UNDP Global Fund and Health Implementation Guidance Manual

- Health Product Management –

Contents

1. Overview: Health Product Management

1.1 Introduction

The main objective of the Health Product Management (HPM) section of this Guidance Manual is to facilitate and guide the implementation of Procurement and Supply Chain Management (PSM) activities **for health products** in alignment with UNDP's, and the Global Fund's, PSM-related policies and procedures. These include the **UNDP Quality Assurance (QA) Policy, Global Fund PSM Policies** and **Health Procurement Architecture** established by the UNDP Global Fund Partnership and Health Systems Team (GFPHST).

This section is intended to guide UNDP Country Office (CO) PSM managers, PSM specialists and Procurement specialists in charge of implementing, managing and/or supervising PSM activities for health products financed by Global Fund grants and/or other sources of funding. This section also guides UNDP's global support activities, in particular the work of Global Fund Partnership and Health Systems Team (GFPHST) HPM specialists and other personnel in the UNDP Global Health Procurement Centre (GHPC), to provide technical support and carry out procurement responsibilities.

The HPM section includes a risk management paragraph that details the key risks that a UNDP Country Office (CO)/Project Management Unit (PMU) may face during implementation and how to prevent or mitigate them.

Given the complexity and multiple stakeholders involved with HPM, GFPHST has developed a **RACI** (Responsible, Accountable, Consulted, Informed) matrix outlining the roles and responsibilities of the key stakeholders.roles and responsibilities of the key stakeholders.

Resources

- **UNDP Quality Assurance (QA) Policy**
- **Global Fund PSM Policies**
- **Health Procurement Architecture**

1.2 Definitions

Health Product Management refers to all activities required to ensure the continuous and reliable availability of quality-assured health products, to achieve programmatic targets, while adhering to the **procurement principles of UNDP**. It comprises six basic functions (Product selection, Forecasting/Quantification, Procurement, Storage and Inventory Management, Distribution, Rational Use) and is supported by management systems (Planning and administration, Organization and management, Information management, Human resources management) as well as policy and legal frameworks.

Health procurement, in the context of this document, refers to all activities associated with the sourcing and purchasing of health products.

Health products includes: (i) pharmaceutical products; (ii) diagnostic products; (iii) vector control products; and (iv) consumable/single-use health products, including products such as PPE, condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes.

Diagnostic products includes: any durable and non-durable in-vitro diagnostic product and microscopes and imaging equipment used for diagnosis, screening, surveillance or monitoring purposes.

In-vitro diagnostic products includes**:** a medical device, whether used alone or in combination with other devices, intended by the manufacturer for in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus and other articles (Global Harmonization Task Force Document SG1/N045:2008).

Medical device includes: any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Quality assurance, refers to all measures taken from manufacturing processes to selection and the use of health products, including Quality Monitoring, to ensure that the products are of the quality required for the manufacturer's intended (registered) use.

Quality control is one part of quality assurance and is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are carried out and that products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.

National Pharmaceutical Policy (NPP), most national health authorities have adopted their own NPP which defines the key principles and responsibilities for regulation and the quality assurance requirements for health products circulating in the country. The NPP is usually complemented by a *NPP implementation plan* which describes, for each policy component, the responsibilities and main activities.

National Regulatory Authority, is the national body that administers the full spectrum of regulatory activities for pharmaceuticals and other health products, including – for example – the following functions: Registration and Marketing Authorization, Pharmacovigilance, Market Surveillance and Control, Licensing Establishments, Regulatory Inspections, Laboratory Testing (Quality control), Clinical Trials Oversight, and NRA Lot (batch) Release.

Insecticide Treated Nets (ITNs): the umbrella term for all nets treated with an insecticide, insect-growth regulator and/or synergist. The term long-lasting insecticide treated net (LLIN) is only being used for ITN classes for which physical and chemical durability have been comprehensively demonstrated against the WHO thresholds of 20 washes and 3 years of use in the field. In practice, this means that only nets treated with a pyrethroid insecticide alone are presently referred to as LLINs in the WHO Guidelines. Other nets which are now prequalified include nets containing "a pyrethroid insecticide and the synergist piperonyl butoxide" (PBO nets), and nets containing "two active ingredients" (dual ai nets).

Resources

- **UNDP POPP: Procurement overview and principles**

1.3 Scope

The scope and the extent of UNDP's role in Health Product Management (HPM) activities are defined by the type of project:

- As principal recipient of a **Global Fund grant**, UNDP's responsibilities are significant in the sense that UNDP is accountable for the entire set of PSM functions, including product selection, ensuring the quality of the products up to end-users, supporting the rational use of products, and promoting/implementing proper destruction of waste generated throughout the system.
- For **other health projects** (i.e., health procurement projects), UNDP's responsibilities depend on the scope of the project, as defined by the project document. It might be limited to only procurement, international freight and reception, but could also cover areas such as quality control or storage.

The Country Office (CO) PSM Officer works with other staff to identify, quantify, procure, and manage the health products required to achieve the grant objectives. They do this with support from the HPM Specialists within UNDP's GFPHST and through collaboration with key stakeholders.

Key stakeholders may include government health programs, the National Regulatory Agency (NRA), the central medical stores, various funding entities, in-country supply chain partners, the UNDP Quality Assurance Services team, the UNDP Health Procurement Services team, and suppliers and manufacturers.

1.4 Guiding Principles for Procurement of Health Products

All UNDP procurement activities related to health products, regardless of the funding source, is governed by the same policies, rules and procedures. As such, the procurement of health products for Global Fund-financed projects, and the procurement of health products with other sources of funding (e.g., government, World Bank), should be executed in full compliance with **UNDP's Programme and Operations Policies and Procedures (POPP)**, the UNDP **Quality Assurance Policy for Health Products** (QA Policy), and in accordance with the **Health Procurement Architecture**.

The following principles guide UNDP health procurement activities:

- Provide the best value for money [1]
- Embody fairness, integrity, transparency
- Engage in effective international competition
- Serve the interests of UNDP

[1] Value for money (VfM) is about providing quality products and services that meet the end-users' needs and presents the best return on investment. VfM is often referred to as the 3Es—economy, efficiency and effectiveness—whereby economy means minimizing the cost of resources (doing things at a low price while complying with the UNDP's quality assurance policy to ensure the quality and safety of the products); efficiency means performing tasks with reasonable effort (doing things the right way, often measured as cost per output); and effectiveness means the extent to which objectives are met (doing the right things, often measured as cost per outcome).

Resources

- **UNDP POPP: Procurement**
- **UNDP POPP: Quality Assurance (QA) Policy**
- **Health Procurement Architecture**

1.5 UNDP Quality Assurance Policy

The **UNDP Quality Assurance Policy for Health Products** (QA Policy) was developed to assure the quality and safety of all health products procured and/or supplied by UNDP. The QA Policy is based on WHO norms and standards for medicines and other health products and is aligned with the QA policies of other UN agencies and international organizations.

The UNDP QA policy focuses on activities that must be built into the upstream Health Product Management (HPM) activities of selection, sourcing, procurement, pre-shipment inspection, sampling, quality control, and freight to ensure that the health products procured and/or supplied by UNDP meet the established minimum quality standards. However, the same principles which govern these upstream activities are applicable to activities which take place within countries, which ensures that products are supplied to recipients in accordance with the WHO norms and standards for health products.

Information contained within this section, together with the **Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain**, should guide the downstream HPM activities that UNDP COs implement – directly, through SR agreements, or through service contracts – to maintain and control the quality of health products, from the delivery point in country up to the end user. It also covers aspects related to rational use, pharmacovigilance and pharmaceutical waste management. Such activities influence the quality of treatment, the safety for the patient and the community, while safe management of health products waste contributes to the protection of the environment.

Implementing activities in accordance with these requirements reduces the risk of introducing substandard or falsified products into the supply chain, which can put patients at risk and damage the reputation of UNDP. ***Accordingly, all UNDP business units are required to carry out health procurement in compliance with the UNDP QA Policy***, which was approved by the Executive Group in July 2018 and included in the **UNDP POPP**.

The National (Drug) Regulatory Authority (NDRA) is the main actor for the regulation of health products in a country. The scope of operation of the NDRA is legislated and may only include pharmaceuticals, but increasingly NDRAs are also regulating medical devices. UNDP COs need to work closely with the NDRA to ensure that any action taken by the UNDP CO is in full compliance with the national regulations and policies.

The UNDP QA policy is independent from the **Global Fund QA policies**, and is broader than GF QA policies as it covers all types of medical products procured and supplied by UNDP (e.g., anti-cancer medicines, anti-diabetics, etc.). It is, however, aligned with GF QA policies and based on the same principles. Compliance with UNDP QA policy therefore ensures compliance with the GF QA policies.

UNDP COs are advised to designate one of the CO PSM officers as the Quality Assurance (QA) focal point for health products, tasked with ensuring that the CO operates in compliance with the UNDP QA policies and requirements for the procurement and supply management of health products.

[1] The WHO's **Model Quality Assurance Systems (MQAS)** for Procurement Agencies, describes the key QA responsibilities for agencies engaged in procurement and supply chain management of health products. and is the main reference areas included in this Manual.

Resources

- **WHO Model Quality Assurance system for procurement agencies**
- **UNDP POPP: Quality Assurance (QA) Policy**
- **Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain**
- **Global Fund QA policies**

(Upstream HPM activities)

2. Product Selection

2.1 Pharmaceuticals

All pharmaceuticals procured through UNDP health procurement support must be included in either the latest editions of the **WHO Model Essential Medicines Lists** (EMLs) for adults and for children, WHO treatment guidelines, or other institutional treatment guidelines.

For entities submitting requests to UNDP for the procurement of pharmaceuticals that are not included in any of these documents, the requests should be supported by an appropriate justification with supporting evidence (e.g., National Treatment Guidelines, National EMLs, transition plan with timelines). These will be assessed by the **UNDP QA Expert Committee** (additional information can be found in the UNDP QA Policy) to determine compliance with UNDP's general principle. Such requests should be submitted to the UNDP Global Fund Partnership and Health Systems Team (GFPHST) Senior Health PSM Advisor through the GFPHST HPM Specialist focal point.

All pharmaceuticals must be procured using the International Nonproprietary Name (INN).

While WHO has recommended treatment guidelines for HIV/AIDS, tuberculosis (TB), malaria and hepatitis, and these can be helpful to governments as reference for the development of national guidelines, it is important that national guidelines are tailored to local requirements and ensure national ownership of the treatment standards.

2.2 In-vitro Diagnostic (IVD) Products

All diagnostic products procured through UNDP health procurement support must be 1) in conformity with WHO guidance (e.g., **WHO Essential Diagnostic List** - EDL), 2) consistent with relevant national laboratory policies and strategic plans, 3) take into account harmonized and standardized practices (e.g., national testing algorithms), 4) consider the physical infrastructure and biosafety level of the laboratory, 5) must take into account the structure, functioning and capacity of the laboratory system (human resources, network, communication system, and specimen transport systems at and between each level of service), and 6) be effectively coordinated with laboratory services and other funding sources.

For entities submitting requests to UNDP for the procurement of diagnostic products that are not included WHO guidance, the requests should be supported by an appropriate justification with supporting evidence (e.g., National Testing Algorithm). These will be assessed by the **UNDP QA Expert Committee** to determine compliance with UNDP's general principles for the procurement of health products. Such requests should be *submitted to the GFPHST Senior Health PSM Advisor through the GFPHST HPM Specialist focal point*.

All diagnostic products must be procured using their generic name or description. Where 1) a National validated testing algorithm, or 2) Closed equipment testing systems that require reagents and consumables that are specific to a diagnostic platform, or 3) National standardized and harmonized practices exists, it may be permissible to procure using a brand (proprietary) name and/or specific product catalogue number. Using no or restricted competition requires prior approval from GFPHST HPM Specialists and, when grant funds are being used, from the Global Fund.

While WHO has recommended diagnostic and testing algorithms for HIV/AIDS, tuberculosis (TB), malaria and hepatitis, and these can be helpful to governments as reference for the development of national guidelines, it is important that national algorithms are established and are tailored to local requirements, ensuring national ownership of the guidelines.

Resources

- **WHO Model Essential Medicines Lists**
- **WHO Essential Diagnostic List**
- **WHO prequalified vector control products**
- **Global Fund quality assurance requirements**

2.2.1 Diagnostics for Research Use Only (RUO)

Research use only (RUO) products are products intended for research procedures and *not intended for the diagnostic or treatment management of patients*. RUO reagents and equipment are not subject to IVD or "medical devices" regulatory requirements and, thus, are not subject to evaluation for accuracy, specificity, precision, and reproducibility, and any evidence provided with RUO products is not certified by a regulatory or independent authority. Therefore, these items should only be used by experienced scientists, biologists and/or microbiologists in an authorized laboratory following strict procedures.

RUO reagents and instruments can only be procured and used for research use, including genomic sequencing purposes, and epidemiology purposes, and may not be used for in vitro diagnostic procedures.

Practice Pointer

it is possible that products, which seem identical, are available but that one is intended for clinical diagnosis while the other is intended for RUO. For example – "Applied Biosystems, QuantStudio 5 real-time PCR systems - A28570 (RUO)" vs "Applied Biosystems, QuantStudio 5 Dx Real-Time PCR System - A47326 (Clinical Diagnostics)".

Under exceptional circumstances, these reagents and instruments can be procured for diagnostic procedures (e.g., when no commercial IVD device exists or when an existing IVD does not meet patient-specific clinical needs); however, this requires documented validated procedures which are implemented by authorized qualified personnel in an authorized laboratory.

UNDP COs must ensure that they obtain the correct product specifications which are aligned with the "intended use/purpose" for the items which need to be procured and, where items are classified as "RUO" that they ***get written confirmation*** from the Government that 1) the RUO products being requested will be used for the intended purpose (i.e., for research use only), or 2) the RUO products being requested will be used for diagnostic purposes. If the latter, the Government must clearly define and articulate the conditions under which the RUO products will be used for diagnostic purposes. In both cases, the information *must be shared with the UNDP QA Team*; the UNDP QA Team will acknowledge the communication and will stipulate that the end-user is fully responsible for any off-label use of these RUO products.

Where the RUO equipment(s) and/or reagents(s) are financed by the Global Fund, the Principal Recipient must confirm to the UNDP QA Team that the RUO equipment(s) and/or reagent(s) have been approved for the stated intended purpose by the Global Fund, and that it is ***included in the approved grant Health Product Management Template*** (HPMT).

2.3 Vector Control Products

For vector control products, the products selected must conform with WHO guidance for the management of public health pesticides and should refer to the list of **prequalified vector control products** recommended by the Vector Control Group of the World Health Organization Prequalification Team (PQT-VC). This applies to: Insecticide Treated Nets (ITNs), Indoor residual sprays (IRS), Space sprays, Larvicides, and Other pesticides.

Furthermore, when procuring major equipment or personal protective gear, which is used for the application of vector control products, entities must ensure that the equipment complies with relevant WHO specifications.

2.4 Male and Female condoms

The specifications for male and female condoms and lubricants, purchased by UNDP COs, must be compliant with those outlined by WHO-UNFPA [1].

2.5 Other Products

All other health products (e.g., medical imaging, incinerators, oxygen generation and supply equipment, cold chain equipment, ambulances, personal protective equipment (PPE)) purchased with Global Fund grant funds, must comply with the technical and regulatory requirements recommended by WHO or other relevant normative agency.

[1] WHO-UNFPA Guidelines for Male Condoms Procurement, WHO-UNFPA Guidelines for Female Condoms Procurement and UNFPA-WHO specifications for plain lubricants

3. Quantification and Forecasting

Quantifying the requirements of health products is one of the most important parts of the procurement and supply chain management cycle. If needs are underestimated, it could lead to insufficient supply, stock outs and ultimately patient treatment disruption. If needs are overestimated, resources may be wasted, as health products have a limited shelf-life and over-stocking increases the risk of expiry.

The determination of health product needs is typically based on one of the following quantification methods:

- **Consumption:** This method is used if the products are being procured for well-established treatment protocols or uses that have 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 medicines or programmes with no historical use data, or for programmes with an expected change of consumption, due – for example – to an increase of patients (number of patients on ART usually increase as new HIV positive patients get enrolled). Initial projections must be based on morbidity data if consumption data is absent. The method estimates the needs 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.

All projections must take into account the health service capacity.

Accurate quantification of needs for health products in a given country and context requires access to technical information about the recipient country's treatment programme and epidemiological data. Supply chain, procurement and disease programme specialists should work together in quantifying and validating the products and quantities to be procured.

The key information and data that should be reviewed to determine products and quantities includes:

- National testing, treatment, and care guidelines for the relevant disease and/or protocols of care at time of submission. *Note: If the protocols are under revision, consider a transition plan (e.g. change of regimens, introduction of new paediatric formulations, shortened regimens for MDR, roll-out plan and timeliness, supply chain preparation for the transition*)
- Diagnostic testing and monitoring algorithm(s) for the relevant disease
- Baseline information, programme capacity and disease specific scale-up plans/targets for a defined period
- Existing investments in health equipment (e.g., GeneXpert): national strategy and information on use across programmes, long-term sustainability strategy for routine maintenance, repairs and services, and procurement of reagents and consumables
- National supply plan that reflects the schedule of all agreed financial (or product) contributions to the national needs over the grant period
- Integrated stock status report showing stock-on-hand and purchase order quantities (pipeline) for key commodities covering all sources, where applicable
- Buffer stock and rationale for inclusion in the calculations
- Country population and target population, broken down by age/weight

In some countries, comprehensive epidemiological data is not available, particularly in low-income countries or countries experiencing civil or national conflict. Countries experiencing conflict may have a high rate of migration, displaced persons and returnees and may not be able to obtain accurate population estimates. If some of the aforementioned information is not readily available, countries should quantify based on the information available, then closely monitor consumption rates, adjusting the forecast as more information becomes available.

4. Supply Planning of Health Products

Supply planning is a critical process to avoid stock-outs and treatment disruption, overstocks and wastage. Accurate quantification, monitoring of consumption levels, establishment of minimum stock levels (the point at which re-ordering must happen) will minimize the risk of stock-outs and ensure continuity of treatment and value for money.

Once the quantification of needs is completed, it is necessary to *determine when and in what quantities orders should be placed*.

The quantification outputs 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.

It is also important that orders include some **buffer stock** in case of any unexpected delays in the supply chain, such as delayed arrival of subsequent orders, unexpected changes in consumption levels, or programmatic changes. Buffer stock should be *expressed with time periods* and calculated based on both the agility of the national supply chain and any programmatic constraints.

The most important factor in this determining when orders should be placed is the **lead time** for a product or product category. The lead time is the length of time between confirming an order with a manufacturer/supplier and actually receiving the products at the service delivery point.

Lead time and buffer stock levels provide the basis for calculating the minimum and maximum stock levels; once stocks reach the minimum level, order should be initiated at the various levels of the supply chain.

Practice Pointer

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.

The following factors must be taken into account during planning:

Lead times for the procurement process: This includes the time from the business unit creating a request up until the time the purchase order is issued to the manufacturer/supplier. The procurement process lead time will vary depending on the selected procurement method (such as open competitive bidding, limited competitive bidding among LTAs holders, direct contracting, request for quotation, or micropurchasing. The procurement officer should determine, in advance, the appropriate procurement method for each product category and estimate the time it will take, according to the procurement policies and guidelines. This includes taking into account any necessary reviews by the local contracts committee, Regional Advisory Committee on Procurement (rACP), or the Advisory Committee on Procurement (ACP). *The use of the UNDP Health procurement architecture noticeably reduces the processing lead time, while ensuring compliance with the QA Policy.*

The **manufacturer's / supplier's lead time**: An average lead time of three to four months, from purchase order confirmation until products are made available to ship, is typical for health products purchased internationally. However, shortages (e.g., due to lack of availability of raw materials or production capacity) happen regularly, resulting in increased lead times. At the planning phase, procurement officers should obtain estimates of the current lead times for the different product categories to be procured to determine the time to launch the procurement and ensure that products will be received when needed. While initial orders will be based on these estimates, subsequent orders should consider prior experience.

Quality monitoring – **pre-shipment** inspection, sampling and testing: For most categories of products purchased through UNDP, pre-shipment inspection and testing is not recommended. For certain categories of products, the implementation of pre-shipment inspection and testing activities may be required, as a risk mitigation measure rather than as a quality assurance mechanism. Pre-shipment inspection with randomized sampling and testing is required for the following product categories: Finished Pharmaceuticals Products (FPPs) Recommended for Use by the WHO Expert Review Panel (ERP); In-vitro Diagnostic Products Recommended for Use by the WHO Expert Review Panel (ERP); Condoms, if the product selected is not listed in the UNFPA list; and all Vector Control products. The lead time for sampling and testing varies depending on the product category.

Shipping, delivery and logistics: It is also necessary to determine how long it will take for the various product categories to be available from the time the products are available "to ship" up to the "last mile" delivery point. This estimate includes the time for customs clearance, inspections, and transfer(s) from the central warehouse to the local facilities where the product will be issued to, or used by, the patient/client.

Practice Pointer

Quality monitoring – **post-shipment** inspection, sampling and testing: UNDP COs must perform post-shipment inspection at the time of the reception of the goods by visual inspection and review of import documentation that the products received are in line with the purchase order and the specifications. UNDP GFPHST does not advise conducting routine post-shipment quality control testing, except if the information collected, on transit and logistic conditions, during the post-shipment inspection indicates the likelihood of a risk on the quality or the performance of the products procured (e.g., temperature excursions during transit, extended periods at port without proper conditions).

Storage capacity: Some products, either due to their high volume (e.g., bednets, condoms) or particular storage conditions (e.g., cold chain products) may present challenges related to the available space/conditions in country and, therefore, the supply plan may need to be adjusted, such as through more frequent deliveries.

Shelf life of the product: Some products, particularly diagnostic products, have a short shelf-life (less than two years, or sometimes only one year) and therefore require more frequent deliveries.

When the above mentioned estimates are added together, the procurement officer has a good idea of when to begin the procurement process. The Health Procurement Action Plan (HPAP) is mandatory for all business units engaged in the procurement of health products, regardless of the funding source and the partner conducting health procurement (see **Health Procurement Architecture**). Using the relevant HPAP template (either **Global Fund** or **non-Global Fund** depending on the source of funding), the procurement officer should always initiate the procurement process based on the date when the end users need the products and calculate backwards based on the lead-time for each product or product category. Guidelines for creating the HPAP are available **here** and **here**.

Resources

- Template for Health Products
- Health Procurement Architecture
- Global Fund HPAP template
- non-Global Fund HPAP template
- UNDP Health Procurement Action Plan SharePoint homepage
- UNDP Health Procurement Action Plan SharePoint shared resources

4.1 Special Requirements for Narcotic and Psychotropic substances ("controlled substances")

Some pharmaceutical products – including those used in Opioid Substitution Therapy (OST) programmes – are placed under international control by the United Nations Conventions on Narcotic and Psychotropic substances.

The purchase, export, transportation, import in recipient countries of those products are strictly controlled by the authorities of the exporting and importing countries ("competent national authority") and by the International Narcotics Control Board (INCB).

Generally, the competent national authority, responsible for liaising with International Narcotics Control Board (INCB) and administering national regulations relating to controlled substances for medical use, is the national drug/pharmaceutical regulatory authority, which is usually part of the Ministry of Health. However, in some countries, this function may lie with another agency such as the Ministry of Interior or Ministry of Justice.

Every year, the competent national authority prepares an estimate of the amount of controlled substances that will be needed in the country during the following calendar year. When approved, the INCB publishes the list of the confirmed estimates for each country. The national estimates confirmed by INCB define the maximum quantity of drugs that a country may acquire through import and/or manufacture. If an annual estimate proves to be inadequate, the competent national authority can submit supplementary estimates to INCB during the course of the year.

Practice Pointer

The importation of controlled substances involves decision making and authorization from several departments/agencies, and the documentation and approvals required prior to shipping make procurement a slow and bureaucratic process. Therefore, it is ***crucial that strong coordination and partnerships are established*** among all such parties and that supply planning occurs well in advance of when the medicines are needed.

4.2 Special Requirements for Pesticides

Pesticides, including those incorporated into netting material, might be regulated by different agencies (e.g., NDRA, MoH, Ministry of Agriculture) within a country depending on their intended use. Before initiating a requisition, UNDP COs should be thoroughly familiar with the local customs procedures and requirements for importation of pesticides.

In countries with functional pesticide registration systems, customs clearance of registered pesticides usually requires close collaboration between the pesticides regulatory authority and customs. Customs offices often have information on the products that are registered and should be given advance notice of the impending arrival of a shipment of the pesticide products.

If coordination amongst stakeholders is weak or if the pesticide is not yet registered in the country, customs clearance may require importation to be authorized by another competent authority. In either case, it is useful to specify in the purchase contract the list of documents that must be provided by the supplier in order for the shipment to clear customs.

5. Sourcing & regulatory aspects

5.1 Global Health Procurement Center (GHPC)

The UNDP Central level Global Health Procurement Center (GHPC) comprises three teams

1. Health Procurement Services team (HPS);
2. Quality Assurance Services team (QAS); and
3. Health Product Management Services team (HPMS).

The three teams work together to deliver on all health procurement projects across the organization.

The GHPC is co-managed by BMS Office of Procurement (BMS/OP) and BPPS Global Fund Partnership and Health Systems Team (GFPHST), and integrates the up- and downstream functions of delivering health products and supply-chain management services to UNDP country offices and business units. Support to country offices include quality assurance for health products, establishment of contracts, sourcing, contract and vendor management, freight, in-country management and delivery services, while incorporating sustainability considerations in all service provisions.

The functions of the 3 teams are:

1. **Health Procurement Services team (HPS)**

   The HPS Team is responsible for category management, support to COs, managing requests for non-standard / non-routine / complex products and services, providing tailored cost-effective supply-chain solutions and insurance coverage management support services, and ensuring seamless flow, integrity and accessibility of procurement and supply chain information.

2. **Quality Assurance Services team (QAS)**

   The QAS Team develops and implements the UNDP QA policy across the organization, providing technical and regulatory compliance support before, during and after the procurement process of health products. The team reviews technical specifications, development of TORs, and technical evaluation of offers. It also assists in the development of TORs for testing laboratories, sampling, and inspection agencies, as well as quality-related issues that arise after procurement.

3. **Health Product Management Services team (HPMS)**

   The HPMS Team works with COs to identify health product needs, ensure alignment with international best practices across the HPM cycle, respond to crisis and emergency situations, and support full compliance with any specific donor requirements as well as UNDP's QA Policy.

5.2 Development of List of Health Products

Once the selection, quantification and supply planning of health products is completed and documented, UNDP requires all Country Offices (COs), implementing Global Fund grants and other health programmes, 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 health products.

For Global Fund grants, the list of health products, quantities and costs must be prepared in the **Global Fund Health Product Management Template (HPMT)**, which is aligned with the grant Performance Framework and the grant Detailed Budget. The Global Fund Principal Recipient (PR), when submitting the HPMT for approval to the Global Fund, should also attach supporting documentation with the relevant quantification, hypotheses and assumptions used to calculate the quantities listed.

For interim Principal Recipients (PR) of Global Fund grants, the HPMT must be approved by the Global Fund during the grant-making process or, in the case of Financing Agreements, the list of health products planned for procurement must be approved by the relevant government authority before initiating procurement.

The List of Health Products should include the following information:

- Complete product specifications:
  - For pharmaceuticals: INN, strength, dosage form, packaging, specific formulation, etc.
  - For diagnostics: product characteristics (e.g., intended use, performance characteristics, operational characteristics) for all items required to complete a test (i.e., all reagents and related consumables), packaging, installation and training, warranties, guarantees, services, and maintenance requirements, etc.
  - For health equipment: also include whether the contracting modality is for "purchasing the equipment", "leasing the equipment", or a "reagent rental agreement".

Practice Pointer

To support UNDP COs with developing robust technical specifications for tendering, procurement and purchasing of the health products that ensure compliance with UNDP's expectations regarding the safety, quality and performance, the GHPC QAS Team has developed **templates** for writing the technical specifications of items not included in Global Fund QA lists (i) medical devices including medical Personal Protective Equipment, medical equipment etc (ii) Rapid kits for diagnostic use (iii) General Lab Use products (iv) IVD Equipment (v) Reagents for IVD uses, and (vi) Finished Pharmaceutical Products. The technical specification details essential criteria that must be provided by the end-user to enable suppliers to meet these requirements when submitting their offer.

- Required quantities together with expected delivery dates and incoterm
  - This is especially important for items with a very short shelf-life requiring multiple staggered deliveries.
- UNDP budgeted (reference) price
- Consignee details
- Delivery address and contact details
- Registration Status

- Regulatory requirements
    - For most health products this will relate to the legislative requirements established by the NRA
    - There may also be specific regulatory requirements for importation of narcotics, precursors, and/or psychotropic medicines into the country
    - For pesticides the requirements might be linked to the Ministry of Agriculture
- Marking or labelling requirements
- **WHO Shelf life requirements**, the remaining shelf life at time of arrival in-country should be in accordance with the NRA's regulations, or as agreed with the NRA in case of deviations
- Language requirements
- Any other requirements

National Regulatory Authority (NRA) authorization

According to the UNDP QA policy, medicines and other health products (as appropriate) should be authorized by the NRA in the recipient country. "Authorization" includes formal registration, temporary import authorization, waiver for non-commercial use or any other exceptional procedure. It is the responsibility of the suppliers to provide appropriate product information as required by the NRA.

Patent Issues

A product's patent provides its inventor with property rights that prevent competitors from making, using, or selling the item, typically for around 20 years. Each country, or region, has its own patent laws, which determine the duration of the patent. It can be challenging to determine the intellectual property status of a health product in a country, and obtain information that is correct and up-to-date.

Most of the medicines on the WHO List of Essential Medicines are off-patent. Some more recent medicines, however, such as anti-retroviral (especially second line and third line), newer cancer, tuberculosis and hepatitis C medicines may be still patent-protected in many LMICs and UMICs countries, leading to high prices.

UNDP is committed to applying national laws and applicable international obligations in the field of intellectual property. This includes applying the flexibilities provided in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and interpreted in the Doha Declaration, in a manner that achieves the lowest possible price for products of assured quality.

In July 2018, UNDP developed a **Standard Operating Procedure (SOP) on Addressing intellectual property matters in procurement of medicines by UNDP** which serves as a framework to:

- Ensure UNDP does not infringe upon patent during health procurement activities;
- Determine whether UNDP can procure an originator or a generic/biosimilar medicine (More information can be found in the UNDP **Methodology for Patent Searches**);
- Determine if a country can utilize any of the flexibilities in the TRIPS Agreement to legally purchase generic versions of the health product.

For support related to **intellectual property**, please contact the UNDP GFPHST HPM Specialist, who serves as a focal point for Country Offices implementing health procurement activities and who liaises with intellectual property specialists in UNDP's HIV and Health Group and with external partners.

Resources

- Global Fund Health Product Management Template (HPMT)
- WHO Shelf life requirements
- SOP on Addressing intellectual property matters in procurement of medicines by UNDP
- Methodology for Patent Searches on Essential Medicines in Developing Countries

5.3 Development of the Health Procurement Action Plan (HPAP)

The List of Health Products constitutes the basis of a Health Procurement Action Plan (HPAP) (either **Global Fund** or **non-Global Fund** depending on the source of funding) that must be developed by the CO as soon as possible after the List is approved and, preferably, before the programme begins. The Procurement plan should be entered for, at least, one year for visibility on the upcoming demand.

UNDP's Health Procurement Action Plan (HPAP) is one of the key planning tools used to consolidate information on health product procurement which is shared with procurement partners, used for forecasting health procurement projections, and used for identifying any critical procurement activities where there may be potential risks or delays.

The Global Health Procurement Center (GHPC) supports Country Offices (COs) with health procurement planning to identify potential opportunities for further efficiencies (e.g., due to volumes and accumulation of discounts) and the potential for new long-term agreements (LTAs) for critical pharmaceutical items and other health products. The information that Country Offices enter into the HPAP enables the Health Procurement Services (HPS) team to secure production capacity with manufacturers and reduce the lead time of manufacturers with whom UNDP has LTAs.

Guidelines for creating the HPAP are available **here** and **here**.

The process for updating the HPAP is conducted semi-annually; this includes two major revisions – one at the beginning of a new cycle and one midway through the cycle – to allow the HPS team to share accurate forecasts with suppliers. As part of this process, it is mandatory for UNDP COs to update the HPAP according to the deadlines.

Delay in the preparation and validation of the HPAP can delay programme implementation.

Practice Pointer

UNDP Country Offices must submit completed Health Procurement Action Plans to the GFPHST HPMS team for review and validation. Any update should be re-validated prior to issuing purchase orders.

Resources

- **Global Fund HPAP template**
- **non-Global Fund HPAP template**
- **UNDP Health Procurement Action Plan SharePoint homepage**
- **UNDP Health Procurement Action Plan SharePoint shared resources**

5.4 Health Procurement Architecture

UNDP COs are strongly recommended to procure all health products through the **Health Procurement Architecture** defined by UNDP GHPC. This architecture ensures procurement of health products that are compliant with the overall UNDP QA policy.

All procurement of health products that is financed through the Global Fund, where UNDP is either the PR or has signed a Financing Agreement (FA) with another PR, must be implemented via the Health Procurement Architecture defined by UNDP GHPC.

To ensure full compliance with UNDP's QA Policy and to mitigate against of risks which are unique to health product procurement, UNDP COs that implement procurement of health products using funds outside of Global Fund grants, are strongly recommended to procure all health products through the UNDP GHPC. COs that implement procurement of health products outside of the UNDP GHPC must develop a procurement sourcing and risk management strategy in consultation and agreement with the relevant Regional Bureau, BPPS (HHG/GFPHST), and BMS (health procurement team) [1]. The strategy should determine how the best value for money and lowest risk is achieved using either CO-led procurement or the specialized services of the BPPS/BMS Global Health Procurement Center (GHPC) while taking into account the relevant project aspect. Furthermore, the strategy should agree on a GMS cost sharing arrangement, as applicable.

All LTAs for health products that have been established centrally by the GHPC are closed and are only available for use by the GHPC HPS team.

UNDP GHPC's Health Procurement Architecture comprises several partnership and sourcing agreements with other UN Agencies, and with manufacturers and other commercial entities. This is described in subsequent sections of this HPM Manual. For each defined product category, a standard sourcing mechanism has been established.

When procurement actions are channelled through UNDP's **Health Procurement Architecture**, Country Offices do not need to launch 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 and QA approval). These processes have already been completed with respective organizations/units as part of the establishment of the long-term agreements (LTAs) that comprise the central procurement architecture, in accordance with internal United Nations procurement rules and regulations.

Practice Pointer

To identify the channel to use for sourcing health products, please refer to the **Decision Tree for Health Procurement Architecture**. If you are unable to find the product category under the Health Procurement Architecture, please contact the GHPC Health Procurement Services Team, based in UNDP, Copenhagen.

It is important, however, for requesting units to observe the standard operating procedures (SOPs) developed by the UNDP HPS team for each of the sourcing options, and to consult with UNDP HPS focal points should any questions arise.

Furthermore, regular analysis of health procurement by Country Offices and the HPS Team serves as a basis for further development of the UNDP health procurement architecture (e.g., the establishment of new global LTAs based on the growing needs in countries). This is particularly important for products that UNDP supports countries to procure outside of the Global Fund portfolio, such as medicines for non-

communicable diseases (NCDs). This will be done through a regular review of the product categories being supplied to countries.

UNDP developed a Guidance Note for UNDP Country Offices providing Health Procurement Services to governments, which is available **here**. The centralized procurement arrangements and services available to UNDP Country Offices promote affordable costs and value for money.

[1] OPG Decisions, 19 November 2017

Resources

- **Health Procurement Architecture**

5.5 Local Procurement of health products

Procurement of health products is associated with very specific and unique risks for the organization. This includes, amongst many others, the risks around the quality of the health products that can pose an immediate risk to human life, and the risk of sub-standard health outcomes.

To mitigate these risks, UNDP's OPG determined that the quality assurance review process for all health procurement should be centrally processed by the Global Health Procurement Center (GHPC) regardless of the funding source, and that all local procurement of health products is fully subject to corporate risk management procedures [1].

All procurement of health products that is financed through the **Global Fund**, where UNDP is either the PR or has signed a Financing Agreement (FA) with another PR, ***must*** be centrally processed by the Global Health Procurement Center (GHPC).

In "special circumstances", UNDP COs that procure health products financed through the Global Fund may submit a request, supported by a detailed justification, to the UNDP GFPHST Senior Health PSM Advisor for authorization to source the health products locally. UNDP GFPHST will review such requests and, based on detailed risk assessment, may authorize local procurement. Such authorizations would be 1) exceptional, 2) for the specific list of health products and quantities, and 3) timebound. Any authorised local procurement must adhere to UNDP's procurement procedures and UNDP's QA policy for health products.

COs that implement procurement of health products using funds outside of Global Fund grants are strongly encouraged to use the GHPC to mitigate against the risks that are unique to procuring health products and to ensure full compliance with the UNDP QA Policy. COs that choose to manage procurement of health products outside of the GHPC, must develop a procurement sourcing and risk management strategy in consultation and agreement with the relevant Regional Bureau, BPPS (HHG/GFPHST), and BMS (health procurement team), and must still engage the services of the GHPC QAS team[1]. The strategy should determine how the best value for money and lowest risk is achieved using either CO-led procurement or the specialized services of the BPPS/BMS Global Health Procurement Center (GHPC) while taking into account the relevant project aspect.

As mentioned in the Risk Management section of this manual "Non-compliance with the UNDP procurement rules and regulations and quality assurance policy requirements could create substantial liabilities for UNDP, which are highlighted in the Potential Liabilities Related to Health Procurement document **here**."

[1] OPG Decisions, 19 November 2017

Resources

- **Quality Assurance Policy - Potential Liabilities Health Procurement**

5.6 Procurement of Pharmaceutical Products

Practice Pointer

To identify the channel to use for sourcing health products, please refer to the **Health Procurement Architecture**. If you are unable to find the product category under the Health Procurement Architecture, please contact the GHPC Health Procurement Services Team, based in UNDP, Copenhagen.

The UNDP Bureau for Management Services (BMS) Office of Procurement (OP) has established multiple Long-Term Agreements (LTAs) with commercial partners (manufacturers & suppliers/wholesalers) for the supply of the medicines that meet the minimum UNDP quality assurance requirements.

UNDP has LTAs established for adult antiretroviral (ARV) medicines, adult and pediatric first-line anti-TB medicines, all malaria medicines, medicines for managing STIs and opportunistic infections, medicines to treat Hepatitis B and Hepatitis C, as well as a range of other essential medicines and medicines for treating non-communicable disease (NCDs), such as diabetes, hypertension, and cancers.

All LTAs for health products that have been established centrally by the GHPC are closed and are only available for use by the GHPC HPS team.

The GHPC procurement team in Copenhagen conducts the procurement process on behalf of the CO for Global Fund programmes and for other health programmes.

Practice Pointer

GHPC processes the requests for medicines **semesterly**, based on the consolidated demands of HPAP validated items.

Where urgent needs are identified outside of this schedule, the UNDP CO can send the request to HPS team focal point with copy to the GFPHST HPM focal point.

Beyond these UNDP LTAs, UNDP engages the services of other UN agencies to support procurement of pediatric ARV medicines and medicines to treat drug-resistant TB.

ARV medicines: pediatric formulations

UNDP has a Memorandum of Understanding (MoU) with the United Nations Children's Fund (UNICEF) Supply Division for sourcing pediatric antiretroviral medicines. For product selection, please refer to **UNICEF online catalogue**.

The COs/Project Management Units (PMUs) can submit the request for cost estimate to UNICEF **psid@unicef.org** by following the guideline **here**.

Drug-resistant tuberculosis medicines: all formulations

In light of the specificities of drug-resistant TB medicines, all **TB medicines to treat drug-resistant TB** must be procured through the Stop TB Partnership's Global Drug Facility (GDF). UNDP COs source these medicines through UNOPS/GDF Stop TB Partnership by piggybacking their LTA with the procurement

agency (i.e., iPlus Solutions). A copy of the agreement is available **here**. If GDF changes its procurement agents based on the outcome of the competitive procurement process, UNDP COs will be informed accordingly.

To be consistent with the policies of other international funding sources, all procurement of medicines to treat multi-drug resistant TB (MDR-TB), which is financed by the Global Fund, must be conducted through the Stop TB Partnership's GDF. This is in adherence with the Global Fund 13th Board Decision of 2006.

A step by step guideline to process the request through GDF is available **here** and **here**. For product selection of SLD, please refer to **GDF Product Catalog | Stop TB Partnership**.

Practice Pointer

Where UNDP relies on other United Nations agencies to assist with the procurement of specific categories of health products and where there are specific cases in which these UN agencies are unable to provide support, alternative arrangements will need to be made to procure products which are compliant with UNDP quality assurance requirements. In this case, the GHPC Health Procurement Services team will need to be informed, and can advise the CO on how to proceed.

Resources

- **Health Procurement Architecture**
- **OMS step by step guide for clients to process requests through GDF**
- **Stop TB Partnership GDF Product Catalog**

5.7 Procurement of non-pharmaceutical Health Products

Practice Pointer

To identify the channel to use for sourcing health products, please refer to the **Health Procurement Architecture**. If you are unable to find the product category under the Health Procurement Architecture, please contact the GHPC Health Procurement Services Team, based in UNDP, Copenhagen.

The UNDP Bureau for Management Services (BMS) Office of Procurement (OP) has established multiple Long-Term Agreements (LTAs) with commercial partners (manufacturers & suppliers/wholesalers) for the supply of non-pharmaceutical health products, such as point-of-care diagnostic kits, laboratory diagnostic systems, medical equipment and consumables, medical waste management and consumables, medical consumables, and vector control products that meet the minimum UNDP quality assurance requirements.

UNDP has established LTAs directly with manufacturers for insecticide treated nets, a sub-set of rapid diagnostic tests, and a sub-set of laboratory diagnostic systems. UNDP has established LTAs with a range of suppliers/wholesalers for all other non-pharmaceutical health products.

All LTAs for health products that have been established centrally by the GHPC are closed and are only available for use by the GHPC HPS team.

The GHPC procurement team in Copenhagen conducts the procurement process on behalf of the CO for Global Fund programmes and for other health programmes.

Beyond these UNDP LTAs, UNDP engages the services of other UN agencies to support procurement of reproductive health products.

Reproductive health products (including condoms and lubricants)

UNDP has a Memorandum of Understanding (MOU) with the United Nations Population Fund (UNFPA) for Reproductive health products (including condoms and lubricants). The MoU between UNDP and UNFPA can be accessed **here**.

A Formal written Procurement Services (PS) request will be submitted by GFPHST to UNFPA request **UNFPA@unfpa.org**.

Practice Pointer

Where UNDP relies on other United Nations agencies to assist with the procurement of specific categories of health products and where there are specific cases in which these UN agencies are unable to provide support, alternative arrangements will need to be made to procure products which are compliant with UNDP quality assurance requirements. In this case, the GHPC Health Procurement Services team will need to be informed, and can advise the CO on how to proceed.

Resources

- **SLA between UNDP GFPHST and UNICEF Supply Division**
- **UNICEF online catalogue**
- **Memorandum of Understanding (MoU) between UNDP and UNFPA**

5.8 Other Elements of the UNDP Procurement Architecture

Practice Pointer

To identify the channel to use for sourcing services related to health products, please refer to the **Health Procurement Architecture**. If you are unable to find the product category under the Health Procurement Architecture, please contact the GHPC Health Procurement Services Team, based in UNDP, Copenhagen.

In addition to the guidelines described in the previous sections of the Manual and, in line with the needs of health programmes funded by the Global Fund and other sources, GHPC has developed a number of complementary bespoke supply systems available for use by requesting units. They pertain to arrangements for quality control as well as the procurement of non-health products.

As an integral part of quality assurance and risk management, the following long-term agreement (LTA) frameworks are available for use:

- Set of LTAs with WHO-prequalified **quality control laboratories** for the provision of **pharmaceuticals** sampling and testing. The existing LTAs expired at the end of 2023 and are being re-tendered. A link to the new LTAs and corresponding standard operating procedures (SOPs) will be shared later in 2024.
- LTAs for pre-shipment inspection and for QC laboratories for sampling and testing of other product categories are being established and should be available during semester 2 of 2024.
- 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**.
- Commercial LTAs for **insurance and freight**, to strengthen procurement and supply management services and risk mitigation. The LTAs and SOPs for insurance are available **here** and for freight forwarding services **here**.
- 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 are encouraged to use existing LTAs to facilitate procurement of non-health products and services. A consolidated list of available LTAs can be accessed **here**.

Resources

- **Health Procurement Architecture**

5.9 Submission of GHPC CO Procurement Request Form

After individual items/rows in the Health Procurement Action Plan (HPAP) have been validated by the HPMS team, the CO must initiate the procurement process by submitting a CO Request Form to the HPS team for items being procured against the UNDP centrally established LTAs.

Guidelines for creating the CO Request Form are available **here**.

For procurement of health products through other UN agencies – as described in the Health Procurement Architecture – COs must initiate the procurement process following these agencies guidelines.

5.10 Guidance on donations of health products

If a CO wants to donate and/or receive a donation of health products for an emergency or any other scenario, the CO needs to follow **WHO's Guidelines for medicine donations** and **UNDP's QA Policy** to assure the quality of medicine being donated or accepted, and adherence to good practices.

The **WHO "Medical device donations: considerations for solicitation and provision"** provides additional guidance on donations of medical devices.

These same guidelines apply to UNDP COs wanting to lend health products to another CO, or to borrow stock from another CO.

For Global Fund programmes, it is a pre-requisite to receive Global Fund's approval for processing any donation of health products that were funded with grant resources. UNDP COs are advised to consult with the GFPHST Senior Health PSM Advisor for guidance.

Resources

- **WHO Guidelines for medicine donations**
- **UNDP POPP: Quality Assurance (QA) Policy**
- **WHO Medical device donations: considerations for solicitation and provision**

6. International freight, transit requirements and use of INCOTERMS

6.1 International freight

Five basic modes of freight transportation – sea, rail, road, air and parcel post – are used, either individually or in combination, in international transportation. In general, rail, road, and air transport costs are comparatively higher than freight by sea, thus UNDP generally recommends sea transport. However, air freight has a shorter duration than sea and land freight, and should always be selected for health products that require "cold chain" conditions (categories [2-8°C] and below 0°C categories). For health products that do not require "cold chain" conditions, any mode of transport (air, sea, land) can be used. The most economical route should be selected based on when products are needed in-country.

During the procurement process, the proper transport conditions, for the products to be shipped, must be requested from the supplier and/or freight forwarder – this can be verified in the transport documents provided by the supplier or the freight company (i.e., airwaybill/bill-of-lading).

Distributors, wholesalers and any parties involved in the supply chain should comply with **WHO Good Storage and Distribution practices (GSDP)** and with **Module 5 of WHO's MQAS**. Shipment containers and vehicles used for transportation should be secured. Transport conditions of medicines and other health products should ensure that their quality is preserved throughout the chain, in accordance with the manufacturer's instructions.

To support UNDP COs in monitoring the health procurement managed through the GHPC, the HPS team has developed an **SOP for Shipment Tracking and Payment** and will launch the Delivery Tracking Dashboard, shortly.

Use of dataloggers

Dataloggers are electronic devices that record temperature and/or humidity conditions and should be used in international shipments of health products, be it by air, sea or land. Therefore, UNDP COs should request inclusion of temperature dataloggers during the procurement process. Before placing/confirming a purchase order, UNDP CO needs to verify that dataloggers have been included in the supplier's offer; if not, the CO should ask the supplier to include it and amend the offer, accordingly.

The UNDP HPS Team (HPS) has established multiple **Long-Term Agreements** (LTAs) 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**.

Special Requirements for Narcotic and Psychotropic substances

When controlled products are requested, the recipient in the country should obtain an import authorization from the National Regulatory Authority (NRA). The import authorization should clearly indicate the name of the medicine (in INN), the concentration in active ingredients and the quantities of medicines requested.

The import authorization must be sent to the supplier (distributor or manufacturer) who will then request their local National Regulatory Authority to issue the export license (exactly the same product, concentrations and quantities).

- Controlled products containing narcotic or psychotropic substances should be transported in secured containers and in accordance with the requirements established by the NRA.

- In addition to the above, cartons must be palletized (whenever possible) and covered by a protective film.

Resources

- **WHO Good Storage and Distribution practices (GSDP)**
- **Health Procurement Architecture**

6.2 Transit

Transit is the period of transport/storage after the goods have arrived in the country and before they are delivered to their destination (e.g., central medical stores). It is important that UNDP COs ensure as much as possible that the right conditions are in place during this transit time and to minimize its duration.

To minimize the transit time duration, clearing and transit procedures must be initiated before the products reach the country. To this effect, the following measures should be taken:

- Use of fast-track clearing procedures whenever applicable
- Plan deliveries with the freight forwarder in a way to avoid arrival of goods at a time that would extend the transit time (e.g., deliveries just before or during a week-end)
- Preliminary assessment by the NDRA of the storage capacity and conditions in the transit area, to estimate the potential risks due to inadequate storage conditions.
- Establishment of a contract for clearing services, with clear instructions to minimize the transit time of incoming goods and including conditions for good storage conditions.

WHO MQAS good practice statement:

"All conditions required for storage should be achievable at the port of entry of goods. This is particularly important for all temperature-sensitive products shipped to ports where temperatures may be less well controlled. Specific arrangements may need to be made with local handling agents and customs to ensure speedy handling and clearance. Security measures to prevent theft, fraud and bribery should be in place during storage at the port of entry."

6.3 INCOTERMS

The International Commerce Terms (INCOTERMS) define the obligations of both buyer and seller relating to shipment of goods. **INCOTERMS 2020** govern shipment terms of all UNDP contracts.

Commonly used terms in UNDP procurement include:

- for local procurement use the term "FCA" (Free Carrier);
- for international procurement where the transportation is arranged by the Business Unit, use the term "FOB" (Free on Board) or "FCA", depending on where the goods are to be delivered;
- for international procurement where the Supplier arranges for transport, use the term "CPT" (Carriage Paid To);
- for international procurement where the Supplier arranges both transportation and insurance, use the term "CIP" (Carriage and Insurance Paid To); and
- for international procurement where UNDP elects for the Supplier to bear all risks and costs associated with the transport of goods to the country of destination, use the term "DDU" (Delivered Duty Unpaid). ***Note:*** *this method is expensive and should be used only during emergency operations or for the procurement of medical supplies.*

All the terms referred to above should be followed by named place/destination point.

Resources

- **Incoterms 2020 – your guide to international trade regulations**

7. Inspection and Receipt

When receiving shipments of health products, the following verifications should be carried out by UNDP CO (and a national reception committee, if applicable):

- **Visual inspection**: Containers and products should be visually inspected for possible contamination, tampering and damage (see **Annex 2** in **Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain**). Damage to containers and any other problems that might adversely affect the quality of the material should be recorded and investigated.
- **Conformity** of received items **with the specifications** of the purchase order: item description; item code (if applicable); strength; dosage form; packaging and labelling
- **Quantities** delivered versus quantities ordered
- **Integrity** of packages and seals
- Presence of **certificates of analysis**, one for each batch number received, and presence of the Certificate of Pharmaceutical Product (in WHO recommended template) if required by the NRA.
- Reading and analysis of **temperature conditions** during transport and transit (dataloggers' readings) – see details further below.
- Verification of **remaining shelf life** (RSL) – should be "at or above" the minimum RSL agreed with the supplier.

A **receiving report** should be completed by UNDP CO (or the reception committee, if applicable) upon each delivery. The report and the annexes (COAs, CPPs) should be archived and kept available for retrospective controls by the PR or other relevant entities (e.g., UNDP QAS Team, NDRA). If there is **national reception committee**, the following entities should ideally be represented in this committee: UNDP CO, NDRA, relevant disease programme (e.g., HIV national programme for reception of ARV medicines), Central Medical Stores (CMS) or other entity in charge of central storage, and the Global Fund Principal Recipient (PR), in case UNDP CO is the procurer for another PR.

GFPHST issued a **Standard Operating Procedure (SOP) for Inspection and Receipt of Health Products** to guide UNDP COs during these activities.

Handling of dataloggers at reception

UNDP COs are responsible to ensure that the dataloggers in the shipments are retrieved, data are read, analyzed and kept as record with the reception report.

Any significant deviation observed (temperature excursion) during transportation should be immediately reported by UNDP CO to the GHPC HPS, QAS, and HPMS focal points. The GHPC QAS team will coordinate with the supplier to obtain information on the appropriate actions to take. This could lead to the replacement of the products if the supplier's assessment is that the quality of the products cannot be guaranteed. "Significant" deviations include:

Product's required storage conditions	"Significant" excursions
"Do not store above 25°C" "Do not store above 30°C"	> 40°C (any duration) > 35°C and > 72 hours
"Store in a refrigerator (2°C to 8°C)"	< 0°C and > 15°C (any duration) < 2°C and > 8°C and > 12 hours
"Store in freezer"	> 0°C (any duration)

If issues of non-conformity or quality are observed at reception:

- UNDP COs must ensure that the rejected products are either put in quarantine (if further investigation is needed) or categorized as rejected products (if rejection is final). The supplier(s) must be informed in writing as soon as possible in order to initiate any needed investigation and/or resolve the dispute.
- Rejected products: Stringent precautions should be taken to ensure that rejected health products cannot be used. This can be achieved through separate storage or by means of a validated computerized system. Rejected products may be destroyed or be returned to the supplier.
- UNDP CO should obtain a written statement from the suppliers about the actions to take (destruction in the recipient country, resending of remaining quantities) and the compensation for the expenses caused.

Resources

- **SOP for Inspection and Receipt of Health Products**

8. Storage

Health products are stored in various storage points along the national supply chain: they are usually stored in the national Central Medical Store (CMS) [1] after reception in-country, before being distributed to intermediate stores (regional and district stores), and then to health facilities where they are dispensed to patients. Health products for use in clinical laboratories may be managed through a dedicated national supply chain system due to temperature requirements and limited shelf-life of many reagents and consumables. Sometimes health products may even be delivered to the community level through community health workers or through non-government organisations (NGOs).

Considering the number of public health facilities storing health products in a country, it is beyond UNDP's reach to guarantee good storage practices in all health facilities of a country. However, when working through the Ministry of Health supply chain (Central Medical Stores CMS, regional/district stores, health facilities), UNDP, as a development partner, should support the MoH in achieving the standards for good storage practices. This can be achieved through technical assistance and financial support, ***to the extent allowed by budget availability***.

Using funds available under the Global Fund grant(s), UNDP COs can support activities that will help government and/or non-governmental organisations to achieve standards for GSP (e.g., QA and GSP training; procurement of temperature recording devices; procurement and installation of cooling units; etc). These activities should be primarily implemented at central level, and then cascaded down the supply chain to the extent the budget allows. GF grant funds may not be used to support system strengthening of private sector facilities.

8.1 Storage Facilities

Existing national storage facilities/warehousing system and distribution mechanisms for health products are the logistics channels of choice for UNDP programmes if they are adequate or if deficiencies can be remedied during the implementation of the programme. If these channels do not meet the necessary standards, storage facilities run by non-governmental organizations (NGOs), other UN agencies, or international organizations may be a viable alternative. It may also be possible to use private facilities and distribution networks run by commercial companies while national systems are being improved.

Situation 1: *the medical store(s) are directly managed by UNDP CO*

UNDP COs must ensure that good storage practices according to **WHO Good Storage and Distribution Practices (GSDP)** is implemented in the store.

Situation 2 (most common): *the medical stores(s) are managed by an external entity (e.g., Ministry of Health or service provider)*

UNDP COs must ensure that good storage and distribution practices, according to **WHO GSDP**, are included or referred to in the agreement (i.e GF Sub-Recipient agreement) or service contract with the entity.

In the context of Global Fund projects, or if UNDP is responsible for the storage of health products, the UNDP CO should ensure that the facilities are secure and compliant with storage requirement in **WHO's Good Storage and Distribution Practices**.

At a minimum, it is expected that UNDP CO:

- Perform a formal assessment of storage conditions in storage entities that have a contract with UNDP CO (usually the CMS, but sometimes also some intermediate stores) on an annual basis (this verification is done using a standardized supervision form – see **Storage and Inventory Management Checklist** issued by GFPHST. The Checklist is also available in **French**.).
- Perform assessment of storage conditions during supervision visits in a selection of other stores (intermediate and peripheral) used in the project, on an annual basis.
- A more thorough assessment (covering a higher number of facilities) could also be funded with funds allocated in the grant, if any.

These assessments should be done jointly with a representative of the NRA (or other designated government entity responsible for GSDP standards) and the recommendations compiled in a report and implementation monitored by the NRA (or other designated government entity).

To support UNDP COs with engaging the CMS either through a SR Agreement or through a Service Contract, GFPHST issued a guidance note. The guidance note is available in **English** and **French**.

[1] The term "Central Medical Stores" (CMS) describes the national warehouse system that is mandated by the government to manage health products. The CMS is, generally, responsible for the procurement, storage, and distribution of pharmaceutical products and other health products such as HIV- and malaria- rapid diagnostic test kits, condoms, lubricants, and laboratory reagents to public sector institutions, including teaching hospitals, clinical laboratories, and other not-for-profit private Institutions.

Resources

- **WHO Good Storage and Distribution guidelines**
- **UNDP GFPHST Guidance Note for contracting CMS services – English**
- **UNDP GFPHST Guidance Note for contracting CMS services – French**

- **Storage and Inventory Management Checklist - English**
- **Storage and Inventory Management Checklist - French**

9. Inventory Management

Stock-out and expiration risk management are the **responsibility of the Country Office** (CO), which must regularly monitor the stock status of health products. This includes close monitoring of the consumption rates against performance targets, of stock-on-hand and stock-on-order (in the pipeline), and of expiry dates of products in-stock so that the CO can make informed decisions (e.g., delaying procurement or accelerating shipments), and take the necessary actions to avoid emergency orders, stock-outs and expiration of products.

Practice Pointer

Regardless of the PU/DR cycle, COs must notify the Global Fund Country Team of all "risks of stock-outs and/or expiry" that they identify.

Ideally, where national mechanisms exist to monitor the supply chain on a monthly/quarterly basis, the UNDP CO should participate in these meetings.

It is important for relevant stakeholders (e.g., the programmes, CMS, UNDP COs) to do periodic audits and inspections ("supervision visits") of all points in the distribution chain to confirm that records are being properly maintained and that information is being accurately reported; regular supervision visits can also help prevent diversion of valuable commodities.

To perform this function effectively, UNDP COs will require access to data from Logistics Management Information System (LMIS) or regular access to reports such as the national stock status report.

9.1 Logistics Management Information Systems (LMIS)

National health systems rely on supply chain systems for the receipt, storage and distribution of health products to ensure timely access to adequate quantities of quality assured health products for the population in need. To ensure quality health products reach the right delivery points or the end users in a timely manner, supply chain managers need to have visibility of the activities in all functions of the supply chain, such as procurement, warehousing, inventory, and distribution.

A logistics management information system (LMIS) is a system of records and reports – whether paper-based or electronic – used to aggregate, analyze, validate and display data from all levels of the supply chain system that can be used to make logistics decisions and manage the supply chain. LMIS data elements include stock on hand, losses and adjustments, consumption, demand, issues, shipment status, and information about the cost of commodities managed in the system.

A strong LMIS can ensure data visibility throughout each function, and essential logistics data can be communicated for decision making.

The adoption of electronic logistics management information systems (eLMIS) can provide cost-effective means for health product data management and promote greater security of the health products in the supply chain compared with paper-based systems, thereby supporting better health outcomes. An eLMIS links storage facilities and health facilities with the central store to collect and distribute logistics data in real time.

Practice Pointer

an eLMIS can help improve timely availability of data, but it will not solve problems related to data quality, data accuracy, data completeness, and timeliness of report submissions. A strong support team is needed to work with facilities to monitor and improve these aspects.

UNDP has established corporate **Long Term Agreements** (LTAs) for development and deployment of electronic logistic management information system (**eLMIS**) **solutions**. The GHPC HPS Team conducts the secondary bidding process to identify the service provider on behalf of the CO for Global Fund programmes and other health programmes. The LTAs together with a set of comprehensive SOPs are available **here.**

9.1.1 Global Data Standards

To improve traceability and end-to-end visibility of health products throughout the supply chain, to enhance efficiency, security and patient safety, and, ultimately, to improve the availability of health products at service delivery level, UNDP has adopted **GS1 Guidelines for Global Health Commodities** for product identification, location identification, and product master data.

UNDP, in collaboration with key stakeholders, is introducing GS1 standards as part of its procurement requirements and will support country uptake of these standards to improve tracking and traceability systems. These include the requirements that:

- Distribution and inventory management systems include a mechanism to trace, by batch number, the patients to whom medicines are distributed, in the event that a product is recalled; and
- All storage facilities and personnel use the 'first expired, first out' (FEFO) system.

Resources

- **SOP for using UNDP Global LTA for service provision of eLMIS Software application**
- **GS1 Guidelines for Global Health Commodities**

10. Distribution

UNDP COs must ensure that good distribution practices, according to **WHO GSDP**, are implemented when health products are distributed through the supply chain up to the end user. To this effect, these requirements should be clearly outlined in the agreement or contract between UNDP CO and the entity managing the distribution (e.g., Sub-Recipient agreement with Central Medical Stores, service contract with private transport company).

The following concrete measures should be adopted:

- The use of direct routes to avoid long exposure to potentially harmful conditions, and
- The use of closed/covered vehicles to avoid direct exposure to sunlight and moisture/water.

10.1 Distribution Networks

The distribution network should be evaluated to optimize the distribution strategy for a reliable and agile supply of health products. This can be achieved through technical assistance and financial support, ***to the extent allowed by budget availability***.

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. 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 storage space at some levels of the supply chain; 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 and storage location will be used, frequency of distribution, maximum stock holding at health facility level.

Specific measures must be put in place for temperature sensitive health products (e.g., use of refrigerated vehicles and/or appropriate cold chain packing) and for controlled products (psychotropic and narcotics). The vehicles carrying the health products should be manned by qualified staff trained on the principles of quality assurance and good distribution practices (alternatively, drivers should receive a training on the basic principles of QA and GSDP)

UNDP COs should also prepare a plan to assess the temperature conditions during transport, using electronic data loggers) in the different segments of the supply chain.

It is important to keep full traceability of batches supplied to the different facilities and this should be part of the contract with the entity responsible for distribution of the products and should appear on packing lists. This information should be available upon request through the warehouse management system in place in central/regional warehouses.

11. Quality monitoring of health products

According to the UNDP QA Policy and the **Global Fund's QA Policies**, the quality of products procured through UNDP must be monitored throughout the supply chain.

To facilitate compliance with, and implementation of, the UNDP QA Policy, GFPHST has developed further **Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain**, which includes a template for developing a **QA Action Plan**. This document provides UNDP COs with guidance on how to maintain and control the quality of health products in national supply chains, from the delivery point in country up to the end user, in collaboration with National Regulatory Authorities (NRA).

Resources

- **Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain**
- **QA Action Plan Template**
- **Global Fund's QA Policies**

11.1 Quality Monitoring at different stages

Pre-shipment inspection, sampling and testing

For most categories of products, pre-shipment inspection and testing is not recommended. For certain categories of products, the implementation of pre-shipment inspection, sampling and testing activities may be required, as a risk mitigation measure rather than as a quality assurance mechanism.

Pre-shipment with randomized sampling and testing is required for the following product categories: Finished Pharmaceuticals Products (FPPs) recommended for procurement by the WHO Expert Review Panel (ERP); In-vitro Diagnostic Products recommended for procurement by the WHO ERP for Diagnostics (ERPD); Condoms (male and female) that are not listed in the UNFPA list; and all Vector Control products.

Post-shipment inspection, sampling and testing

UNDP COs must perform post-shipment inspection at the time of the reception of the goods by visual inspection and review of import documentation that the products received are in line with the purchase order and the specifications. UNDP GFPHST does not advise conducting routine post-shipment quality control testing, except if the information collected on transit and logistic conditions during the post-shipment inspection indicates the likelihood of a risk on the quality or the performance of the products procured.

In-country inspection, sampling and testing

In-country quality monitoring activities should consider a range of activities which are complementary to each other rather than relying on only one specific activity such as quality control testing. Activities include visual inspection of the packaging of the products focussing on reviewing the content of packaging and labelling such as spelling errors, inadequate reference to standards, expiry date.

Full quality control testing of the products is a time consuming, costly and lengthy procedure used to confirm the compliance of a product. This should be engaged using a risk-based approach or when there is already presumption of non-compliance to confirm any doubt on product quality or failure.

Detailed guidelines for in-country quality monitoring of health products can also be found in the following documents:

- Guide to Global Fund Policies on Procurement and Supply Management of Health Products, available **here**.
- Guidance on in-country quality monitoring of pharmaceutical products in Global Fund supported programs, available **here**.
- Global Fund information note on Quality Assurance Requirements for the Procurement of Masks and Respirators, available **here**.
- Global Fund Briefing Note on Quality Assurance Requirements for the Procurement of Oxygen Therapy Medical Devices, available **here**.
- Global Fund Briefing Note: Visual Inspection of Insecticide-treated Nets (ITNs), available **here**.
- Global Fund Briefing Note: Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets (ITNs), available **here**.
- Global Fund Briefing Note: Post-market surveillance of Insecticide-treated Nets (ITNs), available **here**.

- WHO Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics, available **here**.

Resources

- **Guide to Global Fund Policies on Procurement and Supply Management of Health Products**
- **Guidance on in-country quality monitoring of pharmaceutical products in Global Fund supported programs**
- **Global Fund information note on Quality Assurance Requirements for the Procurement of Masks and Respirators**
- **Global Fund Briefing Note: Visual Inspection of Insecticide-treated Nets (ITNs)**
- **Global Fund Briefing Note: Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets (ITNs)**
- **WHO Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics**

11.2 Quality Control (QC) activities

As per the UNDP QA Policy, products purchased through UNDP must be tested according to a randomized sampling plan, which is based on a risk assessment by product category and by product. The GHPC QAS Team has issued guidance for Country Offices outlining 1) how to **prepare a multi-year QC Plan** including a **template**, and 2) how to **prepare an annual Sampling Plan** including a **template** and a **calculation tool** and **instructions** on how to use the tool.

The annual sampling plan should include the number of batches to be tested based on the annual procurement plan. Both random and targeted risk-based sampling is recommended at different points across the supply chain. The selection of batches to be tested should follow the recommendations in section VII of the Guidance for UNDP Country Offices on Health Products Quality Assurance in the Supply Chain.

The PR must implement the annual plan and must maintain a record of the test results. The test results must also be shared with the GHPC QAS team.

For FPPs and Diagnostics approved by the WHO ERP and procured with Global Fund grant resources, the Global Fund Secretariat is responsible for organizing and paying for the quality control of these products prior to their shipment. UNDP COs are responsible for notifying the Global Fund Secretariat of their intent to purchase such products – using the following forms **pharmaceuticals**, **additional Order of ERP Pharmaceutical Products**, and **diagnostics** – and must receive a "no objection letter" (NOL) before confirming the purchase order. The NOL must be provided to the GHPC HPS and QAS teams before the PO can be issued.

Once the products are ready for sampling, the manufacturer informs the Global Fund who organizes the sampling and testing by a third-party laboratory contracted by the Global Fund. Upon receipt of a successful test results, the Global Fund will issue the final letter, including the test report, to the PR and the manufacturer, authorizing the product shipment. This letter must also be provided to the GHPC QAS team for their records.

For pharmaceuticals, other than ERP products, UNDP has established LTAs with Quality Control laboratories that are WHO prequalified for the provision of sampling and testing of pharmaceuticals. LTAs for pre-shipment inspection and for QC laboratories for sampling and testing of other product categories are being established and should be available during semester 2 of 2024.

Resources

- **Notification Form for the Additional Order of ERP pharmaceutical products**
- **Notification Form for the procurement of ERP pharmaceutical products**
- **Notification Form for the procurement of ERPD diagnostic products**
- **SOPs UNDP LTAs for Quality Control "QC" Labs**

11.3 Surveillance and monitoring for substandard and falsified medical products

Substandard and falsified (SF) medical products correspond to the following definitions:

- **Substandard** also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.
- **Falsified** medical products that deliberately/fraudulently misrepresent their identity, composition or source.

SF medical products from all main therapeutic categories and from every region of the world have been reported to WHO, including medicines, vaccines and in vitro diagnostics; however, anti-malarials and antibiotics are amongst the most commonly reported SF medical products. Both generic and innovator medical products can be falsified, ranging from very expensive products for cancer to very inexpensive products for management of pain.

Substandard and falsified medical products contribute to antimicrobial resistance and drug-resistant infections. They may cause harm to patients and fail to treat the diseases for which they were intended and they lead to loss of confidence in medicines, healthcare providers and health systems.

To facilitate the reporting and sharing of information on SF medical products, in 2013, WHO launched a Global Surveillance and Monitoring system for SF medical products. The system allows reporting, coordination and technical support and sharing of information between Member States. The system is designed for use by a trained focal point in the NRA.

If UNDP COs discovers or is informed of a suspected or confirmed SF medical products (at reception of supplies or during supervision visits in the field for instance), it should inform the NRA focal point of the Surveillance system and facilitate the transmission of a report to rapidalert@who.int. The CO should put the UNDP QA Team in copy in all the communication with the NRA and the WHO Rapid Alert team. WHO will then contact the NRA focal point and provide the adequate support.

It is also advised that one person (who is part of the PSM team in the UNDP CO) is made responsible for receiving the alerts published by the Global Reporting Mechanism, and each time an alert is posted to check if the product concerned has been supplied to UNDP. If the product has been supplied to UNDP, the CO should immediately inform the QA team for further instructions.

[Other considerations]

12. Waste management

Health Care Waste (HCW) is an inevitable byproduct of providing services to the population. If not managed properly, HCW can cause unintended harm to human health as well as significant environmental damage. Safe and sustainable HCW management (HCWM) should be seen as an integral part of the procurement and supply chain management of health products, rather than as an add-on or afterthought. UNDP COs are encouraged to incorporate sustainable HCWM practices into their projects and should ensure budgeting of these activities during project planning.

Waste management of health products falls under the overall responsibility of the national Ministry of Health and/or Ministry of Environment. Applicable laws and regulations (i.e National waste management policy) should be known to UNDP CO PSM specialist(s). When UNDP COs are involved in waste management of health products, all activities should be in full compliance with national regulations (if they exist).

UNDP COs should ensure the safe disposal of unusable (e.g., damaged, expired) and used (e.g., used RDTs, laboratory waste) health products, using methods that involve minimal risks to public health and the environment. Guidance is provided in WHO-related guidelines.

UNDP CO are involved in health products waste management in the following cases: 1) Disposal of rejected health products at their reception in country (for instance due to confirmed or suspected quality issues, incorrect specifications), or 2) Disposal of expired or obsolete health products that were procured by UNDP CO.

The preferred mode of disposal is incineration *at high temperatures with double combustion*. For each country, it will be important that UNDP CO identify a site for disposal of the health products (that could be, for example, a cement factory with high temperature combustion facility) or support (if budget allows) in procuring an incinerator, supporting the development of SOPs, and ensuring a mechanism is in-place to sustain operation of the incinerator beyond the project lifespan.

Once products have been destroyed, UNDP COs should obtain a copy of the **destruction certificate**, signed by the NRA and other partners involved, and should prepare a **disposal report** with the quantities of products, the reasons for expiry and/or disposal, and measures taken to avoid similar situations in the future.

Practice Pointer

UNDP guidance on medicines waste management is detailed in the **UNDP online PSM training**, Module on Waste Management.

Additional information developed by the Global Fund can also be found **here**.

Resources

- **UNDP online PSM training website**

13. Rational use

13.1 Pharmaceuticals

Rational use of medicines requires that "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. WHO advocates 12 key interventions to promote rational use.

Generally, the MoH is responsible to ensure rational use of medicines in the country through regularly updating the standard treatment guidelines (STG) and the essential medicines lists (EMLs), and through regular training of prescribers and providing updates to them.

UNDP COs can support the MoH and NRA to implement activities that encourage adherence to treatment, and that encourage rational use and good prescribing practices. This includes:

- 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 information and communications technology (ICT) tools to promote rational use and prescription practices; and
- Conducting research and surveys and disseminating the findings to encourage rational use.

In collaboration with WHO (key technical partner on rational use) UNDP COs can support the MoH and NRA, technically and/or financially, in improving rational use of medicines, through various activities, including the following examples:

- Updating of a National Medicines Formulary (NMF); Training and promotion of the NMF or NEML;
- Technical support to update STG;
- Training of prescribers on STG;
- Organizing surveys to identify causes of non-respect of STG;
- Organizing seminars and other communication activities on the change of treatment regimens and posology; and
- Supporting mass information campaigns (e.g., rational use of antibiotics).

Resources

- WHO Promoting rational use of medicines

13.2 Laboratory diagnostic products

Rational laboratory use is defined as effective and correct laboratory use by providing the most appropriate test selection with the right clinical approach in line with the evidence based data and considering the cost and patient safety

UNDP COs are responsible for ensuring that

i. the laboratory diagnostic products are used in-line with national testing algorithms and protocols on biosafety and biosecurity set forth by WHO and by international health regulations, and

ii. testing sites are operated within a quality management system using internationally accepted standards, specifically

Pratically this means that UNDP COs should support the MoH through ensuring that

iii. The diagnostic products are only used by appropriately trained and suitably qualified individuals;

iv. The environment intended for the utilization of those diagnostic products is suitable;

v. The laboratory organizes calibration and maintenance of the diagnostic equipment; and

vi. The laboratory participates in external quality assessment (EQA) programs.

UNDP COs are encouraged to include activities related to implementing a quality management system into their projects and should ensure budgeting of these activities during project planning.

14. Pharmacovigilance

Pharmacovigilance (PV) is defined by WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. A quality issue with a medicine can trigger an adverse drug reaction (ADR) and this is the reason of the presence of a Pharmacovigilance section in this document.

UNDP COs must ensure that the health authorities responsible for implementing prevention and treatment programmes have a pharmacovigilance system in place for monitoring adverse drug reactions and resistance. If these systems are not in place, the health programme(s) should obtain advice from an international organization or a consultant with technical expertise in this area.

In collaboration with WHO (key technical partner for PV), UNDP COs can contribute in different ways to the strengthening of a national PV programme, for example:

- Provision of specialized technical assistance (consultants)
- Material support to the PV unit (IT equipment, software, premises)
- Trainings of PV unit staff and/or health facilities staff
- Funding of PV pilot projects more particularly for newly introduced medicines (e.g.,: Dolutegravir)
- Support to the designing, printing and distribution of Adverse Drug Reaction (ADR) forms

Based on information received through the national pharmacovigilance system, the NRA may request UNDP CO to send a sample of suspect medicines for QC.

15. Risk Management for PSM of health products

Due to the specialized nature and complexities of health procurement, procuring and managing health products requires relevant expertise and bears some unique risks for UNDP. Noncompliance with the UNDP procurement rules and regulations and quality assurance policy requirements could create substantial liabilities for UNDP, which are highlighted in the Potential Liabilities Related to Health Procurement document **here**.

According to the UNDP–Global Fund **Grant Regulations**, UNDP, as interim Principal Recipient (PR), ***is accountable for the end to end supply chain, from product selection to the rational and adequate use of medicines and other health products***. This differs from normal UNDP procedures for other health programmes, whereby responsibility is transferred to the national entities when they take possession of the products, through a products delivery procedure.

As Global Fund interim PR, or while implementing health projects supported by financing agreements, 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 health products.

Procurement and supply chain management of health products should be carried out by **qualified personnel**, complying with UNDP procurement principles and regulations *to achieve value for money, ensuring transparency and accountability, and fostering development results, while mitigating risks*.

In relation to each existing and new grant or financing agreement, UNDP requires that there be a **detailed mapping and analysis** of the organization's responsibilities and the corresponding capacities of each Country Office (CO) to effectively manage the associated accountabilities and risks. This mapping and analysis must be captured in the UNDP project risk register. Further information is available on the **Risk Management section** of the Manual.

To mitigate some of the risks associated with the procurement and supply chain management of health products, the GHPC HPS 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 in **this section of the Manual**.

As a result of joint tender with other UN agencies, UNDP has a global LTA with Willis for cargo and storage insurance for stocks in warehouses since 1 January 2013. The **Guidance Note for the application of insurance coverage modalities under the global LTA with Willis** outlines the necessary actions that Country Offices must undertake to ensure that all goods for which UNDP is liable are covered.

It is critical that UNDP COs complete *timely monthly reporting* to Willis for maintenance of the insurance coverage on warehouse stocks, stocks in transit, and cargo. Examples of cases in which Willis insurance has recovered losses include:

- A truck transporting goods to a warehouse came into contact with riots and caught fire, causing damage to all cargo;
- Theft of goods from a warehouse in a crisis country context;
- Situations in which pharmaceutical products going through international transit were not maintained at the level recommended by the manufacturer, thereby making the quality of the products doubtful and in some cases unsuitable for use. In cases where loss is confirmed, the insurance can cover it; and
- When a product's quality has been compromised, the insurance can also cover the cost of the disposal.

Practice Pointer

Beyond recovering financial loss, insurance mitigates the spillover effects that the loss of uninsured goods can have on programme delivery, such as stock-outs and disruption in service provision.

Please note that:

- Assets (e.g., physical infrastructure, medical- and laboratory equipment) are not covered by the insurance.
- The insurance does not automatically provide coverage for political violence unless the Country Office requests it. This coverage is under a separate agreement and if activated, involves additional payment.
- The insurance only covers health products procured by UNDP. If a Country Office receives requests to provide additional insurance on behalf of government, or to cover insurance for stocks stored in a warehouse where UNDP is not a PR for the Global Fund programme, it is recommended to contact the GHPC HPS team.
- UNDP should exercise caution when requested to act as a service provider for other PRs, as this can affect the insurance premium rate.

Strengthening of PSM Services and Risk Mitigation

Central to the UNDP's capacity development strategy is a strong focus on strengthening systems for health, in particular the following **5 functional capacities**:

- Financial Management & Systems, including Risk Management
- Procurement and Supply Chain Management (PSM)
- Monitoring and Evaluation (M&E)
- Project Governance and Programme Management
- Sub-recipient (SR) Management

UNDP Country Offices (COs) are encouraged to develop a budgeted Quality Assurance Plan (QAP) at the beginning of each new project that includes the procurement and supply chain management of health products. The QAP should have well defined activities and should reflect the agencies involved, their responsibilities, the indicative budget and the agreed timeframe.

A Quality Assurance plan (see **model**) consists of:

- A list of activities that will help to guarantee quality of the health products procured and managed by UNDP, and to strengthen national systems around storage, distribution, and quality monitoring.
- Allocated budget for each activity
- Performance indicators or milestones for key activities
- Chronogram with anticipated completion date of each activity
- Entity responsible for each activity

The activities selected should be extracted from national documents (e.g., QA part of the Implementation Plan of the NPP, NRA Institutional Development Plan developed following an assessment of the NRA by WHO, QA part of the Strategic Development Plan of the National Procurement Centre/Central Medical Store, Strategic Development Plan of the National Quality Control Laboratory), where available.

Practice Pointer

The **UNDP online PSM training** has an Advanced course with a specific module on how to elaborate QA plan.

Implementation, against the approved QA plan and the approved QAP budget, should be monitored quarterly by the QA working group, and progress should be assessed at the end of every year. Based on the annual review, the QA plan and budget should be updated by the QA working group to reflect any necessary changes.

Regulatory and QA strengthening activities are often supported by a few in-country partners. When developing the QA Plan, it would be important for UNDP to understand the support provided by key partners such as WHO, UNICEF, USP, Chemonics, UNFPA and to ensure synergy and alignment with national plans. Consolidation of funding from other GF PRs and other funding sources (Government, other technical partners) is encouraged as it allows to support a more comprehensive plan.

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 UNDP rules.

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 and the UNDP-GF Framrework Agreement. The Global Fund's PPM is implemented via their procurement platform www.wambo.org.

Overseeing procurement by Sub-recipients

UNDP has determined that direct procurement of health products 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% of the SR agreement's amount or US$100,000 (whichever is less) on procurement.

Resources

- **Quality Assurance Policy - Potential Liabilities Health Procurement**
- **UNDP Capacity Development for Health Website**
- **Guidance Note on Insurance coverage modalities and application under UNDP corporate LTA with Willis**
- **QA Action Plan Template**
- **UNDP online PSM training website**

16. Compliance with the Global Fund requirements

UNDP Country Offices implementing Global Fund grants should ensure that **all** health products are procured in compliance with both the **UNDP QA Policy** for Health Products and the **Guide to the Global Fund Policies on Procurement and Supply Management of Health Products**, which includes the **Global Fund QA policies for pharmaceuticals, medical devices, and vector control products**.

In the case of any disbursement that is not used in accordance with the Grant Agreement, or that finances goods or services that are not used in accordance with the relevant Grant Agreement, the Global Fund may require the Principal Recipient to refund the amount of such disbursement to the Global Fund (Article 8 of the **UNDP Global Fund Framework agreement**).

The **Global Fund Guidelines for Grant Budgeting** provides the Global Fund's definition of non-compliant expenditures, which refer to expenses incurred that do not align with the provisions of the signed grant agreement or the appropriate financial and procurement procedures of the implementer or grant. Pages 42-45 of these guidelines provide the non-exhaustive list of expenditures that could be classified as non-compliant by the Global Fund.

Among them, the following items relate to QA: "Non-compliance with quality assurance for health products, and related issues: procurement of products that do not meet the requirements outlined in the Global Fund's quality assurance policies; biased/tailored tender specification limiting competition and favoring a specific product (or group of products)."

Price and Quality Reporting (PQR)

Countries implementing Global Fund-funded programmes are required to electronically submit information related to health product pricing and quality to the Global Fund for publication in its Price and Quality Reporting Mechanism, a publicly accessible online database.

Upon receipt of health products in the country in the categories indicated below, recipients should promptly report the required procurement information to the Global Fund as specified in, and using the forms required by, the Price and Quality Reporting (PQR) mechanism available on the Global Fund website. This includes reporting information on the price paid and other information related to the quality of the health products. Information can be entered by using **this link**. Recipients are required to report unit prices independently of freight and insurance charges, which must be separately itemized.

The recipients are currently required to report the following categories of health products:

i. ARVs;

ii. Anti-malarial pharmaceutical products;

iii. Anti-TB pharmaceutical products;

iv. Anti-hepatitis C pharmaceutical products;

v. Long lasting insecticidal nets or other insecticide treated nets with WHO Policy recommendation;

vi. Insecticides for indoor residual spraying activities;

vii. Condoms (male and female);

viii. Diagnostic tests for HIV, TB, malaria, and co-infections such as syphilis, hepatitis B and hepatitis C; and

ix. Laboratory equipment for HIV, hepatitis, TB and malaria testing; Polymerase chain reaction (PCR) equipment for HIV viral load and HIV early infant diagnostics (EID), hepatitis and malaria; TB liquid culture equipment, TB molecular and cartridge based molecular testing; CD4 and enzyme linked immunosorbent assay (ELISA) test equipment.

x. Surgical and non-surgical masks and respirators.

Timely entry of procurement information in the PQR mechanism for relevant health products is a prerequisite for the Global Fund to approve disbursements. Disbursements may be delayed if such reporting is not duly completed.

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

In order to ensure the accuracy and completeness of reporting by recipients, the Global Fund requires that Local Fund Agents (LFA) verify all data entries on an ongoing basis, as relevant.

To verify the entries in the PQR for accuracy and completeness, the LFA typically requires 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, ***UNDP COs cannot 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 landing; and payment vouchers or supplier invoices for UN. Therefore, ***COs should not upload such documents into the PQR***.

Instead, **COs should complete the UNDP excel spreadsheet** (see the template **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 the PQR.** The accuracy of the spreadsheet presented to the LFA is extremely important, and inconsistencies and/or inaccuracies may result in disbursement delays.

COs can upload the quality-related documents (e.g., Certificate of Analysis, Certificate of Conformity) to PQR.

Information reported by all PRs can be viewed by selecting the "**Price Reference Report**" or "**Transaction Summary**" links on the site.

Resources

- **UNDP Quality Assurance (QA) Policy**
- **Guide to the Global Fund Policies on Procurement and Supply Management of Health Product**
- **Global Fund quality assurance requirements**
- **Courtesy Consolidation of UNDP Global Fund Framework agreement**
- **Global Fund Guidelines for Grant Budgeting**
- **A Quick Guide to the Global Fund's Price and Quality Reporting System**
- **PQR Sample Template**

17. UNDP Health PSM Roster

To strengthen its efforts to effectively support national stakeholders in health capacity development, the UNDP Global Fund Partnership and Health Services Team (GFPHST) has established a **health procurement and supply chain (PSM) roster** of available **health PSM experts and specialized professionals such as engineers, architects, biologists** to provide support to its programmes in the areas of health products procurement and health supply chain systems, quality assurance for health products and in the design and renovation of pharmaceutical infrastructures in public health systems, solarization to help support and systematically improve all aspects of the health supply chain.

GFPHST's PSM roster of experts is integrated as a sub-category under the Health Roster within the GPN/ExpRes Roster. The **Global Policy Network (GPN/ExpRes) deployment mechanism** provides pre-selected and technically vetted consultants to support the work of UNDP Country Offices/units. For more information, please see **this section** of the Manual.

Depending on the support needs of the requesting CO, the contracting modality of expertise sourced through the GPN ExpRes Roster can either be an **Individual Contract (IC)** / Reimbursable Loan Agreement (RLA) or a short-term International Services Agreement Holder **(IPSA)**.

The Experts sourced from the ExpRes roster on PSA modality can only be contracted for up to 6 months (or 130 working days over 1 calendar year).

The ACP approval under which the GPN/ExpRes Roster operates, allows for the roster to be used for the recruitment of consultants with a contract value of maximum $100,000 on deliverable- based contracts only.

The GPN deployment team works in coordination with the GFPHST roster focal points for incoming requests related to any of the 14 categories mentioned below.

Upon request, the health PSM consultants on the roster are matched to terms of reference (TORs) submitted for a specific assignment. The qualified consultants can be contracted and deployed to provide specific technical advice and short-term assignments.

The **health PSM roster** comprises the following 14 functional technical categories of expertise:

i. PSM quantification, forecasting, budgeting and planning experts for health products;
ii. Quality Assurance experts: 2.A: QA systems and 2.B: QA for Health Products;
iii. Health supply chain management systems experts;
iv. Health products related procurement process such as medical devices, diagnostics, X-ray, scanning, radiological equipment and supplies (consumables and medical equipment) experts;
v. Logistics management information system (LMIS) experts; pharmaceutical supply chain traceability systems experts, GS1 Experts;
vi. Health products regulatory experts/ support to national regulatory systems experts;
vii. Medical laboratory (Rapid Diagnostic Tests, reagents, laboratory equipment) experts;
viii. Health infrastructure engineers (warehouse and health facilities construction or renovation);
ix. PSM capacity development and training experts;
x. Distribution systems /Good distribution and storage practices experts;

xi. Sustainable health supply chain experts;

xii. Waste management experts;

xiii. Market research for health procurement;

xiv. Health procurement experts;

All Deployment Requests take place on the **UNDP Deployments Platform's Agent Portal**.

If the assignment qualifies for GPN/ExpRes, you will receive a notification from the Roster Recruitment Officer (RRO) who will become the focal point for the deployment. The RRO is responsible for ensuring that the CO is provided with at least one available expert (ideally 2 or more) within 5 days of a request being received. For more information on the GPN ExpRes Roster process and costs involved, please refer to the **Human Resources** section of the Manual.