

**UNDP Quality Assurance Policy for Health Products**

Global Fund Partnership and Health Systems Team

HIV and Health Group, Bureau for Policy and Programme Support

United Nations Development Programme

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| *This document has been* ***externally peer-reviewed*** *by Quality Assurance experts from the World Health Organization Regulation and Prequalification teams and The Global Fund to Fight AIDS, Tuberculosis and Malaria.*  *The document has also been subject to* ***internal peer review*** *by United Nations Development Programme (UNDP) Regional Bureaux, Bureau of Management Services Office of Procurement and Office of Legal Services, and the Office of Audit and Investigations.*  *This policy was approved by the Executive Group on 2 July 2018, and its revised version was approved on 10 July 2024.* |

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# Abbreviations and acronyms

|  |  |
| --- | --- |
| **AIDS** | Acquired immunodeficiency syndrome |
| **API** | Active Pharmaceutical Ingredient |
| **BMS** | Bureau of Management Services (UNDP) |
| **BP** | British Pharmacopoeia |
| **BPPS-HHG** | Bureau for Policy and Programme Support – HIV and Health Group (UNDP) |
| **CAB** | Conformity Assessment Body |
| **CTD** | Common Technical Document (ICH) |
| **DNO** | Diagnostics Network Optimisation |
| **EDL** | Essential Diagnostics List |
| **EMA** | European Medicines Agency |
| **EM** | Essential Medicines |
| **EML** | Essential Medicines List |
| **EOI** | Expression of Interest |
| **ERP** | World Health Organization Expert Review Panel |
| **ERPD** | Expert Review Panel for Diagnostics |
| **FDA** | Food and Drug Administration (United States NRA in this document) |
| **FPP** | Finished Pharmaceutical Product |
| **GDF** | Global Drug Facility |
| **GFPHST** | Global Fund Partnership and Health Systems Team (UNDP) |
| **GHTF** | Global Harmonization Task Force (on Medical Devices) |
| **Global Fund** | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| **GLP** | Good Laboratory Practices |
| **GLU** | General Laboratory Use |
| **GMP** | Good Manufacturing Practices |
| **GPSD-H** | Global Procurement Supply Division-Health |
| **GSDP** | Good Storage and Distribution Practices |
| **Health Canada** | Canada National Regulatory Authority |
| **HIV** | Human immunodeficiency virus |
| **IAF** | International Accreditation Forum |
| **IAPQ** | Inter-Agency Product Questionnaire |
| **ICH** | International Council for Harmonization  (of Technical Requirements for Pharmaceuticals for Human Use) |
| **INN** | International Non-proprietary Name |
| **IMDRF** | International Medical Devices Regulator Forum |
| **ISO** | International Organization for Standardization |
| **IVD** | In Vitro Diagnostic |
| **JPMDA** | Japan Pharmaceuticals and Medical Devices Agency |
| **MA** | Marketing Authorization |
| **MD** | Medical Device |
| **MHRA** | Medicines and Healthcare products Regulatory Authority (UK NRA) |
| **MIF** | Manufacturer Information File |
| **ML** | World Health Organization National Regulatory Maturity Level |
| **MQAS** | World Health Organization Model Quality Assurance System  (for Procurement Agencies) |
| **MSF** | Médecins Sans Frontières |
| **NCD** | Non-Communicable Diseases |
| **NRA** | National Regulatory Authority (Pharmaceutical Authority) |
| **OAI** | Office of Audit and Investigations (UNDP) |
| **OOS** | Out of Specification |
| **PA** | Procurement Agency |
| **PAIF** | Procurement Agency Information File |
| **PIC/S** | Pharmaceutical Inspection Co-operation Scheme |
| **PPE** | Personal Protective Equipment |
| **PQ** | Pre-Qualification |
| **PSM** | Procurement and Supply Management |
| **QA** | Quality Assurance |
| **QC** | Quality Control |
| **QMS** | Quality Management System |
| **RUO** | Research Use Only |
| **SOP** | Standard Operating Procedure |
| **SFMP** | Substandard and Falsified Medical Products |
| **SRA** | Stringent Regulatory Authorities |
| **SWISS MEDIC** | Swiss NRA |
| **TB** | Tuberculosis |
| **TGA** | Therapeutic Goods Administration (Australian NRA) |
| **TRS** | Technical Report Series (WHO) |
| **tWLA** | Transitional list World Health Organization Listed Authorities |
| **UNICEF** | United Nations Children’s Fund |
| **UNDP** | United Nations Development Programme |
| **UNFPA** | United Nations Population Fund |
| **USP** | United States Pharmacopoeia |
| **VCP** | Vector Control Products |
| **WHO** | World Health Organization |
| **WHO GBT** | World Health Organization Global Benchmarking Tool |
| **WHOPES** | World Health Organization Pesticide Evaluation Scheme |
| **WHOPIR** | World Health Organization Public Inspection Report  (as published on the WHO PQ website) |
| **WHO PQT** | World Health Organization Prequalification Team |
| **WLA** | World Health Organization Listed Authorities |

# Glossary

**Cold chain equipment**

Cold chain equipment includes all health product refrigerators, combined refrigerator water-pack freezers, freezers and water-pack freezers, power systems, accessories such as temperature data loggers, and passive containers, such as carriers and cold boxes, intended for use with health products and includes cold chain equipment for storing specimens/samples for clinical laboratory analysis.

**Diagnostic Network Optimisation (DNO)**

It is a geospatial network analytics approach to plan diagnostic networks consistent with national health goals and strategies, including universal health coverage. The exercise aims to redesign the diagnostic network set-up to increase access, maximize impact, and generate efficiencies. It aligns testing demand and capacity in the most cost-effective way by defining the optimal instruments mix, identifying the most appropriate locations where instruments should be placed, and designing the most effective and or efficient referral network linkages across that revised network

**Essential Diagnostics List (EDL)**

A World Health Organization (WHO) health policy document first published in 2018, based on scientific evidence, consisting of a list of categories of IVD tests and recommendations for using those tests in relation to the assay format, test purpose, specimen type and health care setting. The list aims to serve as a reference to guide development of or to update a national EDL (NEDL) at the country level within the framework of universal health coverage

**Essential Medicines (EM)**

WHO defines essential medicines (EM) as those that satisfy the priority health care needs of the population. They are selected based on disease prevalence and public health relevance, clinical efficacy and safety evidence, comparative costs, and cost-effectiveness.

**Essential Medicines List (EML)**

A list of medications considered the most effective and safe to meet the most important needs in a health system.

The World Health Organization (WHO) Model List of Essential Medicines (Essential Medicines List or EML) was first issued by the WHO in 1977. Many countries have used the WHO model to develop their own (national) list of essential medicines (National EML or NEML).

**Expert Review Panel (ERP)**

An independent advisory body of technical experts created by the Global Fund and the WHO and coordinated by the WHO. The ERP uses transparent, science-based criteria to assess the quality risks of Finished Pharmaceutical Products (FPPs) and in-vitro diagnostics (IVDs) that are neither WHO-prequalified nor approved by a stringent regulatory authority. Assessment results inform procurement decisions relating to (time-limited) procurement of the products assessed.

**Falsified Medical Products**

The WHO defines Falsified Medical Products as medical products that deliberately/fraudulently misrepresent their identity, composition, or source.

**Finished Pharmaceutical Product (FPP)**

See “Medicine”.

**Global Harmonization Task Force (GHTF)**

The GHTF was established in 1993. It comprises five Founding Members: the European Union, the United States, Canada, Australia, and Japan.

The purpose of the Global Harmonization Task Force was to encourage convergence in requirements and regulatory practices related to ensuring the safety, effectiveness, performance, and quality of medical devices, promoting technological innovation, and facilitating international trade.

The GHTF issued various documents to harmonize the definition, classification, and principles for assessing medical devices’ (MDs)' quality, safety, and performance and for post-market surveillance and vigilance standards.

(Note: In the context of this Quality Assurance (QA) policy, after the United Kingdom’s withdrawal from the European Union, the UK Medicines and Healthcare products Regulatory Authority (MHRA) is considered a GHTF Founding Member country as it was part of the European Union when the GHTF was established.)

**Good Storage and Distribution Practices (GSDP)**

Good Storage and Distribution Practices are part of QA that ensures that the quality of health products is maintained through adequate control of the numerous activities that occur throughout the distribution process.

**Good Laboratory Practices (GLP)**

The WHO defines Good Laboratory Practices as a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that support the analysis of active pharmaceutical ingredients (APIs), excipients, and pharmaceutical products. Other activities covered under the scope of GLP may include sampling, packaging materials stability testing, and investigative testing.

**Good Laboratory Use (GLU)**

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination

**Good Manufacturing Practices (GMP)**

Good Manufacturing Practices ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

**Health Products**

Products include, but are not limited to, finished pharmaceutical products (FPPs), medical devices (MD), including in vitro diagnostic (IVD) tests, and vaccines. In the context of this document, “health products” include FPPs, MDs, IVDs, vector control products (VCP), medical gases, medical gas supply systems, and personal protective equipment (PPE) intended to protect patients and medical staff while carrying out their duties.

**International Medical Devices Regulatory Forum (IMDRF)**

Established in 2011, IMDRF is a voluntary group of medical device regulators (Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, and the United States) who have come together to build on the work of the GHTF and aims to accelerate international medical device regulatory harmonization and convergence. The WHO is an official observer at the IMDRF.

**International Council for Harmonization (ICH)**

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use is a project that brings together regulatory authorities and experts from the pharmaceutical industry to discuss scientific and technical aspects of product registration. The ICH produces quality, efficacy, and safety guidelines that member countries adopt, often included in national pharmaceutical legislation.

**International Organization for Standardization (ISO)**

The ISO is an independent non-governmental organization made up of national standards bodies. The main aim of the ISO is to set standards covering almost all aspects of technology, management, and manufacturing. The standards may be generic (e.g., ISO 9000 series) or product-specific requirements for implementing a quality management system (e.g., ISO 13485 for medical devices).

**Medical Laboratory Equipment**

Medical laboratory equipment includes apparatus, electrical, and non-electrical instruments used in a medical/clinical laboratory and are not classified as IVDs or medical devices.

**Medical Laboratory Supplies**

Medical laboratory supplies are products used in the laboratory as part of medical laboratory work and are not classified as IVDS or medical devices, e.g., lab chemicals.

**In Vitro Diagnostic (IVD) medical device[[1]](#footnote-2),[[2]](#footnote-3)**

A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes.

**Manufacture (Manufacturing)**

All or any operations of purchase of materials and products, production, quality control, release, storage, and distribution of health products and the related controls.

**Manufacturer**

Any natural or legal person with responsibility for the design and/or manufacture of health products with the intention of making them available for use under the Manufacturer’s name, whether or not such a Health Product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s).

**Marketing Authorization**

A legal document issued to an applicant by the competent medicine regulatory authority for marketing or free distribution of a product after evaluation for safety, efficacy, and quality. It must set out, among other things, the product’s name, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Non-proprietary Name (INNs) or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g., “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence.”). It also contains the product information approved for health professionals and the public, the sales category, the authorization holder's name and address, and the authorization's validity period. Once a product has been given marketing authorization, it is included on a list of authorized products – the register – and is often said to be “registered” or to “have registration.” Market authorization may occasionally be referred to as a “license” or “product license.”

**Medical Device[[3]](#footnote-4)**

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 a physiological process,
* supporting or sustaining life,
* control of conception,
* disinfection of medical devices and
* providing information using 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.

**Medical equipment**

Medical devices requiring calibration, maintenance, repair, user training, and decommissioning, which are activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used alone or in combination with any accessory, consumable, or other medical equipment. Medical equipment excludes implantable, disposable, or single-use medical devices.

**Medical furniture**

Medical furniture includes beds, chairs, infusion stands, medical lighting, operating tables, and medical trolleys for healthcare. Some medical furniture is classified as medical devices.

**Medical Gas**

Medical gases consist of active substances or a mixture of active substances and gaseous excipients.

They are manufactured, packaged, and intended for administration to a patient in anaesthesia, therapy, or diagnosis. Depending on the intended use, the country of manufacturing, and the country of use, medical gases can be classified as medicines or medical devices.

**Medical Gas Supply System**

An assembly of devices designed to supply compressed medical gases [i.e. oxygen (O2), nitrous oxide (N2O) or medical air] from a central source to endpoints throughout a medical facility. The system typically consists of several gas supplies (e.g. bulk oxygen concentration system, bottled gas with air compressors, etc.), a pipework system that includes pressure regulators, pressure relief valves, zone valves, an alarm system with remote and/or local indicators, emergency backup devices for medical gases, and wall outlet terminal units at the point of care.

**Medical Oxygen Concentration System**

A stationary assembly of devices designed to concentrate oxygen (O2) from ambient air and deliver the concentrated O2 to the hospital medical gas supply system. It typically consists of an air compressor, refrigeration dryer, water and oil separators, high pressure oxygen pump and various storage tanks. The concentrated oxygen is delivered via the medical gas supply system to the user and/or a gas cylinder filling station.

**Medicine (Finished Pharmaceutical Product – FPP)**

Any substance or pharmaceutical product for human or veterinary use intended to modify or explore physiological systems or pathological states for the recipient's benefit. The terms medicine and Finished Pharmaceutical Product are used interchangeably in this document.

**Model Quality Assurance System for Procurement Agencies (MQAS)**

The MQAS is a WHO guidance document developed at the request of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) and adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in 2006.

The purpose of the MQAS is: (i) to help procurement agencies formulate and implement an adequate quality assurance system and (ii) to guide the assessment of the procurement agencies by third parties (inspections, audits) and the agencies themselves (self-assessment).

**National Regulatory Authority (NRA)**

A national body that administers the full spectrum of medicine regulatory activities, including at least all of the following functions in conformity with national health product legislation: marketing authorization of new products and variations of existing products; quality control laboratory testing; monitoring of adverse health product reactions; provision of health product information and promotion of rational health product use; good manufacturing practice (GMP) inspections and licensing of manufacturers, wholesalers and distribution channels; enforcement operations; and monitoring of health product utilization.

**Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of GMP of medicinal products for human or veterinary use. It is open to any authority that has a comparable GMP inspection system.

**Personal Protective Equipment (PPE)**

Personal protective equipment is used to prevent or minimize exposure to hazards such as:

* Biological hazards
* Chemical hazards
* Radiological hazards
* Electrical hazards
* Mechanical hazards

Without PPE, exposure could lead to injuries and illnesses. A range of industries use PPE to protect their workforce from occupational hazards. The construction, mining, chemical, and pharmaceutical industries are among those using PPE regularly. Healthcare workers also use PPE to ensure safety during working hours; in this case, the PPE is considered a health product.

**Qualification**

The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The product or service and the facility where it is manufactured are examined by trained and qualified inspectors against common standards.

**Procurement Agency (PA)**

This document defines a procurement agency as any organization purchasing pharmaceutical products, medical devices, IVDs, and other health products or otherwise involved in their qualification (see above), purchasing, storage, and distribution. Distributors, wholesalers, traders, and brokers are considered in this policy as “procurement agencies” bound by WHO guidelines set for them.

**Product information**

In the context of this document, product information means information on health products submitted by manufacturers or suppliers in any formats specified in the PA’s guidelines (including product dossiers, product questionnaires, or other forms) to obtain qualification for the products.

**Quality Assurance (QA)**

Quality Assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a health product in the context of this policy. It is the totality of the arrangements to ensure that procured health products are of the quality required for their intended use.

**Quality Control (QC)**

Quality Control of health products is concerned with sampling, specifications, inspection, and testing, and with the PA’s documentation and acceptance/rejection procedures, which ensure that the necessary and relevant tests are carried out and that starting materials, intermediates, and finished products are not accepted for use, supply or distribution to patients until their quality has been judged to be satisfactory.

**Quality Management System (QMS)**

In the context of procurement of health products, a QMS is a management system to direct and control an organization about quality of service and health products (for quality system essentials) for facilities and safety, organization, personnel, equipment, purchasing and inventory, process control (QC), information management, document and records, customer service, external quality assessment.

**Quality Monitoring**

All activities are undertaken to ensure that the health products continue to conform with the manufacturer’s established quality specifications during the storage, distribution, and use of such products, including but not limited to lot testing, reporting of deficient health products, and surveillance, as part of a QA system throughout the supply chain.

**Research Use Only products**

Research Use Only (RUO) products are products intended for research procedures and not intended for medical use, e.g., diagnosis or treatment management of a specific patient; i.e., RUO products are not in vitro diagnostic procedures.

**Source**

A source in the context of this document is a pair “health product – manufacturing site” or a triad “health product – procurement agency – manufacturing site” when the product is not directly purchased from the manufacturer but through a PA.

**Standard Operating Procedure (SOP)**

An authorized written procedure is giving instructions for performing operations (both general and specific).

**Stringent Regulatory Authority (SRA)**

Interim definition of the WHO (Evaluating and publicly designating regulatory authorities as WHO listed authorities, Policy document, 2021:[[4]](#footnote-5) A regulatory authority that is:

* a) a member of ICH before 23 October 2015, namely the US Food and Drug Administration, the European Commission, and the Ministry of Health, Labour and Welfare of Japan, also represented by the Pharmaceuticals and Medical Devices Agency;
* or b) an ICH observer before 23 October 2015, namely the European Free Trade Association, as represented by Swiss Medic and Health Canada;
* or c) a regulatory authority associated with an ICH member througha legally binding, mutual recognition agreement before 23 October 2015, namely Australia, Iceland, Liechtenstein, and Norway.

**Substandard medical products**

WHO defines substandard medical products as authorized medical products that fail to meet either their quality standards or specifications. Substandard medical products are sometimes called "out of specification" products.

**Supplier**

An entity or company providing health products on request. Suppliers may be agents, distributors, manufacturers, traders, etc. Suppliers must be authorized by their regulatory authority.

**Transitional WHO Listed Authority (tWLA)**

The tWLA list replaced the WHO Interim list of listed authorities, which compiled categories of authorities recognized by WHO to have achieved levels of operation necessary for the regulation of medicines and/or vaccines. The tWLA list is valid for five years from the date of publication of the interim WLA Operational Guidance (31 March 2022) during which time the authorities will be evaluated against the requirements for designation as a WLA.

**UNDP Quality Assurance team**

The UNDP QA Team comprises the QA Advisor, QA Specialists, QA Associates, and a pool of experts with specific high-level skills in QA for health products. The UNDP Bureau for Policy and Programme Support – HIV and Health Group (BPPS-HHG) and Global Fund Partnership and Health Systems Team (GFPHST) host it and provide QA services across UNDP business units.

**Vector Control Products (VCP)**

Vector control products reduce the populations of vectors or reduce human contact with vectors.[[5]](#footnote-6)

**WHO Listed Authority[[6]](#footnote-7)**

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system that has been documented to comply with all the indicators and requirements specified by the WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

# Introduction

In line with the UNDP Strategic Plan (2022-2025)[[7]](#footnote-8) and the UNDP HIV and Health Strategy (2022-2025),[[8]](#footnote-9) UNDP supports countries to implement large-scale health programmes and strengthen national capacities to deliver inclusive, essential services for resilient health systems within the framework of national policies and priorities. This is done to support countries in achieving the Sustainable Development Goals in close cooperation with the WHO[[9]](#footnote-10) and other UN agencies. More specifically, this helps countries to build a solid foundation for universal health coverage and ensure that no one is left behind.

Since 2003, UNDP has worked as an interim Principal Recipient of Global Fund grants in over 50 countries. In these countries, UNDP provides a broad range of implementation support, including procurement of medicines and other health products for HIV, tuberculosis (TB), and malaria (accounting for 50-60% of the budgets), which are complemented by longer-term capacity building efforts that include strengthening procurement and distribution systems for health products.

A rapidly increasing number of governments are requesting UNDP to help strengthen national capacities and systems to provide health services, especially for the procurement and supply management of health products for communicable and, more recently, for non-communicable diseases (NCD).[[10]](#footnote-11) In 2022 alone, UNDP procured over US$420 million in health products.

Procuring health products in a globalized but fragmented health product marketplaces UNDP at particular risk of providing substandard products, which could put patients’ health at risk, expose UNDP to legal actions, cause loss of funds, and severely damage the organization's reputation. The WHO estimates that about 10% of health products in low- and middle-income countries are either substandard or falsified.

Consequently, and in line with established best practices, UNDP has decided[[11]](#footnote-12) to develop and implement its QA Policy for all health products supplied by UNDP. This policy is indispensable given the immediate risk to human life associated with the distribution of substandard or falsified health products to individuals (inefficacy or toxicity of medicines, inappropriateness of medical devices, lack of sterility, etc.) and the community (risk of development of resistance to anti-infectious agents).

The UNDP QA Policy is based on international standards and best practices, including WHO guidelines for medicines and health products. It aligns with QA policies from other UN organizations and international organizations such as the Global Fund.

Regular monitoring and oversight of compliance with the QA policy and support to its implementation will be the responsibility of BPPS-HHG as part of its overall technical support to the organization, including UNDP Country Offices and the Global Procurement Supply Division/Health/Bureau of Management Services (BMS), as per the UNDP Organizational Performance Group decision.[[12]](#footnote-13) This policy will also guide the development of national quality assurance systems through longer-term UNDP capacity building activities in countries.

The UNDP QA Policy is a crucial document for all parties involved in health procurement activities across UNDP and for national partners, suppliers, and donors as it details UNDP’s requirements for health procurement in line with international best practices.

The QA Policy is structured into different sections, starting with the scope of the products governed by the policy. It explains the responsibilities of all UNDP entities that procure health products. Specific regulatory and technical requirements for each product category are stipulated. Once products are procured, there is a need to monitor compliance with approved specifications; a section on quality monitoring has been included.

# Scope

The UNDP QA Policy applies to all health products such as medical furniture, medical laboratory instruments, and cold chain equipment for the storage and transportation of health products procured and/or suppliedby or donated through UNDP, whether through its specialized procurement services at the corporate level, UNDP Country Offices, or other business units.

This document covers all up-stream QA activities, i.e., from the qualification of the sources of health products until their delivery to the final consignee in the recipient country. The QA Policy also covers quality monitoring activities of products after procurement.

The UNDP QA system includes clear quality requirements for health products, manufacturing sites, and all entities involved in storing, distributing, and transporting such health products.

The same product can sometimes be classified as a medical or a non-medical product, depending on the intended use, context, and regulatory status in the country of origin (manufacturing) or recipient country. For example, vitamins and minerals can be registered as medicines in some countries or marketed as nutriments in others. Equipment (refrigerators, incinerators, autoclaves, printers for X-ray machines, etc.), devices, consumables (swabs), and protective equipment (masks, goggles, face shields, etc.) may be regulated as medical devices in some countries and not in others. Based on the nature of the product, the intended use, international guidelines, and good practices, the UNDP QA Team in consultation with the Health Product Management (HPM) Team, will determine the product’s status for the appropriate application of the quality assurance criteria.

# Responsibilities

Pursuant to the recommendations of the WHO,[[13]](#footnote-14) the UNDP Organizational Performance Group has established a QA Policy that describes the overall intentions and direction of the organisation related to quality of health products.

All UNDP business units undertaking health procurement shall apply this QA Policy.

In line with international best practices and WHO recommendations, the QA function is independent of the health procurement function of UNDP. BPPS-HHG is responsible for implementing, monitoring, and ensuring compliance with the QA Policy based on international best practices.

Under the leadership of BPPS-HHG, the UNDP QA Team is responsible for ensuring that all health products procured, received as donations, donated, stored and distributed by all UNDP business units, and donated to UNDP comply with the requirements of the UNDP QA Policy.

# Norms and standards

## Selection of health products to procure

WHO recommendations and relevant international clinical standards are used by UNDP as a primary reference to assess health products’ eligibility for procurement. For the selection of medicines (Finished Pharmaceutical Products, FPPs) to be procured, UNDP primarily refers to the latest editions of the WHO EMLs for adults and children[[14]](#footnote-15) , WHO rapid communications, and WHO treatment guidelines. Requests for FPPs included in a national EML or recommended as per national treatment guidelines are accepted.

Specifications of other health products (non-pharmaceuticals) are not usually standardized. Therefore, requests for other health products, such as medical devices, PPE, vector control products, etc., should be submitted with explicit and appropriate specifications for their intended use. UNDP refers to the latest versions of the WHO model list of Essential Diagnostics (WHO EDL), WHO global lists of priority medical devices, WHO rapid communications and WHO guidelines for diagnosis. Requests for IVDs included in the national EDL or recommendations from the Diagnostics Network Optimisation (DNO) assessments, or recommended as per national disease management guidelines, are accepted.

Specifications will be reviewed by UNDP technical specialists against WHO specifications for health products, GHTF/IMDRF guidelines, and other WHO and international guidelines as appropriate.

UNDP reserves the right to require detailed information on the request, including but not limited to the context of use, the current practices in the recipient country (e.g., protocols, algorithms), national policies, existing technical capacities (e.g., clinics, medical laboratories, emergency units, etc.), available resources for maintenance of equipment and post-delivery surveillance.

UNDP Country Offices and the UNDP QA Team will liaise with Health Product Management Specialists, WHO experts, working groups, and coordination mechanisms in emergencies to facilitate access to health products that meet the requirements of the UNDP QA Policy, as appropriate.

## Quality Assurance

The UNDP QA system for health is conducted according to the principles of the MQAS. The UNDP QA Team is independent of procurement. The UNDP qualification process includes assessing three components by international best practices: the supplier, the manufacturing site(s), and the product.

An essential part of the assessment is completed based on the information provided by the suppliers. Any manipulation or alteration of the documents submitted to UNDP, as well as any usurpation of regulatory approvals, logos, markings, or certifications, will be considered as a falsification as defined by the WHO[[15]](#footnote-16) and regulators[[16]](#footnote-17), [[17]](#footnote-18) and may lead to the disqualification of the product, the supplier or the manufacturer.

The QA Team will report evidence of alleged fraud and falsifications to the Office of Audit and Investigations (OAI), which will handle the case in line with their internal procedures.

All health products procured or supplied by UNDP must be authorized for use by the relevant National Regulatory Authority in the recipient country.

## References

The UNDP QA system is based on:

* + - WHO standards for pharmaceutical preparations, as published and regularly updated in the WHO Technical Report Series (TRS);
    - WHO disease treatment guidelines;
    - WHO rapid communications;
    - WHO health products technical specifications, e.g. WHO Medical Device Technical Series, WHO standards for prequalification of immunization devices;
    - Guidelines of the IMDRF[[18]](#footnote-19) for Medical Devices and IVDs;
    - WHO specifications for pesticides used in public health;[[19]](#footnote-20)
    - ICH for Pharmaceuticals for Human Use guidelines; and
    - The International Pharmacopeia, European Pharmacopoeia, the British Pharmacopoeia (BP), the United States Pharmacopoeias (USP).

UNDP refers to the latest editions of the pharmacopoeias and the latest versions of technical documents published by the WHO, regulatory authorities, or international bodies.

# Product and Manufacturer Requirements

## Finished Pharmaceutical Products (FPPs)[[20]](#footnote-21)

### Manufacturing sites

All manufacturing sites involved in the manufacturing of FPPs must:

* Be authorized by the National Regulatory Authority (NRA) of the country of location and
* Comply with WHO or equivalent Good Manufacturing Practices (GMP) guidelines.

UNDP recognizes the GMP inspections performed by one of the following:

* WHO Prequalification Team;
* WHO Listed Authorities (WLA) for the relevant product stream and regulatory function;
* NRAs participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) members;
* Stringent Regulatory Authority (SRA[[21]](#footnote-22)) listed in the transitional list World Health Organization Listed Authorities (tWLA);
* Other NRAs listed in the tWLA for the relevant product stream[[22]](#footnote-23) and regulatory function; In this case, the supplier will submit or facilitate the submission of a full inspection report of the manufacturing site.
* NRA operating at Maturity level 3 (ML3) or Maturity Level 4 (ML4) by WHO for the relevant product stream and regulatory function as assessed using WHO Global Benchmarking Tool (WHO GBT).[[23]](#footnote-24) In this case, the supplier will submit or facilitate the submission of a full inspection report of the manufacturing site.

UNDP may recognize approval of manufacturing sites by other UN entities or international health procurement organizations provided that the UN entity or international health procurement organization’s GMP audits are recognised by at least three different agencies having the same experience in GMP audits. In this case, the supplier will submit a full inspection report or, a letter issued by the inspecting agency for review by UNDP QA Team.

UNDP may recognize approval of manufacturing sites by a qualified PA provided that:

* 1. The UNDP-qualified PA shares a recent copy of the inspection report or corresponding summary in line with the WHO Public Inspection report that the UNDP QA Team considers sufficient to conclude the compliance of the manufacturing site with WHO GMP guidelines and
  2. The PA’s mandated lead GMP Inspector has a minimum of 10 years of experience as a lead inspector in the inspection of manufacturing sites of FPPs.

If there are inconsistencies in the information on the submitted certificates or there is cause showing non-compliance to standards, UNDP reserves the right to commission qualified experts to perform GMP audits of manufacturing sites for qualification, verification, or monitoring purposes.

Any FPP procured or supplied by UNDP should comply with the guidelines for pharmaceutical preparations as published by the WHO.

### Products

The FPPs must meet one of the criteria below:

1. FPPs Anti-retroviral, anti-malarial and anti-tuberculosis FPPs
2. WHO prequalified; or
3. Authorized for marketing by a WLA for the relevant product stream[[24]](#footnote-25) and all the relevant regulatory functions or,
4. Authorized for marketing by an SRA listed in the tWLA; or
5. Have received a positive opinion from the WHO-coordinated Expert Review Panel (ERP) if there is one or fewer products that meet criteria (i), (ii) and (iii) above.
6. Other FPPs must meet one of the following criteria:
   1. WHO prequalified; or
   2. Authorized for marketing by a WLA for the relevant product stream and all the relevant regulatory functions; or
   3. Authorized for marketing by an SRA listed in the tWLA; or
   4. Authorized for marketing by an NRA in the tWLA for the relevant product stream where the products will be used within the jurisdiction of the NRA; or
   5. Authorized for marketing by an NRA in the tWLA for the relevant product stream where the products will be used within the jurisdiction of another NRA where a regulatory reliance mechanism exists; or
   6. Authorized for marketing by an NRA operating at ML3 or ML4 by the WHO for the relevant product stream and regulatory function as assessed using WHO GBT.[[25]](#footnote-26) The products should be used within the jurisdiction of the NRA; or
   7. Assessed for chemistry, manufacturing, control, safety and therapeutic equivalence (where applicable) by the UNDP QA Team in line with MQAS guidelines.
7. Biological pharmaceutical products must meet one of the following criteria,
   1. If the biological is eligible for WHO Prequalification, the product must be:
      1. WHO prequalified; or
      2. Authorized for marketing by a WLA for the relevant product stream and all the relevant regulatory functions or
      3. Authorized for marketing by an SRA listed in the tWLA;
   2. Products not eligible for WHO Prequalification, the product must be:
      1. Authorized for marketing by a WLA for the relevant product stream and all the relevant regulatory functions; or
      2. Authorized for marketing by an SRA listed in the tWLA; or
      3. Assessed for chemistry, manufacturing, control, safety and similarity by the UNDP QA Team in line with MQAS guidelines.

## Medical devices [[26]](#footnote-27)

UNDP follows the GHTF classification principles for medical devices, i.e., they are classified into Class A, B, C, and D based on the level of risk to patient and public health. This section outlines requirements for medical device manufacturers and for the medical device as a product.

### Manufacturing sites

All sites involved in manufacturing medical devices must be authorized by the Regulatory Authorities or be declared to the Regulatory Authorities of the country of manufacture according to the national regulation.

The manufacturing sites of medical devices must comply with the requirements of the current ISO 13485 or an equivalent QMS or appropriate QMS based on the device's risk classification.

Conformity to standards of manufacturers of different classes of medical devices should be established by:

1. For manufacturers of medical devices Class A
   * + a Conformity Assessment Body (CAB) that is accredited to carry out conformity assessment according to international, national, or regional standards by an accreditation body recognizedby the International Accreditation Forum (IAF)[[27]](#footnote-28); or
     + an accreditation authority that is authorized by a national regulatory/competent authority of one of the IMDRF members; or
     + authorized/registered/licensed by or declared to an NRA in one of the GHTF members; or
   * authorized/registered/licensed by an NRA in one of the WLA for the relevant product stream and all the relevant regulatory functions.
2. Manufacturers of Medical devices Class B, C or D:
   * authorized/registered/licensed by an NRA in one of the GHTF founding members; or
   * authorized/registered/licensed by an NRA in one of the WLA for the relevant product stream and all the relevant regulatory functions; or
   * Conformity to standards will be established by a CAB that is accredited to carry out conformity assessment according to international, national, or regional standards by a national regulatory/competent authority of one of the GHTF founding members.

### Products

Medical devices should comply with the following:

* Relevant WHO guidelines/rapid communications and specifications;
* Relevant ISO standards;
* The guidelines of the IMDRF and GHTF as appropriate; and
* The requirements and test methods set for them by the NRA that has issued the market clearance.

Depending on the IMDRF medical device risk classification the devices should meet the following criteria depending on the risk classification of the device:

1. Class B, C, and D devices:[[28]](#footnote-29)
   1. Prequalified by the WHO Prequalification Programme; or
   2. Have a market clearance/market authorization/registration in one of the GHTF founding members[[29]](#footnote-30); or
   3. Authorized for use by the WLA for the relevant product stream[[30]](#footnote-31) and all relevant regulatory functions; or
   4. Recommended for use by the ERP for medical devices.
2. Condoms and intra-uterine devices:
3. Prequalified by the UNFPA Prequalification Programme; or
4. Prequalified by the WHO Prequalification Programme; or
5. Have a market clearance/market authorization/registration in one of the GHTF founding members[[31]](#footnote-32); or
6. Authorized for use by one of the WLA for the relevant product stream[[32]](#footnote-33) and all the relevant regulatory functions; or
7. Recommended for use by the ERP.
8. Personal lubricants:
9. Prequalified by the UNFPA Prequalification Programme; or
10. Prequalified by the WHO Prequalification Programme; or
11. Have a market clearance/market authorization/registration in one of the GHTF founding members[[33]](#footnote-34); or
12. Authorized for use by one of the WLA for the relevant product stream[[34]](#footnote-35) and all the relevant regulatory functions; or
13. Meet the WHO/UNFPA specifications for lubricants; or
14. Recommended for use by the ERP.
15. Class A devices:

The product shall meet the requirements of Essential Principles of Safety and Performance of Medical Devices as described by IMDRF[[35]](#footnote-36). Products must have regulatory approval in or declared to the NRA of the country of manufacture.

For all medical devices, the UNDP QA Team may request additional documents e.g. test reports confirming compliance with the relevant requirements/specifications issued by a laboratory accredited by a signatory member of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement for the scope of testing, declaration of conformity, some component of the IMDRF Standard Technical Document to assess safety and performance of the device.

## In vitro diagnostics

### Manufacturers

All sites involved in manufacturing IVDs must be authorized by the Regulatory Authorities or be declared to the Regulatory Authorities of the country of manufacture according to the national regulation.

The manufacturing sites of IVDs must comply with the requirements of the current ISO 13485 or an equivalent QMS or appropriate QMS based on the risk classification of the IVD.

Depending on the IMDRF IVD risk classification, the manufacturing facilities shall meet the following criteria:

* + 1. For manufacturers of IVDs Class A:
  + a CAB that is accredited to carry out conformity assessment according to international, national, or regional standards by an accreditation body **recognized** by the IAF[[36]](#footnote-37); or
  + an accreditation authority that is authorized by a national regulatory/competent authority of one of the IMDRF member countries; or
  + authorized/registered/licensed by or declared to a national regulatory authority in one of the GHTF members.
    1. Manufacturers of IVDs Class B, C, or D:
  + authorized/registered/licensed by a national regulatory in one of the GHTF founding member countries; or
  + Conformity to standards will be established by a CAB that is accredited to carry out conformity assessment according to international, national, or regional standards by a national regulatory/competent authority of one of the GHTF founding members.

### Products

IVDs should comply with the following:

* Relevant product stream and product-specific WHO guidelines;
* The guidelines of the IMDRF and GHTF as appropriate; and
* The requirements and test methods set for them by the NRA that has issued the market clearance.

The IVDs must meet one of the following criteria:

1. IVDs for the diagnostics of HIV, HIV-syphilis co-infections, tuberculosis, malaria, hepatitis B and hepatitis C should meet the following criteria:
2. Be WHO Prequalified; or
3. Be stringently assessed and have a market clearance in one of the GHTF founding member countries[[37]](#footnote-38); or
4. Authorized for use by one of the WLA for the relevant product stream[[38]](#footnote-39) and all the relevant regulatory functions; or
5. Recommended in the relevant WHO Tuberculosis guidelines; or
6. Recommended for use by the ERP for diagnostics (ERPD).
7. Other IVDs, Class B, C and D:
8. Be stringently assessed and have a market clearance in one of the GHTF founding member countries[[39]](#footnote-40); or
9. Authorized for use by one of the WLA for the relevant product stream[[40]](#footnote-41) and all relevant regulatory functions; or
10. Be WHO Prequalified; or
11. Recommended for use by the ERPD.
12. Other IVDs, Class A

The product shall meet the requirements of Essential Principles of Safety and Performance of Medical Devices as described by IMDRF[[41]](#footnote-42). Products must have regulatory approval in or declared to national regulator in the country of manufacture.

For all IVDs, the UNDP QA Team may request additional documents e.g. test reports confirming compliance with the relevant requirements/specifications issued by a laboratory accredited by a signatory member of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement for the scope of testing, declaration of conformity, some component of the IMDRF Standard Technical Document to assess safety and performance of the device.

UNDP will not accept self-certified IVDs for detecting the presence of or exposure to highly transmissible agents that cause a life-threatening disease, e.g., malaria, HIV, or syphilis.

## Medical furniture

Some medical furniture, such as hospital beds, examination couches, or wheelchairs, are classified as medical devices and should comply with requirements for medical devices. The quality requirements of these types of medical furniture are covered under section 5.2.2. above.

### Manufacturing sites

For medical furniture which does not present any risk to the patient or clinical staff such as patient bedside tables, bed screens or medicine cabinets, the manufacturing sites shall meet the following criteria:

* Authorized to produce medical furniture by the relevant authorities in the country of manufacturer; and
* Be certified for compliance with ISO 9001 or an equivalent QMS.

### Products

The products shall comply with the relevant ISO standards and other internationally recognisable standards.

## Personal Protective Equipment

### Manufacturers

All sites involved in the manufacturing of PPE must be authorized by the Regulatory Authorities of the country of manufacture.

The PPE manufacturing sites must comply with the current ISO 9001 or an equivalent QMS standard.

Conformity to the QMS standard will be established by a CAB accredited to conduct conformity assessment according to international, national, or regional standards by an accreditation body **recognized** by the IAF or IMDRF members or one of the GHTF founding members.

### Products

PPE should comply with the standards set by one of the founding members of the GHTF and in conformity with the WHO guidance on PPE.

UNDP identified three categories of risk of PPE (based on European Union regulation 2016/425[[42]](#footnote-43)):

1. Category I: minimal risks such as contact with cleaning materials of weak action;
2. Category II: risks other than those listed in Categories I and III; and
3. Category III: risks that may cause severe consequences, such as death or irreversible damage to health, such as exposure to dangerous pathogens or toxic chemicals.

If the PPE products are also classified as medical devices, they must comply with the relevant medical device regulatory requirements and PPE regulations.

## Vector Control Products

The selection and procurement of vector control products (VCPs) will be carried out as per WHO guidelines for procurement of public health pesticides.[[43]](#footnote-44) VCP must[[44]](#footnote-45) meet the specifications defined by the WHO malaria programme or WHO Rapid Communication and must be compliant with national policy and/or guidelines. VCP procured by UNDP include insecticide-treated nets and Indoor Residual Sprays.

UNDP procures or supplies VCPs that meet one of the following criteria:

1. prequalified by WHO[[45]](#footnote-46) or;
2. recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES) or received a WHO Policy recommendation and, are in the WHO prequalification pipeline or;
3. recommended by the Expert review Panel (ERP) and linked to a published WHO Specification[[46]](#footnote-47).

Any VCP procured or supplied by UNDP must be authorized for use by the relevant National Authority in the recipient country.

### Equipment related to Vector Control Products

All equipment used to apply vector control products must comply with the relevant WHO specifications[[47]](#footnote-48) and relevant international standards, such as ISO and EN standards.

## Medical Gases Supply System

WHO classifies gases for medical use as a medicine. Medical gases include oxygen, medical air, and nitrous oxide.

### Manufacturers

Medical gases classified as medicines must be manufactured, controlled, stored, and distributed following WHO or equivalent GMP and GSDP guidelines[[48]](#footnote-49) or equivalent guidelines.

All sites involved in the production, storage and/or transportation of medical gases must be authorized by the Regulatory Authorities of the country of manufacture.

The manufacturing sites of Medical Gases Supply Systems and suppliers involved in the production, storage and/or transportation of medical gases must comply with the requirements of the current ISO 13485 or an equivalent QMS or appropriate QMS based on the risk classification of the medical gas.

### Products

Medical gases classified as medicines (including oxygen) supplied as gas in cylinders or tanks and procured or supplied by UNDP must have market authorization in the country of manufacture. They must be authorized for use in the recipient country.

Medical gases classified as medicine must comply with a monograph of either the International, European, US, British, or Japanese Pharmacopoeia.

Oxygen source devices and/or Medical Gases Supply Systems, devices used for oxygen regulation and conditioning, and oxygen monitoring devices should comply with the following:

1. The WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices;[[49]](#footnote-50) and
2. UNDP QA Policy requirements for medical devices; see section 5.2.

## Cold chain equipment

All cold chain equipment should have been assessed for performance and quality. UNDP procures cold chain equipment that meet one of the following criteria:

1. Conform to the relevant ISO or equivalent standards; and
2. Be WHO Prequalified; and
3. Must be authorised by the relevant national authorities in the country of use.

## Biosafety cabinets

All biosafety cabinets must comply with the relevant ISO standards and national regulations of the country of use. Biosafety cabinets procured by UNDP must meet the following criteria:

1. UNDP QA Policy requirements for medical devices; see section 5.2.
2. Be authorised by the relevant national authorities in the country of use.

## Medical laboratory equipment

Medical laboratory equipment and consumables, such as chemicals and laboratory consumables, should meet the following criteria:

1. Conform to the relevant ISO or equivalent standards; and
2. Be manufactured in a site that is compliant with ISO 9001 or an equivalent QMS standard; or
3. Conform to the relevant national standards as set out by the national authorities in the country of use.

## Biosafety Laboratory

Biosafety laboratories procured by UNDP should protect the workers and the public from infection associated with the work in the laboratory. The laboratories should also prevent cross-contamination of samples. At a minimum, the laboratories should comply with all the national laws that govern occupational health, public health, transportation of biohazard substances, and other applicable laws.

## Hospital Equipment

Hospital equipment refers to all other equipment regularly used in healthcare facilities that supports its activities' safe and adequate function. Examples of these equipment include, but are not limited to; hospital waste management and incinerators, water treatment units (e.g. reverse osmosis, desalination plants, etc.), electrical generators, IT equipment, etc.

Hospital equipment procured by UNDP must meet the following criteria:

1. Conform to the relevant ISO or equivalent standards; and
2. Be manufactured in a site that is compliant with ISO 9001 or an equivalent QMS standard; or
3. Conform to the relevant national standards as set out by the national authorities in the country of use.

# Certificates

Suppliers and manufacturers must present valid certificates written in English or an official translation to English authorized by the manufacturer's responsible QA person.

Certificates are considered valid according to the validity date stated in the certificate or maximum of three years after the date of issue, whatever comes first.

The valid certificates must be signed by the authorised CAB/representative.

The valid certificates must specify, at a minimum, the:

* Name and address of the manufacturing sites covered; and
* Activities covered by the certificate; and
* QMS standard or regulation; and
* Full name and address of the CAB.

To ensure product compliance with the QA Policy, the UNDP QA team verify certificates issued by the CAB. If verification cannot be completed due to limitations with the CAB, the product will be deemed non-compliant.

In case there are inconsistencies in the information on the submitted certificates, or there is a cause showing non-compliance with standards, UNDP may conduct an independent review or technical visit of the manufacturing sites involved in producing health products offered to UNDP.

# Research Use Only (RUO) Products

Manufacturers may place a reagent or equipment in the market as an RUO. The RUO reagents and equipment are not subject to IVD regulatory requirements. They have not been evaluated for accuracy, specificity, precision, and reproducibility. Any evidence provided with RUO products is not certified by a regulatory or independent authority.

Suppliers shall not offer RUO products unless this has specifically been requested in the bidding documents.

In cases where there is no regulated IVD in the market, the bidder should explicitly state that in the offer. A UNDP medical laboratory expert should review the offer to ascertain the absence of a regulated IVD in the market before the regulatory compliance review. The UNDP medical laboratory expert should conduct a risk-benefit assessment for the use of an RUO product and submit it to the QA Advisor for approval.

# Recognition of QA approvals by other UN agencies

The UNDP QA Team may recognize the approval of health products approved by other UN agencies and international organizations. In these cases, the UNDP will ascertain and document that the health products under consideration meet the UNDP QA Policy requirements. The UNDP QA Team will communicate the assessment outcome to the procuring entity.

# Storage, distribution, and transportation requirements

The product manufacturer shall have conducted a study to validate the storage and transportation conditions. All products should be clearly labelled, showing storage conditions.

The entity responsible for the product’s transportation and/or storage must:

1. Comply with the requirements of WHO GSDP or equivalent; and
2. Ensure the supply chain (storage and transport) complies with the manufacturer’s requirements (temperature and humidity).

Deviations from transportation and storage conditions must be reported to the UNDP QA Team for analysis and guidance on the disposition of the products. The UNDP QA Team shall engage with the supplier during the analysis to ensure that verifiable evidence and appropriate decisions are taken on the disposition of the products.

# Requirements in WHO-declared pandemics and UNDP-declared crises.

In cases of pandemics, as declared by the relevant WHO department or when the UNDP Crisis Board has activated fast-track procedures in response to a UNDP-declared crisis for a specific region or country, UNDP will:

1. Recognize the:
   * 1. work of the WHO Emergency Use Lists; or
     2. emergency Listing by Founding Members of the GHTF; or
     3. emergency listing by a WLA for the relevant product stream[[50]](#footnote-51) and all relevant regulatory functions; or
     4. emergency listing by an SRA listed in the tWLA.
2. In cases where there are no products that meet criteria A above, UNDP will conduct a risk-benefit assessment of the products.

# Procurement agencies

UNDP may engage the services of a PA to supply health products to a recipient country. In these cases, the PA must be assessed for compliance with GSDP and other relevant standards and guidelines before providing the service.

To be eligible for qualification, the PA must:

* be authorized/licensed in the country of operation; and
* comply with WHO (or equivalent) GSDP guidelines; and
* comply with the MQAS; or
* for medical devices, comply with the requirements of ISO9001 or equivalent.

Procurement agencies must submit a valid copy of their authorization/license issued by the relevant NRA.

# Qualification of procurement agencies and products

UNDP will periodically publish invitations for the qualification of procurement agencies and products. This qualification may be independent of a tender process.

Interested eligible parties will be invited to submit their application, including the requested technical information.

Specific formats will be used to collect the technical information as appropriate:

* + Manufacturer Information File (MIF); and
  + Procurement Agency Information File (PAIF); and
  + Inter-Agency Finished Pharmaceutical Product Questionnaire (IAFPPQ); or
  + UNDP non-pharmaceutical product forms.

The qualification process includes a desk review of the submitted information and may include an onsite or remote inspection of the PA and its contracted parties by UNDP.

A list of qualified procurement agencies and products will be maintained by the UNDP and updated regularly.

Procurement agencies and products that comply with the requirements stated in the qualification call will be considered qualified for a stipulated period, subject to performance.

Qualified procurement agencies will be eligible to participate in the tenders that UNDP launches regularly without assessment of PIF or related regulatory certificates.

Qualified products will be eligible for procurement by UNDP without an assessment of regulatory compliance documentation.

## Reassessment

UNDP QA Team periodically reassesses its qualified suppliers and sources to ensure they continue to comply with the standards.

Re-assessment of qualified sources and suppliers is done every three years per MQAS guidelines; non-routine re-assessment activities (including non-routine re-audit of manufacturing sites and premises) can occur at any time based on an assessment of risks.

# QA in CO Managed procurement

A UNDP Country Office may decide to procure health products and manage the procurement process. The health products procured, supplied by, distributed by, and donated to any UNDP Country Office or Regional Bureau must comply with UNDP QA Policy requirements. If the UNDP Country Office determines the need to do so, then the responsibility for the QA will remain with the UNDP QA Team. UNDP Country Offices should ensure that thresholds for CO-managed procurement complies with the UNDP Procurement Procedures. UNDP Country Offices should adhere to UNDP Programme and Operations Policies and Procedures and seek guidance from the Regional Procurement Advisor where needed.

## Responsibilities for QA related services for CO Managed Procurement

The UNDP Country Office is responsible for engaging the UNDP QA Team's services in a timely manner. The UNDP Country Office is responsible for ensuring the end user submits the complete and clear specifications. The UNDP Country Office is also responsible for obtaining QA clearance to locally manage the procurement of health products before initiating procurement. The QA clearance must be sought at the planning stage. The UNDP Country Office is responsible for budgeting for all QA services, such as reviewing end-user-developed specifications, developing/reviewing bid technical Terms of Reference, and evaluating technical offers.

The UNDP QA Team will enlist adequate consultants for QA services in the Global Policy Network roster to support the UNDP Country Offices with the pre-procurement activities i.e. development of product/system specifications.

The UNDP QA Team will maintain standard Terms of Reference for the QA services experts. Products eligible for CO-managed procurement

The Health Product Access Committee and the QA Advisor will determine the products that may be procured through the UNDP Country Office.

A list of product categories eligible for CO-managed procurement will be maintained by the UNDP QA Team and published on the UNDP intranet. The list will be updated regularly to ensure timely access to health products without compromising the quality of health products to be procured.

## Quality monitoring for CO-managed procurement

The UNDP Country Office should ensure the procured products are subjected to quality monitoring as per this UNDP QA Policy.

## Reporting of CO-managed procurement

The UNDP QA Team shall maintain a record of all CO-managed the procurement of health products. An annual report on locally managed procurement of health products will be shared with Regional Bureaux. The report will include but is not limited to the suppliers’ compliance with the UNDP QA Policy, products assessed, regulatory risk classes of products considered, names of assessors, percentage compliance with the UNDP QA Policy, and quality monitoring activities.

# Quality Monitoring

## Quality Control

The UNDP QA system includes provisions for Quality Control (QC) of health products. QC activities are implemented on a risk-based approach.

## Sampling and inspection of products

The sampling and inspection of products is performed at different levels of the supply chain in line with the relevant WHO guidelines and ISO standards.

Sampling is based on an assessment of risks in accordance with ISO 2859 and/or relevant WHO guidelines.[[51]](#footnote-52),[[52]](#footnote-53)

UNDP may take samples at different points/levels in the supply chain. UNDP may engage the services of an independent sampling and inspection agency to conduct sampling and inspection of selected products in one of the following cases:

1. sampling from a batch of a product; or
2. where there is a quality complaint/quality alert; or
3. where there is a dispute about the test results.

In cases (i), (ii) and (iii) above, the sampling and inspection agent must be accredited for ISO17020 by a CAB that meets one of the following criteria:

* + - CAB is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; or
    - CAB that is accredited by one of the IAF-recognized bodies.

UNDP shall transport all samples according to the approved manufacturer’s requirements (temperature and humidity).

## QC testing and inspection findings

### Pharmaceuticals

Independent QC laboratories perform QC testing of samples according to specifications proposed by the manufacturer and approved by the competent national authority.

All QC laboratories must meet the following criteria:

* Be authorized by the relevant national regulatory authorities in the country of operation; and
* Be WHO prequalified; or
* Be accredited according to ISO 17025 by an accreditation body that is an International Laboratory Accreditation Cooperation Mutual Recognition Arrangement or International Laboratory Accreditation Cooperation signatory member for the scope of testing.

### Non-pharmaceutical products

The laboratory must be accredited according to ISO 17025 for the scope of testing specific products.

For IVDs, testing must be done in a laboratory that meets one of the following criteria: WHO Prequalified laboratory; or a laboratory accredited for ISO 15189 and operating in compliance of ISO 17025.

For VCP, testing must be done by an independent ISO 17025-accredited laboratory or GLP-certified laboratory with the relevant test methods in its scope of accreditation. Testing should be according to WHO-approved specifications and using the Collaborative International Pesticides Analytical Council methods.

The UNDP QA team will publish a list of products that should be subjected to pre-shipment testing.

## QC Test results and findings

The laboratory shall submit all test reports to the UNDP procuring entity and UNDP QA Team within the timeframe stipulated in the procurement agreement or contract. The UNDP QA Team shall review and analyse test results to identify trends to provide guidance on a risk-based approach to testing the health products.

Any deviation (Out of Specifications [OOS] result) and inspection finding reported by a UNDP contracted laboratory is reviewed under the supervision of the UNDP QA Team according to UNDP procedures.

A root-cause analysis will be conducted by UNDP in collaboration with the national partner in cases of dispute of laboratory testing by either UNDP or its partners. Re-testing may be conducted based on the outcome of the root-cause analysis. Any re-testing will be conducted in one of the following laboratories depending on the scope:

1. Pharmaceuticals - WHO Prequalified laboratory for pharmaceuticals;
2. Medical devices, PPE and IVDs (except IVDs for malaria) - laboratory accredited to ISO17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement for the scope of testing;
3. IVDs for diagnosis of malaria – a WHO Malaria Programme designated laboratory;
4. Contraceptive devices and personal lubricants – laboratories assessed and contracted by the UNFPA QA Team or relevant WHO Department;
5. VCP - ISO 17025-accredited laboratory or GLP-certified laboratory with the relevant test methods in its scope of accreditation. Testing should be according to WHO-approved specifications and using the Collaborative International Pesticides Analytical Council methods.

## Variations

During the qualification validity period, qualified suppliers must inform UNDP of any variation in the product in the company file or product dossiers (e.g., related to the manufacturing process and/or product characteristics and/or critical raw material/supplier). Failure to do so might result in disqualification of the product and/or the supplier.

## Validity of certificates and approvals

Should some documents (e.g., certificates, licenses) expire during the agreement period (according to the validity date or maximum of 3 years after the document’s issue), suppliers must submit new documents or evidence of extension of validity issued by the concerned regulatory bodies.

It is the responsibility of the suppliers to ensure that regulatory approvals are maintained and updated regarding the last applicable standard/regulation.

Failure to submit such documents or justification may lead to the disqualification of the supplier /manufacturer of the product.

## Traceability

UNDP encourages its suppliers to adopt and use the Global Standards e.g. GS1 for optimal identification of health products throughout the supply chain.

## Complaints

Any complaint reported by UNDP business units, customers, regulatory authorities, and users will be investigated under the responsibility of the UNDP QA Advisor.

The UNDP QA Team will ensure appropriate measures (including product recalls) will be taken based on assessing the risks for patients, the community, and UNDP.

The UNDP Country Office and UNDP Global Procurement Supply Division/Health will engage with partners and the UNDP QA Team to facilitate reporting and investigation of the complaints and quality issues associated with health products, including monitoring of adverse events that UNDP procured.

## Adverse events

The UNDP Country Office must inform all reports of adverse events they receive from partners to the UNDP QA Team within a period specified in the internal procedures.

In collaboration with the UNDP QA Team, the UNDP Country Office will inform the competent national regulatory authorities about reports of adverse events.

Any adverse event (complaint, internal non-conformity alert, or quality issue related to the qualified product) leading to one of the following outcomes:

* Death of a Patient, User, or Other Person;
* Serious Injury of a Patient, User, or Other Person;
* No Death or Serious Injury Occurred, but the Event Might Lead to Death or Serious Injury of a Patient, User, or Other Person if the Event Recurs;

All adverse events will be reported to the supplier by the UNDP QA Team within the time frames agreed between the supplier and UNDP.

## Regulatory watch procedure

During the qualification validity period, and for the shelf-life or the lifespan of the supplied product, qualified suppliers must inform UNDP of any alert, a notice of concern, or a warning letter issued by any of the following entities:

* WHO; or
* WLAs; or
* SRA listed in the tWLA.

The UNDP QA team will consider this information, which could lead to the temporary suspension or disqualification of the product, suppliers, and/or the manufacturers concerned.

## Supplier performance

Suppliers must comply with the requirements of the UNDP QA Policy. Suppliers should ensure that all qualified or approved products are dispatched according to the approved specifications. UNDP will set out Key Performance Indicators for suppliers to manage their performance according to UNDP procedures.

# Post-procurement QA

The NRA of the recipient country is responsible for market surveillance and pharmacovigilance.

NRAs also set standards for the storage, distribution, and transportation of health products and inspect the supply chain for compliance.

UNDP may conduct GSDP assessments of warehouses and other premises that store health products. These assessments follow WHO guidelines and may be undertaken jointly with other partners.

# Implementation of the UNDP QA Policy

## Systems for implementation of the policy

The UNDP QA Policy is implemented by developing and rolling out a Quality Assurance Manual and Standard Operating Procedures and training materials to build the capacity of UNDP staff engaged in health procurement. UNDP deploys adequate resources to implement the UNDP QA Policy and monitor its compliance successfully.

## Exemptions

In some cases where UNDP BPPS has identified a need to supply a product that does not meet all the requirements of the Policy, the GFPHST Manager may authorize an exemption from the UNDP QA Policy. The GFPHST Manager will do so by appointing a committee comprised of, at a minimum, the Senior Health Product Management Advisor, the Programme Advisor, and a representative of a Regional Bureau not associated with the case to perform a risk-benefit assessment to facilitate access to health products in cases where there are:

* Identified non-compliance with quality, safety, efficacy, effectiveness, or performance requirements and
* There is a limited availability of products that meet the requirements.

The risk-benefit assessment will consider the impact on patient safety, health product intervention outcomes, and timely programme delivery and take the necessary mitigation actions. The Committee will submit a report and a recommendation to the GFPHST Manager for decision.

The Committee will consult the UNDP QA Team for opinions on the quality aspects of the products under discussion and the UNDP Procurement Team for information regarding market research and/or advice on contractual obligations for implementing the risk mitigation actions. Both the QA team and the Procurement team shall not participate in the Committee decision-making process.

If the GFPHST Manager’s decision aggrieves a CO, the affected office may submit appeals against it to the Associate Administrator, who will decide the case.

The GFPHST Manager will report annually on all cases presented to this committee. The report will be incorporated into the QA annual report.

# Monitoring implementation of the UNDP QA Policy

The GFPHST shall monitor the implementation of the UNDP QA Policy through mechanisms such as self-assessments according to the MQAS. In line with UNDP procedures, any findings will be corrected, and preventative plans will be enforced. A minimum of one self-assessment should be conducted in one calendar year. The self-assessment may be targeted to specific aspects of the UNDP QA Policy. All assessments must be documented, and a report should be presented as part of the annual report.

BPPS-HHG shall submit a report to the Associate Administrator with a copy to Regional Bureaux, BMS, and OAI.

# Reporting

BPPS-HHG will submit an annual QA Report to the Associate Administrator with a copy to Regional Bureaux, BMS, and OAI. The report will include successes, challenges, an analysis of incidents, the status and impact of partnerships, and opportunities for improvements.

In case of a critical incident with health products supplied by UNDP, putting at risk human lives and the reputation of the organization, in addition to the management of the incident with UNDP Country Offices and Regional Bureaux, a note will be sent by BPPS-HHG to inform the Associate Administrator.

# Effective date

The implementation of the changes in the updated UNDP QA Policy will start from the date of publication of the revision. In cases where the UNDP office has agreed with a supplier for the procurement of health products before implementation of the present UNDP QA Policy, the affected UNDP office should consult with the UNDP QA Team to decide on steps to transition without negatively impacting access to health products.

1. [GHTF/SG1/N77:2012\_Definition of Terms (imdrf.org)](https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf) [↑](#footnote-ref-2)
2. IVDs include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles. They are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, or determination of physiological status. [↑](#footnote-ref-3)
3. [GHTF/SG1/N77:2012\_Definition of Terms (imdrf.org)](https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf) [↑](#footnote-ref-4)
4. 4 Evaluating and publicly designating regulatory authorities as WHO listed authorities, Policy document WHO 2021 <https://www.who.int/publications/i/item/9789240023444> [↑](#footnote-ref-5)
5. Handbook for integrated vector management <https://www.who.int/publications/i/item/9789241502801> [↑](#footnote-ref-6)
6. Evaluating and publicly designating regulatory authorities as WHO listed authorities, Policy document WHO 2021 <https://www.who.int/publications/i/item/9789240023444> [↑](#footnote-ref-7)
7. UNDP Strategic Plan 2022-2025, Available at <http://strategicplan.undp.org/>. [↑](#footnote-ref-8)
8. UNDP. [*UNDP HIV and Health Strategy 2022-2025*](https://www.undp.org/publications/connecting-dots-towards-more-equitable-healthier-and-sustainable-future-undp-hiv-and-health-strategy-2022-2025). [↑](#footnote-ref-9)
9. Memorandum of Understanding between UNDP and WHO. Signed 4 May 2018. [↑](#footnote-ref-10)
10. “Non-communicable diseases, also known as chronic diseases, are not passed from person to person. They are of long duration and generally slow progression. The four main types of non-communicable diseases are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes” (WHO – Global status report on non-communicable diseases – 2014). [↑](#footnote-ref-11)
11. Organizational Performance Group Decision, 16 November 2017 [↑](#footnote-ref-12)
12. Organizational Performance Group Decision, 16 November 2017 [↑](#footnote-ref-13)
13. WHO Technical Report Series 1025, Annex 13 [↑](#footnote-ref-14)
14. [www.who.int/selection\_medicines/list/en/](about:blank) [↑](#footnote-ref-15)
15. <https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1> [↑](#footnote-ref-16)
16. <https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf> [↑](#footnote-ref-17)
17. <https://www.fda.gov/about-fda/website-policies/fda-logo-policy> [↑](#footnote-ref-18)
18. WHO is an official observer to the Management Committee of the IMDRF [↑](#footnote-ref-19)
19. <https://extranet.who.int/pqweb/vector-control-products> [↑](#footnote-ref-20)
20. “A finished dosage form of a pharmaceutical product, which has undergone all stages of manufacture, including packaging in its final container and labeling” (WHO Annex 15, 45th report, 2011). “The acronym always represents a pharmaceutical product after final release” (WHO Annex 6, 41st report, 2007) [↑](#footnote-ref-21)
21. Evaluating and publicly designating regulatory authorities as WHO listed authorities, Policy document WHO 2021

    <https://www.who.int/publications/i/item/9789240023444> [↑](#footnote-ref-22)
22. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-23)
23. List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4) <https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4> [↑](#footnote-ref-24)
24. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-25)
25. List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4) <https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4> [↑](#footnote-ref-26)
26. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices  
    Annex 4, WHO Technical Report Series 1003, 2017 [↑](#footnote-ref-27)
27. <https://iaf.nu/en/recognised-abs/> [↑](#footnote-ref-28)
28. C = Moderate-high hazard, D = High hazard [↑](#footnote-ref-29)
29. GHTF founding members: European Union, USA, Japan, Canada, Australia [↑](#footnote-ref-30)
30. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-31)
31. GHTF founding members: European Union, USA, Japan, Canada, Australia [↑](#footnote-ref-32)
32. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-33)
33. GHTF founding members: European Union, USA, Japan, Canada, Australia [↑](#footnote-ref-34)
34. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-35)
35. [Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (imdrf.org)](https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf) [↑](#footnote-ref-36)
36. <https://iaf.nu/en/recognised-abs/> [↑](#footnote-ref-37)
37. GHTF founding members: European Union, USA, Japan, Canada, Australia [↑](#footnote-ref-38)
38. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-39)
39. GHTF founding members: European Union, USA, Japan, Canada, Australia [↑](#footnote-ref-40)
40. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-41)
41. [Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (imdrf.org)](https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf) [↑](#footnote-ref-42)
42. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:320116R0425> [↑](#footnote-ref-43)
43. [Guidelines for procuring public health pesticides\_Cover.indd (who.int)](https://iris.who.int/bitstream/handle/10665/44856/9789241503426_eng.pdf?sequence=1) [↑](#footnote-ref-44)
44. [https://extranet.who.int/pqweb/vector-control-products](about:blank) [↑](#footnote-ref-45)
45. [https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list](about:blank) [↑](#footnote-ref-46)
46. [psm\_procurementsupplymanagement\_guidelines\_en.pdf (theglobalfund.org)](https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf) [↑](#footnote-ref-47)
47. <https://www.who.int/publications/i/item/9789241513821> [↑](#footnote-ref-48)
48. <https://www.who.int/publications/m/item/trs1044-annex5> [↑](#footnote-ref-49)
49. <https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?sequence=1&isAllowed=y> [↑](#footnote-ref-50)
50. List of WHO Listed Authorities WLAs <https://www.who.int/initiatives/who-listed-authority-reg-authorities> [↑](#footnote-ref-51)
51. WHO Guidelines for sampling of pharmaceutical products – TRS 929 (Annex 4) [↑](#footnote-ref-52)
52. WHO Guidelines on the conduct of surveys of the quality of medicines – TRS 996 (Annex 7) [↑](#footnote-ref-53)