



GUIDELINES
FOR
PROCUREMENT OF PHARMACEUTICALS
&
MEDICAL DEVICES

2006

NATIONAL PROCUREMENT AGENCY

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ACRONYMS

CDDA	-	COSMETICS, DEVICES & DRUGS REGULATORY AUTHORITY OF SRI LANKA
MOH	-	MINISTRY OF HEALTH
MSD	-	MEDICAL SUPPLIES DIVISION/MINISTRY OF HEALTH
PE	-	PROCURING ENTITY
PG	-	PROCUREMENT GUIDELINES (MARCH 2006)
SPC	-	STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
SPMC	-	STATE PHARMACEUTICALS MANUFACTURING CORPORATION
SLR	-	SRI LANKA RUPEE

DEFINITIONS

Unless the context otherwise requires, capitalized terms used in these Guidelines for the Procurement of Pharmaceuticals & Medical Devices and its schedules, shall have the meanings ascribed to each of them herein below.

For the purposes hereof, capitalized terms which are not defined herein shall have the meanings ascribed to them in the Procurement Guidelines, March 2006 to the extent required.

ABC Value Analysis	means methods by which Pharmaceuticals are divided according to their annual usage (unit cost times annual consumption), into Class A items (the 10 to 20 percent of items that account for 75 to 80 percent of the funds spent). Class B items (with intermediate usage rates), and Class C items (the vast majority of items with low individual usage, the total of which accounts for 5 to 10 percent of the funds spent).
Accessory	means an article which is intended specifically by its manufacturer to be used with the "parent" Medical Device to enable the Medical Device to achieve its intended purpose, and includes reagents.
Change in Law	means any change to existing legislation including the introduction of new laws and the repeal of, or modification of existing laws of, and which relates to taxation or imposes rationing or relates to duties and other import/export levies, which in each case is beyond the control of the supplier/manufacturer and materially affects the performance of the Supplier's/manufacturer's responsibilities under the Contract
Consultant	means medical/dental specialists who have been certified as consultants by the Medical Council of Sri Lanka.
Contraceptives	means mechanical contraceptives such as condoms, diaphragms and intra-uterine devices (IUDs) as well as hormonal contraceptives, implants, pill and injection forms.
Critical Products	means the same as described with reference to Vital Products herein below.
Drugs	means any substance (which may be under patent or a proprietary preparation) intended by the manufacturer to be used, alone or in combination, for human beings, including vitamins which are prescribed in therapeutic formulations, for one or more of the specific purposes of: (a) the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof;

- (b) restoring, correcting or modifying organic functions;
- (c) supporting or sustaining life; but excludes any Ayurvedic or homoeopathic preparation in any form.

Cosmetics, Devices & Drugs Regulatory Authority means the authority established pursuant to the Cosmetics, Devices and Drugs Act No. 27 of 1980 as amended.

Effectiveness means clinical effectiveness when it produces the effect intended by the manufacturer relative to the medical condition.

Efficacy means generally Effectiveness under an ideal controlled setting.

Essential Products means generally Pharmaceuticals which satisfy the health needs of the majority of the population, and are intended to be available in the health system at all times in adequate amounts, appropriate dosage forms and assured quality and refers to products categorized as “essential drugs” in the publication entitled “List of Essential Drugs, Ministry of Health, 1999 or any subsequent revisions thereto.

Force Majeure means an event or circumstance or situation which is beyond the reasonable control of a Party and is not foreseeable, is unavoidable and which makes a Party’s performance of its obligations under the contract impossible or so impractical as to be considered impossible under the circumstances and shall include:

- acts of God, such as exceptionally adverse climatic conditions, lightning, earthquake, cyclone, flood, volcanic eruption; or
- radioactive contamination, epidemics, quarantine restriction or ionizing radiation, or
- an act of war (whether declared or undeclared, invasion, armed conflict, blockade, embargo, riot, insurrection, terrorist or military action, civil commotion, revolution, sabotage; or
- expropriation or compulsory acquisition by any governmental agency or any other governmental intervention in its sovereign capacity.

Force Majeure shall not include the inability of the PE to make payments that are due to the supplier/manufacturer under the agreed terms of contract.

Generic	means products which are the therapeutic equivalent of an originator product whose patent has expired. It contains the same active substance as the originator product and is essentially similar to, and is therefore, interchangeable with the originator product. A generic product is produced and marketed in compliance with international patent law. It is identified either by its scientific International Non-proprietary Name (INN) or less frequently by its own brand name.
Good Manufacturing Practices (GMP)	means that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification and includes criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control and in most cases, stability testing.
Identity	means presence of the correct active ingredient in a Pharmaceutical product.
Inflation	means the percentage increase in the Colombo Consumers Price index , the rate of which is monthly published by the Department of Census and Statistics of the Central Bank of Sri Lanka
Limited Source Products	means: <ul style="list-style-type: none">(i) Pharmaceutical products which are Pharmaceutically Equivalent and are available from a limited number of manufacturers; and(ii) Medical Devices which share a common generic description such as by reference to in the Global Medical Device Nomenclature (GMDN) and/or Universal Medical Device Nomenclature System and are available from a limited number of manufacturers.
Medical Devices	means any instrument, apparatus, implant or contrivance, or related article including any component, part or Accessory thereof, which by nature is a consumable product and which is intended by the manufacturer to be used, alone or in combination for human beings, for one or more of the following specific purposes. <ul style="list-style-type: none">(i) the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof,(ii) restoring, correcting or modifying a body function or the body structure,

(iii) diagnosis of pregnancy and prevents conception,

Medical Equipment means any machine, appliance, software or related article including any component, part or Accessory thereof, which by nature is not a consumable product and is intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the following specific purposes and achieves its purpose;

- (i) the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof,
- (ii) supports and sustains life.

Multi-Source Product means:

- (i) Pharmaceutical products which are Pharmaceutically Equivalent and are available from a wide range of worldwide manufacturers with established pharmacopial specifications and reference standards and are often marketed under international non-proprietary name (INN).
- (ii) Medical Devices which share a common generic description such as by reference to in the Global Medical Device Nomenclature (GMDN) and/or Universal Medical Device Nomenclature System and are manufactured by world-wide manufacturers.

Non-essential products means products which are neither Critical nor Essential and refers to Pharmaceuticals classified as “non-essential drugs” in the publication entitled “List of Essential Drugs, Ministry of Health, 1999 or any subsequent revisions thereto.

Performance means Effectiveness and other factors such as technical functions and others closely related to safety.

Pharmaceuticals means Drugs, biological products, Contraceptives and food items that are deemed to contain components of pharmaceuticals as determined by the CDDA.

Pharmaceutically Equivalent means Pharmaceutical products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendial or other applicable standards of strength, quality and purity.

Procuring Entity	means the Ministry of Health or the State Pharmaceuticals Corporation of Sri Lanka, as the context requires.
Quality	means: (i) for Pharmaceuticals an assessment of product compliance with pharmacopeial specifications concerning its identity, purity, potency and other characteristics, such as uniformity of the dosage unit, bio-availability and stability; (ii) for Medical Devices compliance with international, regional or national, quality system Standards.
Quality Assurance	means the management activities required to ensure that the product which reaches the patient is safe, effective and acceptable to the patient.
Single Source Product	means a product which is generally under patent and is available only from one manufacturer.
Stability	means the ability of a Pharmaceutical product to retain its properties relating to chemical, physical, microbiological and bio-pharmaceutical aspects within specified limits throughout its shelf-life.
Standards	means technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that the Medical Device to be procured is fit for that purpose and which are adopted as the requisite standards for Sri Lanka as determined by the CDDA.
Uniformity of Dosage Form	means consistency of dosage units with regard to appearance, size, shape, weight/ volume and amount of active substance in each unit.
VEN Analysis	means a system of setting priorities for purchasing drugs and keeping stock, in which drugs are divided according to their health impact into vital, essential, and nonessential categories.
Vital products	means generally life saving Pharmaceutical products which are considered as indispensable in treating urgent or emergency medical conditions which generally occur in readily recognizable clinical situations and refers to products categorized as "critical or life saving drugs" in the publication entitled "List of Essential Drugs, Ministry of Health, 1999 or any subsequent revisions thereto.

INTERPRETATION

- (a) The headings are for convenience only and shall be ignored in construing these Guidelines.
- (b) The singular includes the plural and vice versa.
- (c) **These Guidelines are intended to be read in conjunction with the Procurement Guidelines, March 2006. Therefore, the broad principles of procurement outlined in the Procurement Guidelines will continue to be applicable to the extent possible, for the Procurement of Pharmaceuticals and Medical Devices, unless they have been amended/modified in these Guidelines.**
- (d) In the event of a conflict between the Procurement Guidelines and the Guidelines for the Procurement of Pharmaceuticals and Medical Devices, the latter shall prevail.
- (e) These Guidelines shall not be applicable for the Procurement of Medical Equipment and Medical Devices which are not of a consumable nature.

1. GENERAL PRINCIPLES

1.1 All Pharmaceuticals procured must fulfill **Quality, safety and Efficacy** criteria. All Medical Devices procured should satisfy **Quality, safety, Performance, Effectiveness and Efficacy** criteria.

1.2 The strategic objectives of procurement of Pharmaceuticals & Medical Devices should be :

- ◆ procure the most cost-effective Pharmaceuticals and Medical Devices in the right quantities ;
- ◆ ensure supplier reliability with respect to service and quality;
- ◆ arrange timely delivery to avoid shortages and stock outs; and
- ◆ achieve the lowest possible evaluated cost.

2. REGISTRATION

2.1 All Pharmaceuticals and Medical Devices to be procured by the PE shall be registered with the Cosmetics, Devices and Drugs Regulatory Authority of Sri Lanka.

2.2 The PE shall request the prospective bidders to attach a **notarially certified** copy of the original registration certificate and any re-registration certificates where applicable to the bid documents. Submission of back-dated registration certificates after bid opening shall be rejected.

2.3 For products which are imported to Sri Lanka, the registration should also be valid until at least six (06) months after the last consignment of the Pharmaceuticals and/or the Medical Devices to be procured are due to be received in Sri Lanka. . For products which are manufactured in Sri Lanka, the registration should be valid for at least six (06) months after the last consignment of the Pharmaceuticals and or the Medical Devices to be procured are received by the PE.

2.4 If the bidder submits evidence that the Bidder's authorized local agent has applied for re-registration at least six months before the date of expiry of the current registration, as per the relevant gazette notification, this shall be deemed sufficient to satisfy the requirements of registration.

2.5 No contract shall be awarded to any bidder unless the bidder is in possession of a valid certificate of registration at the time of the award of contract.

2.6 The requirement of registration stipulated above may be waived off in exceptional circumstances which is referred to as Emergency and Urgent Procurements under section 6.6 and 6.7 upon the issuance of a "no objection"

letter by the CDDA, provided that the CDDA ascertained whether the particular consignment of a Pharmaceutical product meets the requisite Quality, Safety and Efficacy criteria and in the case of Medical Devices, satisfies Quality, Safety, Performance, Effectiveness criteria by:

- (a) perusing the available documents accompanying the said consignment of Pharmaceuticals or Devices ; and/or
- (b) on the submission by the manufacturer/supplier of any additional documentation as required by the CDDA for the said consignment; and/or
- (c) on the submission by the manufacturer/supplier an analytical certificate issued by a recognized independent laboratory which is identified by the CDDA.

3. PRE-QUALIFICATION

3.1 Multi-Source Products

3.1.1 Pre-qualification shall be carried out for **Multi-Source products only** for the purposes of evaluating supplier/manufacturer capacity and reputation before bids are solicited for specific products, and must be **product specific** and **linked to specific manufacturing units**.

3.1.2 Pre-qualified Suppliers/Manufacturers

The list of pre-qualified suppliers/manufacturers for each product should be revised at least **once in every three years**.

- (a) Continuous efforts should be made by the PE to seek out potential suppliers/manufacturers in order to maintain competitive pressure on established suppliers/manufacturers that had been pre-qualified previously.
- (b) If the PE determines that there are new market entrants or new applicants for any specific product for which there is already an established list of suppliers/manufacturers who have been selected after a pre-qualification process, the PE may at its own discretion, at any time, pre-qualify such potential new supplier/manufacturer **on the most recent and identical criteria** by which other suppliers/manufacturers have been pre-qualified, for that specific product, in order to maintain competition.
- (c) The PE shall ensure that the pre-qualification criteria for any specific product are consistently applied to all such potential suppliers/manufactures and the process is carried out fairly and transparently.

3.1.3 (a) The pre-qualification process referred to above shall be **based on documentation**. The PE shall, particularly in the case of new suppliers/manufacturers, for whom there is no past track record, verify the

authenticity of documentation submitted by any such supplier/manufacturer pertaining to licensing aspects, by independently obtaining confirmation from the regulatory or licensing authorities which purportedly have issued such certification.

- (b) The PE, shall also obtain independent confirmation from the relevant regulatory or licensing authority to ensure that the suppliers/manufacturers who are to pre-qualified have not been blacklisted/suspended by such regulatory/licensing authorities nor have had their products recalled for quality failure.

3.1.4 (a) Once pre-qualified, the supplier/manufacturer for any specific product shall be deemed to remain pre-qualified until the next revision, unless there have been noncompliance with contract obligations or product recalls, or a change in the status-quo of suppliers/manufacturers stated at the pre-qualification stage, which warrants a review of the established list.

- (b) Suppliers/manufacturers who did not pre-qualify previously are eligible to re-apply at the next revision.

3.1.5 The PE shall thereafter solicit bids for each product from the list of such pre-qualified suppliers/manufacturers.

3.2 Criteria for Selection of Products for Pre-qualification of Pharmaceuticals

3.2.1 ABC and VEN Analysis

The criteria for the selection of products to be pre-qualified shall be determined by the MOH/MSD/SPC using the VEN and/or ABC Value Analysis on the following basis:

- (a) All Multi-Source Pharmaceuticals irrespective of whether they are Non-Essential, Essential and Vital products which are categorized as high usage products by the MOH/MSD/SPC shall be pre-qualified no later than twenty four (24) months from the date these Guidelines come into effect;
- (b) All Multi-Source Pharmaceuticals irrespective of whether they are Non-Essential, Essential and Vital products which are categorized as medium usage products by the MOH/MSD/SPC shall be pre-qualified no later than thirty six (36) months from the date these Guidelines come into effect;
- (c) Every effort shall be made to ensure that Medical Devices which are categorized as high and medium usage products by the MOH/MSD/SPC shall be pre-qualified no later than thirty six (36) months from the date these Guidelines come into effect.

3.2.2 The PE may at its own discretion pre-qualify any other Multi-source Pharmaceutical and Medical Devices as it considers necessary.

3.2.3 Uninterrupted Supply during pre-qualification

The PE shall also ensure that the carrying out the pre-qualification process shall Not result in any disruption of the supply of Pharmaceuticals and Medical Devices and cause stock outs.

3.3 Criteria for Pre-qualification

3.3.1 Criteria for pre-qualification must be clearly stipulated in the pre-qualification document and should include but not limited to the following:

- (a) **Required Annual Average Turnover** of the supplier/manufacturer should be at least three (03) times the estimated value of the contract. Annual turnover statements and copies of balance sheets and profit and loss account for the three (3) immediately preceding years duly certified by the company's auditors must be submitted with the bid.
- (b) **Required Annual production capacity** of the supplier/manufacturer should be at least three (03) times the quantities specified under the contract.
- (c) **Required number of similar contracts completed** depending on the size and complexity of the proposed contract a range between three to five within the last five (05) years is acceptable.
- (d) **Required quality Assurance**
 - (i) In the case of manufacturers they must provide the following:
 - x. In the case of Pharmaceuticals a valid certificate of registration (**Certificate of Pharmaceutical Product (CPP)**) issued by the regulatory/competent authority in the country of manufacture that the Pharmaceutical item to be procured has been authorized to be placed in the market for sale and use in the country of manufacture. This certificate should indicate the number of permit and date of issue. If the product is not permitted to be marketed and used in the country of manufacture, reason for such action should also be stated - (a model CPP is given in Schedule 2), and in the case of Medical Devices a valid **free sale certificate** issued by the regulatory/competent authority in the country of manufacture that the Medical Device item to be procured has been authorized to be placed in the market for sale and use in the country of manufacture should be submitted. This certificate should indicate the number of permit and date of issue. If the product is not permitted to be marketed and used in the country of manufacture, reason for such action should also be stated; and

- y. For Pharmaceuticals, the CPP should also certify that the manufacturing plant in which the particular Pharmaceutical to be procured is produced, has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on Pharmaceuticals moving in International Commerce from the regulatory/competent authority from the country of manufacture of goods or has been certified by the competent authority of a member country of the Pharmaceutical Inspection Convention and has demonstrated compliance with the quality standards during the past two years, and in the case of Medical Devices certification that the manufacturing plant in which the particular Medical Device to be procured is produced has received a satisfactory GMP inspection certificate in line with WHO has to be submitted
- (ii) in the case of bidders who are not manufacturers, the bidder should provide evidence of being duly authorized by the manufacturer, meeting the criteria stipulated in Guideline 3.3 (d) (x) & (y) above;
- (iii) If the product certificate is submitted through the manufacturer or the importing agent rather than receiving directly from the issuing regulatory/competent authority, then the PE should seek supplementary references, for example from purchases with previous experience with that bidder.
- (v) The bidder should submit duly certified copies of the Market Standing Certificate if available or its equivalent, for each product quoted issued by the relevant regulatory authority.
- (vi) **An award shall be denied to any bidder who fails to meet the criteria for quality assurance stipulate above.**
- (e) **Required number of years of manufacturing experience**

The bidder should have manufactured and marketed the specific Pharmaceuticals and the Medical Devices to be procured for at least a period of three years and for similar goods for at least five years. Bidders wishing to pre-qualify for products that they do not manufacture must submit documentary evidence corresponding to the primary manufacture of goods who shall comply with these manufacturing requirements.

(f) **Required experience on packaging and distribution**

The bidder should provide proof of experience with knowledge of modes of packing, distribution and transportation of Pharmaceuticals under logistical and climatic conditions similar to Sri Lanka. It should provide names of countries to which the firm has supplied including (package, distributed and transported) Pharmaceuticals products worth at least three times the value of Contract within the past three years.

3.3.2 Monitoring Pre-Qualified Suppliers'/Manufacturers' Performance

- (a) Selected pre-qualified suppliers/manufacturers should be monitored by the PE through a process which considers lead time, compliance with contract terms, product quality, remaining shelf-life, compliance with packaging and labeling instructions etc, service reliability, delivery time and financial viability.
- (b) Any supplier/manufacturer of Multi-Source products whose performance is deemed unsatisfactory by the PE, particularly in product quality and delivery time shall not be eligible to participate in any future bidding process for that particular product, for a period of at least two (02) years.

3.3.3 Invitation to pre-qualify/pre-qualifying documents

- (a) The invitation to pre-qualify for bidding on specific contracts or groups of similar contracts shall be given wide local and international publicity. The PE shall publish such advertisement :
 - in at least one widely circulated in national newspaper;
 - transmit such invitations to embassies and trade representatives of countries where suppliers and manufacturers are likely to participate;
 - post them in relevant websites such as the SPC, NPA and MOH websites.
- (b) The pre-qualification document setting out the scope of the contract (i.e. the magnitude of the contract) and a clear statement of the requirements for qualification shall be issued to the suppliers/manufacturers who responded to the invitation to pre-qualify.
- (c) The results of the prequalification shall be informed to all the applicants who have applied to be pre-qualified for a particular product, in response to such advertisement.
- (d) After the pre-qualification is completed, applicants who meet the specified criteria for a particular product (qualified prospective bidders) will be issued the bidding documents at the time the PE at its discretion wishes to invite bids for such product.
- (e) Verification of the information provided in the submission for prequalification shall be confirmed at the time of award of contract. No award shall be made a bidder who is determined to no longer have the capability or resources to successfully perform the contractual obligations.
- (f) The PE may at its own discretion and where it deems necessary, carry out physical inspections of the manufacturing facilities of any supplier/manufacturer which it intends to pre-qualify for a particular

product/s for purposes of verifying the information provided by such supplier/manufacturer. The composition of the inspection team shall be as stated in Section 9.3.

4. POST QUALIFICATION

- 4.1 (a) Post-qualification of suppliers/manufacturers shall be carried out for each particular product, when the supplier/manufacturer of such product has not been pre-qualified in accordance with the provisions of these Guidelines
- (b) Post qualification of suppliers/manufacturers shall be carried out to:
- (i) ensure that the lowest evaluated, responsive, eligible supplier/manufacturer is qualified to perform the contract in accordance with the qualification requirements;
 - (ii) eliminate substandard suppliers/manufacturers; and
 - (iii) Validate supplier's/manufacturer's capacity to supply good quality products at the optimum price for the Government.
- 4.2 (a) The criteria to be met shall be set out in the bidding documents which shall include the criteria stipulated in Guideline 3.3.1(a), (b), (c), (e), and (f) above.
- (b) **For the avoidance of doubt, any supplier/manufacturer who fails to meet the quality assurance criteria stipulated in 3.3.1 (d), shall be rejected during bid-evaluation.**
- 4.3 If the supplier/manufacturer whose bid is determined to be the lowest evaluated cost is unable to satisfy the criteria for post qualification stipulated above, such bid shall be rejected. In such event, the PE shall make a similar determination for the next lowest evaluated bidder.
- 4.4 Suppliers/manufacturers who have been pre-qualified, verification of the information provided in the submission for pre-qualification shall be confirmed at the time of award of contract and award shall be denied to a bidder that is judged to no longer have the capability/resources to carry out the contract successfully.
- 4.5 The PE may at its sole discretion and where it deems necessary, carry out physical inspections of the manufacturing facilities of any supplier/manufacturer who has been determined to offer the lowest evaluated cost for a particular product/s, for purposes of verifying the information provided by such supplier/manufacturer, prior to contract award. The composition of the inspection team shall be as stated in Section 9.3.

5. **EVALUATION AND CONTRACT AWARD**

5.1 Except to the extent modified hereto the P.E shall strictly comply with the general principles relating to Bid Evaluation set out in the P.G.

- (a) PE shall adopt a pass/fail evaluation criteria for the purpose of evaluating the bids. A bidder who fails to satisfy all the stipulated criteria for evaluation shall be rejected.
- (b) Bids which are submitted with cross conditions such as “*subject to availability*” “*supplies will be made as and when supplies are received*” “*at current market rates*” shall not be allowed.
- (c) A bid for a product that is deemed to be the lowest evaluated substantially responsive, shall not be rejected by the TEC, during bid evaluation, merely for the reason that another product is of a higher quality/standard, provided that such product meets the quality assurance criteria stipulated in 3.3.1(d).

5.2 **Composition of the TEC**

5.2.1 Except in Emergency and Urgent Procurements made hereunder, the Technical Evaluation Committee for purposes herein shall be comprised as follows:

- Representative of the Ministry of Health – rank not below Director.
- Representative of the SPC – rank not below Director.
- A minimum of two Consultants in the relative speciality.
- Representative of the Treasury/NPA nominee.

6. **METHODS OF PROCUREMENT**

Pharmaceuticals and Medical Devices may be procured by International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited/restricted International Competitive Bidding (LIB), in accordance with the **applicable provisions stipulated in PG**, subject to any modifications contained herein.

6.1 **International Competitive Bidding (ICB)**

- (a) For Pharmaceuticals, ICB is appropriate for Multi-Source Products which generally have well-established long history of use, pharmacopoeial specifications and reference standards and are often marketed under international non-proprietary name.
- (b) For Medical Devices, ICB is appropriate for Multi-Source Products which generally have well established Standards.

6.2 (a) ICB with pre qualification of suppliers/manufacturers.

An invitation to bid is issued to group of pre-qualified manufacturers or suppliers who have been selected after carrying out a pre-qualification process in accordance with the Guideline 3 above.

(b) ICB without pre -qualification

An invitation to bid is issued to worldwide suppliers/manufacturers. This method is appropriate for large volume purchasers.

6.3 National Competitive Bidding (NCB)

Bidders supplying products manufactured locally should demonstrate that the quality of the locally manufactured product meets comparable international standards, preferably WHO, and that their prices are competitive with international pricing.

6.4 Limited/restricted International Competitive Bidding (LIB)

(a) This method is appropriate for Limited Source Products.

(b) For Pharmaceuticals if pharmacopoeial quality standards and publicly available reference standards for testing are not available, the PE may validate the quality of such Pharmaceutical product by reference to international or intra-governmental organizations.

Reference to the following sources, are encouraged.

(i) United Nations Procurement Quality and Sourcing Project, list of pre-qualified suppliers who are deemed suitable for procurement by UN Agencies; and/or

(ii) product authorized for use by the appropriate regulatory/competent authority of a member of the Pharmaceutical Inspection Convention or an entity participating in the Pharmaceutical Inspection Corporation Scheme; and/or

(iii) product authorized for use by the regulatory/competent authority of a member of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for human use.

(c) For Medical Devices, if publicly available reference standards for testing are not available, the quality of the product may be ascertained by reference to standards as determined by the CDDA.

6.5 Shopping

6.5.1 This method is only appropriate for procuring **small amounts** of readily available “off the shelf” Pharmaceuticals with established pharmacopoeial reference standards and Medical Devices with established Standards from several local or foreign suppliers/manufacturers, and when a bidding process will be unnecessarily expensive and resource intensive.

- 6.5.2**
- (a) To ensure competitive prices, at least three quotes must be obtained.
 - (b) If there are suppliers/manufacturers who have been pre-qualified by the P.E. for the specific product/s to be procured, quotations should in the first instance be obtained from such suppliers/manufacturers.

6.6 Emergency Procurements

6.6.1 For the purposes herein, Emergency shall be deemed to be a situation which has arisen due to either of the following causes:

- (a) man made or natural disasters which is declared as an Emergency by the Government of Sri Lanka; or
- (b) the sudden outbreak of disease as declared by the Government/MoH.

6.6.2 (a) The PE shall in such exceptional circumstances be authorized to procure the required quantities of Pharmaceuticals and Medical Devices, without resorting to any of the procurement methods stipulated in Guideline 6 from:

- *State Organizations or UN Agencies where appropriate;*
- *established list of suppliers/manufacturers pre-qualified as per the criteria stipulated in these Guidelines;*
- *suppliers/manufacturers registered by the MSD/SPC where appropriate.*

(b) If the product to be procured is not available from the above sources the PE shall procure such items from:

- *local authorized agents for such particular product;*
- *any worldwide manufacturer/s, supplier/s, distributor/s.*

6.6.3 (a) Except in the case of Single Source or Limited Source products, PE shall ensure that the suppliers/manufacturers have not over priced the products to be sourced. For this purpose the PE shall have reference to historical prices.

For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.

Website: www.msh.org/

Address: Development Offices, MSH, 165 Allandale Road, Boston, MA

Telephone: (617) 524 7799

Fax: (617) 524 0783

Email: development@msh.org

- (b) PE may also consult with neighbouring countries to check on prices offered to them by such suppliers and manufacturer.

6.6.4 The limits of authority for such procurements are as follows:

- (a) Secretary MOH, upto a maximum limit of SLR Ten million or the equivalent thereof in any other foreign currency, per event.
- (b) Director -MSD upto a maximum limit of SLR Two Million or the equivalent thereof in any other foreign currency, per event.
- (c) Managing Director-SPC upto a maximum limit of SLR Two Million or the equivalent thereof in any other foreign currency, per event.

6.7 Urgent Procurements

6.7.1 Pharmaceuticals and Medical Devices may be procured from the domestic and/or international market in very limited quantities as an urgent procurement and until the resumption of normal supply, in a situation which has arisen due to one or more of the following causes:

- (a) withdrawal of a product/s due to quality failure; or
- (b) shortage of a product/s due to suppliers default; or
- (c) shortage of a product/s due to an event/circumstance of Force Majeure as defined herein; or
- (d) on a written request made by a Consultant in order to treat a grave/life threatening situation of a patient, on a case by case basis.

6.7.2 (a) Limits of Authority for such urgent procurements are as follows:

- (i) Secretary MOH - Up to a maximum of SLR 1,000,000.00 (one million) or the equivalent thereof in any foreign currency, per event;

- (ii) Director-General Health Services – Upto a maximum of SLR 500,000.00 (five hundred thousand) or the equivalent thereof in any foreign currency, per event;
 - (iii) Director MSD – Up to a maximum of SLR 250,000.00 (two hundred and fifty thousand) or the equivalent thereof in any foreign currency, per event.
 - (iv) Managing Director – SPC – Up to a maximum limit of SLR 250,000.00 or the equivalent thereof in any foreign currency, per event.
- (b) In the aforesaid circumstances every effort shall be made to procure such products initially from the list of pre-qualified suppliers/manufacturers.
- 6.7.3**
- (a) Except in the case of Single Source or Limited Source products, PE shall also ensure that the suppliers/manufacturers have not over priced the Pharmaceuticals to be sourced by reference to historical prices.
 - (b) For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.
- 6.7.4** In circumstances where an Urgency has arisen due to withdrawal of products as a result of quality failure then the PE shall ensure that such suppliers/manufacturers are disqualified from participating in any future bidding process for that particular product at least for a minimum period of three (03) years.
- 6.7.5**
- (a) In circumstances where an Urgency has arisen due to suppliers/manufacturers default in complying with contractual obligations, the PE shall issue a “show-cause notice” to such suppliers/manufacturers.
 - (b) If the PE is not satisfied with the explanation offered by such suppliers/manufacturers, PE shall ensure that such suppliers/manufacturers are disqualified from participating in future bidding process for that particular product at least for a minimum of three (03) years.
- 6.7.6** The names of suppliers/manufacturers who are disqualified under these provisions shall be forwarded to the CDDA for necessary action and to the NPA in accordance with PG 8.11.
- 6.7.7** Any additional costs that are or may be incurred by the PE due to such default on the part of manufacturer/supplier should be borne by such manufacturer/supplier and a provision to this effect should be included in the Bidding documents.

6.8 Purchases from non-manufacturers

6.8.1 The PE is authorized to purchase Pharmaceutical products and Medical Devices from non-manufacturers of such products only in circumstances when manufacturers or their authorized agents for a specific product have not responded to an invitation to bid/failed to quote for such a product, which has been given due publicity in accordance with the provisions of these Guidelines and Procurement Guidelines 2006.

6.8.2 If such procurement is made by the SPC on behalf of the MSD, the SPC must obtain the prior approval of Director, MSD prior to effecting such procurements.

6.9 Purchases from the State Pharmaceuticals Manufacturing Corporation (SPMC).

The MSD is authorized to negotiate with the SPMC and directly purchase Pharmaceutical products from SPMC, provided that the SPMC is able to supply such Pharmaceutical products at a unit price lower than the unit price at which the MSD purchased such a particular Pharmaceutical product through the SPC at the previous tender.

7 DIRECT CONTRACTING

7.1 This method is appropriate only in the following circumstances:

- (a) For Single Source Products; or
- (b) Emergency Procurements; or
- (c) Urgent Procurement;
- (d) Purchases from SPMC in accordance with Guideline 6.9 above; or
- (e) Procurements from UN Agencies, the WHO, Global Drug Facility Inter-Agency Procurement Services Office or the Green Light Committee.

7.2 To ensure that the PE obtains competitive prices the PE should have reference to historical prices and may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences For Health. PE may also consult with neighbouring countries on prices offered to them and inquire into the possibility of pooled procurement schemes.

8. **TYPES OF CONTRACT**

8.1 **Contract Options**

PE may use either of the following contract options to enter into contracts with suppliers/manufacturers to define purchase quantity.

- (a) Fixed quantity - scheduled delivery; or
- (b) Estimated quantity - periodic order.

8.2 **Fixed Quantity/Schedule Delivery Contracts**

The fixed quantity contract specifies guaranteed quantities and delivery in either one large shipment or partial shipments over the life of the contract.

8.3 **Estimated Quantity/Periodic Order Contract**

- (a) This method may be resorted to only in circumstances when the PE is unable to determine the exact quantities to be purchased due to unknown demand for such products. Hence, the quantity is just an estimate.
- (b) The supplier/manufacturer agrees to deliver the required quantities on a draw-down system, at an agreed unit rate which is guaranteed for the entire period of the contract.
- (c) If the period of the Contract exceeds twelve (12) months, a price variation formula may be included to take into account only the following factors:
 - *Price of raw materials; and*
 - *Change in Law.*

8.4 **Long Term Contracts - Multi-Source Products**

- (a) for Multi-Source Products only, PE may award long term contracts for any specific product, for a period exceeding twelve (12) calendar months subject to a maximum of thirty six (36) calendar months.
- (b) PE shall not enter into any contract exceeding a period of twelve (12) calendar months, unless it has carried out a pre-qualification process in accordance with the provisions contained in these Guidelines.
- (c) The criteria for determining the types of Pharmaceuticals and Medical Devices which may be procured on long term contracts are as follows:
 - (i) High and Medium usage products;
 - (ii) Products which have been in usage for more than ten (10) years;

- (x) Pharmaceuticals which have acceptable pharmacopoeial quality standards and publicly available reference standards of testing.
 - (y) Medical Devices which have acceptable Standards.
 - (d) In the above circumstances the value of contract should be sufficiently high to attract competitive bids which results in significant cost advantages to the Government.
- 8.5
- (a) For contracts exceeding a period of twelve (12) months, a price revision formula which is effective after the lapse of a minimum of twelve (12) months should be incorporated into the bidding documents.
 - (b) This formula shall only provide for price escalation as well as de-escalation taking into account the following factors:
 - *Price of raw materials; and*
 - *Change in Law.*
 - *Changes in freight charges.*

9 INSPECTIONS

- 9.1
- (a) As a measure of:
 - (i) reinforcing quality assurance, i.e. verifying adherence to contract specifications and order completeness; and
 - (ii) inspecting samples of products to spot any gross abnormalities,

visual pre-shipment inspections may be carried out by the PE, particularly for new suppliers/ manufacturers who have no past track record.
 - (c) Inspection in the exporting country prior to shipment may also be arranged for early detection of non-compliance with contract terms or defective products through independent agencies.

9.2 The Bidding documents must clearly state:

- (i) the type of inspection which the PE requires;
- (ii) where they are to be conducted; and
- (iii) identity (by institutions) of representatives of the PE, retained for such purposes.

9.3 Composition of the Inspection Team

Pre and post shipment inspections when required shall be carried out by not more than Five (05) technically competent officers who are nominated by the Secretary, MOH, in consultation with the Director General of Health Services. A representative of the CDDA shall always be present. The other members may represent any of the following institutions:

- MSD
- MRI for vaccines
- SPC
- National Drugs Quality Assurance Laboratory (NDQAL)

Only one member from any of the above institutions shall be allowed.

If the situation so warrants, the Secretary, MOH, may also appoint any member external to the above referred institutions as a member of the inspection team, subject only to the limitation of the number of members.

10 TESTING

10.1 The PE may carry out pre-purchase testing of samples in order to detect defective products. However, the PE shall bear in mind that the samples may not be representative of the product that will be actually sold or delivered. Hence, the PE shall to the maximum extent possible carry out laboratory analysis of individual batches, either by itself or through international quality control organizations, in order to ensure that the product to be sourced meet with the stipulated criteria.

10.2 (a) PE may carry out laboratory testing of random batch samples, particularly for new suppliers and manufacturers.

(b) PE may carry out micro-biological tests and pharmacological tests for selected Pharmaceutical products.

10.3 Pre-shipment testing

Pre-purchase/shipment testing, to be carried out by an independent WHO recognized laboratory as determined by the PE, certifying that the product procured meets with the required standards. This shall be a mandatory requirement for new suppliers/manufacturers.

10.4 The type of tests which the PE requires, where they are to be conducted must be clearly stated in the bidding documents.

11 CONDITIONS OF CONTRACT

11.1 The Contract shall specify that:

(i) the Pharmaceuticals and Medical Devices to be supplied under the contract shall comply with the requirements stipulated under section 2 of these Guidelines.

(ii) if all products are to be shipped to the same destination on the same delivery schedule. .

- (iii) that the supplier will indemnify the PE against all claims that may arise on account of patent rights, trademarks, proprietary designs or royalties.
- (iv) When brand names etc., are given in the specifications it should be specifically stated that standards as well as references to brand names designated in the technical specifications are intended to be descriptive only and not restrictive and bidders may substitute [alternative standards,] brand names, and/or catalog numbers in its Bid, provided that it demonstrates to the PEs satisfaction that the substitutions are Pharmaceutically Equivalent to those designated in the technical specifications.
- (v) that the supplier/manufacturer must bear any additional costs that may be incurred by the PE due to default and on the part of the supplier/manufacturer to comply with his contractual obligations particularly in the case of quality and delivery failures.
- (vi) if a Force Majeure situation as defined herein arises, the supplier/manufacturer shall promptly notify the PE in writing of such condition and the cause thereof, and 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, unless the supplier/manufacturer has received written instructions from the PE to the contrary.
- (vii) Pre and post shipment inspections and testing required by the P.E.
- (viii) The PE in its sole discretion has the discretion to split the tender among more than one bidder to ensure sustained supply, provided the rates and other conditions of the tender being equal.

12. MISCELLANEOUS PROVISIONS

12.1 General Technical Specifications/Standards

Technical specifications and Standards stipulated in bidding documents shall be drafted in such a manner in order to promote the broadest competition.

12.2 The general technical specifications shall provide information on:

- *Good Manufacturing Practices (GMPs);*
- *Pharmacopeial standards, nomenclature and description required for each product;*
- *shelf life and expiration date parameters;*
- *labeling and packaging instructions;*
- *GMP and quality assurance certificates required; and*

other evidence of product quality to be submitted with the Bid and with each shipment.

12.3 Pharmacopoeia Reference/ Standards

- (a) Specific Pharmacopoeia reference standard/s, such as the International Pharmacopoeia published by the WHO and the US, European, Japanese and British Pharmacopoeias or other appropriate reference, should be listed for each product.
- (b) Standards will as far as possible be internationally acceptable. Where such internationally acceptable standards are unavailable or inappropriate, national standards may be specified.
- (d) Medical Devices to be procured shall be described by reference to Standards formulated by the Medical Devices Sub Committee of the CDDA.

12.4 Labelling for Pharmaceuticals and Medical Devices.**12.4.1 *For Pharmaceuticals and Medical Devices which have established Pharmacopoeial quality standards.***

- (a) All products should be identified by the approved name found in Pharmacopoeias or formularies (the source should be stated in abbreviation (e.g. B.P., U.S.P. etc.) recognized by the CDDA.
- (b) Finished product specification of the product (e.g. Paracetamol tablets B.P.)
- (c) Brand name of the product (if any)
- (d) List of active ingredients showing:
 - (i) The amount of each present in each dosage unit (e.g. per 5ml etc.)
 - (ii) A statement of the net content (e.g. number of dosage unit, weight or volume)
- (e) Any special storage conditions that may be necessary.
- (f) Warning and precautions that may be necessary.
- (g) The date of manufacture.
- (h) The date of expiry.
- (i) The batch or lot number assigned by the manufacturer.
- (j) Name and address of the manufacturer.
- (k) Child attractive pictures should not be in labels.
- (l) If alcohol is contained in a liquid oral preparation, the content of alcohol should be mentioned on the label.
- (m) Any special indelible identification marks required by the PE.
- (n) Language as required by the PE.

12.4.2 *For other Medical Devices.*

- (a) All products should be identified by the approved name recognized by the CDDA.
- (b) Finished product specification of the product.
- (c) Brand name of the product (if any).
- (d) List of active ingredients showing finished product.

- (i) The amount of each present in each dosage unit (e.g. drug quoted per stent)
- (ii) A statement of the net content (e.g. number of dosage unit, weight or volume)

- (e) Any special storage conditions that may be necessary.
- (f) Warning and precautions that may be necessary.
- (g) The date of manufacture.
- (h) The date of expiry.
- (i) The batch or lot number assigned by the manufacturer.
- (j) Name and address of the manufacturer.
- (k) Child attractive pictures should not be in labels.
- (l) If alcohol is contained in a liquid oral preparation, the content of alcohol should be mentioned on the label.
- (m) Any special indelible identification marks required by the PE.
- (n) Language as required by the PE.

- 12.4.3** (a) For Pharmaceuticals and Medical Devices which are procured from sources other than the principal manufacturer (loan/contract manufacturers, etc.) the label should clearly identify the name and address of such manufacturer as follows:

“Manufactured by ... For ...”

The country of origin should also be clearly stated in the label.

- (b) If the particular Pharmaceutical and Medical Devices item is distributed by a source other than the principal manufacturer the label must clearly identify the name and address including the country of origin of the distributor as follows:

“Manufactured by ... Distributed by....”

- 12.4.4** In addition to the above, any other requirements for labeling that may be mandated from time to time by the CDDA shall be complied with.

- 12.4.5** It should be clearly stipulated in the technical specifications that failure to conform to specifications to print a description of the contents, the date of manufacture and the date of expiry on the primary container and the outer package shall result in the rejection of the products upon inspection.

12.5 Packaging

12.5.1 Product Specifications for Pharmaceuticals

This should indicate:

- (a) dosage form (e.g., tablets, capsules, injection, dry syrup, liquid, ointment emulsion, suspension, etc.) and

- (b) content per tablet, capsule, or milliliter or gram on the basis of weight by volume (W/V) or volume by volume (V/V).
- (c) for Pharmaceuticals or vaccines not included in a compendium, the PE should clearly indicate acceptable limits.

12.6 Product Packaging for Pharmaceuticals

12.6.1 (a) All packaging components must meet compendial standards and be approved for Pharmaceutical packaging by the supplier's/manufacturer's regulatory competent authority.

(b) All the packaging materials primary containers, including immediate packing should be from Pharmaceutical grade materials.

12.6.2 Primary containers should:

- (i) maintain quality, safety and stability of the Pharmaceuticals or vaccine contained;
 - (ii) withstand mechanical hazards of handling and transport;
 - (iii) prevent leakage and environmental degradation ; and
 - (iv) Have no physical or chemical effect on the contents.
 - (v) Be export worthy and suitable to withstand rough handling in transit and during storage.
- (c) For liquids:
- (i) containers should be sufficiently transparent for visual inspection; and
 - (ii) should be covered with outer packaging to protect the contents from incidental radiation;
 - (iii) all liquid oral preparations should be less than 750 ml.
- (d) For injectable Preparations:
- (i) all anti-cancer product should be in vials (not in ampoules)
 - (ii) all parenteral preparations should be in rubber bunk type (not in nipple type)

12.7 Shelf Life and Stability

- (a) The required minimum shelf-life remaining for the products must be clearly stated.
- (b) Pharmaceuticals should have the minimum specified shelf life remaining on arrival at the port of entry.
- (c) suppliers/manufacturers should be required to specify the shelf-life for every product in their bids to enable the PE to consider shelf-life in bid evaluation.
- (d) Any extreme environmental conditions existing in the area of final delivery and use, if any, must be specifically stated.

12.8 Schedule of Requirements

The **schedule of requirements** should provide:

- (a) a concise description of each product and the quantity required along with any technical specifications unique to that item.
- (b) sufficient space to enable the suppliers to enter all relevant information including the name of the original manufacture.
- (c) whether the listed package sizes are the only ones acceptable, or whether the PE shall accept offers on all package sizes available.
- (d) special packaging or labeling or shipping instructions required for a subset of products.

SCHEDULE 1

Guideline for Prequalification

All information provided should be relevant to the specific procurement

Section 1: Company Details and General Information

1. Name of Firm:			
2. Street Address:	Postal Code:	City:	Country:
3. PO Box and Mailing Address:			
4. Telephone Number:			
5. Fax Number:			
6. E.mail Address:			
7. Web Address:			
8a. Contact Name:			
8b. Contact Title:			
9. Parent Company, if any (full legal name)			
10. Subsidiaries, Associates, and/or Overseas Representative(s), if any:			
11. Nationality of the Firm			
12. Type of Business:			
13. Nature of Business:			
14. Year Established:			
15. Key personnel: (include name of candidate, position, professional qualifications and experience)			
Technical	Production	Management	
16. Date, Numbers and Expiration Dates of Current Licenses and Permits:			
17. Current health authority registration information:			

18. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies, (e.g. WHO Certification Scheme, GMP)	
19. Name of government agency(ies) responsibility for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods"	
Date of last inspection:	
20. Quality Assurance Certificate (Please include a copy of your latest certificate with the PQ application:	
21. Production capacity: <i>[Insert peak and average production capacity over the last three years in units/day or units/month, etc.]</i>	
22. List of names and addresses of sources of raw material:	
23. Raw materials tested prior to use:	
24. Presence and characteristics of in-house quality control laboratory:	
25. Names and addresses of external quality control laboratories used:	
26. Are all finished products tested and released by quality control prior to release for sale?	
<input type="checkbox"/> Yes <input type="checkbox"/> No. If not, why?	
28. Procedures for dealing with rejected batches:	
29. List tests conducted after production and prior to release of product on market:	
30. List product recalls linked to defects during the last 36 months. Include reason and date of recall.	
31. Are technical documents available in: <i>[Purchaser should insert language]</i>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
32. Working languages (Language of bid and contract): <i>[Purchaser should insert working language]</i>	
Section 2: Financial Information	
33/34. Annual Sales Value for the last 3 years:	
Year	Total Sales (USD)

35. VAT No./Tax I.D.	
36a. Bank Name:	
36b. Swift/BIC Address:	
36c. Bank Address:	
36a. Bank Account Number:	
36b. Account Name:	
37. Please mail a copy of the company's Annual or Audited Financial Report of the last three years.	

Section 3: Current Contract Commitments/Contracts in Progress

38. Name of Contract(s)
39. Purchaser Contact Information <i>[insert address, telephone, fax, e.mail address]</i>
40. Value of outstanding contracts <i>[current US\$ equivalent]</i>
41. Estimated delivery date
42. Average monthly invoices over the last six months <i>(US\$/mon.)</i>

Section 4. Experience

43. Contracts over [insert amount] during the last three years:				
Purchaser	Value	Year	Goods/Services Supplied	Country of Destination

Section 5: Other

44. Please list any disputes your company has been involved in over the last 3 years.			
Year	Award FOR or AGAINST applicant	Name of client, cause of litigation, and matter in dispute.	Dispute amount (current value, US\$ equivalent)

Signed: -----

Date: -----

In the capacity of: *[Insert title or other appropriate design*

SCHEDULE 2

Model Certificate Of A Pharmaceutical Product *		
CERTIFICATION OF A PAHRMACEUTICAL PRODUCT		
<p>This certificate conforms to the format recommended by the World Health Organization (General instructions and explanatory notes attached).</p> <p>No. of certificate.</p> <p>Exporting (certifying country):</p> <p>Importing (requesting country):</p>		
1.		Name and dosage form of the product.
	1.1	Active ingredient (s) 2 and amount (s) per unit dose. For complete composition including recipients, see attached.
	1.2	Is this product licensed to be placed on the market for use in the exporting country? (Key in as appropriate) Yes/no
	1.3	Is this product actually on the market in the exporting country? Yes/no/unknown
<p>If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B.</p>		
	2.A.1	Number of product license and date of issue:
	2.A.2	Product license holder (name and address):
	2.A.3	Status of product license holder. (Key in an appropriate category as defined in note 8)
	2.A.3.1	For categories b and c the name and address of the manufacturer producing the dosage form is:
	2.A.4	Is a summary basis for approval appended? (Key in as appropriate) yes/no

	2.A.5	Is the attached, officially approved product information complete and consonant with the license? Key in as appropriate. Yes/no/not provided.
	2.A.6	Applicant for certificate, if different from license holder (name and address)
	2.B.1	Applicant for certificate (name and address):
	2.B.2	Status of applicant: (Key in appropriate category as defined in footnote 8)
	2.B.2.1	For categories (b) and (c) and name and address of the manufacturer producing the dosage form is 9.
	2.B.3	Why is marketing authorization lacking?
	2.B.4	Remarks.
3.		Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced. (Key in as appropriate). If not or not applicable, proceed to question 4. Yes/no/not applicable.
	3.1	Periodicity of routine inspections (years)
	3.2	Has the manufacture of this type of dosage form been inspected? Key in as appropriate. Yes/no
	3.3	Do the facilities and operations conform to GMP as recommended by the World Health Organization. (Key in as appropriate) Yes/no/not applicable.
4.		Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product. (Key in as appropriate) If no, explain: Yes/no

	<p>Address of certifying authority: Telephone Fax Name of authorized person: Signature Stamp and date</p>
<p>General Instructions</p> <p>Please refer of the guidelines for full instructions on how to complete this form and information on the implementation of the scheme.</p> <p>The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.</p> <p>Additional sheets should be appended, as necessary, to accommodate remarks and explanations.</p>	
<p>Explanatory notes</p>	
1	<p>This certificate, which is in the format recommended by WHO establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.</p>
2	<p>Use, whenever possible, International Non proprietary Names (INNs) or national non proprietary names.</p>
3	<p>The formula (complete composition) of the dosage form should be given on the certificate or be appended.</p>
4	<p>Details of quantitative composition are preferred but their provision is submitted to the agreement of the product license holder.</p>
5	<p>When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.</p>
6	<p>Sections 2A and 2B are mutually exclusive.</p>
7	<p>Indicate, when applicable, if the license is provisional, or the product has not yet been approved.</p>
8	<p>Specify whether the person responsible for placing the product on the market.</p> <p>(a) manufactures the dosage form; (b) packages and/or labels a dosage form manufactured by and independent company; or (c) is involved in none of the above.</p>
9	<p>This information can only be provided with the consent of the product license holder or, in the case of non registered products, the applicant. Non completion of this section indicates that the party concerned has not agreed to the inclusion of this information.</p>

	<p>It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.</p>
10	<p>This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.</p>
11	<p>This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)</p>
12	<p>In this circumstance, permission for issuing the certificate is required from the product license holder. This permission has to be provided to the authority by the applicant.</p>
13	<p>Please indicate the reason that the applicant has provided for not requesting registration.</p> <ul style="list-style-type: none"> (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export; (b) the product has been reformulated with a view to improving its stability under tropical conditions; (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import; (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient; (e) any other reason, please specify.
14	<p>“Not applicable” means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.</p> <p>The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992.</p> <p>Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992)</p>
15	<p>This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.</p>
<p>Model Statement of Licensing Status of Pharmaceutical Products</p>	
<p>No. of statement.....Exporting (certifying) country: Importing (requesting) country;</p> <p>Statement of Licensing Status of Pharmaceutical Product(s)</p> <p>This statement indicates only whether or not the following products are licensed to be put on the exporting country.</p>	

Applicant (name/address):

Name of Product	Dosage Form	Active ingredient(2) 2 and amount(s) per unit dose	Product

The certifying authority undertakes to provide, at the request of the applicant (or, if different, the holder) a separate and complete Certificate of a Pharmaceutical Product in the format recommended for each of the products listed above.

Address of certifying authority: Name of authorized person.

Telephone/fax numbers: Signature:

Stamp and date:

This statement conforms to the format recommended by the World Health Organization (general explanatory notes below)

General Instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1	This statement is intended for use by importing agents who are required to screen made in response to an international tender and should be requested by the agent as condition of bidding. The statement indicates that the listed products are authorized to be placed on the market of use in the exporting country. A Certificate of a Pharmaceutical Products in the format recommended by WHO will be provided, at the request of the applicant and, if different, the product license holder, for each of the listed products.
2	Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3	If no product license has been granted, enter "not required", "not requested", "under consideration" or "refused" as appropriate.

Model Batch Certificate of a Pharmaceutical Product *	
Manufacturers/Official Batch Certificate of a Pharmaceutical Product	
This Certificate conforms to the format recommended by the World Health Organization (general Instructions and explanatory notes attached)	
1. No. of Certificate: 2. Importing (requesting) authority: 3. Name of product	
3.1	Dosage form
3.2	Active ingredient(s) and amount(s) per unit dose.
3.2.1	Is the composition of the product identical to that registered in the country of export? Yes/no/not applicable (key in as appropriate) If no, please attach formula (including excipients) of both products.
4	Product license holder (name and address):
4.1	Product license number
4.2	Date of issue
4.3	Product license issued by
4.4	Product Certificate number
5.1	Batch number.....
5.2	Date of manufacture:
5.3	Shelf life (years):.....
5.4	Contents of container.
5.5	Nature of primary container.
5.6	Nature of secondary container/wrapping
5.7	Specific storage conditions.
5.8	Temperature range.
6	Remarks
7	Quality analysis:
7.1	What specifications apply to this dosage form. Either specify the pharmacopoeia or append company specifications
7.1.1	In the case of product registered in the exporting country, have these company specifications been accepted by the competent authority? Yes/no.
7.2	Does the batch comply with all parts of the above specifications?

	7.3	Append certificate of analysis.
<p>It is hereby certificate that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries.</p> <p>Name and address of authorized person:</p> <p>Telephone No. Fax. No. Signature of authorized person Stamp and Date.</p>		
<p>General Instructions</p> <p>Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.</p> <p>These forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.</p> <p>Additional sheets should be appended, as necessary, to accommodate remarks and explanations.</p>		
<p>Explanatory notes</p> <p>Certificate of individual batches of a Pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera and biological. For other products, the responsibility for any requirement to provide batch certificates rests with the product license holder in the exporting country.</p> <p>The responsibility to forward certificate to the competent authority in the importing country is most conveniently assigned to the importing agent.</p> <p>Any inquiries or complains regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the produce license holder.</p>		
1	Strike out whichever does not apply.	
2	Use, whenever possible, International Non proprietary Names (INNs) or national non proprietary names.	
3	"Not applicable" means that the product is not registered in the country of export.	
4	All items under 4 refer to the product license or the Certificate of a Pharmaceutical Product issued in the exporting country.	
5	This refers to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.	
6	Indicate any special storage conditions recommended for the product as supplied.	

7	For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.
8	Identify and explain any discrepancies of specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The latter are contained in the manufacturer's certificate of analysis.

- Source WHO