

A. Prequalification of Pharmaceutical Suppliers

I. Introduction

In order to assure the quality of the pharmaceuticals that PAHO procures on behalf of its Member States, the present Prequalification Procedure for Pharmaceutical Suppliers has been created. All prequalified suppliers must offer products that conform to WHO recommendations with respect to Good Manufacturing Practices (GMP) (Report 32, 1992 and updates), Good Storage Practices (GSP), and Good Distribution Practices (GDP), as appropriate. PAHO will issue Purchase Orders (POs) only to prequalified suppliers, save for the exceptions noted in the present document.

Even though manufacturers, agents, distributors, or representatives have been inspected by UNICEF, WHO, or another United Nations agency, or are found on the list of suppliers of any one of them, they must be vetted and approved by PAHO before being added to the PAHO/WHO Prequalified Drug Supplier Directory.

II. Categories

For prequalification by PAHO, suppliers and/or manufacturers must offer products that conform to the WHO recommendations with respect to GMP. The wide therapeutic range of pharmaceuticals, as well as their origin of manufacture, has made it necessary to divide suppliers into three classes:

1. Suppliers of pharmaceuticals with a single origin of manufacture, a single and limited source (innovative/original products, including antiretrovirals for the treatment of HIV/AIDS)
2. Suppliers of pharmaceuticals with several origins of manufacture (multisource or generic)

1. Suppliers of pharmaceuticals with a single origin of manufacture, a single or limited source (innovative /original products, including antiretrovirals for HIV/AIDS)

1. Suppliers can be manufacturers or non-manufacturers, whether agents, distributors, or representatives.
2. Marketing of the pharmaceuticals must be authorized by the regulatory authority of a member of the Pharmaceutical Inspection Convention (ref. <http://www.picscheme.org/index.htm>) or the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals

for Human Use (ref.<http://www.ich.org>). For antiretroviral drugs (ARV), the current WHO list of products and manufacturers should be consulted.

3.1 Manufacturers must submit:

- a) The Company Profile Form (CPF) and PAHO/WHO Prequalification Questionnaire for Pharmaceutical Manufacturers (Annex 1)
- b) Evidence of *ex ante* evaluation by international organizations (as appropriate).

3.2 Agents, distributors, or representatives must submit:

- a) The Company Profile Form (CPF) and PAHO/WHO Prequalification Questionnaire for Pharmaceutical Suppliers (Non Manufacturers) (Annex 1)
- b) Letter of accreditation from the manufacturer confirming their status as a representative or agent.

2. Suppliers of pharmaceuticals with several origins of manufacture (multisource or generic)

1. Suppliers can be manufacturers or non-manufacturers, whether agents, distributors, or representatives.
2. Marketing of the pharmaceuticals must be authorized by the national regulatory authority of the country of manufacture.

3.1 Manufacturers must submit:

- a) The Company Profile Form (CPF) and PAHO/WHO Prequalification Questionnaire for Pharmaceutical Manufacturers (Annex 1)

3.2 Agents, distributors, or representatives must submit:

- a) The Company Profile Form (CPF) and PAHO/WHO Prequalification Questionnaire for Pharmaceutical Suppliers (Non Manufacturers) (Annex 1) for each manufacturer that they represent.
- b) Letter of accreditation from each manufacturer confirming its status as a representative

III. Other Considerations

- A. Suppliers or distributors that are prequalified by PAHO may not use the name, logo, or official stamp of PAHO for any purpose not expressly authorized by PAHO. Suppliers or distributors must abstain from publicizing or advertising the fact that they have been prequalified and added to the official PAHO/WHO Prequalified Drug Supplier Directory without specific written authorization from PAHO in each case.
- B. PAHO reserves for itself or its designated agents the right to inspect or visit the installations of the supplier to verify compliance with GMP, GSP, and GDP, as appropriate.
- C. PAHO reserves the right to modify the present document and all its annexes as necessary. Use of the updated versions shall begin with their publication on its website
- D. Prequalified suppliers that have not responded to requests for price schedules, participated in tenders, or submitted POs to PAHO for two consecutive years shall be removed from the official directory of prequalified drug suppliers.
- E. Prequalified suppliers must update the technical documentation cited in subsection 3) of section C Procedures for Updating the PAHO/WHO Prequalified Drug Supplier Directory every 24 months to retain their status as prequalified suppliers.

IV. Exceptions

The prequalification procedure for suppliers shall not be applicable in the following cases:

- 1) In situations designated “emergencies” by PAHO, in which case the procedure described in Annex 5 shall be applicable.
- 2) For the procurement of second-line pharmaceuticals used in the treatment of multidrug-resistant tuberculosis, in which case the procedure described in Annex 6 shall be applicable.
- 3) For the procurement of pharmaceuticals not destined for use with human subjects.

B. Prequalification Procedures

- 1) All companies wishing to be prequalified and added to the official PAHO/WHO Prequalified Drug Supplier Directory must request the Company Profile Form (CPF) and Prequalification Questionnaire for Pharmaceutical Manufacturers and/or Prequalification Questionnaire for Pharmaceutical Suppliers (Non Manufacturers), as appropriate (Annex 1)
- 2) The documentation must be original or a perfectly legible copy, in English or Spanish, and should be sent to:

Procurement Services (PRO)
525 Twenty-third Street, N.W. Washington, D.C. 20037
USA

- 3) Using a checklist (Annex 2), Procurement Services (PRO) shall ensure that all the documentation is complete. Incomplete applications will not be evaluated. Procurement Services can contact the applicant for further information.
- 4) Procurement Services (PRO) shall determine whether the list of products is of interest to PAHO. If so, it shall request a price schedule to ascertain whether the prices are competitive, based on a 20% variation with the most recent average price of similar products procured through PAHO.
- 5) If the product is of interest to PAHO and its price competitive, Procurement Services (PRO) shall forward the complete documentation to the Quality Assurance office of the Essential Medicines and Biologicals Unit (THR/EM).
- 6) THR/EM, Quality Assurance shall evaluate the documentation from a technical standpoint (see procedure in Annex 3) in two periods annually: January-April and September-November.
- 7) When the company is added to the PAHO/WHO Prequalified Drug Supplier Directory, THR/EM (Quality Assurance) shall issue a letter of notification to the company, which Procurement Services (PRO) shall officially send to the prequalified supplier.

C. Procedure for Updating the PAHO/WHO Prequalified Drug Supplier Directory

- 1) Twice a year, after its evaluation, THR/EM(Quality Assurance), shall send Procurement Services (PRO) an updated list indicating the prequalification status of the companies evaluated.
- 2) Procurement Services (PRO) shall send THR/EM (Quality Assurance) a report on companies with more than two years since prequalification that have not placed purchase orders during the past year or have not responded to requests for price schedules so that they can be removed from the official drug supplier directory. Procurement Services (PRO) shall issue a letter of notification and send it to the company.
- 3) Every 24 months, THR/EM (Quality Assurance) shall ask suppliers to update their technical documentation by submitting a new CPF and GMP or GSP certificate, as appropriate, issued by the national regulatory authority. If the documentation is not updated within three months of the request, the company shall be suspended from the Prequalified Drug Supplier Directory, and Procurement Services (PRO) shall suspend commercial transactions until it receives the documentation complying with the conditions set.

D. Suspension/Removal of a Supplier from the Directory

- A) PAHO, at its sole discretion, reserves the right to suspend/remove from the Prequalified Drug Supplier Directory any supplier that incurs the following as a result of omissions and/or infractions:
 - 1) Suspension for failure to submit the updated documentation requested by PAHO under subsection 3) *supra*, effective until the receipt of such documentation or expiration of the six-month deadline
 - 2) Suspension for having been sanctioned by PAHO for quality problems, product nonconformance, or any other contractual noncompliance, as detailed in Annex 4
 - 3) Suspension for having used the PAHO name or logo for publicity or other unauthorized purposes
 - 4) Suspension for having been sanctioned by PAHO for any other noncompliance or infraction of the present Mechanism for Prequalification of Suppliers

- 5) Removal for failing to respond to requests for price schedules, participate in tenders, or submit POs to PAHO for two consecutive years
 - 6) Removal for failing to submit the updated documentation mentioned in A.1 within the six-month deadline
 - 7) Removal for having been sanctioned by PAHO for serious quality problems, product informance, or any other contractual noncompliance, as detailed in Annex 4
 - 8) Removal for having been sanctioned on three occasions by PAHO with a temporary suspension of 6 months to 1 year due to quality problems, product informance, or any other contractual noncompliance, as detailed in Annex 4
 - 9) Removal for failing to adhere to GMPS, GSP, and/or GDP, as appropriate
 - 10) Removal for having used the PAHO name or logo for publicity or other unauthorized purposes
 - 11) Removal for having been sanctioned by PAHO for any other serious noncompliance, infraction, or fraud related to the present Mechanism for Prequalification of Suppliers
- B) PAHO shall notify the supplier of any the fault or infraction imputed to it and the corresponding sanction through Procurement Services (PRO). The supplier can submit any defense and/or explanations it deems appropriate in writing within ten (10) working days of the date of receipt of the notification of suspension/removal. PAHO shall review the supplier's defense and make a final decision on the applicable sanction. PAHO shall notify the supplier of its decision within 90 days of receipt of the supplier's defense. PAHO's decision shall be final and not subject to appeal.

E. Annex 1

<u>COMPANY PROFILE FORM (CPF) – PRODUCTS</u>		Serial No.
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">   </div> <div style="text-align: center;"> <p>PAN AMERICAN HEALTH ORGANIZATION (PAHO/WHO) <i>Pan American Sanitary Bureau, Regional Office of the</i> WORLD HEALTH ORGANIZATION (WHO)</p> <p>PROCUREMENT SERVICES UNIT (AM/PRO) 525 Twenty-third Street, N.W. Washington, D.C 20037 Telephone: (202) 974-3426 - Fax: (202) 974-3698 E-mail: pro@paho.org</p> </div> </div>		
1. Company Name:		
2. Mailing Address		3. Telephone
		4. Fax:
		5. E-mail:
6. Contact Person:		
7. Years of Establishment:		8. Number of Employees:
9. Gross Annual Sales in US\$:		10. Annual Export Sales in US\$:
11. Type of Business: Manufacturer: <input type="checkbox"/> Agent: <input type="checkbox"/> Supplier: <input type="checkbox"/>		
12. Previous Contracts with United Nations Organizations .:		
Organization:	Value in US\$:	Year:
_____	_____	_____
Organization:	Value in US\$:	Year:
_____	_____	_____
13. Destinations of Previous Exports: .:		
14. List of Products Offered: .:		
<input type="checkbox"/> Anaesthetics	<input type="checkbox"/> Diagnostic agents	
<input type="checkbox"/> Analgesics, antipyretics, nonsteroidal anti-inflammatory drugs (NSAIDs), drugs used to treat gout and disease modifying agents used in rheumatic disorders (DMARDs)	<input type="checkbox"/> Diuretics	
<input type="checkbox"/> Antiallergics and drugs used in anaphylaxis	<input type="checkbox"/> Drugs acting on the respiratory tract	
<input type="checkbox"/> Antidotes and other substances used in poisonings	<input type="checkbox"/> Dialysis solutions	
<input type="checkbox"/> Anticonvulsants /antiepileptics	<input type="checkbox"/> Gastrointestinal agents	
<input type="checkbox"/> Anti-infective agents	<input type="checkbox"/> Hormones, other endocrine agents and contraceptives	
<input type="checkbox"/> Antimigraine agents	<input type="checkbox"/> Immunologics	

<input type="checkbox"/> Antineoplastic and immunosuppressive agents and agents used in palliative care	<input type="checkbox"/> Muscle relaxants (peripherally acting) and cholinesterase inhibitors
<input type="checkbox"/> Antiparkinson's agents	<input type="checkbox"/> Ophthalmic preparations
<input type="checkbox"/> Antiretroviral agents	<input type="checkbox"/> Oxytocics and antioxytocics
<input type="checkbox"/> Blood Products and plasma substitutes	<input type="checkbox"/> Psychotherapeutics agents
<input type="checkbox"/> Cardiovascular agents	<input type="checkbox"/> Solutions correcting water, electrolyte and acid-base disturbances
<input type="checkbox"/> Drugs affecting the blood	<input type="checkbox"/> Vitamins and minerals
<input type="checkbox"/> Dermatological agents (topical)	
<input type="checkbox"/> Disinfectants and antiseptics	

15. Languages: **English** **French** **Spanish** **Other**

_____	_____	_____	_____
Name	Title	Signature	Date

PAHO/WHO PRE-QUALIFICATION QUESTIONNAIRE FOR PHARMACEUTICAL MANUFACTURERS	Serial No.
 <p>PAN AMERICAN HEALTH ORGANIZATION (PAHO/WHO) <i>Pan American Sanitary Bureau, Regional Office of the</i> WORLD HEALTH ORGANIZATION (WHO)</p> <p>PROCUREMENT SERVICES UNIT (AM/PRO) 525 Twenty-third Street, N.W. Washington, D.C 20037 Telephone: (202) 974-3426 - Fax: (202) 974-3615 E-mail: pro@paho.org</p>	

1. General Information on the Manufacturer

1.1 Company Name _____
Address _____
Telephone _____
Fax _____
Website / E-mail _____

1.2 How many production plants do you have? List all and give their addresses.

2. Regulatory Issues and Good Manufacturing Practices

2.1 Products supplied shall be manufactured in conformance with the requirements for Good Manufacturing Practices (GMP) and Quality Control of Drugs as recommended by WHO in Resolution WHA in the 32nd Annual Report for 1992 (WHO Technical Reports Series No. 823) and ratified in the 34th Annual Report in 1996 (WHO Technical Reports Series No. 863).

Please submit a copy of the last GMP authorized inspection report issued by a government regulatory agency. The one-year validity of the report must not have expired.

2.2- If the plant has already been inspected and authorized by WHO, UNICEF, another United Nations agency or MCA-UK, and US-FDA, please attach the reports from the latest of such inspections.

3. Range of Products

Indicate your range of products and attach your product list
Product list attached

Range of Products	YES	NO
Non-sterile, oral preparations, Non β -lactam		
Non-sterile, oral β -lactam antibiotics		
Non sterile external preparations		
Parenterals, dry powder for injection, β -lactam antibiotics		
Parenterals, dry powder for injection, Non β -lactam antibiotics		
Liquid parenterals, heat sterilized in final container		
Liquid parenterals, aseptically produced		
Suppositories		

Tablets / vaginal tablets		
Sterilized ophthalmic solutions		
Sterilized ophthalmic ointments / creams		
Sprays / inhalers		
Other forms (attach)		

4. Registration Status of Products

4.1 – Submit the certificate for products produced for export issued by the National Drug Regulatory Authority using the recommended WHO form (Model Statement of Licensing Status of Pharmaceutical Product(s))

Website: www.who.int/medicines/teams/qsm/modstate.html

5. Stability

5.1 – Have all products been tested to guarantee quality until the end of their shelf life?

6. Production

6.1 - Attach Site Master File (details in the instructions)

6.2 - If products are contracted out to other facilities, list products and Site Master File of the manufacturing facilities

7. Visit/Inspection

7.1 - Manufacturing facilities could be visited by the PAHO/WHO authorities or by PAHO/WHO authorized professionals to verify GMP requirements and attest to the documentation submitted

8. Documentation to be provided in the event of purchase.

8.1- For each product selected/purchased by PAHO/WHO and prior to each shipment, prequalified suppliers shall provide a pharmaceutical product certificate that conforms to the recommended WHO format (website: www.who.int/medicines/docs/modcert.html)

9. Shipping documents

9.1 – A Certificate of Analysis (CA) must be supplied to the consignee with a copy to PAHO for each batch from which product is supplied, in compliance with the specifications in the latest monographs of one of the following pharmacopoeias: the International Pharmacopoeia, United States Pharmacopoeia - National Formulary, European Pharmacopoeia, British Pharmacopoeia, and other PAHO/WHO specifications.

This Certificate of Analysis must include manufacture and expiration dates.

9.2 - Bulk containers are accepted only if the consignee country specifically requires it, ensuring that the country has appropriate quality assurance systems in place to guarantee the repackaging process. Solid products should preferably be packed in blister-packs

9.3 – Label for each product conforming to PAHO/WHO indications must be submitted (details in the requirements below with the instructions)

9.4 - Bioavailability/bioequivalence testing may be required by PAHO/WHO and the consignee country.

INSTRUCTIONS FOR THE PAHO/WHO PREQUALIFICATION QUESTIONNAIRE FOR PHARMACEUTICAL MANUFACTURERS

1. The PAHO/WHO Prequalification Questionnaire should be completed exclusively by the Pharmaceutical Manufacturers and delivered to the PAHO/WHO Procurement Office (PRO), with all the required documentation attached.

The purpose of this questionnaire is to maintain a list of eligible drug manufacturers that can be referred to for PAHO/WHO tenders.

It is therefore necessary that the documentation be current in order to ensure that the company complies with Good Manufacturing Practices (GMP) as recommended by WHO in Resolution WHA of the 32nd Annual Report for 1992 (WHO Technical Reports Series No. 823) and ratified in the 34th Annual Report in 1996 (WHO Technical Reports Series No. 863).

2. The companies may be registered as a pharmaceutical company *per se* or as a company specializing in a particular pharmaceutical product which must comply with quality controls during the production process.

The production plants chosen by a manufacturing company (item 1.2), either its own or one that is contracted (for lack of a facility to produce a particular pharmaceutical product or its inadequate capacity to produce a given volume of the product) shall be evaluated on the basis of the documentation they submit.

Compliance with Good Manufacturing Practices (GMP) (item 7) can be verified through visits by the PAHO/WHO authorities or authorized PAHO/WHO professionals to the manufacturing facilities. Such visits can be waived if the production plants present documentation to corroborate that they have already been inspected and authorized by WHO, UNICEF and other United Nations agencies (item 2.2).

3. When presenting a copy of the last GMP authorized inspection certificate, whose one-year validity must not have expired (item 2.1), reference should be made to the particular production area inspected, the recommendations made, the name of the actual inspector, his signature, and date.
4. The pharmaceutical products that are offered (item 3) will only be those that the company declares as its own and which are guaranteed under stability studies for their quality of shelf life (item 5.1).

These products must correspond to the export license (item 4.1) approved by the national health authorities of the country of origin (not valid if produced by a decentralized entity – provincial, state, or municipal) and be in compliance with the recommended WHO format (Model Statement of Licensing Status of Pharmaceutical Product(s), Website:

[/www.who.int/medicines/tams/qsm/modstate.html](http://www.who.int/medicines/tams/qsm/modstate.html))

5. In order to have a general understanding of the company, its organization, and production, the Site Master File should be submitted (item 6.1 – 6.2), with the following minimum requirements:
 - a) General Information: abbreviated information on the company, address and site description. Number of employees. Brief description of the quality management system.
 - b) Personnel: organizational chart covering quality assurance, quality control, production and storage/distribution. Educational level, experience, and responsibilities of key personnel.
 - c) Quality Control: description of the Quality Control System and the activities of the Quality Control Department.
 - d) Production Contracts and Analysis
 - e) Distribution, Complaints, and Market Recall
 - f) Self-Inspection
 - g) Diagram/Plan of the Installation
6. Once the pharmaceutical products are selected in the bidding process (purchased) the company must, prior to shipment, provide pharmaceutical product certificates that conform to the recommended WHO format, which will be required at the time of a Request for Bid. (Website: www.who.int/medicines/docs/modcert.html) (Item 8.1).
7. For each shipment of medicaments/medicines acquired the pertinent Certificate of Analysis (CA) must be included for each batch (item 9.1) and for each recipient country.

The CA should comply with the requirements corresponding to the most recent monographs of: the International Pharmacopoeia, the United States Pharmacopoeia – National Formulary, European Pharmacopoeia, British Pharmacopoeia, and other PAHO specifications. The certificate should include the manufacture and expiry dates.

8. Bulk containers are accepted only if the consignee country specifically requires it, ensuring that the country has a suitable quality control system in place for repackaging (item 9.2); these systems must have qualified professionals, suitable equipment/containers and environmental conditions - and optimal temperature, humidity, pressure, aseptic - necessary for the particular product. Solid products should preferably be packed in blister packs.
9. Labels should be in the language of the consignee country, and/or in other languages if space permits, and contain the minimum information necessary (item 9.3), as follows:
 - a) Nonproprietary name of the active ingredients (e.g. INN)
 - b) Dosage forms, weight and volume or dosage unit**
 - c) **Strength** of active ingredients per unit dose, weight, volume or in international units
 - d) Administration
 - e) Manufacture's batch number
 - f) Manufacture date
 - g) Expiration date
 - h) Storage conditions and necessary precautions
 - i) Name and address of manufacturer
 - j) Name and address of the PAHO/WHO supplier

Example: The following information should be included in a label of an antifungal ointment

- a) Clotrimazole
- b) 25 g cream (topical 1% - 25g)

- c) 1 g cream containing 10 mg of Clotrimazole (1% - 10mg)
- d) Topical application
- e) Batch No. 210700
- f) Manufacture date : 07/2000
- g) Expiration date: 07/2003
- h) Store at : less than 70° F
- i) Produced by: Laboratory X
- j) Supplier: XX

10. In the case of related products (solution or suspensions) the label must include the amount of active ingredient in terms of mass or biological activity by volume.

In the case of concentrated solutions, the label should indicate the composition and dilution factors prior to use.

If the product is packed in bulk, the label should specify the number of vials contained in the batch, including the requirements as previously detailed above.

11. It is up to the consignee country and PAHO/WHO to require proof of bioavailability - bioequivalence tests (item 9.4) depending on the drug characteristics, as based on its pharmacological activity mechanism, dosage form, biological activity, etc.
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PAHO/WHO PREQUALIFICATION QUESTIONNAIRE FOR PHARMACEUTICAL SUPPLIERS (NON MANUFACTURERS)	Serial No.
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">   </div> <div style="text-align: center;"> <p>PAN AMERICAN HEALTH ORGANIZATION (PAHO/WHO) <i>Pan American Sanitary Bureau, Regional Office of the</i> WORLD HEALTH ORGANIZATION (WHO)</p> <p>PROCUREMENT SERVICES UNIT (AM/PRO) 525 Twenty-third Street, N.W. Washington, D.C 20037 Telephone: (202) 974-3426 - Fax: (202) 974-3698 E-mail: nro@naho.org</p> </div> </div>	

1. General Information on the Supplier/Distributor

1.1 Company Name _____
Address _____
Telephone _____
Fax _____
Website / E-mail _____

1.2 Is the Company an Agent or Supplier?

1.3 Please list all **manufacturers** and countries of origin for each product.

2. Regulatory Issues and Good Manufacturing Practices (GMP)

2.1 Products supplied shall be manufactured and stored in conformance with the requirements for Good Manufacturing Practices (GMP) and Quality Control of Drugs, as recommended by WHO in Resolution WHA 32nd Annual Report for 1992 (WHO Technical Reports Series No. 823) and ratified in the 34th Annual Report in 1996 (WHO Technical Reports Series No. 863).

Please submit a copy of the last GMP authorized inspection report issued by a regulatory government agency, whose one-year validity has not expired.

2.2 - If the plants have already been inspected and authorized by WHO, UNICEF, or other United Nations agencies, or the MCA-UK or US-FDA, please attach the reports of the latest such inspections.

3. Range of Products

Indicate your range of products and attach your product list
Product list attached

Range of Products	YES	NO
Non-sterile, oral preparations, Non β -lactam		
Non-sterile, oral β -lactam antibiotics		
Non sterile external preparations		
Parenterals, dry powder for injection, β -lactam antibiotics		
Parenterals, dry powder for injection, Non β -lactam antibiotics		
Liquid parenterals, heat sterilized in final container		
Liquid parenterals, aseptically produced		
Suppositories		
Tablets / vaginal tablets		
Sterilized ophthalmic solutions		
Sterilized ophthalmic ointments / creams		
Spray / inhalers		
Other forms (attach)		

4. Status of the Company

4.1 -Attach Site Master File (details in the instructions)

4.2 -For each **Manufacturer** included in 1.3, a PAHO/WHO Prequalification Questionnaire for Pharmaceutical Manufacturers (attached) shall be completed

5. Documentation to be provided in the event of purchase.

5.1- For each product selected / purchased by PAHO/WHO and prior to each shipment, the prequalified supplier shall provide a pharmaceutical product certificate that conforms to the recommended WHO format.

(Website: www.who.int/medicines/docs/modcert.html)

6. Shipping documents

6.1 – A Certificate of Analysis (CA) must be supplied to the consignee with a copy to PAHO/WHO for each batch from which product is supplied, in compliance with the specifications in the latest monograph of one of the following pharmacopoeias: the International Pharmacopoeia, United States Pharmacopoeia - National Formulary, European Pharmacopoeia, British Pharmacopoeia, and other PAHO/WHO specifications. This Certificate of Analysis must include manufacture and expiration dates.

6.2 - Bulk containers are accepted only if the consignee country specifically requires it, ensuring that the country has appropriate quality assurance systems in place to guarantee the repackaging process. Solid products should preferably be packed in blister packs.

6.3 – Label for each product conforming to PAHO/WHO indications must be submitted (details in the requirements below with the instructions)

6.4 - Bioavailability/bioequivalence testing could be required by PAHO/WHO and the consignee country.

7. Visit / Inspection

7.1 - Manufacturing facilities may be visited by PAHO/WHO authorities or PAHO/WHO authorized professionals to verify compliance with GMP requirements and the documentation submitted.

INSTRUCTIONS FOR THE PAHO/WHO PREQUALIFICATION QUESTIONNAIRE FOR PHARMACEUTICAL SUPPLIERS (NON MANUFACTURERS)

9. The PAHO/WHO Prequalification Questionnaire must be completed exclusively by the pharmaceutical suppliers or agents (non-manufacturers) and delivered to Procurement Services (PRO) with all the required documentation attached.

The purpose of this questionnaire is to maintain a directory of pharmaceutical suppliers that can be referred to for PAHO tenders.

It is, therefore, necessary that the documentation be current in order to ensure that it complies with the Good Manufacturing Practices (GMP) as recommended by WHO in Resolution WHA 32nd Annual Report for 1992 (WHO Technical Reports Series No. 823) and ratified in the 34th Annual Report in 1996 (WHO Technical Reports Series No. 863).

2. If the company is an Agent, the requirements in item 2 apply to the distributors or company engaged in distribution activity. The production facilities contracted by the Agent (item 1.3) shall be analyzed on the basis of the documentation they present and through visits by PAHO/WHO authorities or PAHO/WHO authorized professionals to verify compliance with GMP requirements and the documentation submitted (item 7). Such visits can be waived if the plants have already been inspected and authorized by WHO, UNICEF or other United Nations agencies, and the report from the latest such inspections is attached (item 2.2).
3. When presenting a copy of the last GMP authorized inspection certificate, whose one-year validity has not expired (item 2.1), reference should be made to the particular production area inspected, the recommendations made, the name of the inspector, his signature, and date.
4. The pharmaceutical products offered (item 3) shall be only those that the company declares as its own responsibility. These products should correspond to the manufacturing license issued by the **national** health authorities of the country of origin (not valid if produced by a decentralized entity—provincial, state, or municipal) and comply with the recommended WHO form (Model Statement of Licensing Status of Pharmaceutical Product(s),
Website: www.who.int/medicines/tams/qsm/modstate.html)
5. In order to have a general understanding of the company, its organization, and production, the Site Master File should be submitted (item 4.1 - 4.2), with the following basic requirements:

- h) General Information: abbreviated information on the company, address, and site description. Number of employees. Brief description of the quality management system.
 - i) Personnel: organizational chart covering quality assurance, quality control, production and storage/distribution. Educational level, experience, and responsibilities of key personnel.
 - j) Quality Control: description of the quality control system and the activities of the quality control department.
 - k) Production contracts and analysis
 - l) Distribution, complaints, and market recall
 - m) Self-inspection
 - n) Diagram/Plan of the installation
6. Only companies registered in the PAHO/WHO list of eligible manufacturers of pharmaceutical products can participate at PAHO/WHO pharmaceutical tenders.
 7. Once the pharmaceutical products are selected through the tender (purchased) the company must, prior to shipment, provide pharmaceutical product certificates that conform to the recommended WHO format, which will be required at the time of the Request for Bid. (Website: www.who.int/medicines/docs/modcert.html) (Item 5.1)
 8. For each shipment of drugs / medicines procured, the pertinent Certificate of Analysis (CA) must be included for each batch (item 6.1) and for each recipient county.
The CA must meet the requirements corresponding to the most recent monographs of: the International Pharmacopoeia, the United States Pharmacopeia – National Formulary, European Pharmacopoeia, British Pharmacopoeia, and other PAHO specifications. The certificate should include the manufacture and expiration dates.
 9. Bulk containers are accepted only if the consignee country specifically requires it, ensuring that the country has a suitable quality control system in place for repackaging (item 6.2). These systems must to have qualified professionals, suitable equipment/containers and environmental conditions - optimal temperature, humidity, pressure, aseptic conditions - necessary for the particular product . Solid products should preferably be packed in blister packs.
 10. Labels should be in the language of the consignee country, and/or other languages if space permits, and contain the minimum necessary information (item 6.3), as follows:
 - k) Nonproprietary name of the active ingredients (e.g. INN)
 - l) **Dosage forms and weight, volume or dosage unit.**
 - m) **Strength** of active ingredients per unit dose, weight, volume or in international units
 - n) Administration
 - o) Manufacture's batch number
 - p) Manufacture date
 - q) Expiration date
 - r) Storage condition and necessary precautions
 - s) Name and address of manufacturer
 - t) Name and address of the PAHO/WHO provider

Example: The following information should be included on the label of an antifungal ointment

- k) Clotrimazole
- l) 25 g cream (topical 1% - 25g)
- m) 1 g cream containing 10 mg of Clotrimazole (1% - 10mg)
- n) Topical application

- o) Batch No. 210700
- p) Manufacture date : 07/2000
- q) Expiration date: 07/2003
- r) Store at : less than 70° F
- s) Produced by: Laboratory X
- t) Supplier: XX

11. In the case of related products (solutions or suspensions) the label must include the amount of active ingredient in terms of mass or biological activity by volume.

In the case of concentrated solutions, the label should indicate the composition and dilution factors prior to use.

If the product is packed in bulk, the label should specify the number of vials contained in the batch, including the requirements as previously detailed above.

12. It is up to the consignee country and PAHO/WHO to require proof of bioavailability - bioequivalence tests (item 6.4) depending on the characteristics of the drug, based on its pharmacological activity mechanism, dosage form, biological activity, etc.

F. Annex 2

DOCUMENT CHECKLIST FOR SUPPLIERS

Procurement Services (PRO) shall use the following checklist to ensure that all the documentation presented is complete.

Incomplete requests will not be evaluated. Procurement Services (PRO) may contact the requestor for additional information or documentation.

When the documentation is complete, Procurement Services (PRO) will forward it to the Program on Essential Drugs (Quality Assurance)

Document checklist

1. The language may be English or Spanish
2. CPF (Company Profile Form)
3. Prequalification Questionnaire, including:
 - Certificate of GMP and Company Registration
 - Site Master File with legible plan of the installations
 - Product list

F. Annex 3

TECHNICAL EVALUATION PROCEDURE

1. The Program on Essential Drugs (Quality Assurance) shall evaluate the documentation received from Procurement Services (PRO) within 30 working days of receipt, using the form attached.
2. This form shall serve as proof of evaluation and shall be the first page in the file on the respective company.
3. If it has been inspected by WHO, UNICEF, another United Nations agency, ACM-UK, or US-FDA, attach a copy of the inspection certificate/authorization.
4. When the supplier is an agent such as ADI, IMRES, MEG, AMSTELFARMA, the report of the inspection conducted by the supplier agent shall be requested from the manufacturer as part of the prequalification documents.
5. When country authorities do not submit copies of the inspection report (India for example) or submit a GMP certificate after the inspection has been conducted, other evidence of compliance with GMP shall be required-- e.g., companies must be suppliers of a known agent, have a complete site master file, have been inspected by the regulatory authorities of a country that exercises a high degree of health surveillance, etc.
6. If necessary, additional information shall be requested from the company.
7. The results of the evaluation must be reported to Procurement Services (PRO), which shall notify the company upon its technical prequalification.
8. Semiannually, the Program on Essential Drugs (Quality Assurance) shall send Procurement Services (PRO) an updated list on the prequalification status of the companies evaluated.

(Technical Evaluation Form on the following page)

TECHNICAL EVALUATION (HSP/HSE)



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

525 Twenty-third Street, N.W. Washington, D.C 20037
phone: (202) 974-3496 - fax: (202) 974-3610

COMPANY NAME:

A - GENERAL INFORMATION:

- Range of products:

beta -lactam

non beta-lactam

- . oral solids
- . oral liquids
- . parenterals
- . sterile dry powder
- . ointments
- . others

- Manufacturing facilities:
- Manufacturing facilities contracted:
- N° of employees:
- Previous contracts with WHO PAHO UNICEF US-FDA MCA (UK) others

B - CPF:

C - GMP certificate:

D - Audit report:

E - Site Master File :

Site Plan:

F - List of products:

Product certificate in conformity with WHO recommendations:

G - Information requested:

H - Prequalify:

Date:

Evaluated by:

Signed:

H. Annex 4

Operating Procedure when Pharmaceuticals Reach the Country of Destination

1. Every purchase of pharmaceuticals made through PAHO must be audited by the requesting Agency within 60 days of reaching the country, and the findings should be sent to Procurement Services (PRO) through the PAHO Representative Office in the respective country.
2. The purchase audit shall consist of two procedures: an administrative audit (a comparison what is received and the purchase order) and a product audit. Eventually, if deemed necessary or at the discretion of PAHO or the authorities of the client country, physical-chemical quality tests shall be performed.
 - 2.1 Administrative audit: the following shall be confirmed:
 - 2.1.1 Number of units received vs., the number requested in the purchase order
 - 2.1.2 Conditions of transport (temperature, cold chain, humidity, etc.)
 - 2.1.3 Certificate of analysis for each batch of pharmaceuticals received.
 - 2.2 Product audit:
 - 2.2.1 Labeling of primary containers:
 - 2.2.1.1 Languages
 - 2.2.1.2 Generic name of the pharmaceutical
 - 2.2.1.3 Concentrations of active ingredient
 - 2.2.1.4 Unit weight or volume
 - 2.2.1.5 Manufacturing batch numbers
 - 2.2.1.6 Expiration date
 - 2.2.1.7 Date of manufacture (if appropriate)
 - 2.2.1.8 Name of producer (if appropriate)
 - 2.2.1.9 Storage conditions (if appropriate)
 - 2.2.2 Labeling of secondary containers:
 - 2.2.2.1 All the information on the label of the primary container (point 2.2.1)
 - 2.2.2.2 Number of primary containers in the secondary container
- 2.3 Physical-chemical testing: this should be done in the country's official pharmaceutical quality control laboratory or a facility designated by that laboratory, on a random proportional sample of each batch of product acquired. Tests for the following will be performed:
 - 2.3.1 Weight, volume
 - 2.3.2 Identification of the active ingredient

- 2.3.3 Hygienic control in nonsterile dosage forms (tablets, capsules, ovules, syrups, powders)
 - 2.3.4 Microbiological potency of antibiotics
 - 2.3.5 Dissolution of tablets
 - 2.3.6 Sterility of injectables, collyria, sterile forms
 - 2.3.7 Absence of particles in injectables (see Annex)
3. When the pharmaceuticals procured do not satisfactorily meet some of the aforementioned criteria, Procurement Services (PRO) and/or the Program on Essential Drugs (Quality Assurance) shall decide on the action to take, depending on nature of the problem detected. The document on pharmaceutical quality problems will serve as a guide for decision-making.

I. Annex 5

PAHO/WHO QUALITY OF PHARMACEUTICALS MOST COMMON PROBLEMS AND APPLICABLE SANCTIONS

No	Problem	Action	Term	Responsibility	Sanctions ¹	Comments
1	The batch certificate is missing or incomplete	PAHO requests the supplier to send the certificate. Goods may need to be replaced by the supplier.	60 days	The supplier is responsible for any product replacement costs and for providing the certificate	Supplier and producer will receive a warning	Samples are analyzed at the discretion of the country or PAHO/WHO.
2	Inadequate transportation conditions	PAHO and/or the recipient country will evaluate the problem and determine appropriate action.	60 days	The supplier is responsible for cost, test and possible partial or total replacement of goods	The supplier will receive a warning	Products may require testing. Freight insurance may be involved and /or may cover costs
3	Inadequate storage conditions at the country of destination	The country will carry out product quality control tests on random samples. PAHO technical units may provide technical support.	Permanent	The recipient country is responsible for testing and any product loss.	Suppliers and manufacturers are not responsible. Recipient country will receive a technical advice from PAHO on best practices	
4	Different dosage form received from that requested (i.e. tablet instead of ampoules)	PAHO requests supplier to replace product	60 days	Cost covered by the supplier including shipment of returned product.	The supplier will receive a warning	All batches involved be replaced by the supplier
5	Incorrect product in primary container (e.g. ampoules labeled Gentamycin but active ingredient in ampoules is Erythromycin)	PAHO requests supplier to replace product	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier will be suspended for 3 months and the manufacturer will be suspended for 2 years	Affected product will be destroyed according to the norms detailed in national legislation of the country of destination

¹ The sanctions listed will be imposed on the supplier/manufacturer the first time a problem has been reported and confirmed. If a quality problem occurs a second time, the duration of sanction listed will be doubled. If the problem occurs a third time or if any number of product quality problems arise, PAHO will decide on the sanctions to be imposed.

No	Problem	Action	Term	Responsibility	Sanctions ¹	Comments
6	Incorrect product in secondary container (i.e. ampoules containing/labeled Penicillin are packaged in outer container labeled Streptomycin)	PAHO requests supplier to replace product	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The Supplier will be suspended for 3 months the manufacturer will be suspended for 2 years	Affected product will be destroyed according to the norms detailed in national legislation of the country of destination
7	Incorrect product name on primary container (i.e. it says Gentamycin HCl instead of Gentamycin Sulfate on the inner container)	PAHO requests supplier to replace product	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier receives warning and the manufacturer will be suspended for 3 months	On review, the National Authority will decide if the batch is to be tested and used in the country of destination. If approved for use, no product replacement will be required
8	Incorrect product name on the secondary container (i.e. it says Gentamycin HCl instead of Gentamycin sulfate on the outer container)	PAHO requests supplier to replace product	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier receives a warning and the manufacturer will be suspended for 3 months	On review, the National Authority will decide if the batch is to be tested and used in the country of destination. If approved for use, no product replacement will be required
9	An added label on the primary container, modifying product information (i.e. expiration date)	PAHO requests supplier to replace product	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 6 months and the manufacturer suspended for 2 years	The batch should be evaluated at the country of destination and affected units destroyed. Unaffected units can be used after quality testing.
10	An added label on secondary container modifying product information	PAHO requests supplier to replace product	60 days	The supplier will replace all affected product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 6 months and the manufacturer eliminated from the PAHO approved list	The batch should be evaluated at the country of destination and affected units destroyed. Unaffected units can be used after quality testing.
11	Discrepancies in expiration date. Certificate of analysis indicates one expiry date Product shows another	PAHO requests supplier to replace product	60 days	The supplier will replace all affected product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier and manufacturer are suspended for 6 months	Stability tests may be performed as well as other tests on all batches of the same product listed in the Purchase Order. Approved products following testing may be used, with an appropriate warning in the secondary container.
12	Alteration of the expiration date	PAHO requests supplier to replace product	60 days	The supplier will replace all affected product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 6 months and the manufacturer eliminated from the PAHO approved list	On review, the National Authority will decide if the batch is to be tested and used in the country of destination. If approved for use, no product replacement will
13	Incorrect language on	PAHO coordinates between	60 days	May not involve costs. The supplier	The supplier will	The batch will be controlled at the country

No	Problem	Action	Term	Responsibility	Sanctions ¹	Comments
	the label but easily understood in the recipient country (i.e. Spanish instead of Portuguese)	National Authorities and Supplier. If National Authorities do not accept product, then PAHO requests supplier to replace product		is responsible for cost, test and possible partial or total replacement of goods.	receive a warning	of destiny. Goods most probably can be used
14	Incorrect language on the label. Text is not understood in the recipient country (i.e. Chinese instead of Portuguese)	PAHO requests supplier to replace product	60 – 90 days	The supplier is responsible for cost, test, destruction and possible partial or total replacement of goods.	The supplier is suspended for 3 months.	The supplier will decide if the affected batches are to be returned or destroyed.
15	Concentration of the active ingredient outside specifications. (Gentamycin 60 mg instead of 80 mg)	PAHO requests the supplier to replace all affected batches	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 6 months	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
16	Cross-contamination (i.e. a different active ingredients in the product)	PAHO requests the supplier to replace all affected batches	60 – 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 3 months and the manufacturer eliminated from the PAHO approved list	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
17	Microbial contamination in hygienic or sterility controls	PAHO requests the supplier to replace all affected batches	60 – 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 3 months and the manufacturer will be eliminated from the PAHO approved list	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
18	Tablet formulations do not conform to dissolution specifications	PAHO requests the supplier to replace all affected batches	60 – 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued
19	Presence of broken tablets	PAHO informs supplier and requests supplier to replace product if necessary	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months	Quality testing will be performed at country of destination. A decision will be taken by the National Regulatory Authority and product will be controlled at endpoints; unaffected product units may be used
20	Tablets or capsules outside specification in color, size, weight, etc.	PAHO requests the supplier to replace all affected batches if necessary	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months	Quality testing will be performed at country of destination. A decision will be taken by the National Regulatory Authority and product will be controlled at endpoints; unaffected product units may be used
21	Injectables with	PAHO requests the supplier	60 days	The supplier will replace all	Both the supplier and	Quality testing will be performed at country

No	Problem	Action	Term	Responsibility	Sanctions ¹	Comments
	presence of particles	to replace all affected batches if necessary		product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	the manufacturer are suspended for 3 months	of destination. A decision will be taken by the National Regulatory Authority and product will be controlled at endpoints; unaffected product units may be used
22	Injectable with differences in ampoule liquid volumes	PAHO requests the supplier to replace all affected batches if necessary	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months	On review, the National Authority will decide if the batch is to be tested and used in the country of destination. If approved for use, no product replacement will be required.
23	Low potency in activity of supplied antibiotic	PAHO requests supplier to replace product	60 – 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier is suspended for 3 months and the manufacturer will be eliminated from the PAHO approved list	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
24	Difference in containers (size, form, color, etc.)	PAHO informs supplier and requests supplier to replace product if necessary	60 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
25	Turbidity or precipitation	PAHO requests the supplier to replace all affected goods	60 - 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	Both the supplier and the manufacturer are suspended for 3 months. If contamination is microbial in nature, the manufacturer will be suspended for 2 years	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.
26	Dissolution problems upon reconstitution of sterile product	PAHO requests the supplier to replace all affected goods	60 – 90 days	The supplier will replace all product free of charge and will cover related costs (quality testing, possible destruction of incorrect units etc)	The supplier will receive a warning and the manufacturer will be suspended for a 3 month period	Once confirmed through testing at two quality control laboratories (one selected by PAHO), affected batches will be destroyed and a destruction certificate issued.

J. Annex 6

Authorization for Local Pharmaceutical Purchases in Emergencies

In order to assure the quality of the pharmaceuticals that PAHO procures on behalf of a Member State in an emergency, PAHO criteria for the prequalification of suppliers/manufacturers should be respected to ensure that the procurement process is transparent, avoiding inferior, counterfeit, and/or contaminated products that endanger the health of patients.

1. In emergencies, when it is necessary to purchase pharmaceuticals without going through Procurement Services (PRO), these products can be acquired at the national level from suppliers that have already been prequalified, following the procedure detailed in this document, subject to authorization from Procurement Services (PRO).
2. If, during the emergency, the country cannot procure the pharmaceuticals from prequalified suppliers, the purchase can be made from a non-prequalified supplier, subject to authorization from Procurement Services (PRO).
3. If the non-prequalified supplier is a manufacturer, the following must be requested:
 - 3.1 Good Manufacturing Practices (GMP) certificate, issued by the National Regulatory Authority
 - 3.2 Health Authority pharmaceutical registration number
 - 3.3 Certificate of analysis for the manufacturing batch.
4. If the non-prequalified supplier is an agent, representative, or distributor, the following should be requested:
 - 4.1 Certificate authorizing operations, issued by the National Regulatory Authority
 - 4.2 Health Authority pharmaceutical registration number, according to the origin of manufacture (single source; multisource, or generic)
 - 1.3 Good Storage and Distribution Practices certificate (WHO Technical Report Series, No.908, 2003 and No.917, 2003)
5. When the amount of pharmaceuticals exceeds 10 presentation units (boxes, cases, bottles), quality tests should be performed in the official pharmaceutical quality control laboratory of the country of destination.
6. In the case of local pharmaceutical purchases in emergencies, Procurement Services (PRO) shall notify the unit responsible for quality assurance of pharmaceuticals (THS/EV).