



Quality Assurance Policy for the Procurement of Medicines

1 September 2023

Annex 2 (a) to the
UNOPS Procurement Manual

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Abbreviations

DRIVE	Delivering Responsibility in Vendor Engagement
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
EUA, EUL	Emergency Use Authorization or Approval or Listing
FPP	Finished Pharmaceutical Product
HQCPC	Headquarters Contracts and Property Committee
LTA	Long Term Agreement
MQAS	Model Quality Assurance System for Procurement Agencies
NCD	Non-Communicable Disease
NRA	National Regulatory Authority
PG	Procurement Group
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SRA	Stringent Regulatory Authority
UN	United Nations
UNGM	United Nations Global Marketplace
WHO	World Health Organization

1. Introduction

1.1. Preface

UNOPS provides infrastructure, procurement and project management services to help build the future. To support the achievement of the Sustainable Development Goals, we respond to our partners' needs and help increase the effectiveness of peace and security, humanitarian and development projects around the world.

In pursuit of its mission, UNOPS is requested by its partners, including governments, United Nations (UN) agencies, international organizations such as The Global Fund to Fight AIDS, TB and Malaria (The Global Fund), international financial institutions and others, to implement projects related to health services, particularly for the procurement and supply of medicines, medical devices and other health products.

The number and value of such projects have increased progressively over the years, making health the largest commodity purchased by the organization since 2020.¹ The range of health products procured by UNOPS has also expanded over the years, including medicines both for communicable and non-communicable diseases (NCDs).

In order to maximize health outcomes and minimize risk for beneficiaries and patients, it is essential for UNOPS to ensure the highest possible standards of quality, safety, sustainability and effectiveness of the health products we supply, in accordance with recognized international best practices, guidelines and norms, including those issued by the World Health Organization (WHO).

UNOPS will strive to continuously improve its policies and process and to harmonize its quality assurance (QA) system with those of other UN agencies and international organizations. In particular, this QA Policy recognizes the harmonization of the quality assurance standards and procedures among United Nations agencies, international organizations, non-governmental organizations and initiatives, and major financing mechanisms/donors.

1.2. Purpose and scope of the QA Policy

The UNOPS Quality Assurance Policy for the Procurement of Medicines ("QA Policy – Medicines") sets out the principles and requirements regulating quality assurance for the procurement and supply of medicines.

The QA Policy applies to the procurement and supply of medicines² by any UNOPS business unit.

¹ Refer to the Annual Statistical Report on UN Procurement, produced by UNOPS on behalf of the United Nations: United Nations Office for Project Services, [Annual Statistical Report on UN Procurement](#), UNOPS, Copenhagen.

² The policy covers medicines as defined by WHO, with a focus on human use only medicine: "Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient" (World Health Organization, ['WHO Model Quality Assurance System for Procurement Agencies'](#), Annex 3, *Technical Report Series 986*, WHO, 30 September 2014, p. 145).

The QA Policy is structured to provide clear requirements to UNOPS personnel and partners, including suppliers. It is divided into four main sections, in addition to this introduction: strategies for the procurement of medicines; requirements for medicines; requirements for suppliers; and quality monitoring activities.

The QA Policy is an integral part of the UNOPS Procurement Manual and is issued by the Director, Procurement Group. The QA Policy will be complemented by additional manuals, guidelines, templates and tools to be developed and released by the Procurement Group.

1.3. Effective date

This Quality Assurance Policy for the Procurement of Medicines takes effect on 1 September 2023 and supersedes the following:

- 1) Quality Assurance Policy for the Procurement of Medicines, Medical Devices and other Health Products from 1 July 2021.
- 2) Authoritative Interpretation for the *Procurement of Medicines on the basis of an Internal Assessment and Risk-Based Evaluation* from 7 July 2022.

1.4. Procurement principles and ethics

UNOPS procurement activities shall be carried out in accordance with the following principles as further detailed in the Procurement Manual: best value for money, fairness, integrity and transparency, effective competition, and best interest of UNOPS and its partners.

All procurement, supply, quality assurance and monitoring activities set out in the QA Policy – Medicines must be implemented by UNOPS personnel to the highest standards of efficiency, competence and integrity. Similarly, UNOPS shall also require that the suppliers we work with operate with high standards of integrity and competency. UNOPS has zero tolerance for fraud and other proscribed practices. Neither UNOPS personnel nor suppliers participating in a procurement process shall have a conflict of interest.

1.5. Sustainable procurement

Sustainability is at the forefront of UNOPS work around the world. We aim to help our partners maximize the positive impact and sustainability of their projects in line with the 2030 Agenda for Sustainable Development, to better serve communities in need.

Sustainable procurement is defined as the practice of integrating requirements, specifications and criteria that are compatible with and in favour of the protection of the environment and of social progress, and are in support of economic development, namely by seeking resource efficiency, improving the quality of products and services, and ultimately optimizing costs.³

³ Sustainable Procurement Statement, adopted by the United Nations High Level Committee on Management Procurement Network (HLCM PN) at its meeting in Vienna, February 2009.

Recognizing the importance of the contribution that the supply of medicines can make to sustainable development and to access to quality healthcare, UNOPS business units shall consider sustainable procurement to the extent possible within the context of their work, the country, the industry sector, and the supply market, in compliance with the requirements laid out in the UNOPS Sustainable Procurement Framework (Annex 1 to the Procurement Manual). This may include but not be limited to following technical sustainability criteria, gender mainstreaming criteria or supplier sustainability requirements (further to the UNOPS Delivering Responsibility in Vendor Engagement [DRIVE] programme).

1.6. Roles and responsibilities

The main responsibilities of UNOPS units and roles that intervene in procurement and supply activities are described in chapter 2 of the Procurement Manual.

UNOPS business units that implement projects related to the procurement and supply of medicines are primarily responsible and accountable, through their respective Procurement Authority, for the implementation of this QA Policy. They shall do so through adequate procurement and health technical resources (e.g., QA specialists, pharmacists, regulatory affairs specialists) to enable the performance of procurement, quality assurance and quality monitoring activities as prescribed in this QA Policy.

This QA Policy has been issued under the authority of the Director, Procurement Group (PG), who also has the authority to interpret and provide exceptions to it. Any questions, comments or suggestions on this QA Policy should be channelled through the PG health advisors by email (gapanelmedicines@unops.org or procurement@unops.org).

2. Strategies for the procurement of medicines

2.1. Selection of medicines

UNOPS undertakes the procurement of medicines on the request of its partners. Wherever applicable, UNOPS will ensure that any needs assessment that may have been done is referenced or validated by health technical experts; that the products appear on project, national, institutional or WHO current treatment or testing guidelines and/or essential product lists or formularies; and that their specifications meet national requirements, in alignment with WHO guidance, other relevant international guidelines, norms and the UNOPS Procurement Manual.

2.2. Procurement methods and strategies

The overall aim of UNOPS is to procure medicines that are safe, effective and of appropriate quality, with the aim of maximizing value for money; and appropriate for the economic and sociocultural context in which they are to be used.

In order to do so, and provided that the requirements described in sections 3, 4 and 5 of the QA Policy – Medicines are met, UNOPS may adopt one or various of the procurement methods and approaches described below.

In evaluating product information during prequalification and/or during tendering, information regarding the intellectual, industrial and commercial property status, and manufacturers' authorizations (where applicable), should be requested and checked so that no infringement of patents, intellectual property or test data protection by UNOPS or its suppliers occurs.

2.2.1. UNOPS prequalification programme

UNOPS may put in place a prequalification programme that includes both product- and supplier-related assessments, following the general guidance included in the Procurement Manual, section 5.6. For the prequalification of medicines, it will do so in alignment with the guidance set out in the Model Quality Assurance System for Procurement Agencies (MQAS).⁴

2.2.2. Tender processes

Tender processes shall conform to the provisions stated in the Procurement Manual, chapter 6. Preferably, these will be of a competitive nature (open or limited competition) through request for quotation (RFQ), invitations to bid (ITB) or request for proposals (RFP). Where justified, the tender process may also be conducted following direct contracting/exceptions to competitive tendering or formal methods of solicitation.

2.2.3. Long Term Agreements (LTA)

Subject to the provisions in the Procurement Manual, section 11.4, including the elaboration of a business case, the review by the Headquarters Contracts and Property Committee (HQCPC) and the approval of the Executive Chief Procurement Officer (ECPO), UNOPS may establish LTAs for selected medicines, medical devices and other health products.

Such LTAs may be displayed in the form of catalogues in [UN Web Buy Plus](#), a UNOPS global e-commerce solution for the aid and development community.

Once established, call-off orders against the LTAs shall follow the provisions set out in the Procurement Manual.

2.2.4. Procurement through another UN entity

UNOPS may procure medicines through another UN entity, subject to the provisions of the Procurement Manual, chapter 14, and to the legal agreement between UNOPS and the other UN entity.

2.2.5. Acceptance of donations

UNOPS may only accept donations of medicines if in compliance with this QA Policy and the UNOPS policy on donations (OI Procedures for the Acceptance and Management of Pro Bono Goods or Services), which is aligned with the principles established in the WHO Guidelines for Medicine Donations.⁵

⁴ World Health Organization, '[WHO Model Quality Assurance System for Procurement Agencies](#)', Annex 3, *Technical Report Series 986*, WHO, 30 September 2014.

⁵ World Health Organization, '[Guidelines for Medicine Donations](#)', WHO, 2011.

3. Requirements for the procurement of medicines

3.1. Marketing authorization

All Finished Pharmaceutical Products (FPPs), biological products and vaccines purchased by UNOPS shall be authorized for marketing and use in the destination country by the relevant National Regulatory Authority (NRA) in accordance with its standard practices for registration or other forms of authorization for use, including for special use. Where such authorization has not been granted by the NRA, a waiver or exceptional permission to import/use the product shall be obtainable from the relevant government authorities.

In addition, UNOPS shall procure FPPs, biological products and vaccines that:

1. Are prequalified by WHO under the WHO prequalification programme; or
2. Have been granted marketing authorization by a Stringent Regulatory Authority⁶ (SRA) (including tentative approval by the United States Food and Drug Administration [USFDA], a positive opinion from the European Medicines Agency under Article 58, and approval by Health Canada under Bill C9); or
3. Have been granted marketing authorization by Regional Reference Authorities for medicines in the Americas (AMRO/PAHO)⁷ or
4. Have been granted marketing authorization by a Regulatory Authority that has been assessed at Maturity level 3 (ML3) or Maturity Level 4 (ML4) by WHO for the relevant product category;⁸ or
5. Have been recommended by the WHO-coordinated Expert Review Panel during the time frame stipulated; or
6. Have been listed under the WHO Emergency Use Assessment and Listing (EUAL) procedure.

Based on specific contextual, country or partner requirements, the Procurement Authority, with advice from the health technical team of the programme or project, may prioritize procurement in and/or restrict it to selected categories in 1-6 above in order to ensure full compliance with such requirements, in consultation with the Procurement Group if needed.

Requests for exceptions to procure medicines outside the requirements outlined in 1-6 above may be made to the UNOPS QA panel for medicines following an [established procedure](#). The panel shall make a recommendation to the PG Director, who will make the final decision.

3.2. Good Manufacturing Practice (GMP) Certification Status

All medicines supplied to UNOPS shall also:

1. Be obtained from sites that have been duly authorized by the NRA in the country where all relevant manufacturing sites are located **AND**

⁶ As defined in World Health Organization, '[51st report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations](#)', *Technical Report Series 1003*, WHO, 14 June 2017.

⁷ Pan American Health Organization, '[Regulatory System Strengthening in the Americas. Lessons Learned from the National Regulatory Authorities of Regional Reference](#)', PAHO, Washington, D.C., 2021.

⁸ World Health Organization, '[List of National Regulatory Authorities \(NRAs\) operating at maturity level 3 \(ML3\) and maturity level 4 \(ML4\)](#)', WHO, 1 April 2022.

2. Be supplied from sites deemed GMP-compliant as inspected by WHO, an SRA, or an NRA that is a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).⁹

Requests for exceptions to procure medicines from sources certified in a manner other than those described in 1-2 above may be made to the UNOPS QA panel for medicines following an [established procedure](#). The panel shall make a recommendation to the PG Director, who will make the final decision.

Relevant certifications and/or other documentation issued by the National Regulatory Authority, as well as the other relevant agencies and regulatory authorities confirming the status of the product and its manufacturing site, shall be provided by the supplier.

4. Requirements for suppliers of medicines

4.1. Requirements for all suppliers

For the purposes of this policy, a supplier can either be a distributor (intermediary who does not manufacture but only provides the health product) or the manufacturer of a product.

All UNOPS suppliers must be registered in the United Nations Global Marketplace (UNGM) and be eligible to conduct business with UNOPS, further to the provisions in the Procurement Manual, chapter 3. In addition, suppliers must comply with other eligibility, qualification and technical criteria as included in the invitation for prequalification or the solicitation documents.

Suppliers shall provide valid operating licences that unequivocally stipulate the types of activities that are authorized in their production or distribution facilities.

Suppliers shall also be required to submit to UNOPS, on request, requisite certifications, relevant product information, and product samples. These shall include but not be limited to valid licences, permits, authorizations or other documents, such as a WHO Public Inspection Report (WHOPIR), GMP certificates, Product Registration certificates, Certificates of Pharmaceutical Product or other proof of approval issued by regulatory authorities attesting compliance with the provisions of section 3.

UNOPS further reserves the right to request at any time additional information to guarantee the quality of the medicines and to conduct, independently, including through a third party, a quality audit (inspection) of the manufacturer or distributor. The observations and conclusions of such audits pertain exclusively to the audited premises and will not be extrapolated to other premises.

Suppliers shall be required to report to UNOPS any information available to them regarding a change in the safety profile of the supplied pharmaceutical product during its shelf life.

4.2. Additional requirements for distributors

Distributors of medicines shall, in addition to the requirements in section 4.1, be required to:

⁹ Pharmaceutical Inspection Co-operation Scheme, 'Members: List of PIC/S Participating Authorities', <https://picscheme.org/en/members>.

1. Have valid licences and authorizations as required under the national legislation of the country of operation issued by the National Regulatory Authority or another relevant government entity;
2. Provide the following documentation if so determined by the health project team for each solicitation event:
 - a. Manufacturer's authorization to distribute the offered products
 - b. Free Sale Certificates for the products
 - c. WHO Good Distribution Practices (GDP)/Good Storage Practices (GSP) Certification
 - d. Quality Management System (QMS) Certification

5. Quality monitoring activities

Quality monitoring has to be done at different stages of the procurement process, including while planning, defining requirements, preparing solicitation documents, evaluating bids (assessing regulatory compliance), and quality monitoring before delivery (sampling, inspection and testing).

5.1. Quality control

UNOPS may test the quality of products procured by the organization at different points of the supply chain, including prior to shipment. Quality control (QC) testing will be done according to sampling and testing protocols and standard operating procedures. For such testing, UNOPS will use labs prequalified by WHO or those that have ISO 17025 accreditation for the specific products and tests that are to be undertaken.

Requests for exceptions to conduct quality control tests in labs not certified in the manner described may be made to the UNOPS QA panel for medicines following an established procedure. The panel shall make a recommendation to the PG Director, who will make the final decision.

5.2. Receipt, storage and distribution

All health products will be subject, on receipt, to inspection according to the destination country's requirements and UNOPS guidelines for conformity to specifications.

Where UNOPS is responsible for storage and distribution, systems shall be put in place to ensure that medicines are stored and distributed in a way that guarantees maintenance of their quality, safety and integrity, and ensures batch traceability. Storage areas shall allow for orderly storage under the appropriate conditions established by the manufacturer, with appropriate segregation of rejected, expired, recalled or returned stock.

5.3. After-market monitoring and surveillance

Where UNOPS has a role in after-market monitoring and surveillance, according to the specific conditions in the engagement, systems for appropriate action, including pharmacovigilance, shall be put in place.

5.4. Management of quality non-conformities

In the event that products are tested and found to be out of specification (OOS), the supplier will be required to investigate the discrepancy and provide a report. Where non-conformity is confirmed either in the quality,

performance or safety of the product, or in agreed packaging or labelling, the supplier shall promptly and effectively replace the affected product at its own cost and take appropriate actions to safely dispose of the defective batches/products in compliance with national legislation or UNOPS requirements. Depending on the nature of non-compliance, replacement from the same source may no longer be acceptable. In such a case, UNOPS reserves the right to cancel or terminate the contract and take other actions as provided for in the UNOPS Procurement Manual.

5.5. Complaints and disputes

Complaints about product quality and safety will be handled in accordance with UNOPS procedures for complaint handling and dispute resolution as provided for in the UNOPS Procurement Manual. Where needed, complaints and disputes shall be escalated by the UNOPS business unit responsible for the process to a Legal Advisor, who shall, in consultation with the PG Health Advisors, take appropriate action based on the risk to end users, the partner and UNOPS. In the event of a dispute about QC test results UNOPS will, in consultation with the supplier, select a third-party laboratory to re-test the product. The third-party lab will comply with UNOPS requirements for QC labs.

5.6. Supplier performance evaluation

UNOPS shall continuously manage the performance of its suppliers of medicines, medical devices and other health products, in line with the requirements of the Procurement Manual, section 13.2.7, including by creating a Supplier Performance Evaluation record in the oneUNOPS system.

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