Procurement and Supply Management
UNDP Global Fund Implementation Guidance Manual

Table of Content

Procurement and Supply Management

Overview

General procurement principles

Procurement in Global Fund-financed projects is governed by the same regulations, rules and procedures applicable to other procurement activities by UNDP. Country Offices (COs) should follow the **UNDP Programme and Operations Policies and Procedures (POPP)** on **contracts and procurement**.

UNDP's **procurement principles** lay out the following general principles guiding procurement undertaken by the organization:

- Provide the best value for money.
- Embody fairness, integrity, transparency.
- Engage in effective international competition.
- Serve the interests of UNDP.

Value for money (VfM) is often referred to as the 3Es—economy, efficiency and effectiveness, whereby (1) economy means minimizing the cost of resources (doing things at a low price); (2) efficiency means performing tasks with reasonable effort (doing things the right way, often measured as cost per output); and (3) effectiveness means the extent to which objectives are met (doing the right things, often measured as cost per outcome).

VfM is about providing services of the right quality, level and cost that reflect the needs and priorities of customers, council taxpayers and the wider community. The criteria defining VfM for the Global Fund have changed to effectiveness, efficiency and additionality. Please see the Global Fund's **guidance on procurement** for further details.

Special procurement strategy for Global Fund-financed programmes

According to the UNDP–Global Fund **Grant Regulations**, UNDP is accountable for the entire supply chain, from product selection to the rational use of medicines. This differs from normal UNDP procedures, whereby responsibility is transferred to the national entities when they take possession of the products.

Over the years, UNDP has developed and continues to manage a procurement architecture designed to facilitate timely supply of quality assured pharmaceutical and health products to meet the needs of Global Fund-financed grants implemented by UNDP, at affordable cost through a value for money service proposition.

The UNDP Global Fund procurement architecture comprises several partnership and sourcing agreements with other UN Agencies, manufacturers and other commercial entities as described in subsequent sections of this Manual. The main principle to follow is that for each specific product category a standard sourcing mechanism has been established. The UNDP Global Fund **Procurement Planning Tool** can be used as further reference for requesting units to easily identify the standard sourcing mechanism and partner applicable to each category of spending.

Risk Management

In its role as Principal Recipient (PR), UNDP is legally accountable for programme performance, including the activities and effectiveness of its employees, Sub-recipients (SRs), all subcontractors, sub-subcontractors, as well as commercial suppliers, including those for pharmaceuticals.

UNDP's vision for procurement is that it be a fully recognized, end-to-end management practice, integrated into programmes and implementation modalities. Procurement should be carried out by a cadre of highly qualified personnel, utilizing best practices to achieve value for money in the most cost-effective and efficient manner, while minimizing risk, amplifying transparency and accountability, and fostering development results.

In relation to each existing and new grant, UNDP requires that there be a detailed mapping and analysis of the organization's responsibilities and the corresponding capacities of each CO to effectively manage the associated accountabilities and risks.

Procurement of Pharmaceuticals and other Health Products

Pharmaceutical Products

Sourcing through UNICEF Supply Division

UNDP Principal Recipients (PRs) are advised by the UNDP Bureau for Management Services (BMS) and the UNDP Global Fund/Health Implementation Support Team, UNDP Bureau for Policy and Programme Support (BPPS), to procure their pharmaceutical products via **Standard Service Agreement (SLA)** established with the United Nations Children's Fund (UNICEF) Supply Division. The rationale for this is the various value-added services provided by UNICEF, such as:

- Technical expertise, management and supply services, including warehousing, quality assurance and quality control in compliance with **Global Fund policies on procurement and supply management of health products**, the **WHO's Good Manufacturing Practice** and **WHO Good Distribution Practices**;
- value for money, as costs are negotiated based on aggregated procurement volumes and volume discounts are obtained where applicable;
- transparency afforded by competitive processes in line with United Nations procurement procedures; and
- strong logistic services and capability, with contracted deliveries under CIP Incoterms with delivery to main airport/port of entry into country.

Relevant documents, including the **UNICEF UNDP Guide**, the **UNICEF cost estimate (CE) request template** and other documents are accessible **here**.

The following exceptions apply to the guidance to source pharmaceutical products through UNICEF Supply Division:

- **ARVs of Tenofovir + Lamivudine + Efavirenz (300/300/600 mg) (TLE) formulation.** In view of the relative large UNDP intake for this ARV formulation, UNDP has developed and manages a system of Long-Term Agreements (LTAs) with all manufacturers that meet the minimum Global Fund quality assurance requirements for this product. Requesting units are advised to source any TLE needs through the UNDP LTAs. The LTAs, together with a set of comprehensive standard operating procedures (SOPs) are available **here**.
- **Emergency procurement of ARVs**. UNDP has developed a procurement planning methodology to assist Country Offices (COs), Project Management Units (PMUs) and any other requisitioning units with a proactive planning of procurement actions leading to timely arrival and in-country distribution of required products to avoid any possible stock out risk. Attention to adequate procurement planning is strongly encouraged in order to prevent the need to resource to emergency procurement actions that may lead to sub-optimal value for money propositions.

However, circumstances may arise, when there is a need to resource to activation of emergency procurement actions to avert any possible ARV stock out at country level placing patients at risk. These may include new grant approval processes for which financial disbursements are delayed, ad-hoc requests received from National Counterparts, etc. In such cases, the option of UNDP directly conducting the corresponding ARV procurement processes, instead of sourcing through UNICEF Supply Division can be activated. Since this is an exception to the standard procedures, such action requires prior approval by the UNDP Global Fund/Health Implementation Support Team.

Anti-tuberculosis medicines

First-line medicines

UNDP has developed and manages a system of LTAs with manufacturers that meet the minimum Global Fund quality assurance requirements for first-line TB medicines. Requesting units are advised to source any first-line TB medicine needs through the UNDP LTAs. The LTAs together with a set of comprehensive SOPs are available **here**.

As a back-up option to the existing UNDP LTAs, requesting units can also source their first-line TB medicines needs through the Procurement Services Unit (PSU)/Global Procurement Unit (GPU). However, since this is an exception to the standard procedures, such action requires prior approval by **Cécile Macé** with the UNDP Global Fund/Health Implementation Support Team.

Second-line medicines

All second-line anti-TB medicines shall be procured in adherence to the Global Fund 13th Board Decision of 2006. To limit resistance to second-line TB drugs, and to be consistent with the policies of other international funding sources, all procurement of medicines to treat multi-drug resistant TB (MDR-TB) financed by the Global Fund must be conducted through the Green Light Committee (GLC) of the Stop TB Partnership.

To procure second-line TB drugs, an application must be submitted to the WHO Global Drug Facility (GDF), which is the GLC's procurement arm. To access the application, please visit **this page** and click on the "Direct Procurement Request Form Medicines". The GDF facilitates GLC reviews of applications from potential Directly Observed Treatment Short-course (DOTS) Plus pilot projects. The GLC review determines whether applications are in compliance with the **Guidelines for Establishing DOTS Plus Pilot Projects for the Management of MDR-TB**. The application must be completed in English along with the MDR–TB Procurement Request Form and Technical Agreement (MPTA) and submitted to GDF. The MPTA template can be provided by GDF, and specific instructions will also come from GDF, which works via a procurement service agent to deliver the drugs. Procurement of second-line TB drugs is channelled via the International Dispensary Association (IDA) foundation. GDF might change procurement agents from time to time, based on the outcome of the competitive procurement process. The UNDP Global Fund/Health Implementation Support Team will inform the COs accordingly.

Antimalaria medicines

UNDP has developed and manages a LTA with Novartis for the supply of Coartem under several presentations. Requesting units may choose to source this product through the SLA with UNICEF Supply Division, which is often able to offer alternative options to meet the needs based on generic products meeting the minimum quality assurance requirements. However, requesting units shall note that Novartis presently remains the sole WHO prequalified option for the supply of Atemether / Lumefantrine (80/480 mg) 6 tablet based treatment. Therefore requesting units are strongly encouraged to source any needs for this specific formulation through the existing UNDP LTA. The LTA, together with a set of comprehensive SOPs is available **here**.

Sourcing through Commercial LTAs (back-up) system

In the event that the pharmaceutical products required are not included in the **UNICEF Supply Division online catalogue** or the UNICEF Supply Division informs the UNDP CO in writing of its inability to provide antiretrovirals (ARVs), antimalarials or other essential medicines, the CO/PMU must provide proof that UNICEF has not responded in a timely manner to its request. The CO, acting as Global Fund PR, must inform the PSM focal points of the Global Fund/Health Implementation Support Team and request clearance to approach commercial long-term agreement (LTA) holders. Further information on current LTA holders and applicable SOPs can be found **here**.

Upon receiving clearance from the Global Fund/Health Implementation Support Team, COs are obligated to solicit quotes from all commercial LTA contract holders selected for the category of supplies. Within seven working days, the Global Fund/Health Implementation Support Team must evaluate the offers before they can be placed by the CO.

The above-mentioned conditions do not apply to the purchase of Coartem and Coartem Dispersible, produced by Novartis (UNDP COs are to purchase Coartem and Coartem Dispersible directly via the active **LTA between UNDP and Novartis**).

Non-pharmaceutical Health Products

Reproductive health commodities (including condoms)

UNDP Country Offices (COs) are advised to procure this category of products via the United Nations Population Fund (UNFPA). All items in the **UNFPA catalogue** can be procured through UNFPA.

According to the latest Standard Operating Procedures (SOPs) for using commercial long-term agreements (LTAs), there are some cases when COs can approach commercial LTAs—namely, when:

- UNFPA cannot provide the product in time, with specific labeling and language requirements, or in the volume or unit size required; and
- UNFPA has not responded within two weeks of the request for a cost estimate being made.

The SOPs for using commercial LTAs can be found **here**.

Diagnostic*/laboratory/medical supplies, consumables and equipment

UNDP COs/PMUs are advised to procure this category of products via the UNDP Procurement Services Unit (PSU)/Global Procurement Unit (GPU) through the existing **Service Level Agreement (SLA)** between the UNDP Global Fund/Health Implementation Team and PSU/GPU. UNICEF and the commercial LTA holders can be used as a backup option under the same conditions as mentioned in SOPs for using commercial LTA holders. If the situation warrants it, the UNDP CO may undertake its own competitive process, upon consultation with and prior approval from the UNDP Global Fund/Health Implementation Support Team.

*For a number of rapid diagnostic tests (RDTs), WHO LTAs are available for direct use by UNDP. These LTAs may be considered as an alternative option for use by requesting units upon consultation with and prior approval from the UNDP Global Fund/Health Implementation Support Team.

Blood-related items

UNDP COs are advised to procure this category of products via UNDP PSU/GPU, with technical support (drafting of specifications and assistance in technical evaluation) from WHO's Blood Transfusion Safety, Department of Essential Health Technologies or from laboratory experts included in the pre-approved **Health PSM Expert Roster**. Requests for activation of roster support should be forwarded by interested business units to **alfonso.buxens@undp.org**.

Bed nets

UNDP COs are advised to procure this category of products via the UNICEF Supply Division.

Indoor residual spraying

UNDP COs are advised to procure this category of products via UNDP PSU/GPU.

When procurement actions are channeled through any of the options outline above, COs do not need to enter into separate tender exercises for price comparison purposes or to obtain further internal approvals (Contract, Asset and Procurement (CAP) and/or Advisory Committee on Procurement (ACP) approval). These processes have already been completed prior to the establishment of those LTAs, by the respective organizations/units, in accordance with their internal United Nations procurement rules and regulations.

It is important, however, for requesting units to observe the SOPs developed by the UNDP Global Fund/Health Implementation Support Team for each of the sourcing options outlined above and to consult with the Team on any questions that may arise. It is equally important to adhere to the reporting instructions provided to ensure that the Team is able to properly monitor the use of LTAs, as requested by UNDP Chief Procurement Officer (CPO), PSU and Bureau for Policy and Programme Support (BPPS) Senior Management.

When neither United Nations agencies nor the above-mentioned commercial LTA holders can assist with procurement, alternative arrangements will need to be made to procure products compliant with the **Global Fund Quality Assurance (QA) policy**. In this case, the UNDP Global Fund/Health Implementation Support Team will need to be informed and will then advise on how to proceed.

Other Elements of UNDP's Procurement Architecture

In addition to the options describe in previous sections of the Manual, that enable procurement of pharmaceuticals and other health products to meet the needs of Global Fund grants implemented by UNDP, UNDP has developed a number of complementary bespoke supply systems of interest to requesting units. The area as follows:

In the area of Quality Control, which is an integrated dimension of quality assurance (QA), the following long-term agreement (LTA) frameworks are available for use:

- Set of LTAs with WHO prequalified laboratories for the provision of pharmaceutical sample testing. The LTAs and corresponding standard operating procedures (SOPs) are available **here**.
- LTA for the supply of dataloggers to ensure adequate temperature monitoring of shipments, in-country distribution and storage. The LTAs and corresponding SOPs are available **here**.

LTAs for the supply of heat resistant paint. Useful in situations when UNDP is promoting sustainability by reduction of cooling energy needs. The LTAs and corresponding SOPs are available **here**.

UNDP has also established a **pre-approved roster** of health procurement and supply management (PSM) Experts & LTAs with specialized Individual Consultants. The pre-approved roster was approved by the UNDP Chief Procurement Officer (CPO) in September 2015 for a three year period and enables quick deployment of vetted and reputed experts within the thematic areas outlined below:

1. PSM quantification, forecasting and planning experts
2. Quality Assurance experts
3. Experts in the design of Health PSM strategies and systems
4. Experts in the evaluation and risk assessments of health supply chains
5. Health related procurement process experts
6. Logistics & Logistics Management Information System (LMIS) experts
7. Experts in regulatory authorities & IPRs for pharmaceuticals & health commodities
8. Pharmaceutical and laboratory supplies experts
9. Medical equipment and supplies experts
10. Health infrastructure PSM experts
11. PSM capacity development and training experts
12. Health warehousing, inventory and stock management experts
13. X-ray, scanning and radiological equipment experts
14. Sustainable Energy experts in the health sector
15. Epidemiology PSM experts
16. Waste Management Experts
17. Pharmaceutical and Health policy and financing

Further information on the roster can be found in the **guidelines for use of the Health PSM Expert Roster**.

Procurement of Non-health Products and Services

For the procurement of non-health products (e.g. vehicles, office supplies, furniture) and services (e.g. rehabilitation or construction services), the standard **UNDP Procurement Rules and Regulations** apply. UNDP Country Offices (COs) are encouraged to use existing long-term agreements (LTAs) to facilitate procurement of non-health products and services. A consolidated list of available LTAs can be accessed **here**.

Strengthening of PSM Services and Risk Mitigation

To strengthen procurement and supply management (PSM) services and risk mitigation, the UNDP Procurement Services Unit (PSU) and the UNDP Global Fund/Health Implementation Support Team have entered into commercial long-term agreements (LTAs) for insurance and freight. Use of these LTAs does not require further internal approvals (via Contract, Asset and Procurement (CAP) and/or Advisory Committee on Procurement (ACP)).

Information on the current LTA holders for insurance and freight can be found **here**.

Stock-out and expiration risk management are the responsibility of the Country Office (CO), which must regularly monitor the Global Fund health products stock status. This includes close monitoring of the consumption rates, of stock on hand and on order, and of expiry dates of products in stock so that the CO can make informed decisions and take the necessary actions to avoid emergency orders, stock-outs and expiration of products.

Practice Pointer

COs are advised to monitor supply chain management indicators and expiry of products at least quarterly, using the provided monitoring tools, and to submit completed tools to the PSM team at least once a year, or as indicated by the PSM team in communications to the COs.

For further information, the UNDP PSU or the UNDP Global Fund/Health Implementation Support Team will need to be informed in order to advise on how to proceed.

Global Fund direct payment method

The Global Fund offers the opportunity for direct payments of grant funds to third parties (rather than to the Principal Recipients (PR)), and this service is primarily used for procurement of health products. However, UNDP cannot use the direct payment mechanism as it is not allowed by the UNDP comptroller.

Global Fund Pooled Procurement Mechanism option

The Global Fund launched the Pooled Procurement Mechanism (PPM), with the aim of obtaining better prices for quality-assured health products by leveraging the Global Fund's position to influence market dynamics.

Generally, the use of the PPM is voluntary for Global Fund PRs; however, for UNDP COs acting as PR, the PPM is not an option, as it is not allowed under current **UNDP Financial Regulations and Rules** or **procurement procedures**.

Overseeing procurement by Sub-recipients

UNDP has determined that direct procurement by Sub-recipients (SRs) constitutes significant organizational and operational risks to UNDP, for a number of reasons, including the process itself, the amount of money involved, the risk of procuring sub-standard products, paying too much and the potential for fraud. As a result, UNDP does not permit SRs to procure health products for their activities. Procurement within the framework of **SR agreements** should be limited to minor office supplies and other similar items of limited value, as well as services. Capital assets should be procured by the CO. In no instance should the SR be authorized to procure for more than 10 percent of the SR agreement's amount or US$100,000 (whichever is less) on procurement.

Development of List of Health Products and Procurement Action Plan

The Global Fund requires all Principal Recipients (PRs) to have a detailed approved **list of health products**, with quantities and costs, including any and all related procurement and supply management costs before any funds are spent on pharmaceuticals or other health products. The list of health products, quantities and costs is incorporated into the standard template, which is aligned with the detailed budget template. The PR should also attach supporting documentation with the relevant quantification, hypotheses and assumptions used to calculate the quantities listed. The list constitutes the basis of a **Procurement Action Plan (PAP)** that should be developed by the Country Office (CO) as soon as possible—preferably before the programme begins.

The PAP needs to be reviewed and updated by the CO every year. COs that implement Global Fund grants are not required to submit a CO's PAP that also includes a PAP for Global Fund grants. An annual PAP for Global Fund grants is prepared separately by the Project Management Unit (PMU) and sent to **alfonso.buxens@undp.org** for consolidation of the global procurement forecast and monitoring. Some pharmaceutical and other medical products have long lead times, and orders need to be placed at the beginning of the programme.

As the PR is not allowed to purchase pharmaceuticals or other medical products prior to approval of its **list of health products, quantities and costs**, delay in preparation of this key document and the PAP can delay programme implementation. The list should be developed according to the **template** prescribed by the Global Fund.

Practice Pointer

For successful procurement and supply management (PSM) implementation, the COs need to take into consideration and to avoid some of the common mistakes in procurement plans that have been reported by the Global Fund, as follows:

- Lack of specificity about which entities are responsible for each aspect of the PSM chain.
- Lack of information about the distribution and storage of products.
- Lack of details about quality assurance and quality control.
- Lack of due diligence with regard to verification of product compliance with the **Global Fund Quality Assurance (QA) policies**, especially for pharmaceuticals and diagnostics.
- Lack of attention to intellectual property rights laws.
- Lack of attention to rational drug use.
- Failure to include a forecast or explanation of how quantities were determined.
- Inappropriate 'cutting and pasting' from the procurement plan of another office without an analysis of the specific problems in the country where the PSM is being implemented.

The list must be approved by the Global Fund during the grant-making process before any expenditure on pharmaceuticals or other health products can be made, unless a waiver is obtained in advance from the Global Fund.

Selection of Pharmaceutical Products

Global Fund resources may only be used to procure medicines that are listed in national, institutional or WHO standard treatment guidelines or essential medicines lists.

Preferably, the pharmaceutical products should be selected from national standard treatment guidelines. WHO and other international health agencies have recommended treatment guidelines for HIV/AIDS, TB and malaria, which can be very helpful to countries in developing their own guidelines. However, it is important that national guidelines be adopted to address local requirements and to provide national ownership of the treatment standards.

If national treatment guidelines or lists of essential medicines are not available, and cannot be developed within a timeframe consistent with the project's needs, Country Offices (COs) can use such guidelines or lists developed by a national institution such as a National AIDS Council or National Malaria Control Programme.

If neither national/institutional guidelines nor essential medicines lists are available, then selection can be based on WHO-recommended treatment guidelines and/or lists of essential medicines.

WHO treatment guidelines and list of essential medicines can be found at the following sites:

- **WHO Prequalification Programme**
- WHO **Model List of Essential Medicines**
- Scaling up antiretroviral therapy in resource-limited settings—**treatment guidelines for a public health approach**
- **Guidelines on care, treatment and support** for women living with HIV/AIDS and their children in resource-constrained settings
- Treatment of Tuberculosis: **guidelines for national programmes**
- WHO **TB page and publications**
- Anti-malarial drug combination therapy—**Report of a WHO Technical Consultation**
- **WHO malaria publications**
- **A strategic framework for malaria prevention and control during pregnancy in the Africa region**
- New **WHO guidelines for ART** (June 2013)
- **Guide to Global Fund Policies on Procurement and Supply Management of Health Products**

Once it has been decided which standard treatment guidelines or essential medicines list will be used, the following steps should be taken to develop the list of products:

1. Identify all products selected by generic names.
2. Cross-reference with the Global Fund quality assurance policy to ensure compliance.
3. Confirm whether it is possible to purchase products in fixed-dose combinations, once-a-day formulations or blister packs.
4. Confirm if products are registered in-country by the national drug regulatory authority. If not, explore the possibility of fast-track registration or a temporary waiver of registration if the product has been prequalified by WHO.
5. Confirm that there are no intellectual property obstacles to purchasing any products on the list.

Patent Issues

Determining the intellectual property and patent status of medical products is a complex task that may require support from UNDP HQ or external resources. While Global Fund policies allow grant funds to be used to contract an intellectual property consultant, if needed, for non-Global Fund engagement, such as procurement services to governments and/or other parties, please consult with the UNDP Global Fund/Health Implementation Support Team.

A patent is an exclusive right granted for an invention, a product (i.e. a drug, an active ingredient) or a process (i.e. manufacturing) that provides a new way of doing something or offers a new technical solution to a problem. A patent provides its owner with protection for the invention for a limited period—generally 20 years. Each country (or region, where applicable) has its own patent laws, and a product that is patented in one country may not be patented in another. For example, a patent may exist in an exporting country but not in the importing country or vice versa. The national or regional patent situation will directly affect what products can be procured from which suppliers and what scope there will be for negotiation on prices.

A country may also be subject to regional patent laws. For example, 17 countries in Western and Central Africa are members of the African Organization of Intellectual Property (OAPI), which has issued patents for many antiretroviral products that are enforceable in its Member States. Nine former Soviet Union countries are parties to the Eurasian Patent Convention and recognize Eurasian patents issued by the **Eurasian Patent Organization**, including those issued for pharmaceuticals.

To initiate a patent search, the enquirer must know the international nonproprietary name (INN), the name of the patent owner (i.e. originator, inventor, university) or the name of the license-holder and the exporting and importing country/countries in question.

The basic steps for resolving the patent status of medical products are as follows:

1. **Determine if the country has patent laws providing for the enforcement of patents for pharmaceutical products.** Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO), all Member States, except least developed countries (LDCs), were obligated to enforce the patenting of pharmaceutical products by 1 January 2005. LDCs have been granted an extension of the waiver on pharmaceutical products until 1 January 2033, further to the previous extension until 1 January 2016. However, almost all LDCs have begun to allow the patenting of pharmaceutical products, so it should not be assumed that there is no patent problem simply because the pharmaceuticals being bought are for an LDC. If an LDC has a patent system, it must publicly elect not to enforce those laws in order to comply with the TRIPS Agreement invoking non-recognition and non-enforceability of patents and data protection. LDCs should complete a declaration that affirms that they are utilizing the transition period for implementing the minimum requirements of the TRIPS Agreement for pharmaceutical patents.

   If it is determined in step 1 that there is no patent law for the patenting of pharmaceutical products, then there is no in-country obstacle to purchasing generic medicines, whether imported or procured locally.

   Tools that are available in the public domain to assist in patent searches include the **Medicines Patent Pool database**. Currently, however, they are limited to antiretrovirals and selected hepatitis drugs.

2. **If it is determined in step 1 that the country provides patent protection to pharmaceutical products, then the enquirer must determine if any products on its procurement list are patented or receive patent protection.** To determine which products are patented, COs should request that the patent office conduct a patent search. Information on whether a product is patented or not should be public; however, if the patent office is unable to provide a conclusive answer, then the CO should consult the UNDP Global Fund/Health Implementation Support Team and consider contracting a patent lawyer or a patent representative to conduct the search.
3. If it is determined in step 1 that there is no patent law for the patenting of pharmaceutical products, then there is no in-country obstacle to purchasing generic medicines, whether imported or procured locally.
4. **If it is determined in step 2 that some of the products on the list are, in fact, patented, it must then be determined whether the patents are valid.** To be valid, patents must comply with national law and the patent-holder must comply with national administrative requirements for maintaining the patent. The latter usually requires the patent-holder to pay a maintenance fee (generally on an annual basis). Failure to pay this fee in a timely manner could result in the patent lapsing.

5. **If there are valid patents on any of the products on the procurement list, determine if the country can utilize any of the flexibilities in the TRIPS Agreement (commonly referred to as 'the TRIPS public health flexibilities') to legally purchase generic versions of the product.** The most common TRIPS flexibilities are voluntary licences, compulsory licences, government use orders, and parallel imports. Use of these flexibilities is consistent with international laws and allows the recipient country to legally purchase generic versions of patented pharmaceutical products. However, it is imperative that the flexibilities be correctly invoked by the relevant responsible governmental authorities to allow for their legal use.
6. **If there are valid patents on any of the products on the procurement list, and no flexibilities in the TRIPS Agreement or other measures to legally purchase generic versions of the product are found, the COs should procure the product from the patent-holder.**

Practice Pointer

A detailed description of how to utilize the public health TRIPS flexibilities to reduce the cost of medicines is provided in **Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement**.

Quantification

Once products have been selected, the quantity required for programme implementation will need to be determined. Quantifying drug needs is one of the most important parts of the procurement and supply chain. If drug needs are underestimated, it could lead to insufficient supply and interruption of patients treatment. If drug needs are overestimated, resources may be wasted, as pharmaceuticals have a limited shelf-life.

Quantification of pharmaceutical needs is usually based on one of the following methods:

- **Consumption**: This method is used if the products are being procured for an established treatment programme that has records of past consumption and predictable needs. The consumption method forecasts future needs by relying on past use and is adjusted for stock-outs, expiration of overstocked items and projected changes in utilization.
- **Morbidity**: This method is used for new drugs or programmes with no historical use, such as new antiretroviral therapy (ART) or artemisinin combination therapy (ACT) programmes. Initial projections must be based on morbidity if consumption data are absent. The method estimates the need for drugs based on the expected number of attendances, the prevalence or incidence of disease, and standard treatment guidelines for the health problem that is to be treated.
- **Health services capacity**: This method uses the morbidity method but adjusts it in light of a realistic estimate of the anticipated capacity to deliver services. This method is used for a new programme, such as ART, when the need for treatment is anticipated to exceed the number of persons that the programme can realistically treat during its initial stages. Drug needs will, therefore, be based on a target number of patients that the programme intends to treat. All projections must take health service capacity into account in their initial projections.

Quantification of pharmaceutical needs requires access to technical information about the recipient country's treatment programme and epidemiological data. To accurately quantify pharmaceutical needs, the following information is needed:

- The national guidelines for the disease for which the pharmaceuticals are being forecast, including the first- and second-line treatment, alternative treatment regimens for toxicity problems or patients with concomitant diseases (such as HIV and TB).
- The recommended dosage for each regime, according to patient weight.
- Country population and target population, broken down by age/weight.
- Resistance and toxicity rates (this information may be available at the local UNAIDS or WHO offices).
- Percentage of the population needing treatment that is likely to seek treatment or have access to a treatment centre.
- The annual pregnancy rate and number of institutional deliveries (if special treatment regimens exist for pregnant women).
- The percentage of the treated population that has a concomitant disease that would require an alternative treatment regime (such as persons who are HIV-positive and infected with TB).
- Prior consumption data broken down by health facility, number of patients, gender, weight, distribution, and other factors (if using this method).
- Country capacity to provide treatment.

In some countries, complete epidemiological data are not available, particularly if the country is at a low level of development or has been experiencing internal conflict. Countries experiencing internal conflict may have a high rate of immigration and returnees and may not be able to obtain accurate population estimates.

If some of the aforementioned information is not readily available, countries should make their forecasts based on the information they have, then closely monitor consumption rates, adjusting them as more information becomes available.

Many pharmaceutical products are purchased from international sources, and delivery times of three to four months from the placement of the purchase order are standard. Do not wait until products are almost out of stock before ordering the next supply. Accurate quantification, monitoring of consumption levels, establishment of minimum stock levels (the point at which re-ordering must happen) will prevent stock-outs and ensure continuity of treatment.

Forecasting

Once quantification has occurred, it is necessary to determine when and in what quantities orders should be placed. The most important factor in this determination is the lead time for a product, which is the length of time between placing an order and actually receiving the product in question. When ordering products, the following factors must be taken into account:

- **The supplier's lead time**: A lead time of three to four months from the placement of the purchase order is common for pharmaceuticals bought internationally. However, extreme shortages of some products (such as Coartem and long-lasting insecticide-treated nets (LLINs) during 2012) have increased lead times for these products to as long as a year. At the beginning of the project, procurement officers should obtain estimates of lead times for various products to ensure that they will be received when needed. Initial orders will be based on these estimates, but subsequent orders should be based on the actual experience with prior orders.
- **Lead times for the procurement process:** These will vary, depending on whether the procurement officer intends to conduct open competitive bidding, limited competitive bidding, direct contracting, or shopping. The procurement officer determines in advance the appropriate process for each product and estimates the time it will take, taking into account any necessary reviews by the local contracts committee or the Advisory Committee on Procurement (ACP). The use of long-term agreements (LTAs) reduces the processing lead time considerably.
- **Distribution**: It is also necessary to determine how long it will take for the product to be available to the end user. This estimate includes the time for customs clearance, inspections and transfer from a central warehouse to the local facility from which the product will be disbursed to the user.

Forecasting must also factor in the shelf-life of the product and storage capacity, bearing in mind the following:

- Some products, such as bed nets, require a lot of storage space, so more frequent deliveries may be needed.
- Some products may need a cold chain.
- Some diagnostics have a short shelf-life, which may also require more frequent deliveries.

Quantification and forecasting **should always be done in basic units**—tablets, vials or capsules. This makes it easier to track consumption needs and to compare the prices of different suppliers.

The quantifications should be broken down into monthly needs. If the coverage is expected to be equal throughout the year, the calculations can be made for one year then divided by 12 months. If, however, it is anticipated that coverage will increase as the programme scales up, then a new calculation will have to be made for each period in which coverage is expected to increase. Similarly, if, as is sometimes the case for malaria, there is a higher prevalence during certain months of the year, the calculations must reflect this.

When the above-mentioned estimates are added together, the procurement officer has a good idea of when to begin the procurement process. Using the **procurement planning tool** developed by the UNDP Global Fund/Health Implementation Support Team, the procurement officer should always start with the date when the end user needs the product and work backwards to determine when the procurement process should commence. Additional resources on procurement planning are available **here**.

It is also important that orders include a 'buffer stock' in case of any unexpected delays in the arrival of subsequent orders or losses due to expiration, theft, damage or other factors. Buffer stocks should be expressed in time periods, with four months minimum recommended for ARV, ACT and limited-supplier TB.

Lead time and buffer stock levels provide the basis for calculating the minimum stock levels, at which point re-ordering must take place at the various levels of the supply chain.

The Country Offices (COs) should monitor deliveries by regularly following up with the procurement partners through email, and by regularly monitoring the status of shipments in transit through **K&N's online tracking and tracing system**. The COs must contact the UNDP Global Fund/Health Implementation Support Team (**Alfonso.Buxens@undp.org**) for support in obtaining online access to the tracking system.

The COs can also develop their own tools for pipeline management.

WHO and partner organizations have developed a regularly updated online **PSM Toolbox** as a central repository for a wide range of health-related procurement and supply management (PSM) tools. The Toolbox can assist with quantification and forecasting exercises, in addition to other areas of a PSM plan. It is also available on CD-ROM.

Please refer to the UNDP online **PSM training** for further guidance on quantification and forecasting.

Global Fund Quality Assurance Policy and Plan

Quality assurance (QA) refers to the policies and procedures required to ensure that health products that reach patients are safe, effective and acceptable to the patient. For pharmaceutical products, this process involves, among other things, registration, prequalification and quality control.

- QA is an essential part of the procurement and supply management (PSM) activities for Global Fund grants. **The Quality Assurance Plan** (QAP) is the key reference document for all QA and quality control (QC) activities for pharmaceuticals under the Global Fund grants. Together with the PA plan and/or the Pharmaceutical and Health Products Management (PHPM) country profile and the Global Fund's **list of health products**, it provides the key information on quality assurance for medicines.
- QAP encompasses all activities that will ensure that the quality of pharmaceuticals is maintained along the supply chain until they reach the intended end users. It identifies objectives and key indicators for QA, specific QA activities, the budget related to all activities and the sources of funding.
- The sharing of the QAP with the Global Fund is a good practice.
- Each QAP will respond to the basic requirements of the **Quality Assurance Policy** of the Global Fund. From a risk-management perspective, the QAP is essential, since health commodities, bed nets and insecticides make up around 40 percent of the total grant value. Limiting risk for patients, health programmes, government, UNDP and the Global Fund in terms of the quality of these products is done by implementing the activities described in the QAP.
- The key elements of the QAP are captured in the UNDP QAP template. Each of the specific activities are to be entered in this template. Parts that, after consultation with all partners, are considered non-essential for the specific country context, can be deleted; others that require more attention can be expanded and more detailed, with new elements introduced, if required.

Key elements of the QAP include:

Introduction
Supply sourcing
Transport requirements
Transit
Receiving

Quality control of pharmaceuticals
Storage at peripheral level
Distribution
Storage at central level
Pharmaceutical waste management

Pharmacovigilance
Rational drugs use
Capacity development
Roles and responsibilities for medicines' quality assurance
Financing

Pharmaceutical Products

Pharmaceutical products procured with Global Fund resources must adhere to Global Fund **Quality Assurance Policy for Pharmaceutical Products**, issued on 14 December 2010 and amended on 5 February 2014.

Antiretroviral, anti-TB and antimalarial pharmaceutical products

For the aforementioned **pharmaceutical products** to be eligible for purchase with Global Fund resources, there must be compliance with the quality standards set by the Global Fund **Quality Assurance Policy**. Global Fund grant monies may only be used to procure antiretroviral (ARV), anti-TB and antimalarial pharmaceutical products that are classified as Category A (WHO-prequalified) or Category B (authorized by stringent regulatory authorities or SRAs).

Note: Only International Conference on Harmonisation (ICH) members, observers or associated members are recognized as stringent regulatory authorities. Pharmaceutical Inspection Co-operation Scheme (PIC/S) members are *not* considered to be SRAs. ICH members, observers and associates include: the European Commission (EU), the European Free Trade Association (EFTA), Australia, Japan, Norway, Iceland, Liechtenstein and the United States. For a full list of member countries, please refer to the **Global Fund Quality Assurance Policy**. For medicines used exclusively by non-ICH members, positive opinions or tentative approval under any of the following three special regulatory schemes are recognized as stringent approval:

- Article 58 of European Union Regulation (EC) No. 726/2004.
- Canada S.C. 2004, c. 23 (Bill C-9) procedure.
- United States of America FDA tentative approval (for antiretrovirals under the PEPFAR programme).

However, if the Country Office (CO) determines that only one or no Category A or B manufacturer can supply a sufficient quantity of products within 90 days of an order being placed (or longer, if this is acceptable to recipients), grant funds may be used to procure a product that is recommended by the **Expert Review Panel (ERP) of the Global Fund Secretariat**.

ERP recommendations are valid only for 12 months, and **these** products are included in the **Global Fund List of ARVs, anti-TB products and antimalarials.**

ERP recommendations for finished pharmaceutical products (FPPs) must be in effect when a Principal Recipient (PR) or Sub-recipient (SR) signs the purchasing contract, and purchase orders under these contracts may be placed for a maximum term of 12 months. An FPP is defined as a medicine presented in its finished dosage form that has undergone all stages of production and is packed in its final container and labelled.

Before the PR completes a purchasing contract for a product that falls within neither Category A nor B, COs are required to inform the Global Fund if they intend to procure ERP-recommended pharmaceutical products. This is done by submitting the **Notification Form** to their Fund Portfolio Manager (FPM) with a copy to the Global Fund Senior Quality Assurance Technical Officer. The Global Fund Secretariat will review the notification request and will issue a 'no objection' letter to the PR if it is accepted. Only at this stage can the CO proceed with the procurement.

When placing an order for an ERP-recommended product, and before shipment of the product, the CO must notify the Global Fund. This will enable the Global Fund to contract a third-party laboratory to conduct random pre-shipment quality-control testing. The Global Fund is responsible for paying for these services. The products cannot be shipped until the PR is notified by the Global Fund that the quality-control test results were acceptable.

The Global Fund does enforce the QA policy with corrective measures when non-compliance is proven. A PR is considered non-compliant if he or she does not notify the Global Fund of his/her intent to procure health products that do not fall under Category A or B drugs or notify the Global Fund of the need for quality testing of such products. The corrective measures depend on the severity of the non-compliance.

Other finished pharmaceutical products (FPPs)

All FPPs, other than antiretrovirals, anti-tuberculosis and antimalarial FPPs, need only to comply with the relevant quality standards that are established by the National Drug Regulatory Authority (NDRA) in the country of use.

Diagnostic Products

Diagnostic products procured with Global Fund resources must adhere to the **Global Fund Quality Assurance (QA) Policy for diagnostic products**, issued on 14 December 2010 and most recently amended on 4 May 2017.

Diagnostic products means all durable and non-durable in-vitro diagnostic products (IVD), imaging equipment and microscopes used for diagnosis, screening, surveillance or monitoring purposes.

Quality standards for diagnostic products

Section 7 of Global Fund QA Policy for diagnostics states that Grant Funds may only be used to procure diagnostic products that meet the following standards:

i. IVDs and imaging equipment manufactured at a site compliant with the requirements of ISO 13485:2003 or an equivalent quality-management system recognized by one of the regulatory authorities of the Founding Members of GHTF[1]; and

ii. any diagnostic product for which Section 7 (i) above does not apply, such as microscopes, manufactured at a site compliant with all applicable requirements of the ISO 9000 series or an equivalentquality-management systemrecognized by one of the regulatory authorities of the founding members of GHTF.

Section 8 of the Global Fund QA Policy for diagnostics states that, in addition to the requirements of Section 7 above, diagnostics products with regards to HIV, tuberculosis and malaria and to hepatitis B, hepatitis C and syphilis co-infections, as well as IVDs providing information that is critical for patient treatment of these diseases, such as testing for G6PD deficiency, shall meet any one of the following standards:

i. prequalification by the WHO Prequalification of In Vitro Diagnostics Programme; or

ii. for tuberculosis: recommendation by relevant WHO programme; or

iii. authorization for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (high risk classification)[2]; or

iv. acceptability for procurement using Grant Funds, as determined by the Global Fund, based on the advice of the WHO Expert Review Panel.

The **quality assurance page** on the Global Fund website provides further guidance on QA requirements and how to ensure that the most recent version of documents and templates are used.

[1] GHTF—the Global Harmonization Task Force—has now been replaced by IMDRF—the International Medical Devices Regulators Forum (conceived in February 2011). IMDRF members are: Australia, Brazil, Canada, China, European Union, Japan, the Russian Federation and the United States. IMDRF observers are: WHO and Asia-Pacific Economic Cooperation (APEC). IMDRF affiliates are: Asian Harmonization working party and the Pan American Health Organization (PAHO). For further information, see: **http://www.imdrf.org/**.

[2] This option is not applicable to RDTs for HIV-Self-Testing.

Non-compliance and Corrective Measures

There are two possible ways in which a Principal Recipient (PR) can breach the Grant Agreement by not complying with the **Global Fund Quality Assurance (QA) Policy**:

Level 1 non-compliance (no notification)

A PR has failed to send notifications required for the procurement of ERP-recommended products. However, the products procured complied with the QA policy.

Corrective measures for Level 1 non-compliance

After a Principal Recipient (PR) fails, for the first time, to send a notification for the procurement of a product that does not comply with Category A or Category B for a specific grant, the Global Fund will send the PR a warning letter. If the PR again fails to send notification for the same grant, the Global Fund may only disburse funds for pharmaceutical products directly to a procurement agent or a supplier for the remaining period of the Grant Agreement.

Level 2 non-compliance (non-compliant procurement)

A PR has failed to send notifications required for the procurement of ERP-recommended products, and the products procured do not comply with the QA policy.

Corrective measures for Level 2 non-compliance

If the PR, using grant funds, procures products that do not comply with the QA policy:

1. the PR must refund to the Global Fund the amount paid for the non-compliant products, and the Secretariat may deduct the amount from future disbursements under the grant, or from the amount recommended for the next grant, if the PR has applied for continued funding; and
2. for the remaining period of the Grant Agreement, the Global Fund will disburse all funds for pharmaceutical products directly to a procurement agent or a supplier.

PRs with a history of Level 2 non-compliance must provide evidence assuring the Global Fund of future compliance in order to obtain approval of the next grant. After a second instance of non-compliance, the Global Fund may stop funding for pharmaceutical products. In severe cases, the grant may be suspended or terminated.

Quality Control

Quality control (QC) is not the same as quality assurance (QA) but is an element of QA that refers to the testing of samples against specific standards of quality. The Country Office (CO) is responsible for quality control for all finished pharmaceutical products (FPPs) (including Category A and Category B products) along the whole supply chain, in accordance with UNDP and Global Fund guidelines.

The Global Fund Secretariat is only responsible for the quality control of the Expert Review Panel-recommended products once the notification of intent to purchase is received from the PR. Testing is performed by a third-party laboratory contracted by the Global Fund. Upon receipt of a successful result from the quality control of the products in question, the Global Fund will issue the **final letter,** including the test report, to the PR and the manufacturer concerned regarding product shipment.

The number of samples to be tested is to be prepared in the annual sampling plan, which is based on the annual procurement plan. Both random and targeted risk-based sampling is recommended at arrival and in the supply chain. The selection of samples to be tested should follow the guidelines in the template.

Practice Pointer

There is no reason for repeated random sampling in the supply chain for products that have been less than nine months in the country, unless specific risks have been identified. Over-testing is a waste of resources; however, appropriate testing must be done as part of the QA activities.

Approval of Quality Assurance Plans (QAP) takes time and, once the plans are approved, their implementation tends not to be a top priority for COs. The COs must implement the plans according to the calendar and to reserve and use the resources in QAP budget. The COs are requested to report progress quarterly to the PSM focal point of the UNDP Global Fund/Health Implementation Support Team.

Please to the Manual section on "**other elements of UNDP's procurement architecture**" for additional information on existing long-term agreements (LTAs) for pharmaceutical sample testing and inclusion of dataloggers in temperature controlled shipments.

Distribution and Inventory Management

Some of the key elements necessary to ensure that medical products actually reach the intended users are adequate storage and distribution systems. Existing public health storage facilities and distribution are the logistics channels of choice, if they are adequate or if deficiencies can be remedied during the programme. If not, then storage facilities run by non-governmental organizations (NGOs) and international organizations may be a viable alternative. It may also be possible to use private facilities and distribution networks run by commercial companies while public health facilities are improved.

Before medical products are procured, the Principal Recipient (PR) must verify the following:

- the storage space for the products is adequate with respect to volume as well as quality (clean, dry, not subject to excessive heat or light, temperature-controlled areas available, if needed, all storage areas free of rodents) and the facilities are secure, with storage areas assessed using the WHO **Guidelines for the Storage of Essential Medicines and Other Health Commodities**;
- there are inventory and information collection systems at each distribution and treatment site sufficient to monitor consumption rates and prevent diversion, stock-outs or expiration of products;
- the inventory and information collection systems are sufficient; if not, it may be necessary to use grant funds to procure/develop a computerized inventory and information collection system;
- distribution and inventory management systems include a mechanism to trace, by batch number, the patients to whom antiretrovirals (ARVs) and other sensitive drugs are distributed, in the event that the product is recalled; and
- all storage facilities and personnel use the ‘first expired, first out’ (FEFO) system.

The distribution network should be evaluated to ensure that there will be a constant supply of medicines. First, it is necessary to confirm the location and adequacy of the different distribution points needed, such as central medical stores, regional stores, local treatment sites etc. It is then necessary to identify any significant distribution challenges, such as the following:

- lack of adequate roads;
- seasonal problems such as flooding;
- areas of internal conflict;
- insufficient transport capacity; and
- long distances between distribution points.

The existence of one or more of these significant challenges will affect the next decision about the distribution network—namely, which method of transportation will be used. It may be a good idea to do a test run of the distribution route to estimate the delivery times and make sure that the route is adequate before starting out in a vehicle full of fragile products.

Once the products arrive, it is important to use the inventory and information collection system to monitor forecasts against actual consumption rates. Only by monitoring this information can stock-outs be avoided and a continuous supply of medicines guaranteed.

It is also important for the programme to do periodic audits and inspections of all points in the distribution chain. This will confirm that information is being accurately reported and to help prevent diversion of valuable commodities.

Rational use of Medicines and Pharmacovigilance Systems

The programme is responsible for ensuring that appropriate mechanisms are implemented to encourage adherence to treatment. This is usually accomplished by:

- incorporating, when possible, fixed-dose combinations, once-a-day formulations and blister-pack presentations of pharmaceuticals, which have been shown to increase patients' ability to adhere to treatment;
- providing peer education and support;
- using ICT materials as a tool to promote rational use;
- promoting rational prescribing practices; and
- conducting research and surveys and disseminating the findings to encourage rational use.

The Principal Recipient (PR) also needs to ensure that the health authorities responsible for administering the treatment programmes have systems in place for monitoring adverse drug reactions and resistance. If they do not have such systems, the programme should obtain advice from an international organization or a consultant with technical expertise in this area.

Price and Quality Reporting (PQR) System

The Price and Quality Reporting (PQR) system is a publicly accessible online database that collects and displays data on procurement transactions made by Global Fund-supported programmes. Data is entered by Principal Recipients (PRs) and verified by Local Fund Agents (LFAs). The objectives of the PQR include:

- to communicate market information to recipients and to inform budgets;
- to enable the Global Fund to benchmark prices achieved against international reference sources and relevant comparators;
- to identify value-for-money opportunities;
- to monitor compliance with the **Global Fund's Quality Assurance Policies**; and
- to build market intelligence and inform policy making.

Currently the Global Fund requires information for the following six product categories:

- long-lasting insecticidal nets and insecticides for indoor residual spraying activities;
- condoms;
- diagnostic products for HIV, TB, malaria and co-infections such as syphilis, hepatitis B and hepatitis C;
- anti-TB medicines;
- anti-malaria medicines; and
- antiretrovirals.

Purchases of products that do not fall within these six categories of products do not need to be entered.

The required data to enter into the PQR include: supplier or manufacturer data, dosage, unit cost, packaging information, shipping or other related costs, total cost of the transaction. **Data should be entered into the PQR upon receipt of consignment** using the best information available at the time (proforma invoice, supplier cost estimate, manufacturer's invoice, or final invoice). There is no need to wait for a final invoice before entering the data. If the data entered into the PQR is based on a cost estimate or pro-forma invoice and the final invoice differs significantly from the data entered, the Country office (CO) should update the data entries based on the newly available information in the final invoice. However, it is not necessary to update the PQR if the differences between final invoice and PQR data entries represent less than a 5% change in unit costs or if the differences are limited to freight, insurance, customs, duties or handling costs.

COs should follow the guidance detailed in the **Quick Guide to the Global Fund's Price and Quality Reporting System** (December 2014) when entering data in the PQR system. The Guide includes step-by-step guidance, frequently asked questions and various examples.

Practice Pointer

In verifying the entries in the PQR for accuracy and completeness the LFA would generally expect to see scanned invoices in the "Attachments" Section of the PQR. However, as per UNDP policy and internal UNDP regulations detailed in the **Global Fund/LFA Access To Information Guidance Note**, COs shall not share or show procurement documentation such as:

- invoices paid by UNDP or any other UN agency;
- cost estimates;
- quotations;
- contracts for goods and services;
- delivery notes signed with a UN agency, clearing documents and bills of lading; and
- payment vouchers or supplier invoices for UN.

Therefore, COs should not upload such documents into the PQR. Instead, **COs should complete an Excel spreadsheet (see an example here) containing the requested information, obtain the signature of the Procurement and Supply Management (PSM) Specialist or the Programme Manager, and upload it in the "Attachments" section of the PQR. It is recommended that the spreadsheet is reviewed internally prior to data entry into PQR.** The accuracy of the spreadsheet presented to the LFA is extremely important, and inconsistencies and/or inaccuracies may result in disbursement delays.