Malaria Control Booster Program

Procurement and Supply Management

TOOLKIT

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Malaria Booster Control Program

Procurement and Supply Management

TOOLKIT

Procurement Policy and Services Group
The World Bank
Washington, D.C.

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FOREWORD

The World Bank's Global Strategy and Booster Program to Fight Malaria represents the Bank's renewed commitment to significantly increase availability of resources to countries most afflicted by malaria. Globally, there are more than 500 million cases of malaria per year; a recent study put the number of cases from a particularly severe form of the malaria parasite *Plasmodium falciparum* at 515 million in 2002 alone[1]. Malaria causes at least 1 million deaths per year, most of them children younger than five years of age in Sub-Saharan Africa infected with this particular parasite.[2] Despite recent decreases in child mortality in Africa, drug-resistant strains of the parasites that causes malaria are to blame for the increase in malaria's share of that mortality.

The UN Millennium Project Task Force on HIV/AIDS, Malaria, TB and Access to Essential Medicines, working toward achieving Millennium Development Goal 6 ("Combat HIV/AIDS, malaria, and other diseases") has identified the need for stronger national health systems as a key element of its strategy. A recent review of malaria projects/components financed by the Bank in eight countries over a five-year period unveiled serious deficiencies in those systems, particularly concerning management of the procurement and delivery of the commodities. This toolkit has been prepared to help tackle these deficiencies and to offer simplified guidance to members of project teams, World Bank staff, and country programs. It is a user-friendly and practical tool that takes readers through the various phases of the pharmaceutical supply cycle, stressing the do's and the don'ts in order to guarantee observance of and compliance with global standards. The toolkit will promote compliance with WHO/WHOPES recommendations and increase adherence to best practices including those reflected in the *World Bank Procurement Guidelines*.

It is anticipated that the toolkit will be useful in the design, preparation, and implementation of the Malaria Booster Program. This will enable the procurement and delivery of essential antimalarial commodities and effective interventions to those at risk of malaria.

James Adams
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Operations Policy and Country Services

1. Snow, R. W., C. A. Guerra, A. M. Noor, H. Y. Myint, and S. I. Yan. 2005. "*The Global Distribution of Clinical Episodes of Plasmodium falciparum Malaria.*" Nature 434 (7030): 214–16.
2. The New England Journal of Medicine 353;18 November 3, 2005.

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
BDS	bid data sheet
CDD	Community Driven Development
CIF	cost, insurance, and freight
CIP	carriage and insurance paid to (place of destination)
CMS	central medical store
CPAR	country procurement assessment report
CT	country team
DTK	diagnostic test kits
EML	essential medicines list
EXW	ex works, ex factory, or off the shelf
FAO	Food and Agriculture Organization of the United Nations
FEFO	first expiry first out
FIFO	first in first out
GCC	general conditions of contract
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practice
HSG	health sector goods
IBRD	International Bank for Reconstruction and Development
ICB	international competitive bidding
ICH	International Conference on Harmonization
IDA	International Development Association
IFB	invitation for bids
INN	international nonproprietary name
ITB	instructions to bidders
ITN	insecticide-treated bed net
JSI	John Snow Inc.
LFA	local fund agent
LIB	limited international bidding
LLIN	long-lasting insecticide-treated net
MAP	Multi-country HIV/AIDS Program
MIS	management information system
MMSS	Malaria Medicine and Supplies Service
MoF	ministry of finance
MoH	ministry of health
MSH	Management Sciences for Health
NCB	national competitive bidding
NDRA	national drug regulatory authority
NGO	nongovernmental organization
NOL	no objection letter
PAD	project appraisal document
PDMS	procurement data management system
PIA	project implementing agency
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PR	principal recipient
PRSC	poverty reduction support credit
PSI	Population Services International
PSM	procurement and supply management
QA	quality assurance
QC	quality control

RBM	Roll Back Malaria
RDT	rapid diagnostic test kit
RFP	request for proposal
RTK	resistance test kits
RUD	rational use of drugs
SBD	standard bidding document
SCC	special conditions of contract
STG	standard treatment guide
SWAP	sector wide approach
TA	technical assistance
TB	tuberculosis
TN	technical note
TOR	terms of reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WB	World Bank
WBPT	World Bank project team
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme
WTO	World Trade Organization

1. Background

The new Booster Program for Malaria Control aims to provide increased financing and technical support to accelerate program design and implementation, increase coverage, and improve outcomes more rapidly than in the recent past. The Booster Program for Malaria Control will be global in scope and consist initially of an intensive effort over a five-year period. It may include one or more Horizontal Adaptable Programs (a series of loans/credits divided into phases with predetermined triggers for each of the phases) at the global or regional level, covering a number of countries, with emphasis on country ownership, measurable outcomes, and rigorous application of epidemiology. While the immediate objectives are fixed—increasing coverage, improving outcomes, and building capacity—the means will be flexible.

The Booster Program for Malaria Control takes into account experiences from previous malaria programs and lessons learned from the Multi-country HIV/AIDS Program (MAP). The Program constitutes a substantial departure from the Bank's previous approach to malaria control.

The working assumption is that a total commitment of US$500 million to US$1 billion is feasible over the next five years. The Bank will mobilize financial and technical resources from within and outside the institution, including the public and private sectors, to stimulate the production of commodities such as insecticide-treated bed nets (ITNs) and antimalarial drugs; lower taxes and tariffs on such commodities; improve and maintain long-term commitment to malaria control by governments and civil society groups; and build public-private partnerships for program design, management, and evaluation.

It is anticipated that significant cofinancing will be leveraged by a demonstration of the Bank's own commitment up front, together with the emphasis on measurable results. Crucially, the Bank's approach will be proactive while respecting and supporting country leadership and ownership. Within the Roll Back Malaria Partnership, it will complement the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the Bill & Melinda Gates Foundation, and others in ensuring sufficient financing as well as technical and implementation support for effective malaria control. Henceforth, malaria control will be mainstreamed into the Poverty Reduction Strategies and large sector-development programs that emphasize outcomes.

2. Booster Program for Malaria Control Funding Options

Under the Booster Program for Malaria Control, different funding options are available for Borrowers, including Specific Investment Loans, poverty reduction support credits (PRSCs), sectorwide approaches

Specific Investment Loans Traditionally, World Bank malaria projects have been financed through Specific Investment Loans (for example, stand-alone Malaria Control Projects), which require compliance with the World Bank standard bidding documents for international competitive bidding (ICB) contracts and acceptable standard bidding documents for national competitive bidding (NCB). Care should be taken that the NCB documents contain the provisions of annex 7.

PRSCs The PRSCs are a series of annual Structural Adjustment Credits that support countries in meeting their cross-sectoral goals. The Borrower is not bound to follow the World Bank's Procurement Guidelines and may use local procurement practices that may or may not adhere to key principles intended to safeguard the quality of the goods procured. The use of annex 7 is highly recommended.

SWAps Donor pooled and non-pooled funding under SWAps, although providing a programmatic approach in any given sector, differ in procurement arrangements. Under pooling arrangements, donors will agree to a single procurement system which may (or may not) be based on the World Bank's Procurement Guidelines. The results of the capacity assessment of the implementing agency, along with the findings of the Country Procurement Assessment Review, will be used to determine whether the country's public procurement systems can be used and if so under which conditions. Generally, though, under most SWAps, WB's procurement procedures are used for ICB, and the country's procurement systems are used for contracts below the ICB threshold, in which case the use of annex 7 is strongly advised.

Regional Initiatives The regional intitiatives need to consider common strategies and methods for the procurement of the antimalarial products and commodities and harmonization of their prodecures with other donors.

(SWAps), and regional initiatives. The funding option and the decision concerning applicability of the procurement guidelines may affect materially the outcome of any malaria program.

Independent of the options, if the standard bidding documents are not used, key provisions aimed at ensuring compliance with minimal standards of quality may be missing. Lack of adherence to these key provisions will have an impact on the attainment of program outcomes. Some of these provisions concern compliance with WHO/WHOPES recommendations and specifications and inappropriate or excessive requirements for registration and certification. Because the funding for malaria will increase exponentially, efforts should be redoubled to ensure compliance with transparent and efficient procurement, thereby curtailing procurement errors.

3. Results of the World Bank Malaria Procurement Study

To learn about challenges encountered by previous malaria operations and devise ways to better support implementation of the Booster Program for Malaria Control, the World Bank conducted a study of previous procurement experience under World Bank–financed projects in eight countries over a five-year period. The study reviewed procurements of ITNs, LLINs, insecticides, and medicines. Of the projects reviewed, procurement ran smoothly under a select few. For the most part,

however, the study found major delays and issues with the quality of the products procured, particularly in those cases where the World Bank procurement guidelines and procedures were not strictly followed. Some of the most significant deficiencies can be broadly categorized as follows:

- Failure to adhere to WHO/ WHOPES recommendations and specifications for medicines, pesticides, and application equipment jeopardizing quality.
- Submission of deficient bid securities, resulting in a small bidders pool and limited competition.
- Use of local procurement rules without appropriate oversight and references to brand names, resulting in de facto sole source and limited or no competition.
- Failure to follow ICB thresholds, effectively bypassing the World Bank's prior review process and limiting competition.
- Requirement that bidders be registered at the time of bid opening rather than at contract award, greatly limiting competition.
- Unnecessary certification requirements, causing disqualifications.

4. Audience of the PSM Toolkit

The deficiencies identified in the Malaria Procurement Study led to the decision to develop a toolkit to assist World Bank staff (e.g., Procurement Specialists, Project Officers, Task Team Leaders) and Country Programs (e.g., staff from the ministries of health and various implementing agencies, from the central medical stores, and from the National Drug Regulatory Authorities) in ensuring that adequate steps are taken throughout the supply cycle, starting with proper assessment and planning of procurement and continuing to implementation of an effective strategy for distribution to end-users, coupled with adequate monitoring.

Content

The *Malaria Toolkit* focuses on ways to effectively address procurement challenges, enabling steady progress toward the Abuja Targets and the Millennium Development Goals. It is strongly recommended that, irrespective of the financing options (e.g., PRSCs investment, SWAps, Regional Initiatives), programs adhere to the provisions identified in annex 7 of the PSM checklist, aimed at ensuring satisfactory technical outcomes.

How to use the toolkit

During preparation of the project, both the project teams and the country teams should review **Phase I**, "Assessment and Project Planning", and assign responsibilities. The Procurement Specialist should conduct or direct the Capacity Assessment using **annex 1** of the Toolkit. Assessment including evaluation of distribution capacity should be conducted during pre-appraisal.

Use **annex 2** as sample TORs—if needed—to arrange technical assistance related to PSM strategy

and policy, management, and coordination as well as technical assistance throughout the stages of the project cycle. Sample TOR No. 1 can be used as a whole (i.e., the entire package) if there is lack of capacity in all areas. Otherwise, use sections as required. Sample TOR No. 2 is intended for the hiring of a Procurement Consultant. This technical assistance should be secured by pre-appraisal.

Use **annex 3** to prepare the Procurement Plan, which should be ready by the time of project appraisal.

Use **annex 4** to select the most appropriate procurement method. Follow guidance on preparation of Bidding Documents in **Phase II** of the checklist and use WB SBDs for HSG with corresponding technical specifications as contained in **annex 5**. Efforts should be made to have the Sample Bidding Documents containing Technical Specifications drafted by the time of loan/credit approval.

Use **annex 6** for sample certificates that can be requested at the time of bidding. Use of WB SBDs for HSGs is strongly recommended, even if the procurement method is different from ICB. If other than WB SBDs for HSG are used, the provisions of **annex 7** must be observed.

During Bid Evaluation, teams should review the guidance under **Phase III**.

For guidance on receipt, storage, and distribution of commodities, teams should consult **Phase IV**.

For monitoring and evaluation of PSM activities, consult **Phase V**.

Box 1 provides guidance on Quality Assurance criteria. **Boxes 2** and **3** depict steps to follow and guidance to observe in cases of prior review.

Throughout this checklist, items in green are general guidance, the others are specific.

PROCUREMENT AND SUPPLY MANAGEMENT (PSM) CHECKLIST

PHASE 1: ASSESSMENT AND PROJECT PLANNIING

The WB Project Team (WBPT) (e.g., Procurement Specialist, Technical Expert [consultant], TTL, or Project Officer) should:	The Country Team (CT) (e.g., staff from the Malaria Control Department [MOH], Central Medical Stores, or the National Drug Regulatory Authorities) should:
☐ Identify and review all current (12 months or less) Malaria PSM Assessments. (If the assessment is current, proceed to Phase I, Forecasting, Selection, and Quantification.)	☐ Work with WB staff, providing all current information (less than 12 months old).
Assessment ☐ Procurement Specialist should conduct a capacity assessment using the new Malaria Questionnaire, which covers supply chain management questions (see annex 1).	☐ Work with WB staff, providing all the relevant information for the capacity assessment. ☐ CT to check with MOH for results of GFATM assessment for current funding and commodity procurement.
Forecasting, Selection, and Quantification ☐ Task Manager should provide the template TOR and ensure that the CT has support to undertake the scope of work: • Selection and Quantification of commodities • Forecasting of supply availability, costs, and delivery ☐ Task Manager should ensure that project team has made contact with WHO to request assistance with forecasting.	☐ Draft TOR to get PSM TA (see annex 2 for sample TORs). ☐ CT should refer to "Sources and Prices of Selected Products for the Prevention, Diagnosis and Treatment of Malaria" (can be downloaded at http://rbm.who.int/mmss/products.html) during selection and quantification of the malaria commodities.
Planning Procurement ☐ Provide Procurement Plan Template for PSM Plan (see annex 3) to CT. Assist team with completion of the plan.	☐ Secure TA to help with Procurement Plan drafting (see annex 2 for sample TORs). ☐ Note that artemisinin-based pharmaceuticals are a single-source product and plan accordingly. ☐ Even with current production of artemisinin combination therapies (ACTs) sufficient to cover the orders, the normal lead time remains about 12 weeks. ☐ Note that global shortages of long-lasting insecticide bed nets (LLINs) exist and plan accordingly. ☐ In a context of insufficient production of LLINs, insecticide-treated bed nets (ITNs) are the best choice. ☐ The total procurement cycle, including transport for nets (including ITNs), is close to 12 months.

PHASE 1: ASSESSMENT AND PROJECT PLANNIING

	☐ Make sure that the cost associated with supply chain management (e.g., bid packages to support distribution, storage, transportation, etc.) is included in the Procurement Plan. ☐ Ensure that the Procurement Plan is complementary to GFATM or any other program funded by either the government or international donors.
☐ After examining the results of the assessment, the project team should determine: • Who will conduct procurement? • Will it be outsourced or will it be carried out by the IA? If outsourced, suggest list of qualified firms. ☐ Examine the capacity of the government for registration. ☐ Ensure that the registration process is rational and does not limit competition (registration should be a requirement of contract effectiveness, not of bid submission).	☐ Agree with WBPT on who will conduct procurement and whether it will be outsourced or whether it will be carried out by the IA. ☐ Inquire about and evaluate the National Drug Regulatory Authority regarding its capacity for registration. ☐ Suggest fast-track registration procedures for pharmaceuticals, insecticides for public health use, etc., every time possible. ☐ Bidders must be alerted of long delays in registration through the Procurement Notice and/or the Bidding Documents.
Determine procurement methods and prior review thresholds, and initiate drafting of technical specifications. ☐ See annex 4 for the matrix, "Strategies and Methods of Procurement of Malaria Products."	☐ See annex 4 for the matrix, "Strategies and Methods of Procurement of Malaria Products." ☐ Do not use estimated value of lots or schedules to assign procurement method or prior review requirements. Use the full value of the tender instead. ☐ If outsourced to a procurement agency or to a UN agency, determine the type of contract to be used (e.g., framework or multiyear delivery with adjustment clause) and use competitive procedures for selection (or negotiate the fee in the case of a UN agency). ☐ Secure TA for appropriate lot design; market intelligence is key to good lot design.[3] However, please note that lots should generally be discouraged except in cases of limitations of capacity of the producers. If lots are used, please adjust qualification requirements accordingly.

3. In the case of India, use results of market survey to determine optimal lot sizes and composition.

☐ Provide template of Bidding Documents if procurement is carried out by the IA, either Health Sector Goods (HSG) Standard Bidding Documents (SBDs) (e.g., for medicines) or goods SBDs (e.g., for insecticides for public health use, bed nets, and sprayers).

☐ Inform CT that pre- and post-shipment inspections can be funded by grants, credits, or loans, and ensure that there are plans to hire the services of qualified inspectors or a qualified inspection agency.

☐ Prepare Technical Specifications for the Bidding Documents from the samples provided.

- Seek advice from WHO or WHOPES on the development of Technical Specifications. See annex 5 for sample Technical Specifications.

☐ Apply appropriate method for selection of the inspector/inspection agency (refer to section 3.11 in "Guidelines—Procurement under IBRD Loans and IDA Credits," page 42, for more details).

Roles of other relevant partners

☐ GFATM can be consulted concerning results of current assessment.

☐ WHO can provide technical assistance with forecasting, selection, and quantification of malaria products.

☐ Information is also available at http://rollbackmalaria.org/mmss.

☐ Qualified agencies (e.g., JSI, PSI, and MSH) may also help.

☐ If capacity is inadequate, a procurement agency should be engaged.

☐ If not procured through a UN agency or procurement agency and for single-sourced commodities, purchaser country should negotiate with manufacturer a discounted price. (e.g., Coartem© is available from Novartis only).

☐ WHO/WHOPES can provide technical support for development of technical specifications.

PHASE 2: PREPARATION OF BID DOCUMENTS

The WB Project Team should:	The Country Team should:
☐ Ensure that the bid document is based on the World Bank's Standard Bidding Document. ☐ Ensure that provisions for inspection and testing of products are being included in the Bid Document. ☐ Ensure that the qualification criteria are rational, in accordance with the World Bank's Standard Bidding Document, and promote competition. ☐ Provide a sample list of certificates and check that the CT makes the appropriate selection according to country context and realities (see annex 6). ☐ Ensure that registration requirements are reasonable and that they do not limit competition.	☐ Follow instructions in Box 1 to assure quality of products procured under the Booster Program. ☐ For those using bidding documents other than the WB Standard Bidding Documents for ICB (e.g., for NCB), the provisions of annex 7 should be used.[4] ☐ Do not change performance criteria of Standard Bidding Documents without consulting the WB. ☐ International nonproprietary names must be used. If brand names or chemical names are used, the words "or equivalent" should be inserted. ☐ Select the final list of certificates out of the sample list. Do not request an extensive number of certificates that are not relevant. Use guidance provided in annex 6. ☐ WB needs to approve any registration requirement that differs from Standard Bidding Documents. Inform bidders of the steps for registration and warn them of potential delays. ☐ Do not request registration by Bid Submission. Registration must be a requirement of contract effectiveness. ☐ Settle registration requirements in Sample Bid Documents at the beginning of the project. ☐ Use text provided in annex 7 for inspections and testing requirements.
☐ Bid security—WBPT should inform the CT that: • Bid security is not mandatory. • If requested, bid security should cover the period of bid validity—often 60 days—PLUS an additional 30 days. • Firms should be informed that they must submit the original bid security, not copies of it. • Misspellings of bidder's name on bid security will cause disqualification of the bid. • Miscalculations concerning amount of bid security are a cause for disqualification. • Bidders must be promptly notified of delays in bid opening and evaluation, in which case, bid security should be extended accordingly.	☐ Ensure that all bid security requirements are properly reflected in the bidding document. ☐ If disqualifications for failures on bid security are a common occurrence, bidding documents should contain warnings in the form of Notes to Bid Data Sheet (ITB 19.1), informing bidders that "misspellings of bidder's/firm's name, submission of copies rather than original versions, miscalculations of bid amount, and inappropriate period of bid validity are reasons for disqualification."

4. Annex 7 contains sample provisions to address issues related to quality, registration, certification, bid security, and evaluation matters that should be useful to reflect in the bid documents used for procurement of malaria products regardless of the funding options and irrespective of source of funding (e.g., whether the contract is being financed by the Bank, by other donors, or by the government).

Roles of other relevant partners

☐ WHO can provide technical support.
☐ WHO can assist with the list of certificates to be requested (see annex 6 for sample certificates).

Box 1 Quality assurance criteria for products funded by the Booster Program

The text below should replace the current Bid Data Sheet instructions ITB 7.1(a)(i)(d) of the Standard Bidding Documents for Health Sector Goods (May 2004):

A. Approved by the WHO prequalification program or recommended by WHOPES for use or application in public health.
B. Approved by a stringent regulatory authority defined as a National Drug Regulatory Authority (NDRA) participating in ICH (International Conference on Harmonization) or PIC/S (Pharmaceutical Inspection Cooperation Scheme).

1. When utilizing category A or B for any given limited-source product where two or more suppliers exist AND the product is available from these suppliers (defined as the ability to supply a sufficient quantity to the country within 90 days of the date of order), then the product must be sourced from the above set of suppliers.
2. If the above condition does not apply (i.e., there is only one supplier that meets category A or B standards or the product is not available from two or more suppliers that meet this standard), then the product can be sourced from any supplier that has submitted the product to WHO/WHOPES or to an ICH or PIC/S member AND that manufactures the product at a GMP-compliant site (based on inspection by WHO or an ICH of PIC/S NDRA).
3. If the product cannot be sourced from two or more suppliers based on either of the above categories, then it can be sourced from any supplier that at least manufactures the product at a GMP-compliant site (again based on inspection by WHO or an ICH or PIC/S member).

In addition:
☐ Ensure that Technical Specifications are completed and cleared by the time PAD is finalized!
☐ Include WHO GMP-compliance with the quality standards during the past two years prior to bid submission.
☐ Make sure that clauses on pre- and post-shipment inspections are included in the SBD and that funding is set aside to cover the cost of the inspections.
☐ INN must be used. If brand names (or chemical names in the case of insecticides for public health use) are used, the words "or equivalent" should be used after references to brand names.

PHASE 3: BID EVALUATION AND CONTRACT AWARD

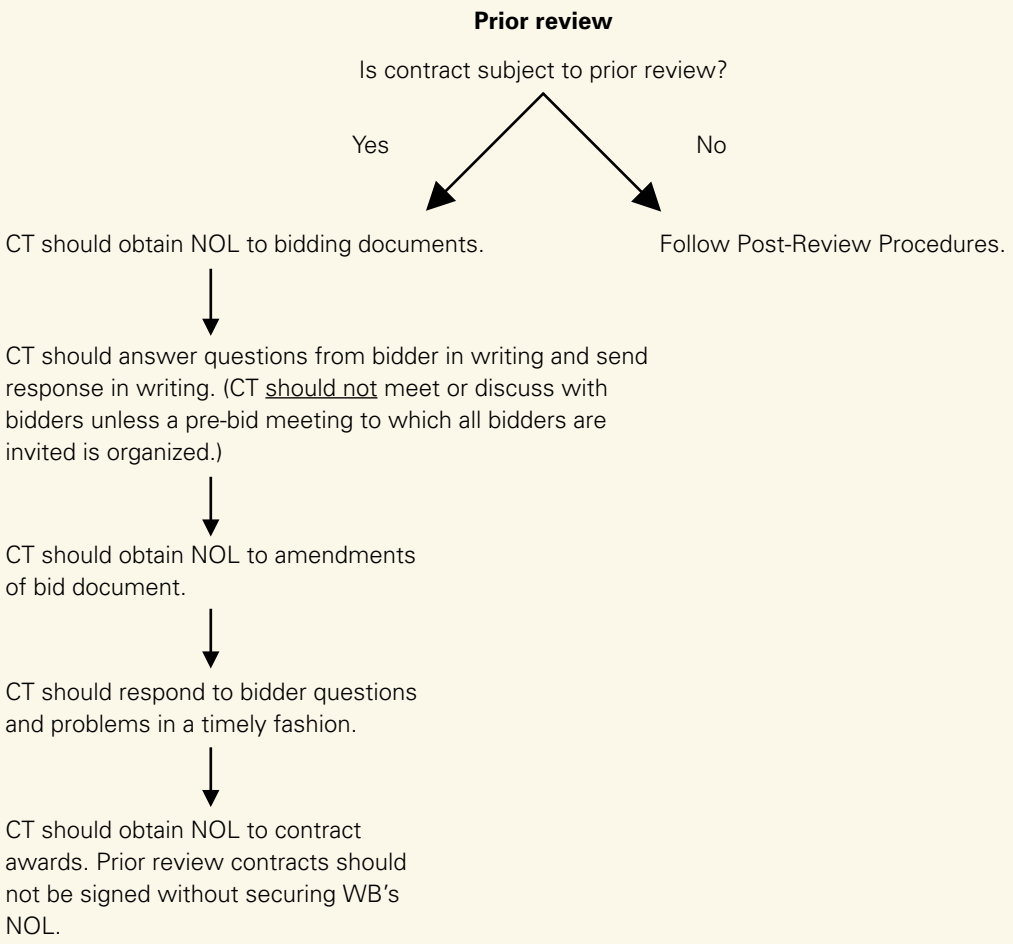
The WB Project Team should:

☐ Ensure that international nonproprietary names (INN) are used. If brand names are used in any of the products (or chemical names in the case of insecticides for public health use), they should be followed by the words "or equivalent."
☐ Ensure that the right quality criteria, including the requirement of compliance with GMP and WHOPES, have been applied in the evaluation, and that plans to carry out pre- and post-shipment inspections are included.
☐ WBPT should provide oversight.

The Country Team should:

☐ Refer to Boxes 2 and 3 for prior review thresholds and guidance concerning the review process.
☐ Ensure that Evaluation and Award are conducted within the period specified and anticipated in the Bidding Documents (e.g., 60–90 days), and that in cases of extension of bid evaluation periods, bidders are notified and the Bid Security period gets extended.
☐ Do not apply Domestic Preference to any evaluation process that is not an ICB (e.g., LIB) and observe domestic preference procedures as per guidelines.
☐ Plan for TA to conduct pre- and post-shipment inspection. Ensure the use of qualified firms for inspections. Refer to WHO's list of prequalified laboratories (http://mednet3.who.int/prequal/).
☐ CT should seek no objection for contract award based on overall tender value and regardless of the value of each lot.
☐ Countries should use "Sources and Prices of Selected Products for the Prevention, Diagnosis, and Treatment of Malaria" to guide them with respect to worldwide prices of same commodities (can be downloaded at http://rbm.who.int/mmss/products.html).
☐ Observe the following procedure (from "Guidelines—Procurement under IBRD Loans and IDA Credits") concerning treatment of taxes and duties during evaluation: The comparison shall be between the EXW price of the Goods offered from within the Purchaser's country plus local transportation, such price to include all costs; as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the Goods, and the CIF named port of destination (or CIP border point, or CIP named place of destination) price of the Goods offered from outside the Purchaser's country, plus local transportation. The evaluation of bids shall not take into account: (a) customs duties and other taxes levied on imported goods quoted CIP (which are excluded from custom duties); (b) sales and similar taxes levied in connection with the sale or delivery of the goods.

Box 2 Phase 3 Review + clearance process after completion of bidding documents



Box 3 About thresholds

☐ All procurements must follow the thresholds specified in the PAD and put forward in the Procurement Plan. Any exceptions should be cleared by the WBPT.
☐ Values of schedules and lots or individual packages should not be used to determine whether the tender is subject to prior review. Instead, the full value of the tender (comprising all schedules and lots) should be the determining factor.
☐ Any increase in quantities that would transform a post-review contract into a prior review contract must be approved and cleared by the WBPT.
☐ Quantity increases beyond 15% allowed by the provision of the bidding documents must be cleared by the WBPT.
☐ All emergency purchases must be cleared by the WBPT and must be pertinent and occur in a reasonable timeframe for the emergency at hand.
☐ A tender valued at or above the threshold for prior review must be cleared by the WBPT regardless of whether it contains several price schedules, each below the threshold (e.g., lots).

PHASE 4: RECEIPT, STORAGE, AND DISTRIBUTION

The WB Project Team should:[5]

Port clearing

☐ WBPT should ensure that arrangements have been made by the CT for post-shipment inspections of goods before distribution of goods.

☐ WBPT should make sure that the CT has a team experienced with clearing and forwarding malaria commodities from ports. Alternatively, a specialized import unit or firm should be used or hired.

The Country Team should:

Port clearing

☐ CT should implement post-shipment analysis of commodities before distribution.

☐ If CT manages clearing and forwarding of the malaria commodities, conduct an assessment of the designed process.[6]

☐ CT should ensure that the storage facilities at the clearing location are sufficient to maintain the quality of the commodities should there be an issue with clearing the goods.

Receipt at the warehouse and inspection

☐ Ensure that procedures for receiving and checking malaria commodities exist and that they are observed.[7] They should include that a prompt and thorough inspection of the malaria commodities, including testing of insecticides for public health use, is carried out at a designated place in the warehouse on arrival, and that the incoming goods are quarantined and not distributed until appropriate quality control has taken place.

Inventory control

☐ Make sure that random and periodic stock checks are carried out and that a stock auditing system is in place. (Complete Physical Inventory should be used at warehouses that manage smaller quantities of products, and Cyclic or Random Physical Inventory should be used at warehouses that manage larger quantities of products.)

☐ Ensure that physical inventory check of all products is carried out at least semi-annually.

☐ Make sure that, as a minimum, the following information is kept in the stock records: product name, beginning stock balance, receipts, issues, losses and adjustments, ending stock balance, and transaction reference.

5. The sections in this phase contain important issues that the WBPT and the CT must clarify before the procurement of the malaria commodities takes place. The sections encompass port clearing, receipt at the warehouse and inspection, inventory control, warehouse management, requisition of supplies, delivery, and health facility storage and dispensing to patients.
6. See "Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals" (MDS), second edition, revised and expanded, Kumarian Press, 1997, p. 340, for an example of an assessment.
7. Inspection Checklist for Drug Receipts (MDS, p. 346) or a similar approach should be applied.

Warehouse management

☐ Ensure that adequate and appropriate storage capacity for the malaria commodities exists. Are there plans for expansion or improvement of existing capacity?

☐ Make sure that an operations manual adequately describing procedures and responsibilities at the warehouse exists, and that the manual is being followed.

☐ Ensure that sufficient and adequately trained staff are available to operate the warehouse.

☐ Determine the average stock turnover time.

☐ Make sure adequate security measures are in place to prevent theft.

☐ Make sure that adequate storage equipment (e.g., pallet racks, trolleys, forklifts) is available to handle the malaria commodities.

☐ Make sure that storage conditions (e.g., temperature, humidity, cleanliness) are appropriate for the malaria commodities.

☐ Check whether a cold chain will be needed for the malaria commodities. If so, make sure that the cold chain works satisfactorily.[8]

☐ Make sure that the malaria commodities are sufficiently ventilated and protected against cold, heat, and direct sunlight during storage at the warehouse. The temperature across the storeroom should be monitored and recorded regularly.

☐ Make sure that drugs are zoned appropriately and that the warehouse is neat and in good condition.

☐ Make sure that product quality is monitored on an ongoing basis and that no damaged products are issued to clients. Never issue products with broken or ripped packaging.

☐ Never issue products with missing, incomplete, or unreadable label(s).

☐ Make sure that the expiry date of all products is checked before receipt of the products.

☐ Make sure that systems to deal with expired products are in place.

Requisition of supplies

☐ Identify what method is applied when issuing products: FEFO or FIFO?[9] Is the method being followed?

8. See MDS, p. 349, for a comprehensive list of equipment and supplies needed to operate a cold chain.
9. FEFO is recommended because it minimizes wastage from product expiry.

☐ When issuing supplies, make sure that batch samples are kept at the warehouse until expiry for control purposes.

Delivery

☐ Examine whether any major transportation problems exist.[10]
☐ Is delivery troublesome in certain periods of the years (e.g., due to excessive amounts of rain)?
☐ Are the vehicles available suitable for transportation of malaria commodities?
☐ Is there a vehicle replacement policy?
☐ Is there a preventive maintenance policy? If so, how is vehicle replacement funded?
☐ What percentage of vehicles is in working condition? Analyze by type and location of vehicle.
☐ Make sure that drugs are transported safely:

- Voids in cartons should be filled with packaging materials to avoid breakages.
- Vehicles should be loaded carefully and systematically, First-Out-Last-In.
- Vehicle doors should be secured to prevent loss and theft during transportation.
- Supplies should be adequately protected against sun, rain, cold, and heat.
- Start early in the day, especially when driving on hazardous roads.

Health facility storage/Dispensing to patients

☐ Make sure that a standard inventory control system is in place and that system procedures are being followed.
☐ Make sure that stock cards or stock books are used for every movement of stock in or out of the facility storeroom.
☐ Make sure that the personnel responsible for ordering, storing, and distributing drugs have been formally trained in inventory management.
☐ Make sure that the stock storage facility is properly organized and in neat condition.
☐ If cold storage is needed for the malaria commodities, make sure that there is a refrigerator and that the temperature is regularly recorded.

10. See MDS, p. 405, for a comprehensive guide on transportation issues.

Roles of other relevant partners

☐ A specialized agency experienced with clearing and forwarding of malaria commodities may perform port clearing or provide assistance. The agency should be chosen on a competitive basis.

☐ Qualified agencies (e.g., JSI, PSI, and MSH) may provide supply chain management expertise.

☐ Consider private sector transport alternatives (if transportation is not already outsourced to the private sector).[11]

11. See MDS, table 26.3, p. 402, for a comparison of alternatives.

PHASE 5: MONITORING AND EVALUATION OF PROCUREMENT

The following indicators (or a selected group of them) can be used for monitoring and evaluating procurement results and the performance of the supply chain.

Indicator name	Indicates	Measured by	Satisfactory threshold[a]
1. Advertisement of bids and publication of awards	Transparency and openness of system	Number of bids (in %) for which invitation to bid and contract award results are publicly advertised	95% or more
2. Time for preparation of bids	Real opportunity for bidders to submit bids	Number of days between invitation to bid and bid opening	21 days or more for open bidding, 10 days or more for restricted bidding, and 3 days or more for shopping
3. Time for bid evaluation	Efficiency of bidding process	Number of days between bid opening and publication of award	90 days or less
4. Method of procurement used	Level of competition	Number of bidding processes using a method less competitive than the process recommended for the estimated contract amount	1% or less
5. Number of protests	Quality and fairness of process	Ratio (in %) between the number of protests posted and the number of bids submitted	Not less than 10% and not more than 50%
6. Protest results	Effectiveness of protest system	Number (in %) of contracts with award recommendation modified because of a protest	5% or less
7. Late payments	Quality and consistency of payment process	Number (in %) of payments made more than 45 days late	10% or less
8. Contract amount increase	Quality of bidding and contract management	Percentage increase of final contract amount due to changes and amendments	15% or less (calculated as the average for the sample of transactions)
9. Product registration		Verifying that registration is mandatory to import products	Yes
10. Forecasting methods		What forecasting methods are used by main government procurement agency for procurement: consumption, adjusted consumption, or morbidity	1, 2, or 3
11. Forecasting reliability	Availability of basket items on a central level	Ratio (in %) of number of days that basket items were in stock over the past 180 days	

Indicator name	Indicates	Measured by	Satisfactory threshold[a]
12. Stock management system	Proper quantification and stock management and minimized waste due to over-ordering at health facility level	Verifying whether there is an agreed national stock management system for health facilities to inform on quantification	Yes
13. Diagnostic supplies and equipment		Verifying that the national stock management system includes the selection, forecasting need, procurement, etc. of diagnostics and laboratory supplies	
14. Pre-qualification		Verifying whether any form of pre-qualification of suppliers or manufacturers are used	Yes
15. Procurement plan		Verifying that all procurement agencies have a procurement plan for the current year	Yes
16. Procurement lead-time		Verifying time from date of launch of tender to award of most recent contract	< Certain set standard
17. Supplier lead-time		Verifying time from award of contract to receipt of first consignment	According to contract
18. Health facility lead-time		Average lead time between drugs order by health facility/customer and receipt of order	Depends on target date set
19. Storage capacity and conditions		Whether present storage capacity (including cold storage) is sufficient for the scaling up	
20. Storage capacity		Written estimation/plan of the storage requirements, on national level including cold storage, is available	Yes
21. External security	External security measures are sufficient at the central warehouse where the bulk stocks of drugs are kept		
22. Internal security	More than one person is responsible for the reception and the supply of drugs	Whether supplier order reception SOPs and customer order processing SOPs include sufficient security checks	Yes

PHASE 5: MONITORING AND EVALUATION OF PROCUREMENT

Indicator name	Indicates	Measured by	Satisfactory threshold[a]
23. Routine sampling and testing of batches		Whether procurement agencies have a system for routine sampling and testing of batches	
24. Batch testing result		Ratio (in %) of batches that failed QC out of a sample of batches	< 0.1%

a. These thresholds/targets are very tentative and should be revisited once the indicators are going to be adopted.

Sources: World Bank study commissioned to Euro Health to develop indicators to monitor application/impact of the recommendations of *Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* (2004) and *Bangladesh Public Procurement Monitoring Indicators* (2005).

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Annex 1: Capacity Assessment Questionnaire

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B Patents
C Forecasting
D Procurement systems
E NDRA, QA, and QC
F Receipt and storage
G Distribution
H Rational drug use
I Specific issues
J Management and coordination

Source: Global Fund to Fight AIDS, TB and Malaria.

Introduction

Procurement and supply management of health products is a cornerstone activity of most malaria programs financed by the Global Fund to Fight AIDS, TB and Malaria (GFATM) and by the World Bank. Available resources provide unprecedented opportunities to procure and distribute significant volumes of health products used in the fight against malaria. However, there are also significant risks involved; not only could scarce resources be wasted, poor quality products may potentially cause severe damage to the health and well-being of those affected by the diseases.

Purpose

This tool enables a focused assessment of procurement and supply management performance of World Bank and Global Fund financed public health interventions. It is to be used to determine whether the procurement plan of a nominated Implementing Agency (IA) or Principal Recipient (PR) adheres to World Bank and Global Fund procurement policies and whether this plan is in fact implementable. Based on the findings of the assessment, the WB Project Team or Local Fund Agent (LFA) will determine whether a nominated IA or PR is ready to implement a procurement plan or which steps should be taken before it may do so.

Application

This tool should be applied only by the Procurement Specialist of the World Bank or the Lead Procurement Expert of the LFA under the Global Fund Grant, who is responsible for the quality of the assessment. If consultants are hired to carry out the task, their work should be done under the supervision of procurement and supply management experts designated by the corresponding institution.

Scope

The scope of this assessment is limited to:

- Conducting an offsite background analysis based on existing information (Global Fund users: see *Guidelines for the PR Assessment*).
- When necessary, conducting an onsite assessment.
- Only applicable for Global Fund users: Conducting two reviews of the procurement plan (one before and one after the onsite assessment). Only under exceptional circumstances and with the consent of the Global Fund's Procurement Manager and Fund Portfolio Manager are additional reviews acceptable. Because the LFA's responsibility is to assess the procurement plan, the LFA procurement experts should under no circumstances actively assist the nominated PR with the development of the procurement plan.

Planning and duration

The procurement assessment should be initiated before the development of a procurement plan, to ensure that the IA has the capacity to oversee the procurement and supply management needs of the project. Under normal circumstances, the assessment should be finalized within 3–5 days per component, per nominated IA/PR.

Recommended background reading

- *Guidelines on Global Fund procurement and supply management* (available at http://www.theglobalfund.org)
- *Guidelines for the PR Assessment* (available at http://www.theglobalfund.org/pdf/12_pp_guidelines_pr_assessment_4_en.pdf)
- *Interagency guidelines on operational principles for good pharmaceutical procurement* (available at http://www.who.int/3by5/en/who-edm-par-99-5.pdf)
- *Sources and Prices of Selected Products for the Prevention, Diagnosis, and Treatment of Malaria* (available at http://whqlibdoc.who.int/publications/2004/9241592508.pdf)
- *Drug Patents Under the Spotlight* (available at http://www.accessmed-msf.org/documents/patents_2003.pdf)
- *Guidelines—Procurement under IBRD Loans and IDA Credits*. World Bank, May 2004 (available at http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Procurement-May-2004.pdf)
- *Standard Bidding Documents—Procurement of Health Sector Goods*. World Bank, May 2004 (available at http://siteresources.worldbank.org/INTPROCUREMENT/Resources/health-05-04-ev1.pdf)
- *Technical Note—Procurement of Health Sector Goods*. World Bank, May 2000 (available at http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:20062738~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266,00.html)

A
Product selection

		Yes No N/A
A.1	**Who/which department is responsible for product selection under the grant, loan, or credit?** Comments:	
A.2	**Is the (nominated PR/IA) aware of Global Fund/World Bank policy regarding product selection and how does the (nominated PR/IA) intend to adhere to this policy?** Comments:	

B
Patents

		Yes No N/A
B.1	**Does the country have a patent law that allows for the patenting of pharmaceutical products? If no, skip the remaining questions, but indicate whether the country is planning to adopt a patent law.** Comments:	
B.2	**If yes, indicate which specific pharmaceutical products that may be procured (for example, "Coartem®") are under patent in the country and the name of the patent holder (for example, "Novartis").** Comments:	
B.3	**Are the procurement authorities presently purchasing generic (off-patent) versions of pharmaceutical products that are on patent in the country?** Comments:	
B.4	**If yes, are such products produced within the country or imported? On what basis are such purchases presently authorized?** Comments:	
B.5	**Is the country a member of the World Trade Organization (WTO)?** Comments:	

B.6 **If yes, is the country "least developed" according to its submissions to the WTO? If no, skip to question 10.**

Comments:

B.7 **If yes, have government authorities within the country taken steps to permit the non-enforcement of patents on pharmaceutical products?**

Comments:

B.8 **If no, are government authorities within the country amenable to taking such steps?**

Comments:

B.9 **If no, does the patent law (or other national law) provide for the grant of "government use" or compulsory licenses? If yes, what are the relevant procedures and requirements? Skip to question 13.**

Comments:

B.10 **If the country is not a "least developed country," does its patent law (or other national law) provide for the grant of "government use" or compulsory licenses?**

Comments:

B.11 **If "government use" licensing is provided for in the law, what are the relevant procedures and requirements?**

Comments:

B.12 **If the procurement authority is not associated with or acting on behalf of the government, what are the procedures and requirements of the generally applicable compulsory licensing law?**

Comments:

B.13 **Does national law permit "parallel importation" of patented pharmaceuticals?**

Comments:

B.14 **Are the pharmaceutical products that may be procured presently registered by the relevant medicines regulatory authority for use within the country?**

Comments:

B.15	**If no, does national legislation or practice within the country recognize an exception to patent rights for regulatory submissions by third parties?** Comments:	

C
Forecasting

		Yes No N/A
C.1	**Who/which department is responsible for forecasting (including forecasting of buffer stocks) under the grant, loan, or credit?** Comments:	
C.2	**How were forecasts developed for the required quantities of health products under this grant, loan, credit?** Comments:	
	Consumption method, using quantities of drugs distributed and dispensed to patients? Comments:	
	Morbidity method, using population, case detection rate, and patient segmentation? Comments:	
	Other: Comments:	
C.3	**How are forecasts validated?** Comments:	
C.4	**Are adequate volumes of buffer stocks planned at relevant levels?** Comments:	
C.5	**How are forecasting data managed (e.g., use of Information Systems)?** Comments:	

C.6 **Are forecasts presented based on reliable data and methods?**

Comments:

C.7 **Are forecasts of parallel procurement efforts appropriately harmonized with the procurement under this grant, loan, or credit? How?**

Comments:

D
Procurement systems

Yes
No
N/A

D.1 **Who is/are responsible for procurement under the grant, loan, or credit?**

Comments:

If procurement is outsourced to an agency acceptable to the Global Fund/ World Bank, please skip to section D.6.

D.2 **Review Procurement Procedures Manual and identify its strengths and weaknesses. (a) For Global Fund recipients, drug procurement procedures in the manual should correspond with the Interagency Guidelines on Operational Principles for Good Pharmaceutical Procurement. (b) For World Bank-funded programs, the manual must be consistent with the principles of "Guidelines—Procurement under IBRD Loans and IDA Credits."**

Comments:

D.3 **Is competent procurement staff available and, if so, is it adequately equipped?**

Comments:

D.4 **Is the actual procurement process efficient and transparent?**

Comments:

D.5 **Complete the product price comparison sheet in appendix A1 for a selected group of products. Include the currently negotiated (or anticipated) price for each product as well as an international reference price. Record the main conclusion here.**

Comments:

D.6 **What is the anticipated duration of the procurement cycle (as applied under this grant, loan, or credit) calculated in months from product selection until arrival of goods?**

Comments:

D.7 **Does an adequate and functional supplier tracking system exist? (If not, indicate when such a system will be implemented.)**

Comments:

E
NDRA, QA, and QC

Yes
No
N/A

National Drug Regulatory Authority (NDRA)

E.1 **Is there a functioning NDRA?**

Comments:

E.2 **Which of the following QA/QC procedures does the NDRA apply:**

Drug registration?

Comments:

Import licensing?

Comments:

E.3 **Are NDRA requirements likely to have a negative impact (e.g., delays, limiting competition) on the implementation of the grant, loan, or credit?**

Comments:

E.4 **If yes, how can this impact be overcome (e.g., registration waiver, fast-track registration)?**

Comments:

Please skip to section F if procurement is outsourced to an agency acceptable to the Global Fund/World Bank.

E.5 **Who/which department is responsible for quality assurance and quality control (QA/QC) of products procured under the grant, loan, or credit?**

Comments:

Pre-qualification of single- and limited-source products

E.6	**Are single- and limited-source products exclusively procured from WHO-approved sources?** Comments:	
E.7	**If no, how is the quality of single- and limited-source products assured? Describe the procedures in detail:** Comments:	

Pre-qualification of multi-source products

E.8	**Are the multi-source products procured under the grant, loan, or credit subjected to and in compliance with NDRA requirements (e.g., registration)?** Comments:	

Quality control

E.9	**Does the party responsible for QA/QC (see question E.5) systematically draw random samples of all pharmaceutical batches?** Comments:	
E.10	**Are samples regularly tested by a qualified laboratory (e.g., accepted for collaboration with WHO pre-qualification project; accredited in accordance with ISO17025 and/or EN45002) or accepted by a stringent authority?** Comments:	

F
Receipt and storage

		Yes No N/A
F.1	**Who/which department is responsible for receipt and storage of procurements under the grant, loan, or credit?** Comments:	
F.2	**Is the storage and safe handling capacity adequate and appropriate for the expected products (e.g., insecticides for public health use, ITNs, LLINs)? If not, describe plans to improve or expand storage capacity (with a timetable).** Comments:	

F.3	**Is sufficient and adequately trained staff available to handle the supplies procured under the grant, loan, or credit? If not, describe plans to improve capacity or train staff (with a timetable).** Comments:	
F.4	**Is adequate storage equipment available at critical levels (e.g., pallet racks, trolleys, forklifts, refrigerators) to handle products procured under the grant, loan, or credit?** Comments:	
F.5	**Are storage conditions (e.g., temperature, humidity, cleanliness) appropriate? If not, describe plans to improve or expand storage conditions (with a timetable).** Comments:	
F.6	**Which inventory control mechanism is used (e.g., bin cards, ledgers, computers) and is this system reliable?** Comments:	
F.7	**Is a physical inventory check of all products carried out at least annually?** Comments:	
F.8	**What is the average stock turnover time?** Comments:	
F.9	**Are adequate security measures in place to prevent theft of stored products? If not, describe plans to improve or expand security measures (with a timetable).** Comments:	
F.10	**Is there a policy and practice of storing and issuing stock according to first expiry/first out inventory control procedures at all levels?** Comments:	
F.11	**What systems are in place to dispose of or return expired products at either the (nominated PR/IA) or (project implementation/subrecipient) sites?** Comments:	

F.12	**Is cooling equipment available for the storage of certain malaria commodities (such as rapid diagnostic test kits)?** Comments:	
F.13	**Is there a plan for phasing out and disposing of the previous malaria drugs?** Comments:	

G Distribution

		Yes No N/A
G.1	**Have detailed distribution arrangements been described and agreed upon? Please specify.** Comments:	
G.2	**Is there a documented product distribution schedule for all recipients (e.g., monthly, quarterly)?** Comments:	
G.3	**Are resources available for product distribution, including a sufficient number and capacity of vehicles as well as petrol and drivers, to ensure timely product delivery? Explain.** Comments:	
G.4	**Is transportation outsourced at any level of the supply chain management system? If yes, to whom is the responsibility outsourced and how effective has it been?** Comments:	
G.5	**Describe the sources of significant delays to malaria product distribution in the last 12 months (if any) and the actions taken since to prevent such delays in the future.** Comments:	
G.6	**For products that are susceptible to product theft, what additional security measures are taken in distribution systems, e.g., locked cases or covered vehicles?** Comments:	

G.7	**What material accounting systems and processes are in place to ensure that the exact amount and type of products dispatched are received?** Comments:	
G.8	**Does the shelf life of products appear to be well managed throughout the supply chain?** Comments:	
G.9	**Is cooling equipment available during transportation as is relevant for malaria commodities such as rapid diagnostic test kits?** Comments:	

H

Rational drug use

Standard treatment guidelines

		Yes No N/A
H.1	**Are updated National Standard Treatment Guidelines available for malaria?** Comments:	
H.2	**Are available guidelines consistent with protocols by the WHO? If not, how will inconsistencies be resolved?** Comments:	
H.3	**Are all guidelines supposed to be available at central, regional, district, and local levels? If not, explain which guidelines are available at which level.** Comments:	

Adherence, resistance, and adverse drug reactions

H.4	**Are there appropriate mechanisms (including but not limited to fixed dose combination drugs, once-a-day formulations, blister packs, and peer education and support in accordance with existing international guidelines) in place to encourage:**	
	Adherence to treatment? Comments:	

Monitoring and containment of resistance?

Comments:

Monitoring of adverse drug reactions?

Comments:

Specific issues related to the procurement of malaria commodities (antimalarial medicines, mosquito nets, insecticides for public health use, spraying equipment, rapid diagnostic test kits, and resistance test kits)

Yes
No
N/A

I.1 **Are nondurable products quality assured using the same principles as for pharmaceuticals, namely from 1) lists of prequalified products, where they exist, or 2) products accepted by stringent regulatory agencies, or 3) products accepted by national standards?**

Comments:

I.2 **For durable products, has the lowest possible price taken into account the total cost of ownership (TCO), including the cost of reagents and other consumables as well as costs for annual maintenance, such as insecticide retreatment kits for regular bed nets? Please comment.**

Comments:

I.3 **Has the (nominated PR/IA) provided a plan for service and maintenance of durable products?**

Comments:

I.4 **Long delivery times for LLINs may exist due to global shortages. Has the current supply situation been assessed?**

Comments:

I.5 **Long delivery times for ACTs may exist due to the single-source nature of the product. Has the current supply situation been assessed?**

Comments:

J

Management and coordination (including of subrecipients)

		Yes No N/A
J.1	**Who/which department is responsible for the overall management and coordination of activities related to procurement and supply management of health products under the grant, loan, or credit?** Comments:	
J.2	**Does this overall management and coordination capacity appear to be adequate?** Comments:	
J.3	**How does the (nominated PR/IA) intend to direct, monitor (and where necessary, take corrective action), and report on the PSM activities to ensure that the Global Fund/World Bank policies are implemented and enforced?** Comments:	
J.4	**Does the (nominated PR/IA) have adequate capacity to ensure project compliance with Global Fund/World Bank procurement policies?** Comments:	
J.5	**Are plans in place to expand the availability of human resources where applicable?** Comments:	
J.6	**Have any cost items been underestimated or overlooked in the budget?** Comments:	
J.7	**Will patients/clients be charged for products procured? If yes, explain in detail (in principle, this is against Global Fund/World Bank policy).** Comments:	
J.8	**Is there a risk of overlap or duplication of health product provision by the Global Fund, World Bank, and other donors? If yes, how is this risk mitigated? Please specify in detail.** Comments:	

Appendix A1 Price comparison sheet

Product (include INN when applicable)	Dosage (when applicable)	Quantity	Local supplier	Local price per unit (A)	Reference agency	Reference supplier	Reference price per unit (B)	"Price variance = A/B"
				$			$	
				$			$	

Contents

A Context and background
B Objective
C Requirements
D Proposal requirements
E Proposal evaluation criteria
F Timeline

Sample TOR #1 of 2

Please note that the following TOR is applicable to both World Bank projects and Global Fund projects. Accordingly, please observe that the text contains terms used only by the World Bank (such as Implementing Agency, or IA) or by the Global Fund (such as Principal Recipient, or PR).

(The sample is not prescriptive. It is attached as an aid and, if used, should be tailored to fit particular circumstances.)

(Source: UNDP Kinshasa.)

Deadline: [*Insert deadline*]

Terms of Reference

Consultancy services in procurement and supply management of malaria commodities

Date of publication [*Insert date*]
Date of submission [*Insert date*]
Contact information [*Insert contact information*]

A. Context and background

[*Insert agreement*] has been signed between [*Insert name of funding agency*] and [*Insert name of country/PR/IA*] to fight malaria. The funding request amounts to [*Insert amount*], of which [*Insert amount*] has already been approved by [*Insert name of funding agency*]. [*Insert name of country/PR/IA*] has been designated as the PR/IA by [*Insert funding agency*]. The PR/IA will act as the operational unit and will be responsible for the implementation of the project(s) and the operational management of the [*Insert name of funding agency*] project(s).
A significant proportion of the funding will be spent on procurement and supply management (PSM) of malaria commodities such as antimalarial medicines, mosquito nets, and insecticides for public health use. As part of its responsibilities as PR/IA, [*Insert name of country/PR/IA*] will coordinate and manage all PSM-related activities. To strengthen its strategic, operational, and technical capacity in PSM, [*Insert name of country/PR/IA*] is seeking to contract technical assistance from reputable organizations which will help [*Insert name of country/PR/IA*] meet its targets as defined under [*Insert agreement*].
PSM is an area of expertise that includes a large number of specialties, including, among other things, PSM strategy and policy, management and coordination, product specification and selection, forecasting of needs, procurement systems and procedures, contracting, quality assurance, inventory management, distribution, management information systems, and rational use of medicines. Appreciating the fact that no one single expert is likely to specialize in all these individual but interlinked areas of expertise, [*Insert name of country/PR/IA*] is requesting companies to offer three particular services: (1) one Strategic (PSM) Adviser; (2) one Procurement Manager; and (3) a pool of technical experts in all of the areas listed above who are available as needed.

The sections below provide more details on the objective of the requested services, the requirements for each of the three services, and the requirements and evaluation criteria pertaining to the proposal submitted by interested parties.

B. Objective

The contractor will assist [*Insert name of country/PR/IA*] with the following activities:

- Refine and regularly update the PSM strategy;
- Manage and coordinate all PSM activities under the [*Insert name of funding agency*] project(s);
- Identify potential risks for patients, [*Insert name of country/PR/IA*], sub-recipients, and the [*Insert name of funding agency*] associated with the PSM strategy and the implementation thereof;
- Recommend to [*Insert name of country/PR/IA*]'s Principal Coordinator solutions to any anticipated or arising obstacle to successful implementation of the PSM strategy;
- Assist [*Insert name of country/PR/IA*] with selecting, contracting, and managing third-party service providers such as procurement agencies and distribution companies;
- Design and implement a comprehensive monitoring and evaluation system for all PSM activities under the [*Insert name of funding agency*] project(s);
- Ensure [*Insert name of country/PR/IA*]'s strict compliance with [*Insert name of country/PR/IA and funding agency*] PSM policies;
- Provide support to [*Insert name of country/PR/IA*]'s Principal Coordinator in responding to changing market dynamics associated with PSM, such as de-listing of WHO pre-qualified medicines, legal issues, and changing [*Insert name of funding agency*] policy, as well as PSM-related issues stemming from the (inter)national media;
- Attend to any other PSM-related issue that may arise during implementation of the [*Insert name of funding agency*] project(s).

C. Requirements

As noted above, the contractor must provide three closely related types of services and expertise:

1. Strategic Adviser
2. Procurement Manager
3. Pool of PSM experts

In addition, the contractor will be responsible for all administrative, legal, and managerial matters necessary to ensure results-oriented, flexible, and effective performance of the Strategic Adviser, the Procurement Manager, and all consultants drawn from the pool of PSM experts. The following sections outline the detailed requirements for each area of support.

1. Strategic Adviser

Responsibilities

- the Principal Coordinator of [*Insert name of country/PR/IA*]'s [*Insert name of funding agency*] project(s) on any strategic matter related to PSM of malaria commodities under the [*Insert name of funding agency*] project(s);

- Design strategies to overcome any anticipated or arising obstacle to ensuring the effective implementation of PSM plans;
- Recruit, contract, manage, and supervise the Procurement Manager (to be located in [*Insert location*]), as well as additional PSM experts (as described below);
- Ensure [*Insert name of country/PR/IA*]'s strict compliance with all requisite [*Insert name of funding agency*] PSM policies and paperwork requirements;
- Provide assistance in the evaluation of offers from subcontractors, including international malaria commodity procurement services and in-country logistics companies.

Level of expertise
The Strategic Adviser must be senior in his or her professional experience and expertise.

Professional experience
As a minimum, the Strategic Adviser must have:

- Intricate and in-depth knowledge of, and operational or managerial experience in working with [*Insert name of funding agency and/or name of other multilateral or bilateral organizations*] PSM policies;
- Direct contractual experience with the [*Insert name of funding agency*] (as a contractor or employee) is strongly preferred;
- Provided technical assistance to [*Insert name of funding agency*] recipients in PSM;
- Direct involvement with pharmaceutical policy development in major (international) organizations;
- Significant experience with the recruitment and management of PSM consultants;
- Operational experience with purchasing medicines and other health products (preferably malaria commodities) for (public) health facilities in developing countries;
- Experience with sales and marketing of medicines and other health products (preferably malaria commodities) in developing countries.

Education
Relevant advanced degree from an internationally accepted university.

Language skills
Proficiency in [*Insert language*] is needed. Good knowledge of [*Insert language*] and other languages would be considered a plus.

Other skills

- Strong analytical skills;
- Highly developed strategy development skills;
- Strongly focused on results;
- Outstanding communications skills, both orally and in writing;

- Proficiency in personal computer applications such as Microsoft Word, Excel, and PowerPoint.

Level of input
The Strategic Adviser must:
- Make at least [*Insert # of trips*] trips of [*Insert duration*] to [*Insert location of project(s)*] per year;
- Be able to respond to ad hoc queries within one working day at any given time during the duration of the contract.

Location
The Strategic Adviser must be located in a time zone that differs no more than one hour from that of [*Insert location of project(s)*] and be easily accessible through telephone and email.

2. Procurement Manager

Responsibilities
Supervised by and working closely with the Strategic Adviser, the Procurement Manager is responsible for the following activities:
- Manage and coordinate all PSM activities under the [*Insert name of funding agency*] project(s);
- Identify potential risks for patients, [*Insert name of country/PR/IA*], subrecipients, and [*Insert name of funding agency*] associated with the PSM strategy and the implementation thereof;
- Recommend to *[Insert name of country/PR/IA*]'s Principal Coordinator solutions to any anticipated or arising obstacle to successful implementation of the PSM strategy;
- Assist [*Insert name of country/PR/IA*] with selecting, contracting, and managing third-party service providers such as procurement agencies and distribution companies.
- Assist with the design and implementation of a comprehensive monitoring and evaluation system for all PSM activities under the [*Insert name of funding agency*] project(s);
- Assist in the selection and quantification of the malaria commodities;
- Assist in the design and development of a method for forecasting;
- Ensure [*Insert name of country/PR/IA*]'s strict compliance with [*Insert name of funding agency*] PSM policies;
- Provide support to [*Insert name of country/PR/IA*]'s Principal Coordinator in responding to changing market dynamics associated with PSM, such as de-listing of WHO pre-qualified medicines, legal issues, and changing [*Insert name of funding agency*] policies, as well as PSM-related issues stemming from the (inter)national media;
- Assist with the planning, preparation, and implementation of PSM training seminars for the PR/IA as well as the subrecipients;
- Attend to any other PSM-related issue that may arise during implementation of the [*Insert name of funding agency*] project(s).

Level of expertise
Mid-level management.

Professional experience
- At least three years of operational experience with the provision of essential health products in support of the fight against malaria in developing countries;
- At least three years of experience with developing solutions to problems related to the provision of the health products mentioned above in developing countries;
- Track record of collaboration with key stakeholders in the fight against malaria (e.g., the World Bank, the Global Fund, governments, UN agencies, [inter]national NGOs, manufacturers of health products, [inter]national procurement agencies);
- Knowledge of and experience with global pharmaceutical markets and related policies in developing countries;
- In light of the significant number of NGO subrecipients involved in the project(s), previous experience with medical humanitarian NGOs is required.

Education
Relevant advanced degree from an internationally accepted university, preferably in a public health field.

Language skills
Excellent knowledge of [*Insert language*] and a good working knowledge of [*Insert language*]. Additional linguistic skills are an advantage.

Other skills
- Excellent analytical skills;
- Strongly focused on results;
- Team player;
- Outstanding management and organizational skills;
- Outstanding communications skills, both oral and written;
- Proficiency in personal computer applications such as Microsoft Word, Excel, and PowerPoint.

Level of input
- [*Insert full-time, part-time, etc.*];
- [*Insert # days*] days of vacation per 12 months, including official holidays.

Location
[*Insert location*].

3. Pool of Consultants

Responsibilities
A pool of consultants must be available to provide technical assistance to the Strategic Adviser and the Procurement Manager on specific, well-defined, and highly technical tasks. Not all obstacles to successfully implementing [*Insert*

name of country/PR/IA]'s PSM Plan can be defined up front—many must be addressed as they come up. The pool of consultants must, therefore, be very flexible and include experts in all of the areas listed under *Professional experience* below.

As a minimum the pool of consultants must, in support of the Strategic Adviser and Procurement Manager, successfully complete the following tasks during the course of the contract, in accordance with a mutually agreed on timeline:

- Draft terms of reference (TOR) for the selection and contracting of one or several international malaria commodity procurement service(s);
- Draft TOR for the selection and contracting of an in-country logistics company or companies;
- Assist [*Insert name of country/PR/IA*]'s legal department with the design of contracts with subcontractors in PSM;
- Develop indicators and the requisite systems for monitoring performance of the subcontracted procurement services and logistics companies;
- Develop appropriate standard operating procedures for the management of the procurement services and logistics companies by [*Insert name of country/PR/IA*];
- Assist with the preparation and evaluation of orders to be placed at the subcontracted procurement agencies;
- Develop and implement an ordering and tracking system for subrecipients;
- Assist with the improvement of the existing health product distribution systems and infrastructure;
- Assist with the design and implementation of a comprehensive monitoring and evaluation system for all PSM activities under the [*Insert name of funding agency*] project(s);
- Assist in the selection and quantification of the malaria commodities;
- Assist in the design and development of a method for forecasting;
- Assist with the planning, preparation, and implementation of at least [*Insert # of days*] [*Insert duration*]-day PSM training seminars for the PR as well as the subrecipients.

Level of expertise

Senior, in accordance with specific in-depth expertise required to fulfill the responsibilities listed above and in accordance with the required professional experience listed below.

Professional experience

The pool of consultants must include senior specialists in the following areas:

- Supply chain management of health products (preferably malaria commodities) in developing countries, particularly [*Insert name of country*];
- Procurement of services in logistics and procurement;
- Procurement of health products (preferably malaria commodities): at least one of the available consultants should have senior-level experience with procurement of health products for developing countries, particularly [*Insert name of country*];
- Quality assurance of pharmaceuticals and other essential health products (preferably malaria commodities);

- Monitoring and evaluation of PSM-related activities;
- Management information technology systems related to PSM;
- Conducting PSM training workshops (in [*Insert language*]).

Education
Advanced degrees from internationally accepted universities, depending on the area of required expertise.

Language skills
Proficiency in [*Insert language*]; working knowledge of [*Insert language*] required when traveling to [*Insert country*].

Other skills
- Excellent analytical skills;
- Strongly focused on results;
- Team player;
- Outstanding communications skills, both oral and written;
- Proficiency in personal computer applications such as Microsoft Word, Excel, and PowerPoint.

Level of input
The level of required input depends in part on the obstacles with which [*Insert name of country/PR/IA*] will be confronted during the course of the contract. However, the proposal submitted should be based on approximately [*Insert # of days*] of input.

Location
Anywhere in the world, but with easy access to telephone, the Internet, and email.

4. Consultancy Services

The contractor is responsible for the sourcing, contracting, management, and payment of the required expertise as outlined above as well as the quality control of the work performed. In addition, the contractor should appoint one contact person for [*Insert name of country/PR/IA*]. This position should be based in a time zone which differs no more than [*Insert zero/one/two] hour(s) from that of [Insert location*] to facilitate easy communication.
The contractor should be highly flexible and able to respond to the dynamics that are commonly associated with implementing complex health care interventions such as the [*Insert name of funding agency*]-financed project(s) in [*Insert name of country*].
[*Insert name of country/PR/IA*] will make available adequate office space for the Procurement Manager in the office of [*Insert name of country/PR/IA*]'s [*Insert name of funding agency*] project(s). The contractor should provide the Procurement Manager with a notebook computer and cellular telephone.

D. Proposal requirements

Interested parties should submit their proposal to [*Insert contact information*].
Closing date is [*Insert closing date*].
Proposals should include the following:

- CVs of all offered expertise, accompanied with a brief but detailed narrative on how each professional meets the requirements listed above;
- A lump sum cost. The contractor is required to offer a fixed total cost per month, which covers the salaries and all expenditures of the Strategic Adviser, the Procurement Manager, and all additional consultants, as well as all communications, legal, and administrative support and other costs. Hence, the proposal should not include a detailed line-item budget.
- No costs pertaining to traveling to [*Insert destination*]. All such costs are borne by [*Insert name of country/PR/IA*] directly and should therefore not be included in the cost. The Procurement Manager is not entitled to receive any per diem during his/her stay in [*Insert destination*].
- Any additional terms and conditions. The contractor will receive a payment equal to 15% of the total contract value upon signature of the contract. Additional payments will be made at the beginning of each of the [*Insert duration of project(s)*]. Each monthly payment is equal to 85% of the total contract value divided by [*Insert duration of project(s)*].

E. Proposal evaluation criteria

Proposals will be rated in accordance with the criteria below. The proposal with the highest weighted total score will be awarded the contract.

Criterion Score	**% Weighted Total**
Qualifications of Strategic Adviser	35%
Qualifications of Procurement Manager	25%
Qualifications of Pool of Consultants	25%
Qualifications of Consultancy Services	5%
Cost	10%
Total	**100%**

F. Timeline

The contract will cover [*Insert duration of project(s)*] with an option for a [*Insert duration of renewal*] renewal and will start on [*Insert date*].

Contents

A Price components
B Objectives of the assignment
C Specific responsibilities
D Expected output
E Qualifications and experience
F Reporting arrangements and resources to be provided by the client
G Duration of assignment

(The sample is not prescriptive. It is attached as an aid and, if used, should be tailored to fit particular circumstances.)

(Source: World Bank.)

MINISTRY OF HEALTH

MALARIA BOOSTER PROGRAM

TORs FOR A PROCUREMENT CONSULTANT

[*Insert country*] is preparing the Malaria Booster Project on a fast-track basis. As a condition of effectiveness for the Project, the recipient is expected to put in place procurement arrangements that meet acceptable fiduciary capacity levels. In order to meet this requirement, [*Insert implementing organization*] is expected to have in place the Procurement Plan, Procurement Manual, and a training plan acceptable to [*Insert government name*] and the World Bank. These documents need to be ready in a period of [*Insert duration*].

A Project components

The Project will comprise the following components:

Project Component 1: Support to the National Health System

This project component will support expansion of supply and distribution of insecticide-treated bed nets, increase coverage of indoor residual spraying, scale up laboratory diagnostic capacity through procurement of rapid diagnostic test kits and microscopes, strengthen health-seeking behavior and intermittent presumptive treatment of pregnant women, and strengthen the human resource capacity within the health sector to deal with the increased demand as a result of the malaria epidemic. The component will also support strengthening the institutional capacity of the Ministry of Health in procurement, supply and logistics, financial management, and monitoring and evaluation. The project will provide incremental financing to improve service delivery and support malaria-related interventions to district health teams for their contractual action plans through the district basket mechanism.

Project Component 2: Community Response to Malaria

This project component will provide support for community demand-driven interventions. Communities have a critical role to play in spreading appropriate information for malaria prevention and care seeking.

Project Component 3: Program Management

This project component will support strengthening the [*Insert implementing organization*] to provide technical leadership for the malaria program, coordinate implementation of the program, strengthen human resource capacity, and strengthen monitoring and evaluation.

B Objectives of the assignment

1. Provide technical assistance to the procurement function within [*Insert implementing organization*] and the Ministry of Health and suggest the best procurement arrangement and system, taking into account the agreed institutional arrangement between [*Insert government*] and the World Bank.
2. Assist in the consolidation of annual work plans and budgets, quantification of drugs and other malaria commodities, and preparation of procurement packages (including invitations for bids, requests for proposals, and requests for quotations under shopping and their evaluation). Strategize, with the involvement of the stakeholders, select appropriate procurement methods, and prepare the Procurement Plan covering the first [*Insert duration*] of project implementation. Establish a Procurement Data Management System (PDMS) and train staff in its effective use.
3. Prepare the Procurement Manual, undertaking training and mentoring of staff on the application of procurement guidelines.

C Specific responsibilities

- Consolidation of the individual component's work plans and budgets, to develop a [*Insert duration*] Procurement Plan detailing the packages, strategies, and appropriate methods of procurement.
- Preparation of bidding documents for goods, works, and consultant services using existing SBDs as templates and referencing World Bank country thresholds and WHO/WHOPES product technical specifications.
- Preparation of Procurement and Logistics Manual, taking into consideration the institutional arrangements and reporting mechanisms.
- Training and mentoring activities for staff of the [*Insert implementing organization*], Ministry of Health, and other affiliate agencies in World Bank and [*Insert government*] procurement guidelines.
- Development of an acceptable PDMS and monitoring and evaluation system that enables [*Insert implementing organization*] to monitor compliance with procurement procedures in the utilization of grants.

D Expected output

- Development of a [*Insert duration*] Procurement Plan for the project.
- Preparation of bidding documents for goods, works, and consultants services.
- Preparation of Procurement Manual.
- Training for [*Insert implementing organization*], Ministry of Health, and other affiliate agencies in World Bank and [*Insert government*] procurement procedures.
- Development of a Procurement Data Management System.
- Development of a procurement monitoring system based on identified critical indicators and benchmarks and of a performance baseline against which procurement performance will be monitored.

E Qualifications and experience

- First degree in a relevant field.
- Graduate diploma from the Chartered Institute of Purchasing and Supply (UK) or equivalent is a definite advantage.
- At least 10 years of relevant working experience, particularly in public health, 5 of which should be at senior management level.

- Experience in World Bank and [*Insert government*] Procurement Guidelines and procedures is desirable.
- Proficiency in ICT-based applications is required.

F Reporting arrangements and resources to be provided by the client

- In carrying out the assignment, the consultant is expected to consult with and work closely with key relevant staff at the [*Insert relevant organizations*] and Ministry of Health to ensure that all major issues are addressed and factored into the work of the consultant.
- It is expected that the consultant may be assigned office space and access to a computer, telephone, and email to facilitate the execution of the assignment. Reasonable access to transport will be provided on request to facilitate execution of the assignment.
- The consultant shall operate under the general supervision of [*Insert implementing organization*]

G Duration of assignment

- [*Insert duration*]

Contents

Introduction
1 PIA's capacity to conduct procurement and supply management—PSM
2 Procurement and supply management cycle

Source: Global Fund to Fight AIDS, TB and Malaria; World Bank's Procurement Plan.

The initial PSM will cover the first 18 months of the project. After that it should be updated annually or more frequently as necessary.

Project information	[*Example: Country, Borrower, Project Name, Loan/Credit No., Project Implementing Agency (PIA) etc. The project team may decide to have different sections to reflect projects with many PIAs.*]
Bank's approval date of the procurement Plan	[*Original : … Revision 1: …*]
Date of General Procurement Notice	
Period covered by this procurement plan	

Table A3.1 Procurement overview

Product category	(US$)
1. Pharmaceuticals	
2. Health products and commodities (excluding pharmaceuticals)	
3. Health equipment (X-rays, laboratory equipment, etc.)	
4. Services (related to PSM, e.g., QA, MIS, RUD)	
5. Non-health products and services (e.g., vehicles, computers, construction, financial consultants)	
Total	
Total loan size (US$)	
Total procurement as % of loan	

Person (name, title, department) with overall responsibility for this grant/credit/loan. Provide name and contact details (telephone, email address, etc.)

Person (name, title, department) with overall responsibility for all PSM activities. Provide name and contact details (telephone, email address, etc.)

Date of submission(s)

Introduction

- Provide a brief introduction of no more than one page, including key objectives of the project, and a brief overview of key implementing partners and their respective roles and responsibilities.
- Provide an organizational chart of the PSM unit and indicate how it fits into the overall structure of the PIA, NDRA, MOF, and MOH (indicate all relevant dependencies).
- Address any other relevant issues.
- Specify information regarding responsibilities in table A3.2.

1 PIA's capacity to conduct procurement and supply management—PSM

1.1 Management capacity

This section is intended to assess the PIA's capacity to manage and implement various activities.

1.2 Procurement policies, systems, and capacity

- Does the organization that will conduct the procurement have written and detailed regulations and manuals that emphasize the need for transparency and competitiveness? If not, indicate how and when this gap will be addressed.
- Indicate the estimated total value of procurement conducted by this department during the past 12 months (include all products and all sources of funding).
- Indicate the estimated value of total procurement to be conducted over the next 12 months, including all new sources of funding. Express the numbers in US$ and as a percentage of current procurement capacity. Explain how the PIA will manage this increase in procurement efficiently.
- Please provide any additional comments or information.

1.3 Quality assurance systems and capacity

For a proper disease intervention, a health product must be safe, effective, and of suitably consistent quality to ensure predictable therapeutic outcomes. The objective of a Quality Assurance (QA)/Quality Control (QC) system is to ensure that the product consistently meets its target quality standards. For pharmaceutical products, these are quality, safety, and efficacy.

It is the responsibility of the PIA to ensure that products procured under World Bank financing meet national drug regulatory authority requirements (in terms of registration, registration waivers, etc.) as well as relevant World Bank requirements.

The following four paragraphs point to QA/QC issues specifically related to the procurement of malaria commodities: antimalarial medicines (artemisinin-based, ACT, and non-artemisinin-based, non-ACT), insecticides for public health use and nets, laboratory supplies, and spraying equipment.

Antimalarial medicines—artemisinin-based

WHO is engaged in an ongoing process for assuring the quality of suppliers of artemisinin-based products.[1] As of January 2006, WHO has identified three suppliers whose artemisinin-containing products are acceptable for

1. See http://mednet3.who.int/prequal for the latest list of pre-qualified suppliers.

Table A3.2 Responsibility matrix

Activity	Which organization or department is responsible for this activity? If outsourced, indicate where (include all organizations). (e.g., MOF, MOH)	What type of organization is responsible for this function? (PIA, Procurement Agent, or Other)	Indicate if additional staff or technical assistance are needed[a] (Yes/No)
Procurement policies and systems			
Quality assurance and quality control of pharmaceuticals			
International and national laws (patents)			
Coordination			
Management information systems (MIS)			
Product selection			
Forecasting			
Procurement and planning			
Inventory management			
Distribution to other stores and end-users			
Ensuring rational use			

a. Include the costs in the budget.

Table A3.3 Pre-qualification status of single and limited source pharmaceuticals to be procured

Product category	Generic name	Strength	Pre-qualified by WHO or registered for use in ICH/PIC/S country? (Yes/No)

procurement.[2] If one or more of your potential suppliers/products have not been assessed and pre-qualified by WHO, a process should be identified whereby the quality of that supplier or product will be assessed. Please provide the pre-qualification status of the procured pharmaceuticals in table A3.3. Please check WHO's regularly updated website on pre-qualification (http://mednet3.who.int/prequal) before submitting this PSM plan to the World Bank.

Antimalarial medicines—non-artemisinin-based
Multiple manufacturers of non-artemisinin-based antimalarial medicines exist today. When selecting products, price should not be the sole determining factor. Quality is equally important because, for example, several studies have shown a high prevalence of antimalarial drugs containing less than the stated amount of active ingredient. This situation can lead to suboptimal treatment and promote the emergence of drug resistance. Programs should evaluate quality (bioequivalence, bioavailability, adherence to Good Manufacturing Practices, etc.) through a procurement agent, drug regulatory authority, or other mechanism.

Insecticides for public health use and nets
While minimum specifications have been developed for polyester netting material and polyethylene LLINs, a complete quality control procedure of netting materials, ITNs, and LLINs is currently being developed by WHO. It is imperative that LLINs are tested in full for compliance with WHO specifications. Insecticides for public health use and insecticide application equipment should undergo quality control according to WHO specifications. WHO specifications for public health pesticides, including LLINs, are available at the WHO website at http://www.who.int/whopes/quality.

2. It should be noted that not all suppliers of such products have undergone review by the WHO.

WHO specifications for pesticides application equipment are available at http://whqlibdoc.who.int/publications/1990/9241544031.pdf.

Laboratory supplies
Although laboratory supplies (rapid diagnostic tests, resistance testing kits, microscopes, slides, and reagents) are generally less scrutinized in terms of quality, equal importance should be placed on quality control of these materials.[3] Specific attention should be directed to rapid diagnostic tests, whose recent development and novel entry into malaria control require further evaluation and validation.

Taking the points outlined above into consideration, the following questions should be addressed in the PSM Plan:

- Is there a functioning National Drug Regulatory Authority (NDRA) with capacity for registration of drugs and good manufacturing practice (GMP) inspections, and a functioning national pesticide registration authority?
- Are all single- and limited-source pharmaceutical products that are to be purchased pre-qualified by WHO or registered for use in ICH or PIC/S countries? This information is required for ACTs in particular.
- If drugs are being purchased, are there adequately equipped and staffed laboratory facilities available for testing products being purchased under this grant, credit, or loan? What is the highest level of laboratory rating in the country (levels 1–3, as prescribed by WHO). If adequate laboratory facilities are not available, will this activity be outsourced? Where?
- What is the procedure in case of product failure?

1.4 International and national laws

World Bank policies emphasize that PIAs must adhere to international and national laws. The focus of this section is to ensure that intellectual property rights, or patents, are not violated. If it is certain that none of the products the PIA intends to procure are patented in its country or that there is no functioning patent law, then mention this and skip to the next section.

However, if the PIA's country has a functioning patent law in place and if generic products are being purchased, PIAs must ensure that these products are being imported and manufactured in accordance with national and international laws. It is not always easy or even possible to obtain reliable information on the patent status of health products in many countries. PIAs are therefore encouraged to request external technical assistance to collect the necessary information from organizations such as the WHO.

The following paragraphs provide some general guidance on patent issues of specific malaria health commodities. PIAs can go to the MMSS website for more country-specific information on patents: http://rbm.who.int/mmss.

3. Please visit http://www.wpro.int/rdt/ for useful information regarding quality assurance of rapid diagnostic tests.

All World Trade Organization signatory countries are under regulation by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. However, the details of when and to what extent a country must abide by this and other relevant trade agreements is in flux and varies from country to country. Importation or production of patented products may have become more difficult after 1 January 2005 for several countries. In addition, a country may have invoked certain provisions of TRIPS to balance the possible limitation by TRIPS of access to essential malaria commodities. To ensure intellectual property laws are not being violated in reference to a specific product, please check with the national patent office (or its equivalent)[4]

Antimalarial medicines—artemisinin-based or ACT
Because artemisinin and its derivatives[5] are sourced from a plant, these compounds cannot be patented. However, in a combined formulation it is possible to obtain a patent because of the non-artemisinin compound. Currently, artemether/lumefantrine is patented in some countries by Novartis under the names Coartem™ and Riamet™. Other ACTs are not patented anywhere (as of yet).

Antimalarial medicines—non-artemisinin-based or non-ACT
Of the medicines recommended for chemoprophylaxis or treatment in their singular form,[6] none are patented in any country classified by the World Bank as middle-income or below. Of the combined formulation medicines existing as multiple compounds combined into a fixed ratio formulation,[7] three are patented in some countries: atovaquone/proguanil (by GlaxoSmithKleine under the name Malarone™) chlorproguanil/dapsone (by GlaxoSmithKleine under the name LAPDAP™) and mefloquine/sulfadoxine/pyrimethamine (by Roche under the name Fansimef™).

Insecticides for public health use and nets
Most insecticides for public health use, netting material, insecticide-treated nets (ITNs), and insecticide-spraying equipment are not under patent. Some long-lasting insecticidal nets (LLINs) have been patented in some countries.

Laboratory supplies
New rapid diagnostic tests are emerging in the malaria market. Some of these tests may be patented in your country. In addition, specific technologies for genotypic testing of the Plasmodium species or resistance testing (but not WHO plates for in vitro assessment) to specific drugs may include products or processes that are patented. For most of the commonly used microscopes, slides, and reagents, patent issues are not relevant.

Taking into consideration the comments above, please describe how the PIA will ensure strict compliance with national and international laws.

4. For a more complete review of the topic of intellectual property rights, consult: *Battling HIV/AIDS: A Decision Maker's Guide to the Procurement of Medicines and Related Supplies* (http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-Procure-HIV-AIDS-Meds.pdf).
5. Artemether, artesunate, and dihydroartemisinin.
6. Amodiaquine, chloroquine, doxycycline, halofantrine, mefloquine, primaquine, quinidine, quinine, and tetracycline.
7. Atovaquone/proguanil, chlorproguanil/dapsone, mefloquine/sulfadoxine/pyrimethamine, quinine/quinidine/cinchonine/cinchonidine, sulfadoxine/pyrimethamine, and sulfalene/pyrimethamine.

1.5 Coordination

- If a country/PIA is receiving other sources of funding to target malaria, indicate how the various streams of funding will be utilized. It is not necessary to provide amounts of funding being provided by other donors.
- Explain how the procurement and supply management of these products will be coordinated.

1.6 Management information systems (MIS) capacity

- Describe the type of MIS that exists at the central and regional levels, and whether the MIS is able to gather information related to procurement values and timing, inventory values at different sites, numbers of people treated, etc.
- If there is no comprehensive MIS in place, indicate if, when, and how the PIA intends to obtain and implement such a system.

2 Procurement and supply management cycle

2.1 Product selection

Indicate how pharmaceutical products are selected (e.g., whether from WHO, national or institutional Standard Treatment Guidelines, or Essential Medicines Lists). Please fill out the applicable columns of table A3.4. If, for example, only

Table A3.4 How products were selected

		WHO		National		Institutional	
Treatment/ prevention commodities	Product (generic name)	Listed in EML (Yes/No)	Listed in STG (indicate 1st/2nd line treatment)	Listed in EML (Yes/No)	Listed in STG (indicate 1st/2nd line treatment)	Listed in EML (Yes/No)	Listed in STG (indicate 1st/2nd line treatment)
ACTs							
Non-ACTs							
Bed nets (ITNs)							
LLINs							
Insecticides for public health use for re-treatment of bed nets (ITNs)	Indicate if listed by WHO/WHOPES						
Insecticides for public health use for indoor residual spraying	Indicate if listed by WHO/WHOPES						

national guidelines were used to select products, do not fill out the WHO and institutional columns. Also, indicate the year the Standard Treatment Guidelines (STG) or Essential Medicines List (EML) was last updated and indicate whether the treatment is first or second line.

2.2 Forecasting procedures

Describe which products are to be procured in which quantities and why (e.g., how many targeted end-users).

- Describe the forecasting process and method (e.g., morbidity, consumption, or both) and indicate how many patients (or other end-users in the case of nets) are to be targeted during year 1 and 2 (only aggregate numbers).
- Indicate which method was applied to forecast product needs (e.g., morbidity, consumption, or both).
- Explain how buffer stocks were calculated.

2.3 Procurement and planning

The focus of this section is to understand which goods and services are being purchased, when they will be purchased, who will purchase them, which procurement procedures will be used (e.g., ICB, LCB, sole source), and what their expected total cost is. All this information should be provided in the Procurement Plan in appendix A3.

- Provide product cost information by using the prices listed in "Sources and Prices of Selected Products for the Prevention, Diagnosis and Treatment of Malaria." For the most recent version of this publication, please refer to the MMSS website: http://rbm.who.int/mmss.
- Provide a short summary of related financial issues, such as total value of procurement, additional products included in the PSM plan that were not listed before, etc. Ensure that the budgets in the work plan, annexes, and the front page are consistent.

2.4 Inventory management

- Is sufficient storage space available at all levels of the distribution chain? Provide estimates of total storage space that exists, is available, and will be required because of additional procurement under this loan/credit. If there is not sufficient space, indicate an alternative solution. Link the projected increase in procurement with the total procurement capacity (for example, if total procurement is expected to double, is there sufficient space?).
- Are adequate cold chain facilities available? Explain.
- Briefly describe your policy for reducing loss and wastage through expiry, theft, damage, etc.
- Does the inventory management system allow collection of inventory data at each distribution and treatment site?
- Does the storage facility have adequate conditions to control temperature, humidity, and cleanliness? If not, please indicate how this will be corrected.

2.5 Distribution

- To approximately how many points are products being distributed? Distinguish between distribution points; for example, central medical stores, regional stores, and number of treatment sites, and hospitals and clinics.
- Approximately what percentage of the country is being covered for distribution?
- Are there any significant challenges in distributing products to health facilities (e.g., lack of roads, war zone, very long distances)?
- What is the average schedule for distribution to the health facilities (e.g., monthly, quarterly)?
- Is there sufficient capacity to ensure that products are distributed in a timely and safe manner (for example, in covered trucks, in cars, in sealed boxes on motorcycles)? If not, describe alternative solutions such as renting or purchasing additional vehicles or outsourcing.

2.6 Ensuring rational use of medicines

Please refer to the MMSS website for the most recent WHO publications on rational use of medicines (http://rbm.who.int/mmss) before completing this section.

- What strategies will be used to encourage initiation of, adherence to, and compliance with treatment (e.g., use of fixed-dose combination drugs, once-a-day formulations, blister packs, peer education and support, length of treatment)?
- Is there a system for monitoring adverse drug reactions and drug resistance? If yes, describe briefly how the system works. If no, describe plans to establish a system.

2.7 Other

- Will patients/clients be charged for products procured through this project? If yes, indicate how much a patient will be charged and what the funds will be used for.
- Were patients/clients being charged for these products before this project (i.e., using other sources of funding)?

Appendix A3

This is only a sample, with the minimum content required for disclosure on the Bank's website in accordance with the guidelines. The Project Team will agree with the client on a procurement plan which may contain additional information and may be prepared in a different format as desired by the borrower.

I. Goods and Works and Non-Consulting Services.

1. Prior Review Threshold: Procurement decisions subject to prior review by the Bank as stated in appendix A1 to the Guidelines for Procurement: [Thresholds for applicable procurement methods (not limited to the list below) will be determined by the Procurement Specialist /Procurement Accredited Staff based on the assessment of the IA's capacity.]

Table A3.5 Prior review thresholds

Procurement method	Prior review threshold	Comments
1. ICB and LIB (Goods)		
2. NCB (Goods)		
3. ICB (Works)		
4. NCB (Works)		
5. ICB (Non-consultant services)		
[Add other methods if necessary]		

2. Prequalification: Bidders for _____ shall be prequalified in accordance with the provisions of paragraphs 2.9 and 2.10 of the Guidelines.

3. Proposed Procedures for Community Driven Development (CDD) Components (as per paragraph 3.17 of the Guidelines: [Refer to the relevant CDD project implementation document approved by the Bank]

4. Reference to (if any) Project Operational/Procurement Manual:

5. Any Other Special Procurement Arrangements: [including advance procurement and retroactive financing, if applicable]

6. Procurement Packages with Methods and Time Schedule:
[List the packages that require Bank's prior review first, then the other packages]

Table A3.6 Procurement matrix

1	2		3	4	5	6	7	8	9	10	11	12
Ref. No.	Contract (description)		Estimated unit cost[a] (US$)	Estimated quantity	Estimated total cost (US$)[b]	Procurement method	Prequalification (yes/no)	Domestic preference (yes/no)	Review by Bank (prior/post)	Expected bid-opening date	Procurement to be conducted by[c]	Comments
	Antimalarials											
	Health products	Rapid diagnostic test										
		All other diagnostic products, supplies, equipment										
		Bed nets (ITNs, LLINs, other)										
		Insecticides for public health use										
	Health equipment	Various health equipment										
	Services[d]	MIS systems										
		QA strengthening										
		Other[e]										
	Non-health products	All non-health products and services[f]										

Please categorize procurement as

1. Antimalarials
2. Health products (rapid diagnostic test, all other diagnostic products and supplies and equipment, bed nets [ITNs, LLINs, other], and insecticides for public health use,
3. Health equipment (various health equipment),
4. Services related to procurement and SCM (MIS systems, QA strengthening, and Other), and
5. Non-health products (all non-health products and services, large-value product and services such as vehicles, computers, etc.)

a. Indicate whether PIA/buyer is able to access any special prices (e.g., through Clinton Foundation, other).
b. For the duration of the PSM plan, corresponding to 18 months.
c. Indicate whether in-house or outsourced to a procurement agent; indicate name of department or organization conducting procurement.
d. The focus of this section is only for services related to procurement and supply management (e.g., consultants to strengthen PSM).
e. Indicate type of assistance segmented into categories as listed in table A3.3 (do not provide information not related to PSM).
f. It is not necessary to itemize this entry; provide a single-line entry and include some large-value product and service items as examples (e.g., vehicles, computers, construction, financial consultants).

II. Selection of Consultants

1. Prior Review Threshold: Selection decisions subject to prior review by Bank as stated in appendix Ai to the Guidelines for Selection and Employment of Consultants:

Table A3.7 Prior review thresholds

Selection method	Prior review threshold	Comments
1. Competitive methods (Firms)		
2. Single source (Firms)		
[*Add specific methods if necessary*]		

2. Short list comprising entirely of national consultants: Short list of consultants for services, estimated to cost less than $_____equivalent per contract, may comprise entirely national consultants in accordance with the provisions of paragraph 2.7 of the Consultant Guidelines.

3. Any other special selection arrangements: [including advance procurement and retroactive financing, if applicable]

4. Consultancy assignments with selection methods and time schedule

Table A3.8 Consultancy assignments

1	2	3	4	5	6	7
Ref. no.	Description of assignment	Estimated cost	Selection method	Review by Bank (prior/post)	Expected proposals submission date	Comments

III. Implementing Agency Capacity-Building Activities with Schedule

1. In this section the agreed capacity-building activities (some items could be from Country Procurement Assessment Report recommendation) are listed with their schedule.

Table A3.9 Implementing agency capacity building

No.	Expected outcome/activity description	Estimated cost	Estimated duration	Start date	Comments

Annex 4: Methods and strategies for antimalarial products

Does the local implementing agency have the capacity to buy medicines and supplies for prevention, diagnosis, and treatment of malaria?

→ No

Can procurement be conducted by a qualified national central medical store?

→ No

Procurement could then be outsourced to a private agency with proven quality track records. The procuring organization must have proven capacity. Procurement could also be done through a low-cost supplier (such as the United Nations Children's Fund, Médecins Sans Frontières, Mission Pharma, PSI, or the International Dispensary Association).

↓ Yes

↓ Yes

The range of medicines and medical products required include:

Category	Antimalarial medicines	Mosquito nets	Diagnostic tests	Insecticides for public health use	Insecticide spraying equipment	Resistance test kits
Single source	Artemether-lumefantrine, and artesunate + mefloquine	Long-lasting insecticide-treated nets (LLINs)				Insecticide resistance kits (Insecticide-impregnated papers: DDT, dieldrin, malathion, and so on) and drug resistance kits (chloroquine, quinine, dihydroartemisinin mefloquine, and so on)
Limited source	Amodiaquine+ artesunate, artesunate+ SP, artesunate injection, artemeter injection.	Long-lasting insecticide-treated nets (LLINs)	Antigen-detecting tests: *P falciparum* only (HRP2-detecting) and *P. falciparum* and pan-specific (HRP2, other antigens)	Alphacypermetrin, cyfluthrin, deltamethrin, lambda-cyhalothrin, etofenprox, permathrin , fenitrothion, malathio, pirimiphos-methyl, and so on		
Multi source	Chloroquine, doxycycline, mefloquine, primaquine, quinine, and sulfadoxine + pyrimethamine	Netting material, non-treated nets, ITNs			Hand-operated compression sprayers, backpack motorized mist blowers, and hand-carried thermal foggers	

Depending on contract value, market situation, and the existing country procurement thresholds, the procurement options available are:

MARKET SITUATION

CONTRACT VALUE	On patent and available from originator and generic manufacturers	On patent and available from originator only	Off patent (multi-source)
Example	*Note: No product in this category at this time.*	*ACTs such as Coartem, LLINs[1] such as PermaNet and Olyset, and resistance test kits*	*Bed nets (ITNs), insecticides for public health use, spraying equipment, and non-ACTs*
SMALL	Shopping	Direct contract or single source	Shopping
MEDIUM use SBD standard conditions of contract	Limited international bidding or international competitive bidding with prequalification	Direct contract or single source	Limited international bidding or international competitive bidding with prequalification
LARGE use SBD standard conditions of contract	Limited international bidding or international competitive bidding with prequalification	Direct contract or single source	Limited international bidding or international competitive bidding with prequalification

Indicative contract values only. Final figures should be agreed upon during project preparation.
Small: Less than $100,000; Medium: Between $100,000 and $500,000; Large: More than $500,000.

Source: World Bank.

1. To direct contract or single-source LLINs, a Preference Assessment must be completed or one of the criteria for sole sourcing included in the World Bank Procurement Guidelines must be present. In the absence of either, LIB must be carried out among the existing suppliers.

Annex 5: Sample Technical Specifications

Contents

1 Product and package specifications
2 Labeling instructions
3 Case identification
4 Unique identifiers
5 Standards of quality control for supply

Antimalarial Medicines

1 Product and package specifications

Source: World Health Organization
For up-to-date information on specifications visit http://www.rollbackmalaria.org.

1.1 The antimalarial medicines to be purchased under this Invitation for Bids are included in the Purchaser's *current* national Essential Medecines List (EML) or national formulary. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")

1.2 Product specifications indicate dosage form (e.g., tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension) and drug content (exact number of mg or international units [IU] or % v/v, w/w, or v/w acceptable range). The antimalarial medicines should conform to standards specified in the following compendia: [The Borrower should specify an acceptable pharmacopoeia standard from one of the following: the *British Pharmacopoeia*, the *United States Pharmacopoeia*, the *French Pharmacopoeia*, the *International Pharmacopoeia*, or the *European Pharmacopoeia*, the latter particularly for raw materials.] The standards used will be the latest edition unless otherwise stated by the Purchaser or other if applicable. If the pharmaceutical product is not included in the specified compendium, but included in the Purchaser's national EML, the Purchaser should clearly indicate acceptable limits and the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.

1.3 Not only the pharmaceutical item but also the packaging and labeling components (e.g., bottles, closures, and labeling) should meet specifications suitable for distribution, storage, and use of antimalarial medicines in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tamper-proof.

1.4 For blister-packaged antimalarial medicines, the material used for the blister packaging should be selected in accordance with the type of antimalarial medicine (e.g., PVC/PVDC foil for those that are sensitive to light and humidity). The packaging should comply with *International Pharmacopoeia* standards. Blisters should be designed in a user-friendly manner (i.e., one treatment course per blister) with easily identifiable dose subunits. The design of the aluminum foil lining should facilitate understanding of its functional mechanism and ease of administration. Storage and quarantine regulations applying to raw materials used for packaging and finished products must follow the GMP guidelines. Aluminum–aluminum material for lidding and the forming film for strip packaging should not be used for products that are copackaged, since these products need to be visually identifiable by size, color, or shape.

1.5 Packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national drug regulatory authority (NDRA). The Purchaser should specify any additional special requirements.

1.6 It is recommended that the following general information and the following concepts be communicated to the consumer of the product on an insert:

Information

- Malaria is a curable disease.
- The earlier you treat it with the right medicine the better.
- Completing the whole course of treatment is important.
- If you do not complete the treatment, the malaria is not cured.
- People need to use the right dosage for their age and weight.
- If you become sicker during or after completion of the treatment, see a trained health worker.
- If a child vomits, give the unit dose to replace the one which is lost.

Concepts

- Malaria is caused by a parasite.
- The longer the parasite is in the body, the more chance there is that it can kill.
- The full treatment is needed to kill all the parasites; if the treatment is not completed, malaria will come back.
- Bigger and older children require higher dosage levels.
- Other diseases may coexist with malaria, or the parasite may be resistant to the medicine.

1.7 All labeling and packaging inserts shall be in the language requested by the Purchaser, or in English if not otherwise stated.

1.8 Antimalarial medicines requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers, and they must be shipped in special containers to ensure stability during transportation.

1.9 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific antimalarial medicine the Purchaser may request.

2 Labeling instructions

2.1 The label of the primary container for the antimalarial medicines shall meet the W210 GMP standard and include:

(a) The international nonproprietary name (INN) or generic name prominently displayed next to the brand name, where a brand name has been given. Brand names should preferably not be bolder or larger than generic names;

(b) Dosage form (e.g., tablet, ampoule, syrup);
(c) The active ingredient "per unit, dose, tablet or capsule, etc.";
(d) The applicable pharmacopoeial standard;
(e) The purchaser's logo and code number and any specific color coding if required;
(f) Content per pack;
(g) Short directions for use (detailed instructions will appear in the accompanying insert);
(h) Special storage requirements;
(i) Batch number;
(j) Date of manufacture and date of expiry in clear language, not code. (Ensure that the expiry date is defined as the earliest expiry date of any of the active components in the product.);
(k) Name and address of the manufacturer;
(l) Any additional cautionary statement.

2.2 Where multiple blister packs are marketed, the container or dispenser should bear the information above and a corresponding number of patient inserts should be included.

3 Case identification

3.1 All outer cases should prominently indicate the following:
(a) Purchaser's line and code numbers;
(b) The generic name of each active ingredient and the amount per dosage unit;
(c) The dosage form (e.g., tablet, ampoule, syrup);
(d) Date of manufacture and expiry (in clear language, not code);
(e) Batch number;
(f) Quantity per case;
(g) Special instructions for storage;
(h) Name and address of manufacture;
(i) Any additional cautionary statements.

3.2 No case should contain antimalarial medicines from more than one batch.

4 Unique identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and in certain dosage forms, such as tablets and ampoules, and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.

5 Standards of quality control for supply

5.1 The successful Supplier will be required to furnish to the Purchaser:
(a) With each consignment and for each item, a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the antimalarial medicines being supplied, and the manufacturer's certificate of analysis.

(b) Assay methodology of any or all tests if requested.
(c) Evidence of bio-availability and/or bio-equivalence for certain critical antimalarial medicines upon request. This information will be supplied on a strictly confidential basis only.
(d) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
(e) Evidence of stability data (climatic zone 4, preferably).

5.2 The Supplier will also be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.

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1 Product and package specifications
2 Labeling instructions
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5 Standards of quality control for supply

1 Product and package specifications

Diagnostic Test Kits and Resistance Test Kits

Source: World Health Organization
For up-to-date information on specifications and quality assurance recommendations visit http://www.rollbackmalaria.org or http://www.wpro.int/rdt.

1.1 The diagnostic test kits (DTK) and resistance test kits (RTK) (referred to as "Kits") to be purchased under this Invitation for Bids should meet World Health Organization (WHO) standards. The required packing standards and labeling must meet the latest requirements of WHO good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")

1.2 Product specifications should indicate

- *Plasmodium* species to be detected (*P. falciparum* only or pan-specific);
- Format of the test (e.g., cassette, dipstick, or card);
- Sensitivity;
- Minimum requirements for shelf life (18 months suggested and at least 15 after purchase);
- Minimum requirements for temperature stability in intended conditions of storage and use;
- Real time or accelerated temperature stability data;
- Storage temperature;
- Demand for product support.

1.3 Packaging specifications should indicate

- if the kits should be packaged individually (recommended),
- if the packaging should be in moisture-proof envelopes (recommended);
- The number of Kits per box (this should be based on the expected rate of use).

1.4 Not only the kits but also the packaging and labeling components (e.g., bottles, closures, and labeling) should meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tamper-proof, and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national drug regulatory authority (NDRA). The Purchaser should specify any additional special requirements.

1.5 All labeling and packaging inserts shall be in the language requested by the Purchaser, or in English if not otherwise stated.

1.6 Indicate storage requirements on labels and containers. Consider shipping the kits in special containers to ensure stability in transit from point of shipment to port of entry.

1.7 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request.

2 Labeling instructions

2.1 The label of the primary container for the kits shall meet the W210 GMP standard and include (highlighted requirements must be complied with):

(a) Test kit type;
(b) The applicable pharmacopoeia standard;
(c) The purchaser's logo and code number and any specific color coding if required;
(d) Content per pack;
(e) Instructions for use;
(f) Special storage requirements;
(g) Batch number;
(h) Date of manufacture and date of expiry (in clear language, not code);
(i) Name and address of manufacture;
(j) Any additional cautionary statement.

Small envelopes should come in outer boxes.

2.2 The outer case or carton should also display the information above. Instructions can be on a separate insert.

3 Case identification

3.1 All cases should prominently indicate the following:

(a) Purchaser's line and code numbers;
(b) Test kit type;
(c) Date of manufacture and expiry (in clear language not code);
(d) Batch number;
(e) Quantity per case;
(f) Special instructions for storage;
(g) Name and address of manufacture;
(h) Any additional cautionary statements.

4 Unique identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and in certain dosage forms, such as tablets and ampoules, and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.

5 Standards of quality control for supply

5.1 The successful Supplier will be required to furnish to the Purchaser:

(a) With each consignment, and for each item, submission of a sample to a lab of WHO's choice for assessment.
(b) Assay methodology of any or all tests, if requested.
(c) Evidence of basis for expiration dating and other stability data concerning the commercial final package, upon request.

5.2 The Supplier will also be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.

5.3 For the purpose of pre-shipment inspection and testing, the Supplier will be required to provide the Purchaser or his representative with access to the product as packed for shipment at the sellers' factory or warehouse at a mutually agreeable time before shipment of the product.

(a) The Purchaser may inspect and sample, or cause to be sampled, such product.

(b) The Purchaser may cause independent laboratory testing to be performed as deemed necessary to ensure that the kits conform to prescribed requirements. The testing laboratory shall be of the Purchaser's choice and suitably equipped and qualified to conduct quality control tests on biological products.

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Insecticides for Public Health Use

1 Product and package specifications

Source: World Health Organization
For up-to-date information on specifications and technical recommendations, visit http://www.who.int/whopes/quality. For up-to-date information on pesticide application equipment, visit http://whqlibdoc.who.int/publications/1990/9241544031.pdf.

1.1 The insecticides for public health use to be purchased under this Invitation for Bids must have been evaluated successfully by the World Health Organization Pesticide Evaluation Scheme (WHOPES) and should be manufactured in accordance with WHOPES specifications.

Any national guidelines for purchase of insecticides for public health use should strictly be adhered to, and all insecticides for public health use offered must conform to WHO/WHOPES specifications.

The required packing standards and labeling must conform to national regulations and comply with WHO/WHOPES recommendations for procurement of public health pesticides.

1.2 Product specifications must indicate

- The name of the insecticide;
- Formulation type (e.g., stable liquid free from suspended matter and sediments, wettable powder, water-dispersable powder, emulsifiable concentrate);
- Intended use;
- WHO specification number;
- Name and concentration of active ingredient (expressed in g/l for liquids, and g/kg for solids);
- Tolerance of the active ingredient (expressed in g/l +/-5% of the nominal content);
- Minimum requirements of expiry date (e.g., at least two-thirds of shelf life and not less than 16 months).

1.3 Not only the insecticide but also the packaging and labeling components (e.g., bottles, closures, and labeling) should meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the Purchaser. The packaging must guarantee the safety of the insecticides for public health use during transportation, allowing for the probability of reshipment, long-distance transportation, and the use of different means of transport.

The packaging should be of suitable size and design so that

- Decanting or repackaging of insecticides for public health use before use can be minimized;
- Convenience in use is facilitated and exposure of users to concentrate is minimized;

- Closures are sufficiently robust to preclude leaking, taking into account handling during shipment and local transport;
- Packaging is selected taking into account the possibility of prolonged storage under adverse storage conditions so that storage life in maximized;
- Packaging will satisfy the requirements laid down by relevant international organizations concerned with transport (ICAO, IMO, RID, and IATA, in particular).

Description of primary containers should specify color, size, shape, sealing, and a description of the measuring cup including divisions if applicable. The Purchaser should specify any additional special requirements.

1.4 All labeling and packaging inserts shall be in the language requested by the Purchaser, or in English if not otherwise stated.

1.5 Insecticides for public health use requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

1.6 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific insecticides for public health use the Purchaser may request.

2 Labeling instructions

2.1 The label of the primary container for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:

(a) The name of the Insecticide;
(b) Formulation type (e.g., stable liquid free from suspended matter and sediments, wettable powder, water-dispersable powder, emulsifiable concentrate);
(c) Name and concentration of the active ingredient (expressed in g/l for liquids, and g/kg for solids);
(d) The purchaser's logo and code number and any specific color coding if required;
(e) Rate of application (l/ha or kg/ha as appropriate, on an active ingredient basis);
(f) Instructions for use;
(g) Special storage requirements;
(h) Instructions for disposal of container;
(i) WHO hazard classification and appropriate warning;
(j) If necessary, include the following warning: "Keep the material out of reach of children and well away from foodstuffs, animal feed and food containers," and include appropriate instructions on first aid in case of accidental ingestion or eye contact;
(k) Batch number;

(l) Date of manufacture and date of expiry (in clear language, not code);
(m) Pictograms selected from those recommended by FAO;
(n) Name and address of manufacturer;
(o) Any additional cautionary statement.

The labels should be able to withstand the rigors of handling, transportation, and storage in the open.

2.2 The outer case or carton should also display the information above.

3 Case identification

3.1 All cases should prominently indicate the following:
(a) Purchaser's line and code numbers;
(b) The name of the insecticide;
(c) Formulation type (e.g., stable liquid free from suspended matter and sediments, wettable powder, water-dispersable powder, emulsifiable concentrate);
(d) Date of manufacture and expiry (in clear language, not code);
(e) Batch number;
(f) Quantity per case;
(g) Gross weight in kilograms and package number on two adjacent faces of each package;
(h) Special instructions for storage and lifting on three sides of the case;
(i) Name and address of manufacture;
(j) Any additional cautionary statements.

Do not abbreviate or omit any details. Attach metal labels securely to loose or bundled articles.

4 Unique identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and in certain dosage forms, and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.

5 Standards of quality control for supply

5.1 The successful Supplier will be required to furnish to the Purchaser:
(a) With each consignment, a certificate of analysis for compliance with WHO specifications and for each item, a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the insecticides for public health use being supplied and the manufacturer's certificate of analysis.
(b) Assay methodology of any or all tests, if requested.
(c) Evidence of basis for expiration dating and other stability data concerning the commercial final package, upon request.

5.2 The Supplier will be required to furnish to the Purchaser (or its identified independent inspection/sampling agency should take) samples of pesticide

consignment before shipment and on delivery for quality control by an independent national laboratory, or a WHO Collaborating Center for quality control of pesticides for public health use.

5.3 The Purchaser should indicate the name of the inspection agent or laboratory responsible for determining whether the insecticides for public health use meet all the requirements of the specifications and the purchase order, and the processes should be clearly described.

5.4 The Purchaser should be acquainted with the Supplier's return policy in case of failed performance.

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1 Product and package specifications

Long-Lasting Insecticid-Treated Nets (LLINs)

Source: World Health Organization
For up-to-date information on specifications and recommendations, visit http://www.who.int/whopes/quality.

1.1 The LLINs to be purchased under this Invitation for Bids should follow WHO/WHOPES Interim or Full Specifications. LLINs are manufactured using either polyester or polyethylene. If a preference assessment has been completed, use the appropriate specifications from the table below.

1.2. Specifications should contain information regarding the active ingredient, netting material, net design, and net packaging.

Specification of Net	Polyester	Polyethylene
Denier	75 or 100 +/- 5%	150 denier +/- 5%
Fabrication	Warp knitted	Warp knitted
Filaments	32	Monofilament
Mesh size	156	56
Weight	30–40g/m2, +/- 10%	50 g/m2, +/- 10%
Dimensional stability/ shrinkage	+/- 10%	+/- 10%
Bursting strength/minimum	220 or 320 Kpa for net and seams	350 Kpa for net, 220 Kpa for seams
Fire safety	Class 1 16-CFR	Class 1 16-CFR

For the active ingredient, please provide the following information:

- Name of active ingredient;
- How the identity of the insecticide will be verified;
- Content of active ingredient;
- Initial surface concentration of active ingredient method, as specified by WHO/WHOPES;
- Release index of active ingredient (describe verification method to be applied);
- Stability at elevated temperate (describe method to be applied);
- Specify the minimum number of standard WHO washes under laboratory conditions that the LLIN is expected to retain its biological activity (e.g., 20 standard WHO washes);
- Specify the minimum period under field conditions that the LLIN is expected to retain its biological activity (e.g., three years).

Net design:

- Net type (e.g., rectangular, single net, double net, conical);
- Net size including inaccuracy tolerance (in cm);
- Net weight (in g/m2);
- Door (if any);
- Net borders (e.g., stitched or hemmed);
- Describe reinforcement points;
- Suspension of nets (e.g., aluminum rings, non-rusting rings, or reinforced netting loops);
- Describe folding of nets;
- Describe hanging hooks.

Net packaging:

Specify how each individual net should be packaged (e.g., in plastic bags).

It can be useful to include a drawing of the mosquito net including dimensions, door(s), reinforcement points, etc.

1.3 The packaging and labeling components should meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tamper-proof. The Purchaser should specify any additional special requirements.

1.4 All labeling and packaging inserts shall be in the language requested by the Purchaser, or in English if not otherwise stated.

1.5 Upon award, the successful Supplier shall, on demand by the Purchaser, provide a translated version of the directions for use of the mosquito nets in the language of the bid.

2 Labeling instructions

2.1 The nets should have labels containing the following information:

- Size in cm (L, W, H);
- Water absorption in ml per net;
- Five ISO 3758 pictograms
  - o Washing 40° C,
  - o No bleaching,
  - o No drying machine,
  - o No ironing,
  - o No dry cleaning;
- Below pictograms the following text: "Gentle wash. No bleach. No ironing. No dry cleaning. No tumble."

2.2 Additionally, the labels for LLINs should include:

- Name of insecticide manufacturer;
- Name of insecticide used;
- Name of insecticide formulation;
- Dose in mg of active ingredient per m2;

- Date of treatment;
- Instructions not to leave the net in the sun;

The outer case or carton should also display the information mentioned under *Labeling*.

3 Case identification

3.1 All cases should prominently indicate the following:

(a) Purchaser's line and code numbers;
(b) The name of the product;
(c) Quantity per bale;
(d) Special instructions for storage;
(e) Name and address of manufacture;
(f) Any additional cautionary statements.

4 Unique identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.

5 Standards of quality control for supply

5.1 The Purchaser should specify whether a sample of the mosquito net or sewing thread should be submitted.

5.2 The Supplier will also be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.

Contents

1 Product and package specifications
2 Labeling instructions
3 Case identification
4 Unique identifiers
5 Standards of quality control for supply
6 Inspection and testing

1 Product and package specifications

Mosquito Nets

Source: World Health Organization

1.1 The mosquito nets to be purchased under this Invitation for Bids should follow WHO standards in "Specifications for Netting Materials," WHO/CDS/RBM2001.28.

1.2 Specifications should contain information regarding the netting material, net design, and net packaging.

Netting material:

- Fabrication (e.g., Warp knitted [ISO 8388], optional);
- Netting material (e.g., 100% polyester [ISO 1833]);
- Filaments (e.g., multi-filament, 36 filaments or higher);
- Mesh size (e.g., minimum 156 holes/inch2 [25 holes/cm2]);
- Denier (e.g., 75 or 100 [ISO 2060, DUPRO], optional);
- Weight (e.g., 75 denier: 30 g/m2, 100 denier: 40 g/m2 [ISO 3801]);
- Dimensional stability (e.g., shrinkage less than 5% [ISO 5077]);
- Bursting strength (75 denier: minimum 220 Kpa [ISO 2960], 100 denier: minimum 405 Kpa);
- Fire safety[1] (e.g., 16 [CFR 1610]);
- Impregnation (if applicable);
- Stability (e.g., 5 years);
- Color (per local preference).

Net design:

- Net type (e.g., rectangular, single net, double net, conical);
- Net size including inaccuracy tolerance (in cm);
- Net weight (in g/m2);
- Door (if any);
- Net borders (e.g., stitched or hemmed);
- Describe reinforcement points;
- Suspension of nets (e.g., aluminum rings, non-rusting rings, or reinforced netting loops);
- Describe folding of nets;
- Describe hanging hooks.

Net packaging:
Specify how each individual net should be packaged (e.g., in plastic bags).

It can be useful to include a drawing of the mosquito net including dimensions, door(s), reinforcement points, etc.

1.3 The packaging and labeling components should meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tamper-proof. The Purchaser should specify any additional special requirements.

1. ISO 6941: 1984 Textile fabrics - burning behavior - measurement of flame spread properties of vertically orientated specimens.

1.4 All labeling and packaging inserts shall be in the language requested by the Purchaser, or in English if not otherwise stated.

1.5 Upon award, the successful Supplier shall, on demand by the Purchaser, provide a translated version in the language of the bid of the directions for use of the mosquito nets.

2 Labeling instructions

2.1 The nets should have labels containing the following information:

- Size in cm (L, W, H);
- Water absorption in ml/net;
- Five ISO 3758 pictograms
  - o Washing 40° C,
  - o No bleaching,
  - o No drying machine,
  - o No ironing,
  - o No dry cleaning;
- Below pictograms the following text: "Gentle wash. No bleach. No ironing. No dry cleaning. No tumble."

Additionally, the labels for ready-treated nets should include:

- Name of manufacturer of Insecticide for public health use;
- Name of WHOPES (full or interim specification) for insecticide used;
- Name of formulation of insecticide for public health use;
- Dose in mg of active ingredient per m2;
- Date of treatment;
- Instructions not to leave the net in the sun;
- Expected effective life of treatment after opening of the bag and the need for regular retreatment (unless long-lasting treated net).

Labels for non-treated nets should include:

- Size of the net in cm and surface area in m2;
- Water absorption in ml;
- Information on insecticide for public health use and treatment instructions if single-dose insecticide for public health use and treatment kit is provided with the net (optional), expected effective life of the treatment, and the need for regular retreatment.

The outer case or carton should also display the information mentioned under *Labeling*.

3 Case identification

3.1 All cases should prominently indicate the following:

(a) Purchaser's line and code numbers;
(b) The name of the product;
(c) Quantity per case;
(d) Special instructions for storage;
(e) Name and address of manufacture;
(f) Any additional cautionary statements.

4 Unique identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the labels of the containers used for packaging and this will be in the Technical Specifications. The design and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.

5 Standards of quality control for supply

5.1 The Purchaser should specify whether a sample of the mosquito net or sewing thread should be submitted.

5.2 The Supplier will also be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.

6 Inspection and testing

6.1 The Purchaser should specify whether a sample of the mosquito net or sewing thread should be submitted.

Annex 6: Sample Certificates

Contents

A Pharmaceutical Product—CoPP
B GMP Compliance
C Analysis
D Manufacturing License

With regard to certification, the current Standard Bidding Documents only require Bidders to submit a Certificate of Pharmaceutical Product (CoPP). However, if the Borrower/Grantee finds that there is a further need to secure quality, other certificates may be requested. The list below contains a list of certificates that can be requested from the bidder.

List of certificates

- Certificate of Pharmaceutical Product—CoPP (a sample certificate is included below).
- Certificate of GMP compliance (two sample certificates from Switzerland and China are included below).
- Certificate of Analysis (six sample certificates from Germany, India [2], Belgium, France, and Spain are included below).
- Manufacturing License (a sample from Switzerland is included below).
- Free Sales Certificate.

The following pages contain samples of all the certificates from the list above except the Free Sales Certificate. Please note that the list is merely included to provide examples of certificates. The appearance of the certificates will vary from case to case. Some details have been intentionally masked.

Source: World Health Organization and the World Bank.

A Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization (*general instructions and explanatory notes attached*).

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredients[2] and amount(s) per unit dose.[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no (*key in as appropriate*)

1.3 Is this product actually on the market in the exporting country? yes/no/unknown (*key in as appropriate*)

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.[6]

2A.1 Number of product license[7] and date of issue:

_____

2A.2 Product license holder (name and address):

_____

_____

_____

2A.3 Status of product license holder:[8] a/b/c (*key in appropriate category as defined in note 8*)

2A.3.1 For categories b and c, the name and address of the manufacturer producing the dosage form are:[9]

_____

_____

_____

2A.4 Is Summary Basis of Approval appended?[10] yes/no (*key in as appropriate*)

2A.5 Is the attached, officially approved product information complete and consonant with the license?[11] yes/no/not provided (*key in as appropriate*)

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c (*key in appropriate category as defined in note 8*)

2B.2.1 For categories b and c, the name and address of the manufacturer producing the dosage form are:[9]

_____

_____

_____

2B.3 Why is marketing authorization lacking?
not required/not requested/under consideration/refused (*key in as appropriate*)

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
   yes/no/not applicable[14] (*key in as appropriate*)
   If no or not applicable, proceed to question 4.

   3.1 Periodicity of routine inspections (years):_____

   3.2 Has the manufacture of this type of dosage form been inspected?
   yes/no (*key in as appropriate*)

   3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]
   yes/no/not applicable[16] (*key in as appropriate*)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[11]
   yes/no (*key in as appropriate*)
   If no, explain:_____

   _____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

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

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses typed rather than handwritten.

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

Explanatory notes

1. 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.
2. Whenever possible, use international nonproprietary names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.
5. When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional or if the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
   (a). manufactures the dosage form;
   (b). packages and/or labels a dosage form manufactured by an independent company; or
   (c). is involved in none of the above.
9. This information can be provided only with the consent of the product license holder or, in the case of non-registered products, the applicant. Noncompletion of

this section indicates that the party concerned has not agreed to inclusion of this information. 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 must be updated or it will cease to be valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
    (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. Not applicable means that 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.
15. 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, annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, annex 1).
16. This section is to be completed when the product license holder or applicant conforms to status (b) or (c) as described in note 7. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting 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.

Certificate of GMP Compliance—Switzerland

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX has been duly authorized to manufacture and distribute medicinal products, the manufacturing license excluding products for which the pharmacopoeia requires sterility and being restricted to following dosage forms:

- liquid dosage forms
- semi-solid dosage forms
- solid dosage forms

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of medicinal products according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention /Co-operation Scheme (PIC/S) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last inspection was conducted on **October 31, 2002**;

that the requirements regarding manufacture and quality control for medicinal products for export are identical to those applicable to products sold in Switzerland.

Bern, October 27, 2003
No. 03-836

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

XXXXXXXXXXXXX

03-421ffe.doc

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Swissmedic • Erlachstrasse 8 • CH-3000 Bern 9 • www.swissmedic.ch • Tel. +41 31 322 02 11 • Fax +41 31 322 02 12

Certificate of CMP compliance—China

中华人民共和国

药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS
PEOPLE'S REPUBLIC OF CHINA

证书编号：
Certificate No.: [illegible]

企业名称：
Manufacturer: XXXXXXXXXXXXXXXXXXXXXXXXXX

地　址：
Address: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

认证范围：
Scope of Inspection: Bulk(Hydroxychloroquine Sulfate, Piperaquine Phosphate, Fluoxetine Hydrochloride, Ondansetron Hydrochloride, Pyrimethamine)

经审查，符合中华人民共和国《药品生产质量管理规范》要求，特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2010 年 2 月 7 日
This certificate remains valid until 7/2/2010

发证机关：
Issued By

Date for Issuing 8/2/2005　2005 年 2 月 8 日

国家药品监督管理局制
PRINTED BY STATE DRUG ADMINISTRATION

Certificate of Analysis—Germany

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

XXXXXXX
XXXXXXX
Intern. Dispensary Association
XXXXXXXXXXXX

XXXXXXXXXXXXX

XXXXXXXXXXXX

XXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXX

Date 15.04.05
Reference Dr.Bylsp
Certificate of Analysis No.: 500810000
Mat.-No.: KETSA01DA0160

CERTIFICATE OF ANALYSIS

Product declaration

Vials of 10 ml: **KETAMINE HYDROCHLORIDE INJECTION USP**

Batch No.: 50081 Manuf. date: 01/2005 Expiry date: 01/2010

	REQUIREMENTS	RESULTS
Description:	clear, colourless to almost colourless solution, < Y5	complies
Particulate matter	practically free from visible particles	complies
Extractable volume:	10,0 - 11,0 ml	10,5 ml
Identification	complies	complies
pH-value of solution	3,5 - 5,5	4,2
Test for sterility:	sterile	sterile
Test for bacterial endotoxins:	≤ 0,4 EU/mg	< 0,4 EU/mg
Assay: Ketamine as ketamine hydrochloride	95,0 - 105,0 %	50,4 mg/ml = 100,8 %

Date of analysis: 02/05

The batch complies with the requirements of the USP.

Head of the Quality Control Department Dr. W. Boye

Approved by IDA Quality Control

Signature: Date: 07 JUNI 2005

Certificate of Analysis—India

XXXXXXXXXXXXXX
XXXXXXXXXXXX

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

Page 1 of 1

PRODUCT : GENTAMICIN INJECTION BP 80mg

CODE	: FABGP066	QC REF NO	: FP05/G/154
STRENGTH	: 80 mg/2 ml	MARKET	: Export
BATCH NO.	: CY503X	BATCH SIZE	: 450 L
PACK SIZE	: 2 ml	MFG. DATE	: 04/2005
SAMPLE QTY.	: 270 x 2 ml ampoules	EXP. DATE	: 03/2008
SAMPLED BY	: XXXXXXXXXXXX	SAMPLING DATE	: 21/04/2005

S. NO	TESTS	SPECIFICATIONS	RESULTS
1.	Description	Clear, almost colourless solution.	Clear, colourless solution.
2.	Identification - TLC	The three principal spots in the chromatogram obtained with solution (1) correspond to the three principal spots in the chromatogram obtained with solution (2).	Complies
3.	Identification - HPLC	In the test for composition of Gentamicin Sulphate, the retention times of the four principal peaks in the chromatogram obtained with solution (2) correspond to those of the four principal peaks in the chromatogram obtained with solution (1).	Complies
4.	Acidity - pH	3.0 – 5.5	4.7
5.	Composition of Gentamicin Sulphate - C1	25.0% – 50.0%	25.8 %
6.	Composition of Gentamicin Sulphate - C1a	10.0% – 35.0%	30.2 %
7.	Composition of Gentamicin Sulphate - C_{2a} + C_2	25.0% – 55.0%	44.0 %
8.	Extractable Volume	Not less than 2.0 ml	2.1 ml
9.	Particulate Contamination (Visible particles)	Must comply	Complies
10.	Sterility	Must comply	Complies
11.	Bacterial Endotoxins	Not more than 1.67 IU/mg of Gentamicin.	Less than 0.06 EU/mg of Gentamicin.
12.	Quality of Raw Material	Must comply.	Complies
13.	Assay - (Assay of Gentamicin Sulphate as Gentamicin)	38.8mg/ml - 42.0 mg/ml. 97.0% - 105.0% of the label claim (40.0 mg/ml)	40.4 mg/ml
Additional test			
14.	Total Parabens	1.8mg/ml -2.2 mg/ml. 90.0% - 110.0% of the label claim (2 mg/ml).	1.9 mg/ml

REMARKS : The sample complies/does not comply with Specification No. SFABGP066-00
Released/ Rejected

RPG GLAND PHARMA LIMITED

ANALYSED BY (Sign/Date)	CHECKED BY (Sign/Date)	APPROVED BY (Sign/Date)

A.M. LAOU
Manager-QC

GDFM/QC065-00

Approved by IDA
Quality Control
Sign
Date 18 JUL 2005

Certificate of Analysis—India

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

QUALITY CONTROL DEPARTMENT

Approved by IDA Quality Control

Certificate of Analysis

Agreed: Date: 11.03.2005

IDA code No. 702100.01

Report No: UNP 1205

Product :ERYTHROMYCIN STEARATE TABLETS BP.250 mg! Mfg. Date :MAR'2005

Batch No : LRI 001 ! Exp. Date :FEB'2007

Batch size :10,00,000 TABLETS ! Date of sampling:10.03.2005

Sample Quantity : 100 TABLETS ! !

TEST	RESULTS	LIMITS
Appearance	Pink circular biconvex film coated tablets.	Pink circular biconvex film coated tablets.
Identification	Passes for Erythromycin stearate	Should pass for Erythromycin Stearate.
Average weight	510 mg	491 to 511 mg
Uniformity of weight	Passes (+2.5 % to -2.2 %)	+/- 5% of the average weight
Dissolution	Passes (100% to 102 %)	Not less than 70% of the labelled amount is dissolved in 45 min's
ASSAY: Each Tablet contains:		
Erythromycin stearate equivalent to Erythromycin	250 mg	237.5 mg to 262.5 mg
Additional tests		
Disintegration time	1 minute	Not more than 30 minutes
Thickness	5.4 mm	5.3 mm to 5.8 mm
Diameter	12.1 mm	12.0 mm to 12.3 mm

Remarks : The sample complies with ....B.P/In-house..... Specification.

ANALYSED BY: S.M.H CHECKED BY: Q.C.MANAGER

DATE :11.03.2005

F-1007/01a

Certificate of Analysis—Belgium

Certificate of Analysis

Print Date	31.03.2005
Certif nr / version	500113 / 2
Your order	PS0359 / 27.01.2005
Our order	11001755.040 / 27.01.2005
Customer number	100126

XXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXX

MATERIAL SPECIFICATIONS

Material nr / description	500113 COTRIMOXAZOLE DRY POWDER FOR SUSPENSION 240 MG/5 ML IDA - PLASTIC BOTTLE 100 ML
Customer product code	513001.01

FORMULA

Contains after reconstitution sulfamethoxazole 4 g and trimethoprim 800 mg per 100 ml.

Approved by IDA Quality Control
Signature
Date 05 APR 2005
05 apr. 05

BATCH SPECIFICATIONS

Batch nr Puma / Expiry Date	0005126330 / 03.2007
Production date	03.2005
Quantity	20.760.000 PC
Inspection lot	400000006446

TESTS	REQUIREMENTS	RESULTS
Yellow-white powder with a sweet, pleasant taste and a characteristic fruity flavour	Conforms	Conforms
Loss on drying (100 °C)	maximum 2 %	1 %
Identification sulphamethoxazole (HPLC)	Positive	Positive
Identification trimethoprim (HPLC)	Positive	Positive
Assay sulphamethoxazole (on powder as such) (HPLC)	31,00 - 35,66 %	33.43 %
Assay sulphamethoxazole % of the theory	93,0 - 107,0 % theory	100.3 % theory
Assay trimethoprim (on powder as such) (HPLC)	6,20 - 7,14 %	5.48 %
Assay trimethoprim % of the theory	93,0 - 107,0 % theory	97.2 % theory
Weight variation : nominal weight 12,00 g ; max. deviation 3 %	Conforms	Conforms
Appearance reconstituted suspension : yellowish-white suspension with a characteristic fruity odour	Conforms	Conforms
pH reconstituted suspension	6,0 - 6,5	5.5
Redispersibility (after 12h) of the reconstituted suspension	Conforms	Conforms

Certificate of Analysis—France

XXXXXXXXXXX
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CERTIFICATE OF ANALYSIS / CERTIFICAT D'ANALYSE

Product / Produit: Potassium chloride injection
Potassium chlorure 10%

Dosage : 1 g/amp
13.4 mmol/Amp

Volume : 10 ml

Batch / Lot : 45086
Blend / Vrac : 12844
Man / Fab : 11/2004 Exp. / à ut. avt. : 12/2009

Specifications / Normes : AWM, USP

Validity / Validité : 60 months / mois

	SPECIFICATIONS NORMES	RESULTS RESULTATS
PHYSIO-CHEMICAL CONTROLS / CONTROLES PHYSICO-CHIMIQUES		
Control / Contrôle : PP.11742 (13/12/2004)	Operator / Opérateur : KC	
Identification of potassium chloride / Identification du potassium chlorure		
Identification of chlorides / Identification des chlorures	Positive	Complies / Conforme
Identification of potassium / Identification du potassium	Positive	Complies / Conforme
Assay for potassium chloride / Dosage du potassium chlorure		
------>	9.50 - 10.50 g/100 ml	9.76 g/100 ml
Assay for potassium / Dosage du potassium	4.98 - 5.50 g/100 ml	5.02 g / 100 ml
Control / Contrôle : PP.11742 (13/12/2004)	Operator / Opérateur : KC	
Characteristics / Caractères organoleptiques	Clear solution, colourless, odourless / Solution limpide, incolore, inodore	Complies / Conforme
Extractable volume / Volume extractible	>= 10.00 ml	10.06 ml
pH	4.0 - 8.0	5.9
Particulate matter / Comptage particulaire		
Particles >= 10 µm / Particules >= 10 µm	<= 6000 per ampoule / <= 6000 par ampoule	264
Particles >= 25 µm / Particules >= 25 µm	<= 600 per ampoule / <= 600 par ampoule	11
MICROBIOLOGICAL TEST / ANALYSE MICROBIOLOGIQUE		
Control / Contrôle : ST.2019 (10/12/2004)	Operator / Opérateur : SU	
Thyptocase soy medium / Milieu trypticase - soja	Steril / Stérile	Steril / Stérile
Thioglycolate medium / Milieu thioglycolate	Steril / Stérile	Steril / Stérile
BACTERIAL ENDOTOXINS / ENDOTOXINES BACTERIENNES		
Control / Contrôle : ES.1549 (09/11/2004)	Operator / Opérateur : SU	
Limit of endotoxins dose / Dose limite en endotoxines bactériennes	<= 5.8 EU=Eq	Complies / Conforme

XXXXXXXXXX
Control laboratory supervisor
Resp. de contrôle qualité de laboratoire
Acceptation : 13/12/2004
Edition : 13/12/2004

Complies / Conforme

L R

IDA CODE : 67810.10

21 DEC. 2004

Certificate of Analysis—Spain

Approved by IDA
Quality Control

Date 9 JUL 2005

20-July-05

XXXXXXXXXXX
XXXXXXXXXXXXXX

Certificate of Analysis

Formula 240

Code: XUT00645M	Batch n°: 05F29E1M	Volume: 1000 ml
Check digits: 27	Manufacturing date: 2005-06-29	Expiry date: 2008-05
Description:	Glucose 5% w/v	Quantity: 18504

Composition

Ingredient	Quantity	mmol/l	Reference
Glucose monohydrate	55.0 g	277.5	EP
Water for Injections to	1000 ml		EP

Tests	Product Limits	Results	References
pH	3.5 - 6.5	4.54	EP 2.2.3 (Potentiometric determination)
Glucose id.	Positive (discriminatory)	positive	BP + EP 2.2.7 (Optical rotation)
Glucose Assay (as anhydrous)	4.75 - 5.25 %	4.99	BP + EP 2.2.7 (Optical rotation)
5-HMF	<0.25 Absorbance	0.02	BP + EP 2.2.25
Particles	Container >100ml ≥10µm:<25 part./ml ≥25µm:<3 part./ml Container ≤100ml ≥10µm:<6000 part./cont. ≥25µm:<600 part./cont.	=>10µm: 7 / ml =>25µm: 0 / ml	EP 2.9.19
Sterility	Sterile	Conforms	EP
Bacterial Endotoxins	<0.25 EU/ml	Conforms	EP

THE BATCH IS APPROVED

Released by: XXXXXXX

Quality Control Assurance

QUALITY CONTROL LABORATORY

Date: 14-07-05

Signature:

Manufacturing License—Switzerland

Received

April 5, 2001

Economics and Sanitation Directorate
Canton Basel-Land

Liestal

Disposition No. 617 Date: April 2, 2001 HM/nb

AUTHORIZATION
- to produce pharmaceuticals -
- for wholesale trade of pharmaceuticals -

This document deals with health care based on the completed inspection from November 14 to 16, 2000, by the Regional Center for Control of Health Medicines in accordance with § 49, Section 1 of the December 10, 1973 Law.

The company, xxxxxxx, receives this authorization with the following conditions based on the testimony of the Canton's pharmacist and with reservation about the documents in the inspection report of December 29, 2000.

1. Authorization owner
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

2. Responsible Director

2.1 Overall Responsibility
**xxxxxxxxxxxxxxxxxxxx

R F S
Regional Center for Healthcare Control
For the Cantons of Bern, Lucerne, Solothurn, Basel-City, Basel-Land, Aargau

Extent of Production Authorization

Company: xxxxxxx
Address: xxxxxxxxxxxxxxxxxxxxxxxxx

Production Categories

Human medication	☒
Veterinarian medication	☐
Agent/intermediary products	☐
Medical feed	☐
Other:	☐
Special authorization or limitations	☐

Sterile Products

Large volume parenteralia and rinsing solutions:

• Aseptically produced	☐
• Final sterilization	☐

Small volume parenteralia and eye drops:

• Aseptic production	☐
• Final sterilization	☐

Semi-solid consumable agents	☐

Solid consumable agents:

• Powder filling	☐
• Lyophilisate	☐

Non-sterile products

Liquid consumable agents	☒
Semi-solid consumable agent	☒
Solid consumable agents	
• Single dose (e.g., tablets, capsules)	☒
• Multiple dosages (e.g., powder, granulates)	☒

Biological Products

Blood products (e.g., albumin, clotting factors)	☐
Genetic, technologically manufactured products	☐
Others:	☐

Substances requiring special precautions

Penicillin	☐
Cephalosporins	☐
Hormones	☐
Cytostatics	☐
Others:	☐

Filling and Packaging

Liquid consumables	☒
Semi-solid consumables	☒
Solid consumables	☒
Only secondary packaging	☐

Sterilization methods

Steam	☐
Hot air	☐
Gamma rays	☐
Beta rays	☐
Ethylene oxide	☐

Medicines for clinical trials ☐

Other Products and Processes

Medicinal gases	☐
Transdermal systems	☐
Others:	☐

Number of x 8

Basel, March 26, 2001

Regional Center for
Healthcare Control

xxxxxxxxxxxxxxx

Annex 7: Sample Provisions for Bid

Contents

A Instructions to Bidders
B Bid Data Sheet
C General Conditions of Contract
D Specific Conditions of Contract

Due to complications associated with the purchase of malaria products, including medicines and other commodities such as bed nets, it is strongly recommended that Bank Standard Bidding Documents for Health Sector Goods are used. The application of the following provisions should be observed irrespective of which documents are used for bidding. Clause numbers and reference correspond to the WB Standard Bidding Document for Health Sector Goods. The document can be downloaded at http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/.

Source: The World Bank.

INSTRUCTION TO BIDDERS (Source: World Bank's Standard Bidding Documents for Health Sector Goods, May 2004)

ITB 6.3

Documentation of eligibility

6.3 The documentary evidence of conformity of the Goods and Services to the Bidding Documents may be in the form of literature, drawings, and data and shall consist of:

(a) A detailed description of the essential technical and performance characteristics of the Goods;

(b) An item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the Goods and Services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;

(c) Any other procurement-specific documentation requirement as stated in the Bid Data Sheet.

ITB 6.4

Product registration requirements

6.4 Unless the Bid Data Sheet stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's country. A Bidder who has already registered its Goods by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Purchaser either:

(a) A copy of the Registration Certificate of the Goods for use in the Purchaser's country.

OR, if such Registration Certificate has not yet been obtained,

(b) Evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified in the Bid Data Sheet.

6.4.1 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's country. The agency and contact person able to provide additional information about registration are identified in the Bid Data Sheet.

6.4.2 If the Goods of the successful Bidder have not been registered in the Purchaser's country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

ITB 6.5

Standard specifications

6.5 For purposes of the commentary to be furnished pursuant to ITB Clause 6.3 (b) above, the Bidder shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalog numbers in its bid, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

ITB 7.1

Qualifications of the Bidders

7.1 The Bidder shall provide documentary evidence to establish to the Purchaser's satisfaction that:

(a) The Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the Bid Data Sheet, and has a successful performance history in accordance with criteria specified in the Bid Data Sheet. If a prequalification process has been undertaken for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for prequalification;

(b) In the case of a Bidder offering to supply Health Sector Goods identified in the Bid Data Sheet that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such Goods to supply the Goods in the Purchaser's country;

(c) In the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(d) The Bidder meets the qualification criteria listed in the Bid Data Sheet (see additional clauses of Bid Data Sheet for pharmaceuticals and vaccines).

ITB 19

Bid security

19.1 If required, in the Bid Data Sheet, the Bidder shall furnish, as part of its bid, a bid security as specified in the Bid Data Sheet, or a Bid Securing Declaration. The amount of the Bid Security shall be as stipulated in the Bid Data Sheet in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

19.2 The Bid Security shall remain valid for a period of 28 days beyond the validity period for the bid, and beyond any extension subsequently requested under Sub-clause 18.2.

19.3 The Bid Security shall, at the Bidder's option, be in the form of either a letter of credit or a bank guarantee from a reputable banking institution, or a bond issued by a surety selected by the Bidder and located in any country. If the institution issuing the bond is located outside the Purchaser's country, it shall have a correspondent financial institution located in the Purchaser's country to make it enforceable. The format of the bank guarantee/bond shall be in accordance with the forms included in the bidding documents; other formats may be permitted, subject to the prior approval of the Purchaser.

19.4 Any bid not accompanied by an acceptable Bid Security shall be rejected by the Purchaser as non-responsive. The Bid Security of a joint venture must be in the name of the joint venture submitting the bid.

19.5 The Bid Securities of unsuccessful Bidders will be returned as promptly as possible.

19.6 The Bid Security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security.

19.7 The Bid Security may be forfeited

(a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 18.2 and 25.3; or

(b) in the case of a successful Bidder, if the Bidder fails within the specified time limit to:

(i) Sign the contract, or

(ii) Furnish the required performance security.

ITB 32

Evaluation and Comparison of Bids

32.1 The Purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 29.

32.2 The Purchaser's evaluation of a bid will exclude and not take into account:

(a) In the case of Goods manufactured in the Purchaser's country or Goods of foreign origin already located in the Purchaser's country, sales and other similar taxes, that will be payable on the Goods if a Contract is awarded to the Bidder;

(b) In the case of Goods of foreign origin already imported and to be imported from abroad, customs duties and other similar import taxes paid or payable on the Goods if the contract is awarded to the Bidder; and

(c) Any allowance for price adjustment during the period of execution of the Contract, if provided in the bid.

32.3 The comparison shall be between the EXW price of the Goods offered from within the Purchaser's country plus local transportation, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the Goods, and the CIF named port of destination (or CIP border point, or CIP named place of destination) price of the Goods offered from outside the Purchaser's country, plus local transportation.

32.4 The Purchaser's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Sub-Clause 16.2, one or more of the following factors as specified in the BDS, and quantified in ITB Sub-Clause 32.5:

(a) Delivery schedule offered in the bid;

(b) Deviations in payment schedule from that specified in the Special Conditions of Contract;

(c) Other specific criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.

32.5 For factors retained in the Bid Data Sheet pursuant to ITB Sub-Clause 32.4, one or more of the following quantification methods will be applied, as detailed in the Bid Data Sheet:

(a) Delivery schedule.

(i) The Purchaser requires that the Health Sector Goods under these Bidding Documents shall be delivered (shipped) at the time specified in the Schedule of Requirements. The estimated time

of arrival of the Health Sector Goods at the site will be calculated for each bid after allowing for reasonable international and inland transportation time. A delivery "adjustment" will be calculated for and added to each bid by applying a percentage, specified in the Bid Data Sheet, of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Bidding Documents for evaluation purposes. No credit shall be given for early delivery.

or

(ii) The Health Sector Goods covered under these Bidding Documents are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirements. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as nonresponsive. Within this acceptable range, an adjustment per week, as specified in the Bid Data Sheet, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

(iii) The Health Sector Goods covered under this invitation are required to be delivered (shipped) in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the Bid Data Sheet, of EXW/CIF/CIP price per week of variation from the specified delivery schedule.

(b) Deviation in payment schedule.

(i) Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment schedule offered by the selected Bidder.

or

(ii) The SCC stipulates the payment schedule offered by the Purchaser. If a bid deviates from the schedule and if such deviation is permitted in the Bid Data Sheet, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the Bid Data Sheet.

(c) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the Bid Data Sheet and/or in the Technical Specifications.

Bid Data Sheet

ITB 6.3 (c)

Documentation of eligibility
Documentation requirements for eligibility of Goods. In addition to the documents stated in Clause 6.3 (a) and (b), the following documents should be included with the bid: [*Insert: any other eligibility documentation required*].

ITB 6.4

Product registration requirements
[Note: If the Purchaser's country does not require registration of the Goods, delete 6.4 (b) and 6.4.1 below and insert the following language: ITB Sub-Clause 6.4 is inapplicable. The Applicable Law does not require registration of the Goods to be supplied under the Contract.]

Note: The Purchaser shall not annul award of a Contract on the basis of a Bidder's failure to successfully register the Goods, without first seeking and obtaining the World Bank's no objection. There shall be no forfeiture of a bid or a performance security based on the failure to obtain registration.

Registration can be a long process, so any options for fast-track registration should be pursued.

ITB 6.4 (b)

By the time of Contract signing, the successful Bidder shall have complied with the following documentary requirements in order to register the Goods to be supplied under the Contract: [*Insert: specific documentary requirements or any other country specific requirement*].

Note: Because of the potential for delay when various government agencies must intervene in the registration process, Bidders are alerted to inquire about registration requirements and procedures as early as possible.

ITB 6.4.1

For the purpose of obtaining additional information about the requirements for registration, Bidders may contact [*Insert: name of agency, contact person, phone/fax/email address*].

ITB 7.1 (a)

Qualifications of the Bidders
Qualification requirements for Bidders are: [*Insert, as appropriate: quantifiable qualification criteria for experience and/or financial viability*].

The following documents must be included with the bid:
Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

(i) That, in the case of a Bidder offering to supply Goods under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:
   (a) Is incorporated in the country of manufacture of the Goods;
   (b) Has been licensed by the regulatory authority in the country of manufacture to supply the Goods;

(c) Has manufactured and marketed the specific goods covered by this Bidding Document, for at least two (2) years, and for similar Goods for at least five (5) years;

(d)

A. Approved by the WHO/WHOPES prequalification program.

B. Approved by a stringent regulatory authority defined as a National Drug Regulatory Authority (NDRA) participating in ICH (International Conference on Harmonization) or PIC/S (Pharmaceutical Inspection Cooperation Scheme).

1. When utilizing category A or B for any given limited-source product where two or more suppliers exist AND the product is available from these suppliers (defined as the ability to supply a sufficient quantity to the country within 90 days of the date of order), then the product must be sourced from the above set of suppliers:
2. If the above condition does not apply (i.e., there is only one supplier that meets category A or B standards or the product is not available from two or more suppliers that meet this standard), then the product can be sourced from any supplier which has submitted the product to WHO/WHOPES or to an ICH or PIC/S member AND which manufactures the product at a GMP-compliant site (based on inspection by WHO or an ICH of PIC/S NDRA).
3. If the product cannot be sourced from two or more suppliers based on either of the above categories, then it can be sourced from any supplier which at least manufactures the product at a GMP-compliant site (again, based on inspection by WHO or an ICH or PIC/S member).

(ii) That, in the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce,

(a) That the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's country; and

The Bidder shall also submit the following additional information:

(a) A statement of installed manufacturing capacity;
(b) Copies of its audited financial statements for the past three fiscal years;
(c) Details of on-site quality control laboratory facilities and services and range of tests conducted;
(d) List of major supply contracts conducted within the past five years.

Note: In addition, guidance on what qualification requirements are reasonable is given in the Bank's TN on the Procurement of Health Sector Goods. If bids for individual lots are permitted, the qualification criteria for each lot should be given separately. In the case where a prequalification process has been undertaken, the qualification criteria stated here should mirror the criteria established in the prequalification.

ITB 19.1

Bid security

[*Insert one of the following options*]:

(a) No Bid Security is required; or

(b) Bid shall include a Bid Security (issued by bank or surety) included in Section VIII Sample Forms; or

(c) Bid shall include "Bid Securing Declaration" using the form included in Section VIII Sample Forms.

The amount of Bid Security required is: [*Insert: fixed amount and currency*].

Note: The amount may be expressed as either a fixed amount or an amount "not less than" a specified percentage of the Bidder's bid price. To avoid premature disclosure of bid prices by commercial bank personnel or others, a fixed amount of not less than 2 percent to no more than 3 percent of the budget estimate for the contract (estimated) bid amount is strongly recommended. (Requiring higher Bid Security risks driving away potentially qualified Bidders.) Asking for smaller, or even no Bid Security at all, however, is acceptable for simple contracts where the market is relatively stable and mature.

Also, in the case of Bidding Documents covering multiple lots, a Bid Security should be specified as representing not less than "x" percent of the total Bid Price for all lots covered by the bid.

Examples of actions leading to a rejection of a bid security include (but are not restricted to):

- Submitting a copy of the Bid Security instead of the original
- Misspelling the bidder's name on bid security
- Submitting Bid Security with an incorrect amount (due to miscalculations)

ITB 32.5

Evaluation and Comparison of Bids

The factors retained pursuant to ITB Sub-Clause 32.4 and the quantification methods are: [*Insert: factors*].

Delivery schedule [*Specify: relevant parameters in accordance with option selected*].

The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is [*Specify: adjustment in percentage*].

or

The adjustment per week for delivery delays beyond the range of weeks specified in the Schedule of Requirements is [*Specify: adjustment in percentage*].

or

The adjustment for partial shipments is [*Specify: adjustments for early and late deliveries*].

Note: For evaluation purposes, a rate of one-half (0.5) percent per week is a reasonable figure.

The Purchaser [*Select: will/will not*] accept deviations in the payment schedule in the SCC.

Note: If deviations are accepted, add the following text.

The percentage adjustment for payment schedule deviations is: [*Insert: percentage*] % per week.

Note: If inflation expectations widely diverge between local and foreign currencies, and Bidders are expected to quote significant amounts in local currencies, different adjustment rates for local and foreign currency prices should be provided.

[*Insert: other factors to be used in the evaluation and their evaluation method or reference to the Technical Specifications.*]

Evaluation criteria for items/lots
[*Select one of the two sample clauses below*]:

> If bids have been invited for items only, the Bid Data Sheet should state the following:
> Bidders may bid for any one or more items. Bids will be evaluated for each item and the Contract will comprise the item(s) awarded to the successful Bidder.
>
> If lots will be accepted, the Bid Data Sheet should state the following:
> Bidders can bid for one or more lots. Bids will be evaluated lot by lot. Bidders must quote for the entire quantity of each item and at least eighty percent (80%) of the number of items in the lot to be treated as substantially responsive.
>
> Bid evaluation of such bids will be carried out as per the following procedures. The average price of an item quoted by substantially responsive bidders will be added to the bid price of those who did not quote for that item and the equivalent total cost of the bid so determined will be used for bid comparison, evaluation, and award.

General Conditions of Contract

GCC 1

Effective date

1.1(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.

Registration certificate

1.1(k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the Applicable Law.

GCC 6

Certification of Goods

6.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Purchaser's country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's country.

6.2 Unless otherwise specified in the SCC, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the Goods have been registered for use in the Purchaser's country.

6.3 If thirty (30) days, or such longer period specified in the SCC, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

GCC 9

Inspection and tests

9.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. The SCC and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

(a) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

GCC 15

Warranty

15.1 All Goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise specified in the SCC; have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

15.3 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period specified in the SCC, the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

15.5 Recalls. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall, and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

Specific Conditions of Contract

SCC 1.1 (k)

Registration certificate
The Site is/are: *[Insert, if applicable: identity of Site, street address and city, or insert: "as specified in the Schedule of Requirements"*].

SCC 6.1-3

Certification of Goods
[*Insert: details of registration and other certification necessary to prove registration in Purchaser's country.*]

The Effective Date of the Contract is [*Insert: date of Contract signing if EITHER: (i) the Goods have already been registered at the time of Contracting signing OR (ii) registration of the Goods is not a requirement under the Applicable Law. Otherwise, delete and insert "NOT USED."*].

The time period shall be [*Insert: a number greater than 30*] days. [*If not used, delete and insert "NOT USED."*].

SCC 9.1

Inspection and tests
[*Insert: any additional requirement related to the inspections and tests, or state: "There are no SCC applicable to GCC Sub-Clause 9."*]

SCC 15.1-4

Warranty
[*Insert: necessary and appropriate clauses, or state "There are no SCC applicable to GCC 15."*]

The period for the replacement of defective goods is: [*Insert: period for replacement of defective goods*].

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Operations Policy and Country Services Vice Presidency
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Link to *the World Bank Global Strategy and Booster Program*:
www.worldbank.org/malaria

Link to *the Booster Program for Malaria Control in the Africa Region*:
http://www.worldbank/afr/malaria