Pan American Health Organization

Regional Office of the World Health Organization

A Practical Guide
For Procurement Planning And Management Of Strategic Public Health Supplies

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Preface

Access to medicines and strategic public health supplies is a global priority which has assumed a central position in National Health Agendas in the Region of the Americas. Medicines save lives and as such cannot be treated like other commercial products. On the contrary, the supply of medicines and strategic public health supplies must be prioritized within our health systems.

The challenges that PAHO Member States face in ensuring access to essential public health supplies are being addressed at multiple levels – national, regional and global – with support from initiatives such as the PAHO Strategic Fund and publications such as this Guide. PAHO continues to promote and strengthen the Strategic Fund, addressing the need to improve access to strategic public health supplies through the strengthening and integration of supply systems within the national healthcare framework.

The unfinished health agenda has highlighted the cause of marginal groups and poorer populations within countries of the Americas that still do not have access to essential medicines. It is our obligation to use all means possible to ensure the basic right of health for all, guaranteeing access to medicines, as we continue to build and strengthen our health systems and services.

The strengthening of procurement and supply managent processes is considered a key component of an integrated strategy to ensure access to medicines that meet international standards in quality, safety and efficacy. The four strategic lines of action proposed by PAHO in this area include: the promotion of coherent generic medicine´s policy to ensure a greater level of competition in pharmaceutical markets; the implementation of cost containment strategies focusing on issues relating to pricing and intellectual property regulation; the strengthening of supply systems to ensure continuous availability and affordability of essential medicines; and the consolidation of regional mechanisms for joint price negotiations and pooled procurement.

The process of globalization in the Americas is bringing many diverse and new challenges to countries in issues relating to access to medicines and strategic public health supplies, this at a time when disparities and inequities within and between countries still persist. Our challenge is therefore becoming ever greater!

This Practical Guide for Procurement Planning and Management of Strategic Public Health Supplies aims to provide a series of operational instruments that will support countries throughout the Region in programming and planning of product needs, at the same time building national capacity in procurement and supply management. The document proposes a self assessment approach, evaluating critical areas within the supply system, identifying key areas for improvement and highlighting the importance of evaluation and monitoring through the development and

implementation of performance indicators. At the same time, the PAHO Strategic Fund is proposed as a concrete alternative for the acquisition of quality products, at prices that either have been negotiated previously or are referenced to the lowest regional reference price.

The Guide complements our previous publication presenting the Operating Principles for the Regional Revolving Fund for Strategic Public Health Supplies. In this way PAHO is responding to the mandate handed down by Member States, which is renewed annually during meetings of the Governing Bodies.

In recognizing that health is one of the corner stones of the Millenium Development Goals, we must renew our commitment and responsibility once again to continue strengthening our health systems throughout the Region, to ensure above all the continuous availability of essential public health supplies.

Jorge Bermudez
Unit Chief, Essential Medicines, Vaccines and Health Technologies
Pan American Health Organization

Section 1: Background, Objectives, Use and Structure of the Guide

Background

To support Member States in the procurement and management of strategic public health supplies, the Director of the Pan-American Health Organization (PAHO) established the Regional Revolving Fund for Strategic Public Health Supplies (the Strategic Fund) during the 42nd Meeting of the PAHO Directing Council, Washington, D.C., September 25-29, 2000. In September 2004, the 45th PAHO Directing Council adopted a Resolution (CD45.R7) to promote access to strategic public health supplies and medicines in the Region of the Americas. As a key component of the strategy, Member States endorsed the proposal to strengthen regional procurement mechanisms including the PAHO Strategic Fund. The Directing Council noted that: "The [Strategic] Fund's development will strengthen Member State´s capacity in programming, planning and purchasing; it will facilitate the achievement of economies of scale by consolidating product demand and will promote continuity in supply through the development of a cyclical purchasing system."

The Strategic Fund seeks to strengthen capacity in procurement and supply management at the national level. It is a regional mechanism that may be used for the supply of priority public health products, within the context of PAHO technical support to Member Countries and beneficiaries of the Global Fund to fight AIDS, Tuberculosis, and Malaria. The Strategic Fund is a mechanism that facilitates access to medicines and other public health supplies based on the principles of Pan-Americanism. By supporting Member States in issues of procurement and supply management of public health supplies, the Strategic Fund is contributing to the achievement of public health objectives presented in the Millennium Development Goals, the PAHO Regional HIV/STI Plan for the Health Sector 2006–2015, the WHO Global Strategic Plan for Malaria 2005–2015, and the Global Plan to Stop TB 2006–2015. Through the development of the Strategic Fund, PAHO is working to address issues of access to strategic public health supplies in neglected disease areas such as Chagas and leishmaniasis.

Countries in the Americas are currently developing strategies to address problems in access to strategic public health supplies. The strategies aim to improve access by improving and implementing innovative financing mechanisms, developing mechanisms to monitor prices, strengthening selection processes and strategies in the rational use of medicines, and developing reliable supply systems. The procurement and supply management of public health products is a responsibility of the public health system. It requires the development of an efficient procurement system within a comprehensive supply model that links processes of selection, procurement, storage, distribution, and rational use, built on the core principle of quality.

The **Selection** process involves the critical assessment of medicines and supplies required in diagnosis, treatment and care, taking into consideration specific needs required within each level of the health care system: effective product selection processes can result in resource optimization and

efficiencies within the procurement system. The **Procurement** process includes: the quantification of medicines and supplies; selection of the most appropriate purchasing method; development of procurement plans detailing product specifications, purchase conditions and quality assurance criteria for medicines and supplies; and the evaluation of services and products provided by suppliers. The **Storage** process should guarantee the quality of all supplies stored in the warehouse, storeroom, or pharmacy: storage areas can effectively control the movement of stock by ensuring adequate physical infrastructure for the storage of product, and the implementation of stock management and administrative procedures, including procedures governing the management of staff and environmental storage conditions. The **Distribution** process ensures the delivery of supplies in a timely manner to health facilities in accordance with procedures that ensure the quality of supplies during transfer. **Rational use** ensures the therapeutically sound and cost-effective use of medicines and public health supplies by health professionals and consumers.

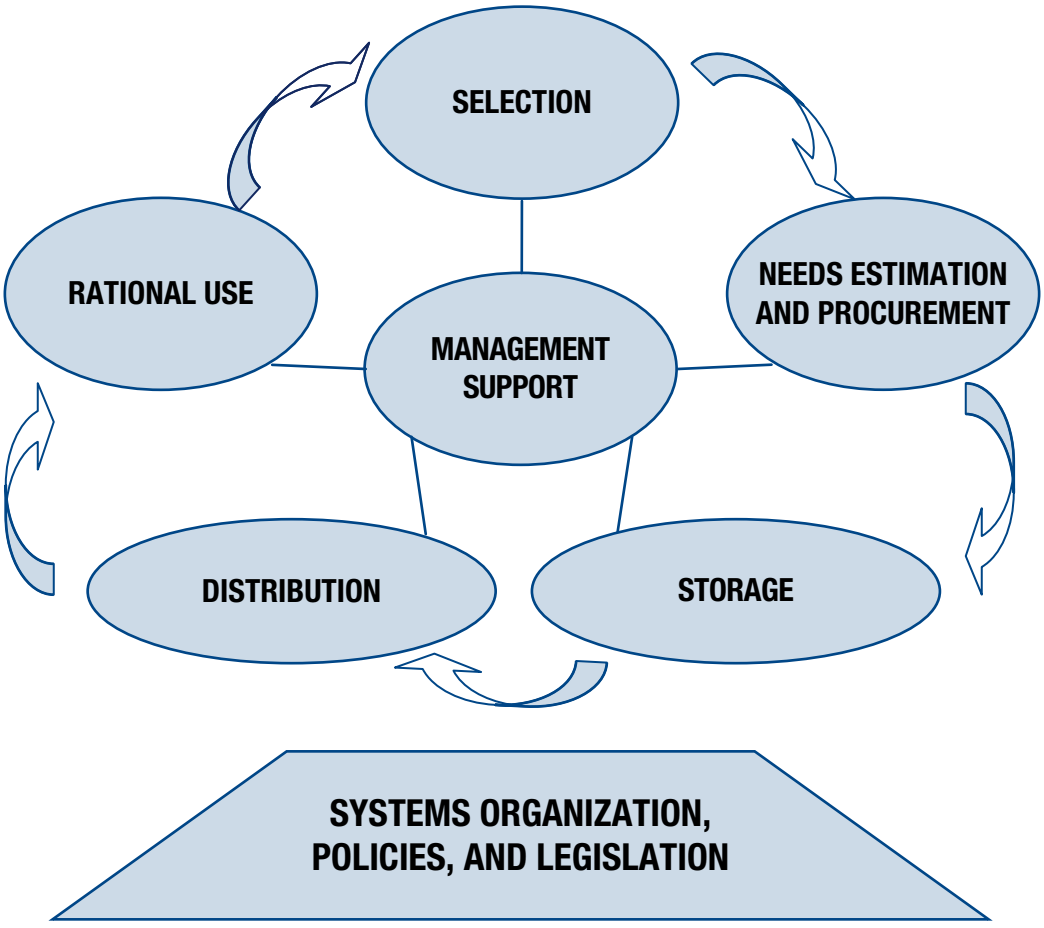
National medicines supply models (Figure 1) are cyclical systems in which each function or process depends on, and is supported by the previous function. For example, the selection of medicines is based on the assessment of medicines needs and use, and products to be purchased are identified based on decisions made during the selection process. If individual processes are executed independently of each other and not as part of an integral system, product costs increase and stock shortages occur more frequently, ultimately leading to poorer quality in service delivery and patient care. At the core of the supply management cycle is a set of administrative support processes that include organizational management, financing, information management, and administration of human and physical resources, all critical to ensure the sustainability of the supply system. The national supply management cycle should be clearly defined within the national health and medicines policy, and regulatory framework.

Our experience in supporting countries through the PAHO Strategic Fund suggests that national health and medicines policies throughout the Americas are not resulting in the development of integrated supply systems at the national level. It is not uncommon to find isolated and disconnected procurement processes, parallel supply systems in operation, and duplication of functions with poor coordination between authorities at the district and national level. The supply of products is often ensured through isolated procurement systems designed and operated without taking into consideration the importance of managing and monitoring system processes as a whole: this ultimately leads to stock shortages, cost increases, and missed opportunities to utilize avilable funding.

The range of problems experienced as a result of supply system fragmentation has lead PAHO Member States to execute evaluations of existing supply processes with a view to developing more integrated systems that facilitate access to medicines and strategic public health supplies. The PAHO Strategic Fund has been designed with input from Member States not only as a mechanism

to facilitate the procurement of strategic public health supplies, but also to provide the necessary technical support to Member States and principal beneficiaries of Global Fund financed projects, to strengthen national capacity in procurement and supply management, to assess and strengthen national supply systems, and to implement quality assurance standards in procurement and supply management.

Figure. 1. Schematic Representation of a Comprehensive Model for Essential Medicines Supply Management. From *"Drug Supply Management".* Management Sciences for Health, World Health Organization, Boston, 2002. Modified by the authors.



Within this context, PAHO/WHO, jointly with key partners, the Cooperative of Antioquia Hospitals (COHAN) Colombia / PAHO/WHO Collaborating Center in Supply Management Systems, and Management Sciences for Health (MSH) / Rational Pharmaceutical Management Plus Program (RPM Plus), has developed this Practical Guide for Procurement Planning and Management of Strategic Public Health Supplies, to support countries in strengthening national processes in procurement planning and supply systems management, and to improve access to strategic public health supplies.

Objectives

This practical guide has two main objectives:

1. To provide practical guidance in:
   - Identifying critical areas within the national supply system.
   - Identifying alternatives for improving the supply system.
   - Developing a procurement plan for the adquisition of strategic public health supplies.

2. To present the PAHO Strategic Fund operational and technical framework to participating Member States in :
   - Strengthening the supply system.
   - Planning procurement through the Strategic Fund.
   - Monitoring and evaluating procurement through the PAHO Strategic Fund.

Using the Guide

Procurement planning is a dynamic process that requires input from many different categories of professionals. It is therefore recommended that procurement planning be carried out by a multidisciplinary team established specifically for the purpose, with the participation of different technical and administrative professionals who have experience in procurement and supply management of strategic public health supplies, and knowledge and experience of national public health programs. The procurement planning team may draw on expertise from specific advisors when necessary.

A multidisciplinary team should be established to ensure continuity in the planning process in the mid to long term. Its responsibilities are not limited to planning of product needs, as it should also monitor and evaluate the implementation of the procurement plan. If a Member State decides to use the PAHO Strategic Fund for procurement of strategic public health supplies, the procurement planning team acts as the national counterpart for PAHO in the procurement process, in order to facilitate the efficient implementation of the procurement plan through the Fund mechanism.

This Guide has been developed specifically to support the multidisciplinary team in preparing a procurement plan for strategic public health supplies. It assumes that the team has been established with a clear mandate to develop the procurement plan, and is composed of technical and administrative personnel from the national medicines program, procurement services, priority national public health programs, finance and planning departments, as well as central medical stores and peripheral storage depots.

This Guide may also be used as a tool for planning procurement of medicines and supplies for specific projects: as such it may also be a useful tool for beneficiary organizations or principal recipients of Global Fund financed projects or other projects financed by donors and other agencies.

The Guide recommends that prior to purchasing, the procurement planning team conduct a rapid assessment of critical elements of the supply system that may impact on the future availability of strategic public health supplies. The rapid assessment may lead to the identification of potential bottlenecks in the supply system, hence facilitating corrective action at the policy, structural or functional level. The Guide may be used to support the development of project proposals aimed at strengthening capacity in procurement and supply management, or alternatively by a PAHO Member State to develop a procurement plan that will be executed through the Strategic Fund.

The Guide presents information on how to purchase through the PAHO Strategic Fund, but it may also be used to support procurement planning irrespective of the procurement mechanism (national or international). It proposes key indicators to monitor and assess the procurement process.

The Guide includes technical support tools, bibliographic references, and a list of useful websites that the procurement planning team may consult during the planning and programming process. In addition, the Guide includes a section on alternative supply models that countries may wish to assess with a view to overcoming critical problems identified in the existing system.

Structure of the Guide

The Practical Guide for the Procurement Planning and Management of Strategic Public Health Supplies has four sections.

- SECTION 1 provides background to the PAHO Strategic Fund, the Guide's objectives, structure, and use.
- SECTION 2 guides the procurement planning team through a rapid assessment of the supply system using a series of key questions which when answered will provide a critical assessment of the procurement and supply management system, and information required to develop the procurement plan. In addition this section presents information on alternative structures for the supply system for the consideration of the procurement planning team and decision makers.
- SECTION 3 presents practical steps for developing a procurement plan.
- Annexes include: technical resources that may be useful in the development of the procurement plan; a glossary of terms, concepts and definitions used in the Guide; bibliographic references and important websites specific to the area of procurement and supply management.

Section 2: Identification of Critical Areas and Alternatives for Improvement

The procurement of essential medicines and public health supplies requires a complete knowledge of the supply system, the organizations and institutions involved. To ensure continuous availability of products within the system, the procurement planning team, established to develop, coordinate, implement and monitor the procurement process, should conduct a rapid situation analysis of the supply system in order to identify potential problems and/or bottle-necks that may adversely affect the availability of product at the institutional level.

As mentioned in SECTION 1, a medicines supply system is cyclical in nature where each function is supported by the previous and leads logically to the next. If each function is executed independently of each other rather than as part of an integral system, costs increase, stock shortages become more frequent and quality of patient care deteriorates. An example of this can be seen in the needs estimation process; with precise, well-written, and frequently updated epidemiological reports and information on product use, purchases may become increasingly accurate, timely, and efficient. Additionally, a well planned procurement process facilitates product storage and timely availability of supplies to users, thus ensuring continuity in the supply process.

Identification of Critical Areas

In order to identify and evaluate critical areas within the supply system, it is necessary for the procurement planning team to have an understanding of the core components of the system. The team should therefore initiate the program of work by assessing the efficiency and adequacy of each component so that the system as a whole can ensure continuous availability of product. An assessment of the system can be implemented by collectively answering a series of key questions which have been developed in this Guide to identify principle determinants of the procurement process. This process facilitates the collection of information required to develop the procurement plan, and stimulates discussion within the procurement planning team on challenges and opportunities that will effect the organization and efficiency of the procurement and supply process.

1. Organization of the system, policies, and legislation

The organizational structure of a country's health system, its policies and legislation are critical areas that require review by the procurement planning team. This review is important as it will generate information in support of the process, including the identification of main stakeholders, procurement coordination and control mechanisms, standards and procedures governing procurement in the public sector, product selection processes and authorized product lists, regulations governing the importation of medicines and public health supplies, and quality assurance and control criteria for strategic public health supplies.

A review of policy, structure and legislation will help the team to take decisions on issues relating to product specification, procurement scheduling, financing, selection of the purchasing method, procedures to be applied in the acquisition or importation of products that are too costly or have limited availability on the local market, and other factors that can affect the availability and quality of the product within the system.

The key questions presented in Question Box No. 1 together with the corresponding checklist in Annex No. 1 may facilitate the analysis of policies, structures and legislation governing the procurement of strategic public health supplies.

Key Questions Box No. 1: Organization of the System, Policies, and Legislation.

1.1	What institutions participate in the national supply system, and what are their respective roles?
1.2	How does the Ministry of Health coordinate and integrate the management of strategic public supplies for priority public health programs?
1.3	What national policies guide the procurement and supply management of strategic public health supplies?
1.4	Is there legislation or do regulations exist that facilitate (i) the importation of strategic public health supplies purchased through the PAHO Strategic Fund or (ii) granting of fast-track product registration?
1.5	What regulatory and technical requirements have been defined to ensure the quality of strategic public health supplies?
1.6	What regulations, standards and procedures govern public sector procurement of strategic public health supplies? Do they allow procurement through the Strategic Fund?

2. Selection and rational use

Careful selection of medicines and strategic public health supplies can contribute significantly to improving quality of patient care and at the same time improve the efficiency of the supply system and use of available resources. It is recommended that essential medicines and other strategic public health supplies be included in clinical protocols or standard treatment guidelines as a means of promoting the rational use of these products.

The use of approved lists of essential medicines and supplies within the public health system has a direct impact on the pharmaceutical sector: it is the departure point for countries in the definition of product technical specifications, leading thereafter to needs estimation, product forecasting, manufacture, procurement and storage, prescribing and dispensing of medicines. The use of specialized or high cost products is restricted by Selection/Therapeutic committees that select products based on principles of safety, quality and efficacy.

Nonetheless, the procurement planning team may also have to purchase non-listed items that have been exceptionally approved for use in specific circumstances. The team should review procedures to be applied for the purchase of such products, and remain in close contact with selection/therapeutic committees to obtain updated information on products included in authorized lists.

If a country is considering using the PAHO Strategic Fund for the procurement of products, the procurement planning team should ensure that the required products are included in the Strategic Fund product list. If products are not included in the Strategic Fund, the procurement team must identify the procurement method for such products. A country may also request the addition of a product to the PAHO Strategic Fund list. As indicated in the Principle Operating Procedures for the PAHO Strategic Fund, consideration is given to requests from Member States and Principle Recipients of Global Fund financed projects to include additional products: the request is reviewed by the PAHO technical unit working in the disease area, and a recommendation to include (or not) is made. PAHO retains sole discretion to include or remove products from the Strategic Fund product list.

Finally, the procurement planning team, within its scope of work, should provide support to priority public health programs to promote the rational use of medicines, capacity building in programming and planning, and information management on product use, making recommendations as appropriate that will improve the use of medicines by program beneficiaries.

The key questions presented in Question Box No. 2 together with the corresponding checklist in Annex No. 1 may facilitate the analysis of the selection and rational use of products, guiding the procurement process.

Key Question Box No. 2: Selection and Rational Use.

2.1	What institutions and official structures participate in the selection and rational use of the strategic public health supplies? What role does each play?
2.2	Do national standard treatment guidelines in priority disease areas differ from the PAHO/WHO guidelines? If so, how?
2.3	Are products included in standard treatment guidelines also present in national authorized lists? Of these, which products are included in the PAHO Strategic Fund product list?
2.4	What strategies and activities have been developed by priority public health programs to promote the rational use of the strategic public health supplies?

3. Product forecasting and aquisition

Product forecasting is often considered to be the most critical element of the procurement and supply management process. It can also be the most challenging for a number of reasons: available information for product quantification is often inadequate; procurement planners are not aware of the different quantification methods available, and how each method should be applied; a systematic approach to product forescasting is rarely implemented; and the quantification process is often executed by one person without consulting other professionals or persons experienced in the process. Poor communication and inadequate procedures guiding the product forecasting process will produce incorrect forecast estimates which in turn will result in either product stock-outs or surplus, and the irrational use of limited resources.

To achieve optimum stock levels throughout the system, professionals responsible for product forecasting should have an understanding of when different quantification methods should be applied, what information is required for forecasting, and how frequently product forecasts should be adjusted.

The procurement planning team must also review product and supplier specifications as well as administrative procedures for procurement. A review of product / supplier specifications at this stage can avert problems later in the process that may affect lead times and availability of product (due to for example, suppliers not having the capacity to meet demand, or suppliers not being able to provide required documentation etc). In addition it is important to define timelines within the forecasting model, to account for delays that otherwise may render the product forecast inaccurate. Product forecasting must take into consideration the organizational structure of the health system, and security stock levels that will be required at each institutional level. Such parameters should be identified and reviewed by the procurement planning team to ensure an accurate product forecast that will yield timely availability of product in accordance with the needs of the system.

At this stage of the planning process, it is important that the procurement planning team assess the in-country patent status of each product as the result of this assessment will determine whether the product can be purchased in generic form. This is not an easy task as information on patent status of a product is either often difficult to obtain or erroneous.

The PAHO Strategic Fund will purchase medicines and supplies that have been prequalified by WHO whenever possible, on behalf of participating Member States. The national procurement planning team should verify with the appropriate regulatory authority that WHO norms and standards applied in product prequalification meet national requirements in the assessment of manufacturers and product. The Strategic Fund may also source products that have received tentative approval by the U.S. Food and Drug Administration (FDA). Further information on prequalification standards of

products purchased through the Strategic Fund is available at www.paho.org/StrategicFund or in Operating Principles for the PAHO Regional Revolving Fund for Strategic Public Health Supplies.

Operational Principles for Good Pharmaceutical Procurement highlight the importance of a establishing an effective quality assurance system in procurement, using prequalified suppliers whose performance is monitored through a process which assesses product quality, service reliability, and financial status of the supplier. The Operational Principles identify the need to establish a quality management system with documented procedures guiding procurement, to ensure that quality medicines are purchased in a timely manner, maximizing the use of available financial resources.

In addition, sound management practices are required to guarantee the participation of reliable suppliers in public sector procurement. Identifying reliable suppliers and establishing transparent relationships with them can be achieved by developing and implementing processes that assess supplier capacity and performance, and registering suppliers that meet predefined standards (prequalification). To increase the number of price offers received in a given tender, it is occasionally necessary to actively identify potential suppliers and invite them to participate in the supplier registration process.

SECTION 3 of this Guide provides useful information on product forecasting and procurement planning, as well as some useful tools for supplier management. The key questions presented in Question Box No. 3 together with the corresponding checklist in Annex No. 1 may assist the procurement planning team in reviewing important issues in product forecasting and acquisition.

Question Box No. 3: Product Forecasting and Acquisition.

3.1	What timelines have been identified in the supply chain that need to be taken into consideration in product forecasting?
3.2	What procedure will be applied in developing the procurement plan and what roles and responsibilities have been assigned to effectively implement the procedure?
3.3	What methods are used to forecast needs? Why has each method been chosen?
3.4	Have technical specifications been defined for each product to be purchased? What are they?
3.5	What products are protected by patent?
3.6	How does the country use the WHO prequalification program and/or the FDA tentative approval process in the procurement of strategic public health supplies?
3.7	How is supplier quality (product and service) and performance assessed?

4. Product receipt

The receipt of product purchased is normally carried out in two distinct steps. Initially it is important to verify that the product received corresponds to the product ordered. This administrative process is carried out by checking the product order against shipping documents received. Thereafter, the product is inspected to ensure that it conforms to technical specifications and characteristics detailed in the product order. This process is referred to as the technical inspection.

The administrative inspection is carried out on 100% of product received: it should include verification of the product name (International Non-Proprietary Name or generic name of the medicine / supply), concentration, pharmaceutical form, cost (per unit and total), delivery dates and shipping method, and quantities received. In verifying quantities of received product, it is sometimes recommended that the person inspecting the product should not know the expected quantity to be received, this to avoid bias in the verification process (blind counting).

The technical inspection of the product is performed on a sample of each batch the size of which is determined statistically and according to Standard Operating Procedures. The statistical sampling of product ensures that the sample taken is representative of the batch as a whole. The product is inspected for expiry date, manufacturing batch number, product registration number, information provided by the manufacturer (on the label, primary and secondary packaging and patient insert), and physicochemical properties of the product are assessed by the the national quality control laboratory.

The key questions presented in Question Box No. 4 together with the corresponding checklist in Annex No. 1 may assist the procurement planning team in reviewing important issues in the technical and administrative receipt of strategic public health supplies.

Key Question Box No. 4: Technical and Administrative Product Receipt.

4.1	How are supplies received in the central medical stores? How are products received at the regional / local warehouses or storerooms?
4.2	What procedures and criteria have been defined for the inspection of product on receipt?

5. Storage and distribution

Strategic public health supplies should be stored in a warehouse, storeroom or pharmacy in a manner that will guarantee the quality, safety and efficacy of the product. Storage conditions for strategic public health supplies are ensured by maintaining storage areas clean, controlling environmental

conditions and implementing procedures for the stock management of product. Product should be stored according to recommendations detailed in the WHO reference publication, Guidelines for the Storage of Essential Medicines and other Health Commodities (WHO 2003), and in accordance with in-house Standard Operating Procedures. The application of quality standards in product storage will optimize product turnover and minimize product loss through expiry or damage due to environmental factors (water damage, rodent / insect infestation), hence ensuring the availability of product for distribution to regional and district level warehouses and institutions.

Developing capacity in operational planning and logistics management is essential in order to develop a cost effective distribution system. The logistics unit should be comprised of qualified personnel who work together to ensure distribution of strategic public health supplies to regional depots or health institutions. The logistics team will be responsible for the following functions:

- To define distribution channels and determine if distribution should be managed by the public sector or outsourced to a private contractor;
- To dispatch and receive shipments at ports, process shipping documents, and documents necessary for importation and customs clearance: to oversee transport of product in transit to regional and local warehouses;
- To plan the location of warehouses and delivery routes;
- To develop delivery schedules;
- To evaluate and monitor the logistics system.

A well managed distribution system will guarantee a constant supply of product while maintaining conditions that ensure product quality. It will minimize product loss through expiration and damage in transportation, and will generate important information to facilitate future product forecasting. Irrespective of whether the distribution network is being managed by the public sector or has been outsourced to the private sector, a system needs to be put in place to monitor and evaluate the performance of the network against predetermined standards. In the case where the distribution network has been outsourced to the private sector, the public sector must retain responsibility for monitoring the quality of the product in the distribution system, in coordination with the distribution agent.

The key questions presented in Question Box No. 5 together with the corresponding checklist in Annex No. 1 may assist the procurement planning team in reviewing important issues related to the storage and distribution of strategic public health supplies.

Question Box No. 5: Storage and Distribution.

5.1	What procedures are applied to ensure that the product distributed corresponds to the product requested, in terms of technical specification and quantity?
5.2	How are good storage and distribution practices applied?
5.3	How is the performance of the storage and distribution network evaluated?

6. Information system

The management information system (MIS) is a critical component of the support system required for supply chain management of strategic public health supplies. The MIS permits the collection, analysis and communication of information within the supply system, supporting processes that guarantee continuous availability of product.

The coordination of functions and processes within the supply chain requires a MIS that generates timely and accurate information that can be used in the development of a system of indicators, measuring the yield and performance at each level of the system.

Question Box No. 6 and its respective checklist from Annex No. 1 will facilitate the analysis of the management information system for strategic public health supplies.

Key Question Box No. 6: Information System.

6.1	What indicators are generated by the management information system to measure the performance of the supply system?
6.2	What is the level of reliability and usefulness of the information generated by the system?
6.3	What must be done to develop a useful and responsive management information system?

7. Financing

Sustainable financing has been identified by the World Health Organization as one of the critical determinants of equitable access to medicines. If the procurement system does not access the necessary funds to purchase supplies in a timely manner, the system becomes ineffective and product shortages become inevitable.

In many countries funds earmarked for procurement of strategic public health supplies are disbursed irregularly during the fiscal year. Such irregularity reduces the efficiency of the procurement system as it is forced to rely on small and partial disbursements that result in multiple procurement actions, and higher product costs. In addition, partial and irregular disbursements wll lead to delays in

supplier payments and loss of supplier confidence in the system. Budgeting and programming units within the Ministry of Health, in coordination with the Ministry of Finance, should establish mechanisms to guarantee timely access to funds (including foreign currency when required) so that product can be purchased in accordance with product forecasts, and suppliers paid according to the contract conditions.

Donor agencies need to work together and with countries to pool available funding for procurement of strategic public health supplies. Donors often have different eligibility criteria for financing of procurement of strategic public health supplies: they apply different procedures for disbursement of funds, and have different reporting requirements. In so far as possible, countries should work with donors to rationalize eligibility criteria, and harmonize disbursement and reporting requirements, taking into consideration national policies and regulations governing the administration of donor funds and grants.

The team responsible for procurement planning of strategic public health supplies should carry out a review of all sources of financing that will become available during the financial year and verify conditions for using these funds. Allocations for freight/transport, insurance and handling should also be identified.

Question Box No. 7 and its corresponding checklist in Annex No. 1 will facilite the assessment of financing sources for strategic public health supplies.

Question Box No. 7: Sources of Financing.

7.1	What financing sources are available for the procurement of strategic public health supplies?
7.2	What mechanisms exist to coordinate and maximize the use of national funds and financing available from international bodies (development banks, the Global Fund, bilateral agencies and other international cooperation agencies)?
7.3	To what extent are funds disbursed on a timely basis for procurement of supplies?

8. Human Resources

If personnel managing technical and administrative components of the supply system are not appropriately qualified, experienced and trained, the supply system will not be effective in ensuring continuous availability of product at the health institution level. Supply systems management, and particularly procurement, are complex processes that require a good mix of knowledge, skills, and experience.

In so far as possible, the procurement planning team should initiate a systems competency review, to assess the competencies of personnel working within the system against those competencies identified as essential to ensure the efficient operation of the system. The level of motivation of staff should also be considered in this assessment. The planning team should also identify training requirements for personnel managing and operating the supply system.

Question Box No. 8 and its corresponding checklist in Annex No. 1 will facilite the rapid assessment of human resource issues in the management of strategic public health supplies.

Question Box No. 8: Human Resources.

8.1	Does the current pool and profile of available human resources meet the supply system's requirements?
8.2	What needs to be done to adjust the human resource profile to the actual needs of the supply system?

Options for improvement

1. Alternative supply systems

Although there are many variations, supply systems can be characterized by five principal models: central medical stores, autonomous supply agency, direct delivery, primary distributor, and private retail outlet system. These models vary from being fully public to fully private. However, it is common to find systems that combine elements from two or more of these models. Table 1 presents key characteristics of each model and advantages and disadvantages of each for public health program management of procurement and distribution of strategic public health products.

The central medical stores is the most common model found in developing country public supply management systems. Medicines and supplies are purchased and distributed by the appropriate unit within the Ministry of Health or Social Security Institute in coordination with the central medical stores. This system requires that the central medical stores manage human resources, infrastructure, equipment, and communications systems for selection, procurement, storage, and distribution of supplies. Central medical stores frequently experience problems with financial management, product needs estimation and forecasting, tender management, warehouse management, and transport and security of supplies. These problems may be caused by many factors including: political or administrative interference in the medical stores operations; inadequate capacity to resolve fundamental management problems, particularly related to discipline, low productivity or corruption; insufficient financial resources; limitations in tendering and contracting due to the payment cycle and erratic disbursement of Ministry of Health funds, including foreign currency, by the Ministry of Finance; and transport difficulties, particularly with vehicle maintenance.

Supply System Model	Central Medical Store	Autonomous Supply Agency	Direct Delivery	Primary Distributor	Private retail outlets
Key Management Characteristics	Public management of all operations in contracting, receiving, storage, and distribution.	Private management (not for profit) of all contracting, receiving, storage, and distribution operations.	Management of supplier contracts, including delivery services.	Management of supplier contracts and the distributor service contract.	Management of contracts to private retail outlets. Financing mechanism / reimbursement of expenditures.
Storage infrastructure (central, regional, local)	Maintains storage network (own and/or outsourced).	Maintains storage network (own and/or outsourced).	Direct delivery by suppliers to regional or district warehouses or health facilities.	Storage and distribution services provided by a logistics company.	Is not required
Transportation of Product	Own and/or outsourced.	Own and/or outsourced.	Suppliers ship product.	Contracted logistics company.	Is not required
Responsibility for quality control of medicines and supplies	Central Medical Stores.	Autonomous supply agency.	Contracting unit of the Ministry of Health (or Social Security Institute).	Shared by the contracting unit of the Ministry of Health (or Social Security Institute) and the primary distributor.	National Medicines Regulatory Authority
Management information system	Own system and data captured from the supplies network.	Own system and data captured from the supplies network.	Own system with information provided by suppliers.	Own system with indicators provided by logistics company.	Own system to process invoices and payments to private retail outlets.

Supply System Model	Central Medical Store	Autonomous Supply Agency	Direct Delivery	Primary Distributor	Private retail outlets
Advantages	Ministry of Health or Social Security Institute maintain control over the entire purchasing and distribution system.	Maintains the advantages of the centralized system. Flexibility in personnel and management systems may improve efficiency. Less open to interference. Separate finances facilitate revolving drug funds.	Eliminates Ministry of Health, Social Security Institute, or non-govenmental organization operating costs of storage and distribution. Decentralized order quantities and delivery help adjust variations in seasonal and local demand Maintains price benefits of centralized tendering. Reduces inventory costs, expiration for high-cost, low volume products.	Maintains the advantages of a single distributor. Competition in service level and cost between potential primary distributors.	Least demanding and least costly for the Ministry of Health or Social Security Institute.
Disadvantages	High capital cost for offices, storage, and transport facilities. Recurrent cost of staff, transport, and other operational costs. Limited incentive for efficiency. Open to political and other types of interference.	Cost and effort in establishing a supply agency. May retain some of the limitations of the central medical stores model. Limited competition impacting efficiency (if operated as a monopoly).	Coordination and supervision of deliveries, payments, and product quality are demanding. Only feasible when adequate private infrastructure exists. Suppliers are limited to those able to ensure local distribution (may reduce competition, increase cost). Direct delivery by multiple suppliers is inefficient and can increase costs.	Monitoring service level and product quality is demanding Competition depends on well developed private distribution system.	Does not ensure equitable access for the poor and marginalized groups of the population.

Table No. 1: Adapted from Figure 6.2, Comparison of Supply Systems for Government and Institutional Health Services. In: Management Sciences for Health, in collaboration with the World Health Organization. Drug supply management. Selection, purchase, distribution, and use of pharmaceuticals. 2nd ed., revised and expanded. West Hartford, CT: Kumarian Press, 1997.

Operational problems with central medical stores have led some governments to establish autonomous supply agencies under private management. The independent supply agency is a centralized system, not-for-profit in nature, managed by an independent or semi-independent board of directors. Supply operations are managed like a private company, with a view to maximizing resource utilization and efficiency.

Other alternative systems eliminate the need to operate and maintain a network of public warehouses. The direct delivery model is mainly a decentralized system in which supplies are delivered directly by the supplier to the health care facility. The Ministry of Health or the Social Security Institute manages the tender process at the central level to select suppliers. The products may be purchased either centrally or by decentralized institutions and delivered by suppliers to the health facilities without going through a central government warehouse.

In the primary distributor model, the procurement unit in the Ministry of Health or Social Security Institute contracts a single primary distributor, as well as suppliers of medicines and medical supplies. The suppliers deliver to the primary distributor who has been contracted to receive, store, and distribute the medicines and supplies to the health care facilities.

The private retail outlet model is based on the dispensing of medicines and supplies by for-profit or not-for-profit private outlets. These outlets can be located within public facilities or as stand alone establishments within the community. In this system, the responsibility for managing the supply of medicines and supplies has been completely transferred to the private sector.

2. Alternatives for improvement

The analysis of critical areas in the supply system identifies weaknesses in the system, its effectiveness and efficiency. In systems characterized by multiple or parallel programs and sources of financing, it is important to determine what kind of intervention is needed to strengthen the performance of the system as a whole. For example, will the system be strengthened simply by reinforcing or establishing coordination mechanisms between public health programs or should the procurement and supply management components of the different programs be integrated to a greater extent? Improving system performance may require implementing limited measures, targeting one element of the component or process in the supply system, or implementing significant changes in structure and management of the complete system.

The procurement of medicines and supplies may be conducted on an annual basis, according to a set schedule, on a continuous basis, or any combination of these. Contracting and contract specifications, such as period of validity of the contract, quantities, frequency and sites for delivery, among others, are very closely related to storage and distribution requirements. In some cases,

applying different purchasing intervals and contracting methods according to the type of medicine or supply may lead to important improvements in the performance of the system.

In many countries, strengthening the storage and distribution system requires a major investment in storage infrastructure, equipment, and transport vehicles; changes in staffing and retraining, and implementing incentives to improve performance. These measures often need to be accompanied by a clearer definition of roles and responsibilities, standardization of procedures, and the development of information and communications systems. The procurement planning team should determine the best option to strengthen the supply system, either by reinforcing existing structures, equipment, vehicles, processes, and systems, or transforming the system based on the alternative models described previously. The team should conduct a critical analysis of the advantages and disadvantages of each option and assess the probability that the alternative chosen will address the problems identified in the existing system.

3. Viability of the alternatives

Having identified alternative models that may strengthen the performance of the supply system, the procurement planning team should carry out a critical assessment of the viability of implementing the proposed options. The viability assessment should include the following key elements:

- Costs of the existing system, including hidden costs (such as losses due to obsolescence, damage, product expiry and opportunity cost) against costs of alternative models;
- Compatibility of the model with the government's reform policy, national health policy, national medicines policy, policies on decentralization, tendering and contracting services, and privatization;
- Compatibility with legislation and regulations on contracting and payment in the public sector;
- Implications of the alternative systems for quality assurance of supplies and services;
- Management information requirements for monitoring and evaluating the performance of the alternative system (information and communication systems and indicators);
- Private sector logistics management capacity and availability of sufficient qualified companies to ensure competition in the provision of services;
- Degree of resistance to change within the system and potential political implications in mobilizing change.

It is recommended that the implementation of the selected option be prioritized, based on requirements and availability of time and resources. If a decision is taken to introduce significant changes in the supply system model, and particularly to adopt models that involve the contracting of services, then changes should be made in a phased manner: the switch from one model to another cannot be achieved in a single step. It is also important to clearly define criteria, methods, and indicators to monitor and evaluate the impact of the change and facilitate adjustments in the process when necessary.

4. Mobilization of the necessary resources

In some cases the technical and financial resources needed to undertake the desired analysls and implement improvements in the supply system will be available within the country. More often than not, it will be necessary to identify external sources of technical and financial assistance, including support from bilateral and multilateral cooperative agencies, the Global Fund, the World Bank, and the Inter-American Development Bank, amongst others.

Section 3: Practical Steps in Writing a Procurement Plan for Strategic Public Health Supplies

To support the work of the procurement planning team, a stepwise approach is proposed to facilitate the analysis of the supply system and the development of a procurement plan for strategic public health supplies.

As an organization specialized in technical cooperation, PAHO is committed to providing support to Member States through the Strategic Fund to develop and implement procurement plans. Once the procurement plan has been developed, the Member State may choose to purchase supplies through the Strategic Fund mechanism, or opt for an alternative procurement method.

STEP	DESCRIPTION
1. Establishment of the procurement planning team.	A multidisciplinary procurement planning team should be established with responsibility for planning and programming procurement. The team should be composed of professionals from: • Technical and administrative units responsible for medicines supply in the public sector, National Public Health Programs, and the Central Medical Stores. • The Principal Recipient and/or beneficiaries of Global Fund or other donor financed projects. • Administrative and technical personnel responsible for planning and executing budgets. • Technical cooperation agencies. • Other institutions and associations involved in the procurement and management of medicines and health supplies. They may participate as a member of the team or be consulted when required e.g. entomologists, reference hospital pharmacists, laboratory personnel, and patient associations. The procurememnt planning team will: have a leader or coordinator designated or selected by the team; establish a timetable for meetings; and define roles and identify specific tasks for each participant. The outcomes of every meeting should be documented so that results and specific outputs (product lists and forecasts, data analysis, budget estimates, etc.) can be assessed against stated objectives.
2. Drafting of a work plan.	To facilitate the work of the procurement planning team, a work plan should be drafted specifying activities, responsibilities and timeframes, with indicators to measure progress. The activities presented from Step 3 onwards in this table are examples of activities that the team should include in the the work plan. Annex No. 2, ***"Work Plan"***, also provides a reference for preparing the workplan, with some suggested indicators to assess the development and implementation of the plan.

STEP	DESCRIPTION
3. Data collecting and processing.	The identification of key persons and/or institutions responsible for collecting and processing information is critical to facilitate product forecasting and procurement planning. Data collection and processing requires input from numerous professionals and institutions, and should be organized as a team activity to ensure accuracy and efficiency in the procurement planning process. The following information and data should be considered: • Prevailing regulations on public sector procurement of medicines and supplies including: national health regulations governing registration of products; tendering/contracting regulations; regulations governing importation of strategic public health supplies (including supplies currently not registered); product patent status and patent regulations; and quality control standards. • Prevalence and incidence of diseases disaggregated by age group. • National authorized lists of medicines and Standard Treatment Guidelines • Lists of medicines and supplies purchased in previous years, with technical specifications and reference prices. • Recent data on resistance to medicines. • Official procedures for the selection, needs estimation, purchase, storage, distribution, and use of medicines and supplies. • Historical consumption of medicines and supplies during the last two years, including donations received. • Quantities and condition of stocks currently available. Quantity of stock on order. • Quantities of expired or damaged stocks during the last year. • Stock in transit. • Seasonal or climatic conditions that may alter average consumption levels. • Information on program scaling-up that may affect product needs and quantities. • Programmed budgets (governmental and non-governmental) other sources of financing, and disbursements procedures. • National and international reference prices.
4. Description of critical areas.	The procurement planning team should critically assess the existing national supply system by answering the key questions presented in SECTION 2. The assessment of critical areas of the supply system will facilitate corrective action and improve the performance of the system. In addition, the team should consider alternatives that will strengthen and improve the supply system in the medium and long term.

STEP	DESCRIPTION
5. Drafting the list of strategic public health supplies to be purchased.	The list of strategic public health supplies to be purchased is a detailed description of the medicines, reagents, pesticides, and supplies required for diagnosis, care and treatment of priority diseases. The list should be prepared without considering issues relating to financing and the procurement method. Annex No. 3, ***"List of Supplies to be Purchased"***, facilitates the preparation of the list, which should include: • The name of the country, program and technical unit responsible for drafting the list. • The coverage period (target time frame for implementation of the procurement plan). • Type of supplies: differentiating between medicines (MX), reagents (RX), pesticides (P), and supplies for prevention (PI) and diagnosis (DI). • Item number. • Product name: in the case of medicines, the International Non-Proprietary Name (INN) or generic name; for pesticides, generic nomenclature and WHO technical specification (WHOPES); for other products, the generic description should be used. • Product presentation, including pharmaceutical presentation, concentration, primary packaging specification and unit. • Quantity of units to be purchased: this can be calculated using different methods (adjusted historical consumption, epidemiological profile (morbidity method), or a combination of both) based on available information. Annex No. 4 ***"Calculating Needs using the Epidemiological Profile Method"***, provides an explanation on how to apply the morbidity method. • Reference unit price. A review of national and international reference prices is suggested to characterize market behavior and improve efficiency of the procurement process. International reference prices should be adjusted for additional costs associated with shipping, taxes, insurance etc. • Total reference cost: obtained by multiplying the unit price by the number of units to be purchased. • Product technical specifications including: labeling requirements (e.g. language, expiry date); quality certification, (quality control certificates by batch, certification of good manufacturing practices); specific requirements and criteria for supplier prequalification by WHO/PAHO, UNICEF, and/or other agencies. • Other legal and administrative requirements: stamps, seals, and logos required by the country; shipping details and delivery schedule etc.

STEP	DESCRIPTION
6. Analysis of reference prices and delivery times.	Having identified products and defined quantities to be purchased, an analysis of potential suppliers on local and international markets should be carried out, including a preliminary assessment of prices offered by these suppliers against reference prices (MSH, MSF, PAHO, national, and others). The quantities to be purchased should be adjusted taking into consideration estimated delivery times. To ensure that quality supplies will be delivered in a timely manner, supplier performance should be assessed. Suppliers should participate in a registration process that assesses the capacity of the supplier to provide service and quality product. A sample assessment tool is provided in Annex No. 5 ***"Tools for Supplier Management".***
7. Analysis of funding sources.	To determine actual availability of financial resources for the procurement of strategic public health supplies, a review of all available sources of financing should be carried out (provisions made within the national health budget, donations, loans, grants, and funds from international cooperation projects). Annex No. 6 ***"Summary of Financing Sources"***, is a useful instrument for collecting information on available financing. The review of financing sources should include an assessment of timeframes and disbursement conditions for each funding source. The results of this analysis will guide the decision making process and optimize resource utilization by using specific funding sources at specific times and for specific products during the procurement planning period.
8. Budget adjustments	If insufficient financial resources are available to purchase the complete list of strategic public supplies required, it will be necessary to make adjustments to the product list and estimate requirements. VEN and ABC analysis are useful to prioritize and adjust the list of supplies to be purchased.
9. Defining the purchasing method.	With the adjusted list, the most appropriate procurement method for each product is determined in accordance with national legislation and regulations, using criteria of quality, price, and timely delivery of supplies. Purchasing methods to be considered include open public tender, restricted public tenders (using registered or prequalified suppliers), competitive negotiation, and procurement via a regional mechanism such as the PAHO Strategic Fund.
10. Defining management indicators.	Effective management of the procurement process and supply system requires the constant monitoring and evaluation of processes and outputs. Adjustments may be made to the procurement plan based on the outcomes of monitoring and evaluation, to maximize the efficiency of the procurement process. Annex No. 7, ***"Management Indicators",*** provides examples of key indicators to evaluate the management of procurement through a regional mechanism such as the PAHO Strategic Fund.

STEP	DESCRIPTION
11. Finalizing the procurement plan to purchase strategic public health supplies.	To manage the procurement of strategic public health supplies irrespective of purchasing modality, a written plan should be prepared presenting information detailed in the Steps previously outlined in this table, including the work plan, information characterizing the supply system, the list of products to be purchased, management indicators etc.. Annex No. 8 ***"Procurement Management Tool: The Procurement Plan"*** facilitates the consolidation of information collected in previous steps into a Procurement Plan.
12. Implementing the Procurement Plan.	Procurement plans should be submitted in a timely manner to the country's agency or unit responsible for the purchase of strategic public health supplies, with the procurement method per product clearly recommended. If procurement is to be carried out through the PAHO Strategic Fund, the procedures presented in Annex No. 9 ***"Procedure for Procurement through the Strategic Fund"*** should be applied.
13. Procurement monitoring and evaluation.	The procurement planning team should closely monitor the procurement process in coordination with the agency or unit responsible for procurement to guarantee timely availability of the required strategic public health supplies. If the PAHO Strategic Fund is the preferred procurement mechanism, the set of indicators presented in Annex No. 7, ***"Management Indicators***",will be applied for this purpose.

Annexes

Annex No. 1: Supply System Checklist

To answer key questions presented in SECTION 2, 'Identification of Critical Areas', it is important to source and review information relevant to the procurement and supply system, so that a comprehensive procurement plan can be developed that takes into account the multiple processes within the system that affect product availability. The following is a checklist of information that should be sourced and reviewed at the national level to answer the key questions in SECTION 2.

1. Organization of the system, policies, and legislation

- National Health Policy and plans, time frames and period of applicability.
- Specific national strategies for management of priority public health disease.
- National Medicines Policy and period of applicability.
- National Essential Medicines List.
- National Treatment Protocols / Standard Treatment Guidelines.
- Composition of teams responsible for technical, administrative, and financial decisions in procurement of strategic public health supplies.
- National drug regulatory agency regulations and norms.
- Centralized and decentralized procurement agency norms and procedures.
- Organizations participating in supply system processes: Ministry of Health pharmaceutical services, Ministry of Health priority public health programs, hospitals, central warehouses, distributors, insurance companies, transportation companies, etc.
- Procedures governing operations of the supply system, documentation of processes.
- Activities executed by various agencies, teams, and organizations within the supply system. Degree of coherence in implemented activities.
- Monitoring and evaluation of supply system functions, statistical information on the use of medicines and strategic public health supplies.
- Procedures governing personnel (operations, training, review) at each level of the supply system.
- WHO prequalification and FDA tentative approval criteria and processes.
- Importation and fast-track registration procedures for strategic public health supplies.
- Bilateral trade negotiations and agreements: conditions affecting selection of medicines sources.
- Patent regulations and patent status for required products.
- Legislation governing public tendering, selection and contracting of suppliers.
- Quality assurance criteria and regulations for medicines and other strategic public health supplies.
- Quality assurance procedures and strategies for supply system processes: selection processes, estimation of needs, purchasing, receiving, storage, and distribution.

- Legal, technical, administrative, and financial requirements for suppliers managing strategic public health supplies.
- Procedures and strategies applied in quality control (physical, chemical, microbiological) of strategic public health supplies.

2. Selection and rational use

- Procedures governing operations of the National Formulary and Therapeutic Committee, role of members and frequency of meetings.
- Recent reports presenting results or outputs from bodies responsible for selection and rational use of medicines and public health supplies.
- National Standard Treatment Guidelines and recent WHO recommendations.
- National Essential Medicines List (including complementary / exceptional lists) and reports on degree of consistency with prevailing treatment standards or guidelines.
- The Strategic Fund's basic list of Strategic Public Health Supplies.
- National policies to promote rational use of medicines and supplies.
- Programs or plans established to monitor and evaluate treatment efficacy: information and statistics generated by surveillance systems on medicines use, quality and adverse reactions.

3. Product forecasting and acquisition

- National guidelines for procurement planning.
- Product information including physical characteristics and technical specifications.
- Definition of time periods for execution of the following tasks: estimation of needs; preparation and publication of the bidding document or tender; adjudication of bids; contracting; product registration / compliance with other regulatory requirements; importation of product; quality control tests; delivery of supplies to warehouses within the national health services network; technical and administrative receipt of product; distribution of product to healthcare institutions.
- Identification of persons or areas participating in each step of the process with definition (or knowledge) of respective responsibilities.
- Reference prices, national and international.
- Guidelines for applying the selected method of needs estimation.
- Procedures for supplier management, including registration and pre-qualification of suppliers, (assessment of products and services to be provided including the results of prior assessments).
- Up-dated supplier list or database.

4. Product receipt

- Procedures, parameters and controls for inspecting supplies during the receiving process.
- Procedure for recording results of product inspection.

- Criteria for accepting or refusing received supplies.
- Statistics analyzing prior results of product received.
- Assessment of the overall contribution of the process to the quality assurance system, and assessment of suppliers.

5. Storage and distribution

- Procedures applying norms and standards for the storage and distribution of medicines and health commodities in warehouses and health institutions.
- Assessment reports on the condition of storage areas, on personnel capacity and training, the transportation network and distribution system, including recommendations for improvement.
- Statistics on inventory turnover and inventory loss due to environmental conditions, product expiration, damage, and theft.
- Procedures governing operations of the transportation and distribution network (own or outsourced) and results of recent evaluations.
- Up-dated list or database of transportation companies.

6. Information system

- Capacity analysis (usefulness, reliability, responsiveness and timeliness) of the information system to support supply system management.
- Management indicators used to evaluate results and processes, with frequency of application and references against which quantitative indicators can be assessed.
- Evaluation reports on results-based management based on information generated by management indicators.

7. Financing

- Listing of national and international sources of financing for strategic public health supplies.
- Documents (policies, regulations and procedures) describing in-country mechanisms established to manage and optimize utilization of funds by financing source.
- Identification of key personnel (and an understanding of their roles and responsibilities) working in financial departments or institutions; disbursement procedures for each department or institution.

8. Human resources

- A recent situation report on available human resources within the supply system, including information on in-service training programs to meet the supply system's needs, and the evaluation of the impact of training.
- Human resources plan including the identification of human resource requirements against current availability within the system.

Annex No. 2: Work Plan

Work Plan Indicators

Activity	Responsibility	Timeframe (In Months)												Indicator
		1	2	3	4	5	6	7	8	9	10	11	12	
1. Collection and processing information														% of the collected information processed
2. Analysis of Critical Areas														Report on the critical areas within the supply system
3. Preparation of the list of Strategic Public Health Supplies														List of supplies available
4. Needs estimation of product, analysis of reference prices and required delivery times for products														a) Quantities estimated per product b) Document presenting criteria for selection of reference prices
5. Analysis of financing sources														Summary of financing sources available
6. Adjustments to the needs estimate based on available financing														% of the adjustment relative to the initial funds required
7. Selection of the procurement method														Authorization / administrative reference for selection of procurement method
8. Definition of management indicators														List of indicators available
9. Preparation of procurement plan														Procurement plan available
10. Submission of the procurement plan to authorities responsible for adquisition														Official correspondence submitting procurement plan.
11. Monitoring and evaluation of procurement plan implementation														a) Completion of activities programmed. b) % of budget executed by product line and health program c) % price variations between periods.

Indicator	Type of Indicator (Quantitative or Qualitative)	Calculation of Indicator (For quantitative indicators)
1. % of the collected information processed	Quantitative	(Quantity of information reviewed / Quantity of information collected) X 100
2. Report on the critical areas within the supply system	Qualitative	
3. List of supplies available	Qualitative	
4. a) Quantities estimated per product b) Document presenting criteria for selection of reference prices	Qualitative	
5. Summary of financing sources available	Qualitative	
6. % adjustment relative to the initial funds required	Quantitative	((Quantity of products required – Quantity adjusted) / Quantity required) X 100
7. Authorization / administrative reference for the selection of the procurement method.	Qualitative	
8. List of management indicators available	Qualitative	
9. Procurement plan available	Qualitative	
10. Official correspondence submitting procurement plan.	Qualitative	
11. a) Completion of activities programmed. b) % of budget executed by product line and health program c) % price variations between periods.	Quantitative	a) (No. of activities executed / No. of activities programmed) X 100 b (Funds executed / Funds programmed) X 100 c) (Current purchase price – Previous purchase price) / Current Purchase Price) X 100

Annex No. 3: List of Supplies to be Purchased

Country:									
Program:									
Procurement Period:									
Product Type	**Item No.**	**Product INN or Generic Name**	**Presentation**				**Quantity**	**Reference Cost / Unit**	**Total Reference Cost**
			Pharmaceutical Form	**Concentration**	**Specifications Primary Pack.**	**Units / Primary Pack.**			
TOTAL									
							Units		**Cost**
Technical Specifications common for all products:									
Other Legal and Administrative Requirements:									

Annex No. 4: Calculating Needs using the Epidemiological Profile Method

1) **Population Distribution**: Identify the number of patients for each population group. For children, identify age ranges (in accordance with the epidemiological profile) and estimate average weight per age group.

Population Group	Average Weight Kg	No. of Cases Requiring Treatment	No. of Future Cases Requiring Treatment
Children 0 – 12 months			
Children 1 – 5 years			
Children 6 – 14 years			
Adolescents and Adults			
Pregnant Women			
Sub-Total			
Total Population			

2) **Treatment Regimens**: List the treatment regimens per population group. Insert additional rows for additional treatment regimens.

Treatment Regimen	Population Group (insert rows for additional population groups, as ncessary)	No. of Cases Requiring Treatment (Totals should correspond to total in table 1)	No. of Future Cases Requiring Treatment (Totals should correspond to total in table 1)	Total No. of Cases Requiring Treatment (Totals should correspond to total in table 1)
1st Line	Children 0 – 12 months			
	Children 1 – 5 years			
	Children 6 – 14 years			
	Adolescents and Adults			
	Pregnant Women			
2nd Line	Children 0 – 12 months			
	Children 1 – 5 years			
	Children 6 – 14 years			
	Adolescents and Adults			
	Pregnant Women			
nth Line	Children 0 – 12 months			
	Children 1 – 5 years			
	Children 6 – 14 years			
	Adolescents and Adults			
	Pregnant Women			

3) **Calculation of needs**: per medicine per population group.

For each population group, list the required medicines identified in the treatment regimens. Using Daily Doses defined in treatment regimens, calculate the total dose per month for each medicine for one patient. Identifying the pharmaceutical form and strength for each medicine, the unit dose is identified and total dose units required per month for one patient is calculated.
The pharmaceutical presentation unit (PPU) is identified for the product and the total number of PPUs calculated per patient per treatment period. Identifying the total number of patients in the patient group, the total number of PPUs required is calculated for the treatment period.
Using this methodology, the medicine needs of each population group is calculated. By summing the needs of all population groups, the total medicines needs are calculated.

Example:

Programming Period (No. of months). _____
Population Group: _____

Generic Name of Medicine or International Nonproprietary Name (INN)	A	B = A X 30	Pharmaceutical Form & Strength	C	D = B / C
	Daily Dose in mg	Total Monthly Dose per Patient in mg[1]		Unit Dose[2]	Total Dose Units Per Month Per Patient[3]
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

1 Daily dose presented in A multiplied by 30
2 Expressed in mg for solid presentations or in mg/ml for liquid presentations.
3 Monthly dose required per patient, divided by the unit dose.
4 Use the pharmaceutical presentation that is most appropriate for patient treatment: for liquids, bottle x ml; for tablets, individual unit, blister, box or container.
5 Total number of dose units per patient per month, divided by the quantity of units contained in the pharmaceutical presentation.
6 Total number of units required per patient in one month multiplied by the total number of treatment months.
7 Total number of patients identified in the population group, as presented in table 2.
8 Total number of patients in the population group multiplied by the total number of PPUs required per patient for the treatment period.

E		F = D / E	G = F x Period in Months	H	I = G x H
Pharmaceutical Presentation Unit (PPU)[4]		Total No. of PPUs per Patient per Month[5]	Total No. of PPUs per Patient Per Period[6]	Total No. of Patients in the Group[7]	Total No. of PPUs required for the Population Group[8]

4) **Adjustments**: In this final stage it is necessary to adjust estimates calculated to account for product in stock, security stock levels required at each institutional level, purchase orders in process, and product loss through expiration, damage and theft.

Final adjusted quantities should be transferred to the table presented in Annex 3, 'List of Supplies to be Purchased' with quantities rounded off to facilitate execution of the purchase order.

The following table may be used to make the necessary adjustments to estimates calculated in table 3.

Generic Name of Medicine or International Nonproprietary Name (INN)	Pharmaceutical Form and Strength	Pharmaceutical Presentation Unit (PPU)	J	K = J x Percentage Estimate for Loss
			Total Number of PPUs required for all treatment regimens and population groups[1]	Estimated Product Loss[2]
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

1 The sum of all quantities calculated in Column I (table 3) for all population groups
2 The total number of PPUs required multiplied by the percentage estimate that will be lost through product expiration, damage and theft. The percentage used to allocate for losses should be determined by the country, and should not be greater than 1%.
3 The total number of PPUs required with an adjustment for product loss.
4 The total number of PPUs to be ordered including an adjustment for prouct loss, existing stock and stock in order / in transit.

L = J + K	M	N	O = L – (M + N)
Adjusted Total Number of PPUs required[3]	**Product in Stock (including donations)**	**Product on order or in transit**	**Final Adjusted Total Number of PPUs required[4]**

Annex No. 5: Tools for Supplier Management[1]

1) **Registration of suppliers**: the following is an example of a form that may be used to register suppliers. Each country or purchasing unit may adapt this form to register suppliers using legal, financial, administrative and technical assessment criteria established.

<table>
<tr><td colspan="3">Registration No.</td><td colspan="2">Registration Date:</td><td colspan="2">National ID Number</td></tr>
<tr><td colspan="5">Supplier Name</td><td colspan="2">Principal Supplies</td></tr>
<tr><td rowspan="4">Type:</td><td>Manufacturer</td><td></td><td colspan="3" rowspan="4">GMP Authorization No.
Chamber of Commerce No.</td><td colspan="2">Marketing Authorization No.</td></tr>
<tr><td>Distributor</td><td></td><td colspan="2"></td></tr>
<tr><td>Import Agent</td><td></td><td colspan="2"></td></tr>
<tr><td>Other</td><td></td><td colspan="2"></td></tr>
<tr><td colspan="5">Street</td><td colspan="2">Other Address</td></tr>
<tr><td colspan="3">City</td><td colspan="2">Country</td><td colspan="2">Telephone</td></tr>
<tr><td colspan="3">Fax</td><td colspan="4">e-mail</td></tr>
<tr><td colspan="5">Legal Representative</td><td colspan="2">Managing Director</td></tr>
<tr><td colspan="5">Director Quality Control</td><td colspan="2">Technical Director</td></tr>
<tr><td colspan="5">Sales Director</td><td colspan="2">Marketing Director</td></tr>
<tr><td colspan="5">Financial Director</td><td colspan="2">Customers Service Director</td></tr>
<tr><td colspan="7">Contact information in the city nearest to the Procurement Unit / Ministry of Health or Purchasing Institution</td></tr>
<tr><td colspan="5">District Manager</td><td colspan="2">Address:</td></tr>
<tr><td colspan="3">Mobile Tel. No.</td><td colspan="2">Office Tel. No.</td><td colspan="2">Office Fax No.</td></tr>
<tr><td colspan="5">Sales Representative</td><td colspan="2">Mobile Contact No.</td></tr>
</table>

1 Adapted from: Management and Administration of Essential Medicine Supply Systems (in Spanish only). Cooperativa de Hospitales de Antioquia. 4th Edition. Medellin, 2005.

2) **Evaluation of Suppliers**: The following is an example of a form that may be used to evaluate the performance of a supplier. Each country or purchasing unit may adapt this form using legal, financial, administrative and technical parameters established to evaluate suppliers. In addition, the number of points allocated per parameter may vary by country / procurement unit depending on the weight assigned to each parameter.

Parameters	Reference Points	Points Scored
1. Quality of Service		
1.1 Quality in Service Delivery		
Timely delivery	10	
Provision of timely information	5	
Quality of delivery service	5	
1.2 Adherence to Administrative Procedures	25	
1.3 Quality of Communication	5	
1.4 Completion of registration process	10	
Subtotal	**60**	
2. Product Quality		
2.1 Compliance with Technical Specifications		
Physical Characteristics of product	15	
Packaging	15	
2.2 Pysicochemical and Microbiological Properties	10	
Subtotal	**40**	
Total	**100**	

3) **Evaluation of Supplier Documentation**: The following is an example of a form that may be used to evaluate supplier documentation. In addition, the points allocated will vary by country / procurement unit depending on the importance of each parameter. Each country or procurement unit should adjust the evaluation parameters using legal, financial, administrative and technical requirements established.

Area	Parameters	Reference	Points
		Points	Scored
Administrative	Information on Manufacturing Capacity	4	
	Information on Distribution Capacity	4	
	Information on Importation Capacity	4	
	Certification Chamber of Commerce	4	
	Commercial References	4	
	Master Plant Profile	10	
	Subtotal	**30**	
Financial	Presentation of financial accounts	6	
	Statement of financial liquidity	6	
	Financial References	6	
	Price list	6	
	Presentation of payment conditions	6	
	Subtotal	**30**	
Technical	Certification GMP	10	
	Product technical data sheets	6	
	Quality Management Procedures / ISO	6	
	Quality Control protocols	6	
	Marketing Authorization information	6	
	Product registration information	6	
	Subtotal	**40**	
Total		**100**	
Observations			

4) **Qualification of suppliers**: Using the scores aggregated in the supplier management tools presented in this annex (tables 2 and 3), a confidence assessment may be carried out as a means of prequalifying suppliers for use in procurement. A sample assessment is presented below.

   Each country or procurement unit may adjust the ranges of confidence presented based on national qualification criteria and weights established.

Points Scored by Supplier	Qualification	Interpretation
100 – 90	Excellent	High degree of confidence that supplier meets requirements to ensure quality of service and product
89 – 80	Satisfactory	Degree of confidence is satisfactory that supplier meets requirements to ensure quality of service and product
79 – 70	Acceptable	Degree of confidence is acceptable that supplier meets requirements to ensure quality of service and product
Less than 70	Not acceptable	Poor degree of confidence that supplier meets requirements to ensure quality of service and product

Annex No. 6: Summary of Financing Sources

National Health Programs	Financing Sources								
	National Budget	Global Fund	USAID	EU	Donations[1]	Other #1	Other #2	Total / Line	Total / Program
HIV/AIDS								$ –	
* Antiretrovirals								$ –	
* Medicines for Opportunisitic Infections								$ –	$ –
* Diagnostics								$ –	
* Supplies for prevention								$ –	
Malaria								$ –	
* Anti-malarials								$ –	
* Diagnostics								$ –	$ –
* Supplies for prevention								$ –	
* Insecticides.								$ –	
Tuberculosis								$ –	
* Anti-tuberculosis Medicines								$ –	$ –
* Diagnostics								$ –	
Chagas								$ –	
* Anti-chagas Medicines								$ –	$ –
* Diagnostics								$ –	
* Insecticides.								$ –	
Leishmaniasis								$ –	
* Medicines								$ –	$ –
* Insecticides								$ –	
Other								$ –	$ –
								$ –	
Total By Source of Financing	$ –	$ –	$ –	$ –	$ -	$ –	$ –	$ –	$ –

1 Include the value of products donated as well as the value of funds donated

Annex No. 7: Management Indicators

The following indicators have been developed to assess the performance of the Strategic Fund in supplying Strategic Public Health Supplies to Member States. The indicators can be readily adapted however to assess the supply process irrespective of the purchasing method applied.

Indicator	Evaluation Period (Year)	Calculation of Indicator	Result	Interpretation
1. % of supplies required by the country and present in the Strategic Fund Product List (by program and product line)		(Quantity of items required by the country included in the Strategc Fund Product list / Quantity of total items required by the country) X 100		Strategic Fund coverage of needs in the country, information which will support the revision of the Strategic Fund product list
2. % of Strategic Public Health Supplies purchased through the Strategic Fund (by program and product line)		(Quantity of items purchased through the Strategic Fund / Quantity of items required by the country) X 100		Degree of utilization of the Strategic Fund by the Member States
3. Time (in days) between the receipt of the price offer from PAHO and the transfer of funds to the Strategic Fund		No. of days between receipt of the price affer and transfer of funds.		Provides information on the ability of the country to disburse funds to avail of Strategic Fund prices valid for the specified period
4. No. of expired price offers		No. of expired price offers requiring re-quotation.		Provides information on the ability of the country to disburse funds to avail of Strategic Fund prices valid for the specified period
5. Variation in Strategic Fund prices with respect to international price references		((International Reference Price – Strategic Fund Price) / International Reference Price) X 100		Measures the capacity of the Strategic Fund to negotiate prices on behalf of Member States.
6. % variation in purchase price of product compared with previous year.		((Current purchase price – Previous Purchase Price) / Current Purchase Price) X 100		Measure the evolution of product price on a yearly basis. Measures the capacity of the Strategic Fund capacity to negotiate prices on behalf of Member States.

Indicator	Evaluation Period (Year)	Calculation of Indicator	Result	Interpretation
7. % of product with technical problem identified during product receipt.		(No. of items with technical problems identified / No. of items received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
8. % of product with problem identified during quality control		(No. of items with problems detected / No. of items tested) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
9. No. of problems identified with technical documentation received		(No. of problems detected with documentation / No. of documents received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
10. No. of problems identified with administrative documents received		(No. of problems detected with documentation / No. of documents received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
11. No. of suppliers presenting technical problems in the supply of Strategic Public Health Supplies		(No. of suppliers presenting problems / Total number of Stategic Fund suppliers used by the Member State) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
12. No. of suppliers specifically presenting delivery problems in supply of Strategic Public Health Supplies		(No. of suppliers presenting delivery problems / Total number of Stategic Fund suppliers used by the Member State) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.

Annex No. 8: Procurement Management Tool: The Procurement Plan

PROCUREMENT PLAN														
Country:								Period Covered:						
PART I: WORK AGENDA														
Activity	**Responsibility**	**Timetable (In Months)**												**Compliance Indicator**
		J	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	
PART II: CRITICAL AREAS IDENTIFIED (complete according to SECTION 2 of the Guide):														
Organization of the System, Policies, and Legislation.														
Selection and Rational Use.														
Product Forecasting and Acquisition.														
Storage and Distribution.														
Information System.														
Financing.														
Human resources.														
PART III: OPTIONS FOR IMPROVEMENT: ALTERNATIVE SUPPLY SYSTEM														

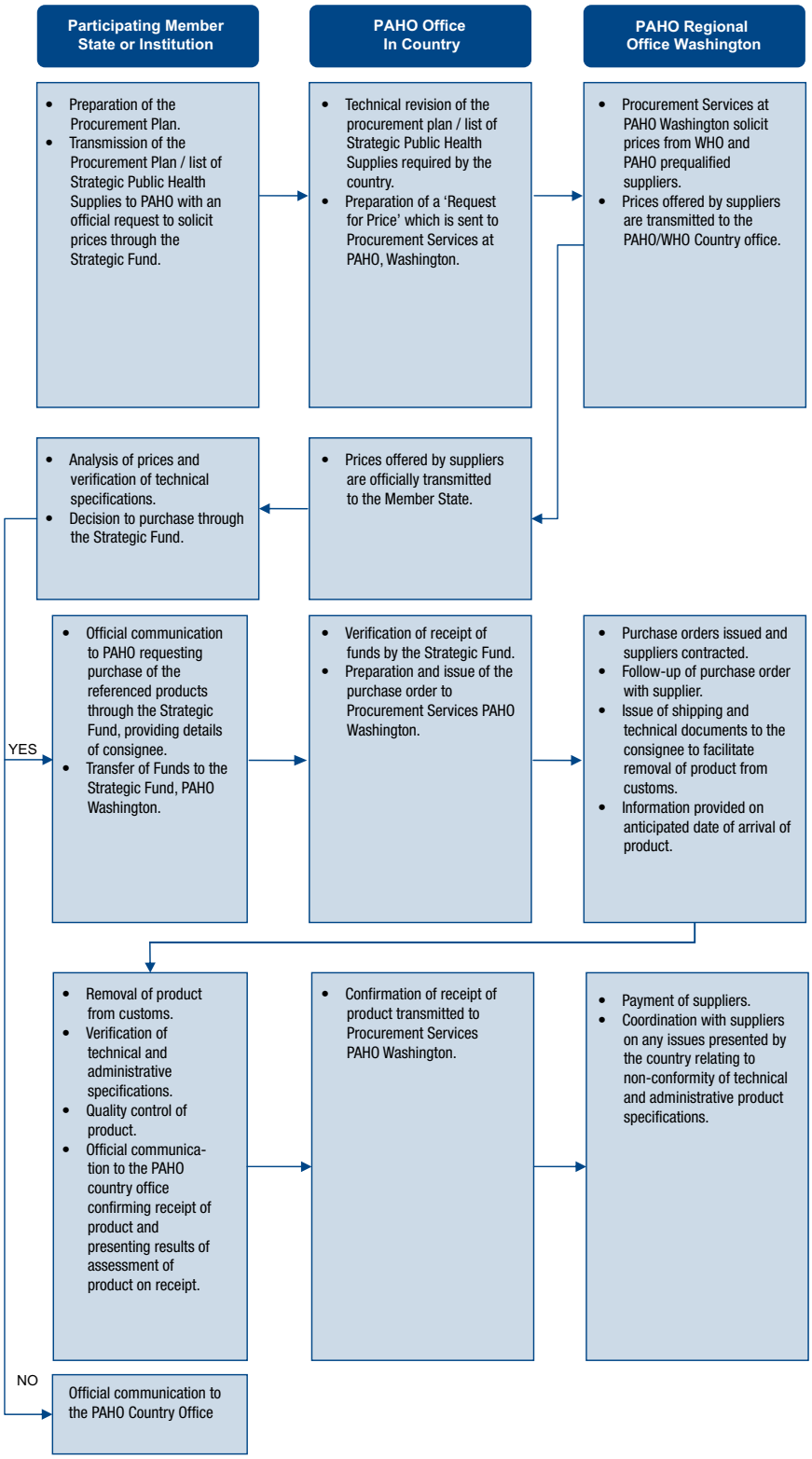
PART IV: LIST OF SUPPLIES TO BE PURCHASED BY HEALTH PROGRAM (Malaria, HIV/AIDS, TB, Leishaniasis, Chagas, others)									
PROGRAM:					**PERIOD COVERED:**				
Type	**Item No.**	**Product (INN) or Generic Name**	**Presentation**				**Quantity Units**	**Reference Cost / Unit**	**Total Ref. Cost**
			Pharmaceutical Form	**Concentration**	**Specifications Primary Packaging**	**Units/ Primary Pack.**			
Totales							Units		Cost
GENERAL TECHNICAL SPECIFICATIONS REQUIRED FOR ALL PRODUCTS:									
OTHER LEGAL AND ADMINISTRATIVE REQUIREMENTS:									

PART V: MANAGEMENT INDICATORS				
Indicator	**Evaluation Period (Year)**	**Calculation of Indicator**	**Result**	**Interpretation**
1 % of supplies required by the country and present in the Strategic Fund Product List (by program and product line)		(Quantity of items required by the country included in the Strategc Fund Product list / Quantity of total items required by the country) X 100		Strategic Fund coverage of needs in the country, information which will support the revision of the Strategic Fund product list
2 % of Strategic Public Health Supplies purchased through the Strategic Fund (by program and product line)		(Quantity of items purchased through the Strategic Fund / Quantity of items required by the country) X 100		Degree of utilization of the Strategic Fund by the Member States
3 Time (in days) between the receipt of the price offer from PAHO and the transfer of funds to the Strategic Fund		No. of days between the receipt of the price offer and transfer of funds		Provides information on the ability of the country to disburse funds to avail of Strategic Fund prices valid for the specified period
4 No. of expired price offers		No. of expired price offers requiring re-quotation		Provides information on the ability of the country to disburse funds to avail of Strategic Fund prices valid for the specified period
5 Variation in Strategic Fund prices with respect to international price references		((International Reference Price – Strategic Fund Price) / International Reference Price) X 100		Measures the capacity of the Strategic Fund to negotiate prices on behalf of Member States.
6 % variation in purchase price of product compared with previous year.		((Current purchase price – Previous Purchase Price) / Current Purchase Price) X 100		Measure the evolution of product price on a yearly basis. Measures the capacity of the Strategic Fund capacity to negotiate prices on behalf of Member States.

PART V: MANAGEMENT INDICATORS				
Indicator	**Evaluation Period (Year)**	**Calculation of Indicator**	**Result**	**Interpretation**
7 % of product with technical problem identified during product receipt.		(No. of items with technical problems identified / No. of items received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
8 % of product with problem identified during quality control		(No. of items with problems detected / No. of items tested) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
9 No. of problems identified with technical documentation received		(No. of problems detected with documentation / No. of documents received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
10 No. of problems identified with administrative documents received		(No. of problems detected with documentation / No. of documents received) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
11 No. of suppliers presenting technical problems in the supply of Strategic Public Health Supplies		(No. of suppliers presenting problems / Total number of Stategic Fund suppliers used by the Member State) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.
12 No. of suppliers specifically presenting delivery problems in supply of Strategic Public Health Supplies		(No. of suppliers presenting delivery problems / Total number of Stategic Fund suppliers used by the Member State) X 100		Indicator of the quality of strategic public health supplies purchased through the Strategic Fund.

PART VI: REQUEST FOR INCLUSION OF SUPPLIES IN THE PAHO STRATEGIC FUND LIST					
Product INN	Pharmaceutical Form	Concentration	Primary Packaging Specifications	Primary Packaging Units	Justification For Request

Annex No. 9: Procedure for Procurement through the Strategic Fund



Annex No. 10: Glossary of Terms

The Glossary of Terms provides definitions for terms and concepts used in the Guide. The information presented here has been sourced from references listed in Annex No. 11, 'Bibliographic and Reference Links'.

- **ABC Analysis**: ABC analysis or Pareto analysis is a method by which medicines are categorized according to their annual usage (unit cost times annual consumption) into Class A items (the 10 to 20 percent of items that account for 75 to 80 percent of the funds spent), Class B items (with intermediate usage), and Class C items, (the vast majority of items with low individual usage, the total of which accounts for 5 to 10 percent of the funds spent.

  a) In ***purchasing***, an analysis of Class A supplies can identify articles for which lower-priced alternatives may be available on the market. ABC analysis is useful to determine frequency of orders and prioritize purchases.

  b) In ***promotion of rational use***, ABC supports the identification of excessive / insufficient and inappropriate medicines consumption.

- **Good Storage Practices (GSP)**: special measures considered appropriate for the strorage and transportation of pharmaceuticals. GSP are defined in Attachment 9 of the WHO Technical Report No. 37.

- **Good Distribution Practices (GDP)**: guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs, intended for human consumption. GDP regulates the division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

- **Pharmaceutical form**: the combination of the form in which a medicinal product is presented by the manufacturer (form of presentation) and the form in which it is administered including the physical form (form of administration). Examples include tablet, capsule, soft capsule, syrup, suspension, elixir, oral solution, solution or suspension for injection, gel, cream, or ointment, amongst others.

- **Primary packaging**: container, recipient, or any other form of packing in direct contact with the medicine or supply. Secondary packaging: packaging used to contain primary packaging.

- **Rational Use of Medicines**: requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

- **Safety stock**: provides protection from stock outs when the time it takes to receive a replenishment shipment exceeds the projected lead time.

- **Strategic Public Health Supply**: a product deemed critical to public health programs that meets the following criteria:
  - is listed, recognized and recommended by a WHO Expert Committee or Working Group (e.g. Essential Medicines, WHOPES recommended compounds, HIV Diagnostics etc.);
  - is included in WHO recommended protocols or diagnostic algorhythms and is considered highly effective in disease treatment or prevention;
  - when continuously available, significantly contributes to improvements in mortality rates and patient quality of life, and/or minimizes possibilities of drug resistance in treatment;
  - is subject to particular challenges in areas of product sourcing, pricing, forecasting, and purchasing;
  - economies of scale are achievable as volumes purchased increase.

- **Supplier management**: the process of selection, administration and monitoring of supplier services and products. Supplier management requires the establishment of relations with suppliers based on mutual trust and respect. It requires suppliers to provide legal, technical, and financial information to the procurement agency or unit for assessment, as well as the preparation of a database or registry of suppliers to permit continuous evaluation of supplier performance.

- **Technical specifications**: Exact description of the medicine or supply, including special requirements. For pharmaceutical supplies, technical specifications include information relating to Good Manufacturing Practices (GMP), Pharmacopoeia standards, required nomenclature and description for each product, storage parameters and expiry date, labeling and packaging instructions (including inserts), required GMP and quality assurance certificates, and other information relating to the product that must be submitted with bid documentation and with each product shipment. The need for special packaging and labeling, as well as the language on the labeling, should be indicated on the list of requirements, but in any case the general technical specifications should include generic information on the packaging and labeling applicable to all the products.

- **Tentative approval process**: Process established by the United States Food and Drug Administration (FDA) to expedite the review process of a medicine to ensure that the United

States could provide safe, effective and affordable quality drugs to developing countries. Tentative approval means that a medicine meets FDA standards for safety, efficacy and quality but that existing patent and exclusivity rights prevents the medicine from being sold in the United States.

- **VEN Analysis**: a methodology used to classify medicines into vital, essential, and non-essential categories, according to the medicine's impact in treating prevelant diseases. VEN analysis sets priorities for the selection, purchase, and use of medicines: priority is given to vital medicines.

- **WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce**: an administrative instrument that requires each participating Member State, upon application by a commercially interested party, to attest to the competent authority of another participating Member State that:

  1. a specific product is authorized to be placed on the market within its jurisdiction or, if it is not thus authorized, the reason why that authorization has not been accorded;

  2. the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP as recommended by WHO; and

  3. all submitted product information, including labeling, is currently authorized in the certifying country.

- **WHO Prequalification Program**: The Prequalification Program, set up in 2001, is a service provided by the World Health Organization (WHO) to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. WHO Prequalification is an essential part of quality assurance in the pharmaceutical supply chain. It verifies that the product meets at least the norms and standards set by international organizations. Key steps in the prequalification process include:
  - the assessment of product dossiers containing data and information as required in the guidelines, norms and standards of the WHO, for safety, quality and efficacy;
  - the assessment of manufacturers for compliance with WHO Good Manufacturing Practices (GMP) and data verification;
  - the assessment of Contract Research Organizations (CRO's) for compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP), and data verification.

Annex No. 11: Bibliographic and Reference Links

	Term	BIBLIOGRAPHIC REFERENCE AND LINK
*	ABC Analysis	Managment Sciences for Health, WHO. Managing Drug Supply. Second Edition. Boston. 1997. Pgs 633 – 638.
*	Access to Medicines	World Health Organization, Medicines. http://www.who.int/medicines/areas/access/en/index.html
		Pan American Health Organization. http://www.paho.org/english/ad/ths/ev/acceso.htm
*	Certification of Pharmaceutical Product WHO	Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html
		WHO Expert Committee on Specifications for Pharmaceutical Specifications. Thirty-Second Report. http://www.who.int/medicines/publications/pharmprep/en/
*	Estimation of Needs	Cooperativa de Hospitales de Antioquia – COHAN. Gerencia y administración de sistemas de suministro de medicamentos esenciales. Cuarta edición. Medellín, 2005. Página 87 – 113 (Spanish only). DELIVER. Guide for Quantifying ARV Drugs. http://www.phishare.org/files/4352_QUANTARV_GUIDE.pdf
*	Good Distribution Practices	World Health Organization. Good Distribution Practices (GDP) for Pharmaceutical products. Working Document. QAS/04.068/Rev.2. http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS_068Rev2_GDPdraft.pdf
*	Good Storage Practices	WHO Expert Committee on Specifications for Pharmaceutical Specifications. Thirty-seventh Report. Annex 9. http://whqlibdoc.who.int/trs/WHO_TRS_908.pdf
*	HIV/AIDS: Procurement and Supply Management	Pan American Health Organization. Regional Plan for the Health Sector 2006 – 2015. http://www.ops-oms.org/english/ad/fch/ai/hiv_reg_plan.htm World Health Organization. Aids Medicines Diagnostics Services. **http://www.who.int/hiv/amds/en/**
*	Malaria: Procurement and Supply Management	The Global Strategic Plan 2005-2015. http://www.rollbackmalaria.org/forumV/docs/gsp_en.pdf World Health Organization. Malaria Medicines and Supplies Services. http://www.rbm.who.int/mmss/
*	Medicines Procurement	Operational Principles for Good Pharmaceutical Procurement. http://www.who.int/3by5/en/who-edm-par-99-5.pdf

	Term	BIBLIOGRAPHIC REFERENCE AND LINK
*	Prequalification Program WHO	World Health Organization. Prequalification Program. http://mednet3.who.int/prequal/
*	Technical Specifications	Managment Sciences for Health, WHO . Managing Drug Supply. Second Edition. Boston. 1997. Pg 243.
*	Tuberculosis: Procurement and Supply Management	Managment Sciences for Health /RPM Plus. Improving Drug Management to Control Tuberculosis. http://erc.msh.org/TheManager/English/V10_N4_En_Issue.pdf The Global Plan to Stop TB 2006 – 2015. http://www.who.int/tb/features_archive/global_plan_to_stop_tb/en/index.html Global Drug Facility. http://www.stoptb.org/gdf/
*	Safety Stock	Managment Sciences for Health, WHO. Managing Drug Supply. Second Edition. Boston. 1997. Pgs 220 – 221.
*	Strategic Fund PAHO	Pan American Health Organization. www.paho.org/StrategicFund
*	Supplier Management	Cooperativa de Hospitales de Antioquia – COHAN. Gerencia y administración de sistemas de suministro de medicamentos esenciales. Cuarta edición. Medellín, 2005. Página 158 (Spanish Only). Managment Sciences for Health, WHO. Managing Drug Supply. Second Edition. Boston. 1997. Pgs 239 – 251.
*	Tentative Approval FDA	USA Food and Drug Administration http://www.fda.gov/cder/reports/rtn/2005/rtn2005-2.htm#GenTent
*	UNITAID.	http://www.unitaid.eu/sommaire.php3?lang=en
*	Rational Use of Medicines	World Health Organization. http://www.who.int/medicines/areas/rational_use/en/index.html The Selection and Use of Essential Medicines. Report of the WHO Expert Committee, 2005. http://www.who.int/medicines/services/expertcommittees/essentialmedicines/TRS933SelectionUseEM.pdf