries with newly-established drug regulatory systems, efforts must be directed toward ensuring that the products being offered meet quality criteria. Sales turnover from export and domestic sales help to distinguish so called “export only” companies that manufacture products that are only for export to developing countries. If such a case, the procurement agency needs to find the reason why such a company does not market its products in its country of origin. A description of the company’s quality assurance system provides useful insights on how the concept of quality assurance is understood and implemented.

Manufacturing Information

Ideally the manufacturer should be inspected, but for some developing countries this may not be feasible due to the lack of funds and qualified inspectors. The WHO Certification Scheme can be used to ensure GMP compliance and establish if the products intended for export are approved for sale in the country of origin. It is useful to request additional information related to the manufacture of the products to verify the information provided through the WHO Certification Scheme. This section provides information on the number and type of the professional staff involved in the manufacture of the pharmaceutical products. It discloses whether the offered products are manufactured by the company or if other manufacturers are responsible for part(s) of the total manufacturing process (manufacture under contract). All companies involved in the manufacturing process will have to submit information under sections II (Manufacturing Information) and III (Quality Control Information). The information provided should be crosschecked with the description of the quality assurance system.

Since manufacture of pharmaceuticals involves many steps from

Be alert if:

- The company manufactures only for export
- The company exports only to developing countries
- The company's product list exceeds 200 products
- The company offers products manufactured only occasionally
- The company has no quality control laboratory
- Stability studies have not been conducted

processing of the raw materials to the late stages of packaging and labelling the products, it is important to know if more than one company is involved in the whole process and compliance with GMP must be documented for all the manufacturing plants involved in the process.

To be able to manufacture products of acceptable quality, such products have to be produced on a routine basis. Some manufacturers have product lists containing 2000-3000 different products and it is difficult for any manufacturer to manufacture such a wide range of products routinely. Such a wide product range is also not economically viable. For a medium-sized company the ideal product range may not exceed more than 80-120 different products. This type of information can be very helpful as many companies attempt to supply any product requested by securing the products from third parties or manufacturers such products for the very first time and therefore does not have the required validation and stability studies for quality assurance. It is important to establish that the products offered have undergone bioavailability testing when required, and stability testing as is routinely required.

Quality Control Information

This information serves to evaluate the quality assurance system of any pharmaceutical company. GMP requires companies to have quality control laboratories. Use of external laboratories is acceptable only for selected tests that require sophisticated instruments and special skills.

Efforts should always be directed towards searching for reliable suppliers of quality products and therefore, prequalification is a continuous process.

Product Information

A useful guide in formulating decisions on drug procurement is the regulatory status of a product in countries with well-established drug regulatory systems with adequate resources and capacity. Products registered for marketing in such countries have complied with efficacy, safety and quality standards and are acceptable for procurement. Products not registered in such countries merit further investigation in light of efficacy, safety and quality issues. Many small countries require prior registration in selected developed countries as a prerequisite for the marketing authorization of products.

As previously mentioned, Certificates of Pharmaceutical Products based on the WHO Certification Scheme establishes that a product has been registered in the country of origin and its manufacturer complies with Good Manufacturing Practice (GMP) standards with regular inspections. Doubt on the authenticity of certificates may be verified by directly communicating with the issuing agency. Many countries still issue such certificates using formats different from that recommended by the WHO. In such cases the issuing agency should be requested to reissue certificates using the recommended format.

Therapeutic equivalence through either a bioequivalence study, a comparative clinical pharmacodynamic study or a comparative clinical trial is important for certain drugs and dosage forms. These include oral immediate release pharmaceutical products with systemic action used for serious conditions, narrow therapeutic range/safety margin (e.g., digoxin, lithium, phenytoin, theophylline and warfarin), steep dose-response curves, pharmacokinetics complicated by variable or incomplete absorption, unfavourable physicochemical properties (e.g., low solubility, instability), high ratio of excipients to active ingredients. In addition, therapeutic equivalence is also important for non-oral and non-parenteral pharmaceutical products designed to act by systemic absorption (e.g., transdermal patches), sustained release formats, fixed combination products and products designed for non-systemic use (e.g., oral, nasal, ocular applications). Further reading may be found in WHO document *Multisource (Generic) Pharmaceutical Products: Guidelines on Registration Requirements to Establish Interchangeability* (Annex 3 of Reference 6).

10. Tender invitation

Attachment 2.a (*“Model for Tender Invitation”*) is an example of a tender invitation. In the tender invitation, the terms and conditions of the procurement are laid down. The document specifies, among others:

- How the quotations should be submitted
- Terms of payment
- Delivery periods
- Delivery schedule
- Product specifications
- Labelling
- Packaging
- Shelf life

The tender invitation is an important document which lays down the technical and basic legal requirements for obtaining products of acceptable quality. It serves as a reference in the event that problems with suppliers should arise. The decision on the final format of the tender invitation will have to take into account the prevailing policies and needs on the procurement of drugs.

Another example of a model invitation is Attachment 2.b (*“Model Invitation to Bid and Contract Form”*). This incorporates important technical and legal elements together in one form.

11. Evaluation of bids

After thoroughly evaluating the bids, a special committee or tender board usually awards the tenders. It is important that a pharmacist or a person with technical knowledge of pharmaceutical products and its manufacture be a member of the tender board. As often the case, the determining factor for awarding a tender is price. Quality must be a more important consideration due to the fact that substandard products give rise to health hazards as well as financial losses to the procurement agency. While products of assured quality

may be priced higher, they may be cheaper in the long run. Drugs are not ordinary commodities and should therefore be treated as such – purchase of cheaper pharmaceuticals without quality assurance invariably result in losses as follows: (1) expiration of stocks soon after delivery because of too short shelf-life; (2) substandard drugs and (3) health hazards.

Transparency must be maintained throughout the procurement cycle by following formal written procedures. Decisions should be based on explicit criteria. A list of all contracts awarded, specifying the supplier and price for each product, should be made available to all bidders.

12. Post qualification procedures

There should be a system for monitoring the supplier's performance. The supplier's compliance with the terms and conditions of the contract should be recorded, with emphasis on timely delivery, quantities delivered as ordered, shelf life after delivery and quality.

Quality is checked through visual inspection of incoming consignments. Attachment 3 is a checklist for drug receipts based on the guidelines of the reference text (1). A system for reporting and recording quality problems noted by the health facilities and users throughout the country should be part of the post qualification procedures.

13. References

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2. Operational Principles for Good Pharmaceutical Practices, Interagency Pharmaceutical Coordination Group (IPC), World Bank, World Health Organization, United Nations Population Fund and United Nations Children's Fund, Geneva, 1999.
3. WHO Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 863, Geneva, 1996.

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4. The Use of Essential Drugs, WHO Technical Report Series No. 895, Geneva 2000.
 5. Estimating Drug Requirements, A Practical Manual, WHO/DAP/88.2.
 6. Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products. A Manual for a Drug Regulatory Authority, Regulatory Support Series, No. 5, World Health Organization, Geneva, 1999.

14. Attachments

- | | |
|--------------|---|
| Attachment 1 | Model Questionnaire for Prequalification of Suppliers |
| Attachment 2 | Model Tender Invitation |
| Attachment 3 | Inspection Checklist for Drug Receipts |

ATTACHMENT 1

PREQUALIFICATION OF SUPPLIERS FOR PHARMACEUTICAL PROCUREMENT

(Country)

This model is intended to facilitate the prequalification of suppliers. Information derived from forms submitted by potential suppliers serve as the basis for evaluating companies and assessing their manufacturing and production capabilities in line with Good Manufacturing Practice and quality standards.

This form contains of four parts:

- | | |
|----------|---------------------------|
| Part I | Business Information |
| Part II | Manufacturing Information |
| Part III | Quality Information |
| Part IV | Product Information |

Applicants for prequalification need to fill out one form for Parts I-III. However, Part IV requires that separate forms be filled out for each product being offered for prequalification.

Information provided by potential suppliers seeking prequalification must be regarded as confidential information.

I. Business Information

1. Name of company : _____
Year established : _____
Form of company : Individual
 Partnership
 Corporation
 Other (specify) _____
Legal status : _____
Trade register number: _____
VAT number : _____
License Number : _____
(attach copy) _____
2. Address : _____
Country : _____
Telephone : _____ Telefax: _____
Telex : _____ E-mail: _____

Please attach the company organizational chart

3. Type of activity carried out by the company
- | | |
|--|--|
| <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Wholesaler |
| <input type="checkbox"/> Branded products | <input type="checkbox"/> Branded products |
| <input type="checkbox"/> Generic products | <input type="checkbox"/> Generic products |
| <input type="checkbox"/> Medical supplies | <input type="checkbox"/> Medical supplies |
| <input type="checkbox"/> Laboratory reagents | <input type="checkbox"/> Laboratory reagents |
| <input type="checkbox"/> Other products (<i>specify below</i>) | <input type="checkbox"/> Other products (<i>specify below</i>) |
| _____ | _____ |

<u>Indicate % of annual turnover:</u>	
Pharmaceutical formulations	: _____ %
Bulk drugs	: _____ %
Medical Supplies	: _____ %

- Products manufactured for export
 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 (<i>specify</i>):	

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. Split export and domestic sales. (*specify currency*)

Annual turnover	Domestic sales	Exports	Year
c			
c			
c			
c			
c			

II. MANUFACTURING 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. State reasons why products manufactured by your company are not marketed in the country of origin

Generic Name	Trade Name	Reason
(1)		
(2)		
(3)		

5. Does your company have GMP certification?

Yes (attach a copy of the GMP certificate if any)

Certified by: _____

No

Indicate if your company has other types of certification

ISO Type of ISO certification: _____

WHO Certification Scheme

Others (specify) _____

Attach Certificates of Good Manufacturing Practices (GMP, ISO or Certificates of Pharmaceutical Products according to WHO. Certification Scheme covering each item you propose to export.

6. Does your Government carry out inspections and controls on the production of drugs in your country? YES NO

If "Yes," give date of last inspection: _____

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

Inspected by	Year	Outcome

8. 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 importer(s)

9. Date, number and expiry date of current business licence or permit.

Date : _____

Number : _____

Expiry Date : _____

10. Date, number and expiry date of manufacturing licence or permit.

Date : _____

Number : _____

Expiry Date : _____

11. If you are a wholesaler, the following information should be obtained from the manufacturers of product you wish to offer.

- A. Give full details on the manufacturer (company name and address), with product lists and brochures of the manufacturing plants, laboratories etc.

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 : _____

12. 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)		

13. Do other companies package any of the products you manufacture?

- YES
- NO

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)		

Provide detailed information on the quality assurance procedures followed.

14. Do you manufacture sterile products?

- YES
- NO

15. Do you manufacture beta-lactam antibiotics?

YES NO

If "Yes," are these production facilities in a separate building?

YES NO

16. Production site

Are the production premises located in the same place as the main office?

Yes No

If not, state address of the production premises: _____

Address: _____

If there are >1 production site, give description of production site as follows:

	Production site	Address
No. of products		
Production capacity		
Air treatment system		
Quality of in process water		

List the products from the different production sites:

Production site	Products			
	(1)	(4)	(7)	(10)
	(2)	(5)	(8)	(11)
	(3)	(6)	(9)	(12)

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

JP Edition CP Edition Other:

Are all recommended tests carried out?

YES NO

If "No," state reason why not:

Are additional 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:

IV. Product Information (Please fill up one form for each product)

1. Active Pharmaceutical Ingredient(s) _____

Indicate if product has any of the following:

- Certificate of Suitability to the European Pharmacopoeia (CEP)
Certificate No.: _____
- The CEP is in our possession (including annex if any)
- Drug Master File (DMF)
registered in (*country*): _____
registration no. : _____
- The full or open part of the DMF is in our possession
- The full or open part of the DMF is in possession of the manufacturer
Manufacturer : _____
Country : _____

2. Trade Name of the Product: _____

Dosage form : Tablets Capsules Ampoules
 vial others (*specify*) _____

Strength per dosage unit: _____

Route of administration: Oral I.M I.V
 S.C. other (*specify*) _____

Number of units/volume or weight per container: _____

Type of container: _____

3. Regulatory Status in Country of Origin

- Product registered in country of origin and routinely manufactured and marketed
License no: _____ year issued: _____
- Product registered in the country of origin but not currently marketed
License no: _____ year issued: _____
- Product registered for export only
License no: _____ year issued: _____
- Product not registered

4. Regulatory Status in Other Countries

List other countries where the product is registered and currently marketed:

Product	Country	Trade Name

5. Certificate of Pharmaceutical Product According to WHO Certification Scheme (WHO Technical Report-s Series No 863/ <http://www.who.int/medecines/team/qsm/certifscheme.html>)

- The Certificate of Pharmaceutical Product (based on the last format recommended by WHO)
- The Certificate of Pharmaceutical Product cannot be obtained from the National Drug Regulatory Authorities because:

6. Dosage Forms

Form	Formulation	Dose
Oral		
Injectable		
Fixed-dose combinations		

7. Production Manager

Name: _____

Title: _____

Experience in pharmaceuticals: _____ years

8. Validation

Are all your production processes validated?

- Yes No

9. Do you use an approved manufacturing formula and processing instructions?

- Yes No

10. Finished Product Specification

CP Edition BP USP Edition

CP JP

Attach a copy of the finished product specifications

Are you willing to provide necessary information (analytical methods) for the tests to be replicated by another control laboratory ?

Yes No

11. Limits in % for the assay in active ingredient(s):

95-105% 90-110 %

Other: _____

Additional specifications to those in the pharmacopoeia:

Attach a copy of the model certificate of analysis for batch release

12. Stability

Stability testing data available: Yes No

Type and conditions of satisfactory testing (without significant change):

accelerated testing

40°/ 75% RH/ 6 months

other:

in the same packaging as marketed

in another packaging:

real time testing

Temperature: ambient 25°C 30°C other: ___

Relative humidity: 45% 60% 70%

not controlled other: _____

Period of time: 1 year 2 years 3 years other: ___

in the same packaging as marketed

in another packaging: _____

13. Label and Insert Information

Shelf life: 2 years 3 years 4 years
 5 years other : _____

Storage conditions (e.g. Store below 30°- Protect from light):

Package insert : Yes No

Attach a copy of the label and package insert

14. Therapeutic Equivalence

Bioequivalence Study

Reference: _____

Reference sourced from: _____

Number of volunteers: _____

Year: _____

Institution, country where study was done: _____

Attach a copy of the report on the bioequivalence study.

Clinical Study

Study design : _____

Sample size: _____

Study objective: _____

Results: _____

Year: _____

Institution, country where study was done: _____

Attach a copy of the report on the clinical study.

15. Dissolution Tests

Method: _____

Results: _____

16. Normal Batch Size: _____

CERTIFICATION

I, the undersigned (full name of the person responsible)

Name _____

Designation _____

Hereby declare that all the information given above is true, and I take the full responsibility for all consequences that might arise from false or erroneous information. If required, I will cooperate with any official of the Ministry of Health and in (country name) in making personal inspection of manufacturing facilities and records.

Certification by the Ministry of Health or the official authority in charge of the control and inspection of pharmaceutical manufacturing facilities:

We hereby certify that the information given is true and that the company concerned fulfils the requirements of local regulations concerning the manufacturing of pharmaceuticals.

Name _____

Designation _____

Signature _____

Date _____

ATTACHMENT 2

2. a. MODEL FOR TENDER INVITATION

INVITATION TO TENDER

Tender No: _____

Tenders are invited for the supply of drugs _____ and _____
to the Government of _____ for the period _____ to _____

Tenders are to be delivered in duplicate to: _____

not later than _____ hours local time on _____

Tenders may be delivered by hand to: _____

Envelopes should be clearly marked with the Tender Number and description.

Tenders received after the closing date and time, telegraphic or telephonic tenders will not be considered.

Tenderers who wish to attend the opening of the tenders, when names of the tenderers will be read out, may do so.

Instructions to tenderers and notes for particular attention.

The Tenderers attention is drawn to the following notes which, if not complied with, may cause the tender to be rejected partially or completely.

1. Prices.

Tenderers should quote the CIF price to:

They should calculate their CIF prices based on freight and insurance charges of (name of clearing and forwarding agent) or their associates _____.

Overseas tenderers who wish to quote CIF Air price, should note that cargo should preferably be routed via _____ or via _____ with _____ Airlines.

1.1 Escalation

Prices should be fixed for a whole year, although escalation due to exchange rate fluctuations will be considered from regional suppliers who import raw materials into _____ provided relevant information is given.

1.2 Terms of payment

The tenderer must include in his bid the terms of payment. Where a Letter of Credit is required, an irrevocable Letter of Credit will be established. If successful tenderer requires a confirmation of L/C, this must be clearly stated in the tender.

2. Currency of tender and currency fluctuations

Firms should tender in their national currencies. Firms that have tendered on the basis of fully imported items or imported raw materials should state in their tender their bank's selling rate between the currency of the exporting country when calculating their tender price. The exchange rate used should be stated.

3. Delivery period

"Delivery Period" is the period in days from the receipt of a telex or telefax order by the supplier to the date of shipment. Tenderers should deliver either by road or air and state the mode of delivery on which the pricing of the tender is based.

4. Quantities

The quantities referred to are only estimates of the Government's requirements for one year.

5. Delivery schedule.

Deliveries will be in one or two lots. Note that the dates below reflect estimated arrival dates at _____ and not shipment dates. Shipping time from overseas by sea is normally two months.

One delivery: (month) _____ (year) _____

Two deliveries:

1st delivery (month) _____ (year) _____

2nd delivery (month) _____ (year) _____

A firm order for the first delivery or the one delivery will be placed immediately after the contract has been awarded. Firm orders for the next delivery will be placed six months thereafter.

All orders will be placed by telex or telefax and confirmed by a written Government Purchase Order. The issue of Government Purchase Order will constitute a firm order.

6. Quality (product specifications)

All items should be based on BP, USP, EP, IP standards unless otherwise stated. If not, the the specification must be submitted.

The following information must be submitted with the quotations:

- 6.1 Name and amount of colouring agents and preservatives.
- 6.2 Shelf-life of each item quoted for. For products with a shelf-life of 3 years or more, shelf-life of 2 years upon arrival is required. For products with a shelf-life of 3 years or less, the remaining shelf-life upon arrival must be at least 80%.
- 6.3 Certificates of pharmaceutical products according to the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce (The "WHO Certification Scheme") " must be enclosed if not previously submitted to.(Country name).
- 6.4 Sample of all labels.
- 6.5 Description of primary packaging material (ie PP-bottle 300 ml w/screw cap, PE tablet container 30 ml w/snap-on lid).

Further to this the following should be noted:

- 6.6 An annex giving the composition for compound preparations is enclosed.
- 6.7 Packaging material must be suitable for the purpose and have no detrimental effects on the pharmaceutical products. Primary packaging must give adequate protection against external influence and potential contamination.

Items should be packaged as follows:

- | | |
|-----------------|------------------------------|
| 100 ml bottles, | not more than 100 per carton |
| 200 ml bottles, | not more than 50 per carton |
| 500 ml bottles, | not more than 24 per carton |
| 1.0 l bottles, | not more than 12 per carton |
| 2.5 l bottles, | not more than 6 per carton |
| 5.0 l bottles, | not more than 4 per carton |

For ear- and eyedrops a maximum of 24 should be packed in each carton and the box must be partitioned if the contents are more than 6.

- 6.8 Light-sensitive pharmaceuticals must be packed in containers that allow maximum protection from light.
- 6.9 Ampoules must be packed in units of 5, 10 or similar multiples.

6.10 Batch certificates must be submitted for each batch of drugs awarded. The certificates should be mailed under separate cover when order is executed.

6.11 Country of origin, if different from country of tenderer, must be clearly stated.

7. Labelling

The labelling of products should comply with guidelines set forth in the WHO Technical Report Series (WHO TRS) 823, "Good manufacturing practices for pharmaceutical products".

7.1 The label should prominently display the International Non-Proprietary Name (INN) or generic name in addition to any trademark or brand name.

7.2 For injections and liquid oral preparations, the concentration of the active ingredient must be given in mg/ml or IU/ml.

7.3 The name and amount of preservatives and colouring agents must be stated on the label.

7.4 The secondary packaging material (box, carton) must be clearly labelled with the names of the item, batch number, expiry date and the number of units per carton/box.

7.5 Different products must not be packed in the same box. Different batches of the same product must not be mixed.

8. Alternative specifications.

Alternative specifications to meet the functional requirements will be considered but must be submitted separately. Quotations for alternative package sizes will be considered and must be clearly stated.

9. Samples

Samples MUST not be submitted with the tender. If required, samples with batch certificates will be requested free of charge. Such samples should be sent to the address given below within fourteen days after receipt of telex or telefax request.

Address:

10. Local preference for (country name) manufacturers.

Local manufacturers who are registered for local preference with the Ministry of Commerce and have been allocated a percentage preference shall be evaluated accordingly. A copy of the Local Preference Certificate issued by MUST accompany the tender.

11. Validity of tender

The whole tender shall remain open for consideration for a period of ninety (90) days from the closing date of the receipt of tenders.

12. Power to accept all or part of tender.

The Central Tender Board reserves the right to award all or part of the tender.

13. Failure to supply

Failure to supply any of the goods contracted for according to the delivery schedule may result in the supplier being disqualified from future tenders. In addition, contracts for other items in the tender might be declared null and void.

Products that do not meet the required specification will be rejected and will be replaced by the supplier with no additional cost.

14. Tenders for selected items

Tenderers need not necessarily quote for all items called for.

15. Storage under transport

Heat sensitive products requiring cool storage under transport should be shipped by air in insulated containers according to the manufacturer's recommended storage conditions.

Enquiries

Any enquiries or requests for information should be addressed to:

Address:

Telephone:

Telefax:

Observe that the closing of the tender is at _____ hours local time

on _____ 19_____

Appendix A

BID FORM

Items	Specifications	Package Size	Quantity	Delivery	Mode of Delivery	Price <i>(currency)</i> CIF

2.b. MODEL INVITATION TO BID & CONTRACT FORM

GOVERNMENT OF _____
DEPARTMENT OF HEALTH

INVITATION TO BID

Department of Health, (country)
invites
Your Pharmaceutical Company
to hand in Bids to supply
essential drugs and medical supplies
destined for the public sector

This INVITATION TO BID herein after referred to as the INVITATION has been issued from and Bids are to be returned to the following address:

Director General of Health
National Hospital (country)

Bids must be made in accordance with the Instructions contained within this document.

Terms and Conditions of Contract

Any order resulting from this invitation shall comply in detail with the Terms and Conditions laid down within this invitation.

TABLE OF CONTENTS

Invitation to bid

General instructions

Technical specifications and specific instructions to bidders

Conditions of contract

Specifications and schedule of requirements

Bid form

Contract form

Annexes:

Special packing instructions

Specific label instructions

GENERAL INSTRUCTIONS

1. BID FORM.

The Bidder shall complete the Bid Form, which shall be accompanied by the requested documentation.

2. LANGUAGE

The Bid must be made in English.

3. COMMUNICATIONS

All communications must be done in the same language as the Bid. Any serious communication should be done in writing by fax, e-mail, telex or mail and the Purchaser shall respond without delay. All responses, estimated by the tender commission to be of any importance, will be sent to all prospective Bidders.

4. DOCUMENTS COMPRISING THE BID

The bid shall comprise of the following documents:

- the Bid Form
- a Price Schedule, presenting unit and total prices
- documentary evidence for Manufacturing License and GMP
- GDP (if applicable)
- Quality Control procedures, capacity and equipment of the Manufacturer
- documentary evidence of Quality Assurance for each item
- Incidental Services and its part of the price (if applicable)

5. MARKING AND MAILING OF BIDS.

The Bidder shall seal the original and each of two copies of the bid in an inner and outer envelope, duly marking the envelopes as "original" and "copy". The outer envelope shall be marked "Do not open before" plus the time and date of opening given in this bid invitation.

The inner envelope shall indicate the name and address of the Bidder, to enable the bid to be returned unopened in case it is declared late.

Bids should be hand delivered or sent by courier mail to ensure timely arrival.

If the outer envelope is not marked and sealed as required above, the Purchaser will not take any responsibility for misplacement or premature opening of the bid.

6. TIME AND ADDRESS FOR RECEIVING BIDS.

Bids must be received at the address no later than the date and time specified in the invitation on the front page. Any bids received after the deadline for submission of the bids will be rejected and returned unopened to the Bidder.

Bids received prior to the time of opening will be securely kept unopened.

Modifications submitted and received prior to the closing time will be considered as a part of the bid.

7. CORRECTIONS.

Erasures or other changes in the Bid must be explained or noted over the signature of the Bidder and communicated before the day fixed for opening.

8. PUBLIC OPENING OF BIDS.

Bidders or their authorised representatives may attend the public opening on the date and at the location indicated.

The Bidder's name, bid price, discounts, modifications, bid withdrawals and the presence of the requisite bid security (when applicable) and such other details as may be considered appropriate will be announced at the opening.

Minutes of the bid opening will be prepared by the purchaser and sent to each participator of the tender.

Withdrawn bids will be returned unopened to the Bidders.

9. ERRORS IN THE BID

Arithmetical errors will be rectified, without disqualifying the Bid, if the Bidder accepts the corrections. The unit price of the original Bid shall be prevailing.

10. WITHDRAWAL OF BIDS.

Bids may be withdrawn on written or telegraphic request received from the Bidder prior to the time fixed for opening. Negligence on the part of the Bidder in preparing the Bid confers no right to withdrawal of the Bid after it has been opened.

11. REJECTION OF BIDS.

The Purchaser reserves the right to reject any bid at any time during the ongoing evaluation, which does not substantially respond and conform to all terms, conditions and technical specifications of the Bidding Document.

The Purchaser reserves the right to reject any Bid, which fails to present fundamental documentation as requested in the Bidding Document and therefore appears inadequate. The Purchaser reserves the right to reject any Bid from a company previously failed to perform properly contracts of a similar nature or did not complete on time.

12. ORIGIN OF PRODUCTS

The origin of the products must be clearly stated with name, address and country of manufacture.

The country of origin must be a signatory of the agreement of the "WHO Certificate Scheme on the Quality of Pharmaceuticals Products Moving in International Commerce".

Any obscurity on the origin of products offered will disqualify the bid.

13. CURRENCY OF BID

The Bid prices shall be in United States Dollars (USD).

14. DISCOUNT

Special payment terms or other discounts should be indicated in the Bid.

15. VALIDITY OF BID.

Bids should be valid for a period of not less than 60 days.

16. DELIVERY TERMS

Bidders should quote CIF to the indicated ports or if possible CIP to the indicated addresses given in the delivery schedule, as annex to the contract.

17. AWARD OF CONTRACT

The determination to award the Contract to a successful Bidder will prior to the price be based on technical, quality assurance system and production capabilities, furthermore experience and credibility of the Manufacturer as well as the controlling authorities.

The Purchaser will notify the successful Bidder in writing by fax or telex.

TECHNICAL SPECIFICATIONS AND SPECIFIC INSTRUCTIONS TO BIDDERS.

1. QUANTITIES.

The required quantities of pharmaceuticals and medical supplies and instructions as to how the packing should be done in kits, will be specified in the "Specifications and schedule of requirements". At the time of signing a contract, there should be a possibility to negotiate with the supplier for the final quantities, independently of the initial request in the invitation.

2. QUALIFICATIONS OF MANUFACTURERS.

The Bidder shall furnish copies of all certificates and documents issued by the proper National Authorities, that the Manufacturer of the pharmaceuticals and equipment proposed is authorised to manufacture and sell these products.

3. APPRAISAL.

Placement of orders with a company, which is not known by the Purchaser or is not well recognised by the international community, will require that the company provide evidence of certification by an internationally recognised authority (e.g. FDA or similar, as approved by the Purchaser) or be subject, at the Company's expense, to inspection by a competent authority designated by the Purchaser in conjunction with the national regulatory authority.

4. STANDARDS AND QUALITY ASSURANCE FOR SUPPLY.

Any pharmaceutical product offered must be manufactured in conformity with the latest edition of British, International, United States, French or European Pharmacopoeia. If the product is not included in the specified Compendia, the Bidder upon being awarded the order, must provide the reference standards and testing protocols to allow for Quality Control.

- **Any offered product must be manufactured in accordance with Good Manufacturing Practices (GMP) standards established by the World Health Organization.**
- **All pharmaceutical products must:**
 - a. **meet the requirements of manufacturing legislation and regulation of pharmaceuticals and medical products in the country of origin;**

-
- b. conform to all the specifications contained herein; and
 - c. be certified by a competent authority in the manufacturer's country according to resolution WHA 28.65B and WHA 41.18 of the World Health Organization "WHO Certification Scheme on the Quality of Pharmaceuticals Products Moving in International Commerce" (which can be obtained in WHO Headquarters or from the WHO Country Representative).
 - d. indicate the dates of manufacture and expiry.
 - e. arrive at the port of entry (for imported pharmaceuticals) or warehouse (for local purchases) with a remaining shelf life of at least 80% of the total stipulated shelf life at the time of manufacture.
 - f. on request, make available samples and studies showing bioavailability and stability, especially stability under conditions of high temperature and humidity.
 - g. prove the Quality of packing and the appearance of labels through representative samples on request.

5. PRODUCT INFORMATION

The following information will be required, when applicable, for each product offered by the Bidder:

- generic name or INN (International Non-propriety Name)
- presentation, strength, quantity in each container
- country of origin, name and address of the Manufacturer
- Pharmacopoeia or other applicable compendia standards
- proper documentation of Quality assurance
- shelf life
- type of container
- Failure to include any of this information may, at the discretion of the Purchaser, disqualify the bid.

6. LABELLING

The language of the labels should strictly be English.

The label for each pharmaceutical product shall meet the W210 GMP standard and include:

- the INN or generic name prominently displayed
- the active ingredient per unit, dose, tablet or capsule, etc. (strength & presentation)
- the applicable pharmacopoeia standard
- the Purchaser's logo and code number if required
- content per container
- instructions for use (only on instructions by the purchaser)
- special storage requirements

-
- batch number
 - date of manufacture and date of expiry.
 - name and address of Manufacturer
 - country of origin
 - "Keep out of reach of children"
 - The outer carton should also display the above information.

7. PHARMACEUTICAL PACKING.

Containers for Pharmaceuticals must conform with any of the latest of the internationally recognised Pharmacopoeia Standards, such as British, United States or European.

The size of the container should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transport.

Containers should be tamper-proof.

Ampoules should be one ended and autobreakable.

8. PACKING OF GOODS.

The Vendor shall ensure that the packing of goods is according to appropriate commercial standards and adequate to protect the goods for carriage by sea to the agreed port of entry or address of delivery.

CONDITIONS OF CONTRACT

1. LANGUAGE

The language of the contract shall be English.

2. INDEMNIFICATION.

The Vendor shall indemnify and protect the Purchaser against any claims, damages, losses, costs and expenses arising out of any injury, sickness or death to persons or any loss of or damage to property, caused by the fault or negligence of the Vendor. The Vendor warrants that the goods offered for sale under the contract do not infringe any patent, trade-name, or trade-mark. In addition, the Vendor shall indemnify, defend and protect the Purchaser from any actions or claims brought against the Purchaser pertaining to alleged infringements of a patent, design, tradesman or trade-mark arising from the contract.

Any export licences or other licences required for the goods shall be obtained by the Vendor.

Any levies imposed on the goods outside the Purchaser's country, shall be the entire responsibility of the Supplier.

3. PERFORMANCE SECURITY.

Within 30 days after the Supplier's receipt of notification of award of the Contract, the Supplier shall furnish performance security to the Purchaser in the amount of ten percent of the Contract Price.

The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete his obligations under the Contract.

The Performance Security shall be paid in a manner agreed on and accepted by the Purchaser.

The performance security will be discharged by the Purchaser and returned to the Supplier not later than four (4) months following the date of final delivery to the destinations indicated in the Contract.

4. INSPECTIONS AND TESTS

The purchaser or its representative shall have full access to the facilities of the supplier at all reasonable times to appraise the production, testing and packaging of the material, and shall provide reasonable assistance to the Purchaser or its representative for such appraisal. That includes also copies of any relevant test results or Quality Control protocols that may be necessary.

Should any inspected or tested Goods fail to conform to the Technical Specifications, the Purchaser may reject them and the Supplier shall either replace the rejected Goods or make all alterations necessary to meet the specified requirements free of cost to the Purchaser.

5. TRANSPORTATION AND DELIVERY.

The goods supplied under this contract shall be delivered "CIF" or "CIP" as defined in the current edition of the International Rules for the -Interpretation of the Trade Terms published by the International Chamber of Commerce, Paris.

Delivery of the contracted goods shall be made to the ports or addresses as specified in the contract by the Purchaser.

6. WARRANTY.

The Supplier warrants that all Goods supplied under the Contract will fully comply in all respects with the technical specifications and with the conditions laid down in the Contract. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days and promptly replace the items covered by the recall at its own cost.

If any item fails to comply with the technical specifications the Supplier shall promptly with all reasonable speed replace the item without cost to the Purchaser.

The Purchaser shall have the right to make claims under the above warranty for the entire period of specified shelf life of each item respectively.

7. DOCUMENTATION ON DELIVERY.

Immediately on shipment of the contracted Goods, the Supplier will advise the Purchaser by telex, fax, or cable of the following details:

- Name of the vessel or carrier
- Date and time of departure from port of shipment
- Quantity of Goods on board
- Invoiced value of the Goods
- Bills of lading number(s)

- Expected time of arrival at port of discharge.
- The Supplier will also despatch to the Purchaser one set of the following documents by courier service and another set through the Master of the vessel:
- One negotiable copy of the clean bill of lading with non-negotiable copies (marked "freight prepaid" in CIF Contracts).
- Certified commercial invoice and ten copies.
- Original copy of the packing list
- Original copy of the certificate of inspection furnished to Supplier by the nominated inspection agency and six copies.
- Certificate of in-house analysis
- Original copy of the certificate of weight issued by the port authority/ licensed authority and ten copies
- Insurance Certificate
- Supplier's/manufacturer's warrantee
- Copy of telex/fax/cable sent to Purchaser by Supplier upon the departure of the vessel.

8. PAYMENT.

Payment shall be made in the following manner:

- (i) On shipment: 90 percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed Letter of Credit established in favour of the Supplier in a bank indicated by the Supplier, on submission of documents specified or any way of payment agreed on between the Supplier and the Purchaser; and
- (ii) On Receipt of Goods: 10 percent of the Contract Price of Goods received shall be paid within 30 days of receipt of Goods on submission of an invoice supported by documentary evidence issued by the Purchaser's representative that the Goods have been received.

Any other agreement on payment performance, made between the Purchaser and the Supplier will, when clearly expressed in the contract, overrule this paragraph.

The Supplier's requests(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by shipping documents, submitted pursuant and upon fulfilment of other obligations stipulated in the Contract.

Payments shall be made promptly by the Purchaser within sixty (60) days of submission of an invoice by the Supplier.

9. PRICE AND CURRENCY.

Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid.

The currency of payment will be United States Dollars (USD).

10. DELAYS.

Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule specified by the Purchaser in its Schedule of Requirements.

An unexcused delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to any or all of the following sanctions: forfeiture of its performance security, imposition of liquidated damages, and/or termination of the Contract for default.

If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the Contract.

11. LIQUIDATED DAMAGES.

If the Supplier fails to deliver any or all of the Goods or perform the Services within the time period(s) specified in the Specifications and Schedule of Requirements, the Purchaser shall, without prejudice to its other corrective measures under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to 0.5 percent of the delivered Contract Price of the delayed Goods or unperformed Services for each week of delay until actual delivery or performance, up to a maximum deduction of 10 percent of the delayed Goods or Services Contract Price. Once the maximum is reached, the Purchaser may consider termination of the Contract.

12. TERMINATION FOR DEFAULT.

The Purchaser may, without prejudice to any other corrective measures for breach of contract, by written notice of default sent to the Supplier, terminate the Contract in whole or in part:

- (a) if the Supplier fails to deliver any or all of the Goods within the time period(s) specified in the Contract, or any extension thereof granted by the Purchaser.
- (b) if the Supplier fails to replace promptly any Goods rejected when submitted for testing or subject to a recall ordered by the applicable regulatory authority in the country of manufacture due to unacceptable quality or reports of adverse drug reactions after giving prompt notice of the recall;
- (c) if the Supplier fails to perform any other obligation(s) under the Contract.

In the event that the Purchaser terminates the Contract in whole or in part, pursuant to paragraph above, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods. If the Supplier fails to reimburse the Purchaser for such excess costs within a reasonable period, the Purchaser may have recourse to the performance security. However, the Supplier shall continue performance of the Contract to the extent not terminated.

13. FORCE MAJEURE.

The Supplier shall not be liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that, its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier, not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such a condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

14. RESOLUTION OF DISPUTES.

The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms specified below:

- (a) in the case of a dispute between the Purchaser and a Supplier which is a national of the Purchaser's country, the dispute shall be referred to adjudication/arbitration in accordance with the laws of the Purchaser's country; and
- (b) in the case of a dispute between the Purchaser and a foreign Supplier, the dispute shall be settled by arbitration in accordance with the provisions of the UNCITRAL Arbitration Rules.

15. APPLICABLE LAW.

The Contract shall be interpreted in accordance with the laws of the Purchaser's country.

BID FORM CONTRACT FORM

This agreement made _____ (date) _____ between (name and address of the Purchaser) (hereinafter "the Purchaser) of the one part and (name and address of the Supplier) (hereinafter "the Supplier") of the other part:

Whereas the Purchaser is desirous that certain Goods and ancillary Services should be provided by the Supplier, viz., (description of the Goods and Services) and has accepted a bid by the Supplier for the supply of those Goods and Services in the sum of (Contract Price in words and figures) (hereinafter "the Contract Price").

NOW THIS AGREEMENT WITNESS AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

the final and by the Purchaser fully accepted Bid and its Price;

the Schedule of Requirements;

Technical specifications and specific instructions to bidders

Conditions of contract

the Purchaser's Notification of Award.

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the date first written above.

Signed, Sealed and delivered by the said (for the Purchaser) _____

in the presence of: _____

Signed, Sealed and delivered by the said (for the Supplier) _____

in the presence of: _____

ATTACHMENT 3

INSPECTION CHECKLIST FOR DRUG RECEIPTS

(Based on Managing Drug Supply, Second Edition, Management Sciences for Health and World Health Organization, 1997).

All Shipments

Compare the good with the supplier's invoice and original purchase order or contract. Note discrepancies on the receiving report.

CHECK THAT:

- number of containers delivered is correct
- number of packages in each container is correct
- quantity in each package is correct
- drug is correct (do not confuse generic name and brand name)
- dosage form is correct (tablet, liquid, other form)
- strength is correct (milligrams, percent concentration, other measurement)
- unique identifiers are present, if required (article code, ministry of health stamp, other code)
- there is no visible evidence of damage (describe)
- Take a sample for testing (if preacceptance sampling is a standard procedure)

A. Tablets

For each shipment, tablets of the same drug and dose should be consistent.

CHECK THAT:

- tablets are identical in size
- tablets are identical in shape
- tablets are identical in color (shade of color may vary from batch to batch)
- tablet markings are identical (scoring, lettering, numbering)
- there are no defects (check for spots, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)

-
- there is no odor when a sealed bottle is opened (except for flavored tablets and those with active ingredients normally having characteristic odor)
 - there is no odor after tablets have been exposed to room air for twenty to thirty minutes

B. Capsules

For each shipment, capsules of the same drug and dose should be consistent.

CHECK THAT:

- capsules are identical in size
- capsules are identical in shape
- capsules are identical in color (shade of color may vary from batch to batch)
- capsule markings are identical
- there are no defects (check for holes, pits, chips, breaks, uneven edges, cracks, embedded or adherent foreign matter, stickiness)
- there are no empty capsules
- there are no open or broken capsules

Parenterals

Parenterals are all products for injection (IV liquids, ampoules, dry solids for reconstitution, suspension for injection).

CHECK THAT

- solutions are clear (solutions should be free from undissolved particles, within permitted limits)
- dry solids for use in injections are entirely free from visible foreign particles
- There are no leaking containers (bottles, ampoules)