



Quality Assurance Policy for the Procurement of Medical Devices and other Health Products

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Annex 2 (b) to the
UNOPS Procurement Manual

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Abbreviations

CAB	Conformity Assessment Body
DRIVE	Delivering Responsibility in Vendor Engagement
GDP	Good Distribution Practice
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
EPP	Emergency Procurement Procedures
EUA, EUL	Emergency Use Authorization or Approval or Listing
HQCPC	Headquarters Contracts and Property Committee
IAF	International Accreditation Forum
IMDRF	International Medical Device Regulators Forum
IPMG	Infrastructure and Project Management Group
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostics
LTA	Long Term Agreement
MD	Medical Device
NCD	Non-Communicable Disease
NRA	National Regulatory Authority
PG	Procurement Group
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
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 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 system with those of other UN agencies and international organizations. In particular, this Quality Assurance (QA) Policy recognizes the harmonization of the quality assurance standards and procedures related to HIV/AIDS, TB and malaria health products 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 for medical devices and other health products

The UNOPS Quality Assurance Policy for the Procurement of Medical Devices and other Health Products ("QA Policy") sets out the principles and requirements regulating quality assurance for the procurement and supply of medical devices and other health products.

The QA Policy applies to the procurement and supply processes of medical devices and health products (excluding medicines) by any UNOPS business unit.

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

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.

medical devices and other health products; requirements for medical devices and other health products; 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 Medical Devices and other Health Products takes effect on 1 September 2023 and supersedes the Quality Assurance Policy for the Procurement of Medicines, Medical Devices and other Health Products from 1 July 2021.

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 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.²

Recognizing the importance of the contribution that the supply of medical devices and other health products 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

² Sustainable Procurement Statement, adopted by the United Nations High Level Committee on Management Procurement Network (HLCM PN) at its meeting in Vienna, February 2009.

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 medical devices and other health products 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, biomedical and clinical engineers, 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 (procurement@unops.org, qapanelmeddevices@unops.org).

2. Strategies for the procurement of medical devices and other health products

2.1. Selection of medical devices and other health products to procure

UNOPS undertakes the procurement of medical devices and other health products on the request of its partners. Wherever applicable, UNOPS will ensure that any needs assessment is referenced or validated by technical experts; that the products appear on national, institutional or WHO current treatment or testing guidelines and/or essential product lists; and that their specifications and implementation requirements are according to national capacity, 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 medical devices and other health products that are safe, effective and of appropriate quality, with the aim of maximizing value for money; and appropriate for the economic, technical 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 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.

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 (HQPC) and the approval of the Executive Chief Procurement Officer (ECPO), UNOPS may establish LTAs for selected 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 medical devices or other health products 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 medical devices or other health products 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 Guidelines for Health Care Equipment Donations.³

³ World Health Organization, Guidelines for Health Care Equipment Donations, WHO, 2000. www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf?ua=1

3. Requirements for the procurement of medical devices and other health products

3.1. Requirements for the procurement of Medical Devices and In-Vitro Diagnostics

UNOPS recognizes and adopts the definitions and principles of classification of “Medical Device” (MD) and “In-Vitro Diagnostics” (IVD) according to the International Medical Device Regulators Forum^{4,5,6} (IMDRF) and the WHO guidelines on the subject.⁷ Other health products meeting any of the medical purposes mentioned in the definitions may be considered medical devices depending on the jurisdiction and the regulatory framework.

In addition, UNOPS considers that MDs, IVDs and health products procured together with or as a component of healthcare infrastructure and vehicles fall under the provisions of sections 3.1 or 3.2 of this QA Policy.

3.1.1. General requirements

All Medical Devices (MDs), In-Vitro Diagnostics (IVD) and other health products falling under national MD and IVD regulations 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, including special authorizations and permissions issued by the competent bodies.

In addition, UNOPS shall procure MDs and IVDs that comply with the following requirements, in accordance with the product’s nature, classification and regulatory status:

1. Have regulatory approval and marketing authorization issued by one of the Global Harmonization Task Force (GHTF) Founding Member countries or be prequalified by WHO;
2. Are manufactured and distributed under a certified Quality Management System (QMS), as described in section 4, and according to the applicable IMDRF requirements.⁸

The following additional aspects should also be evaluated by the project team and considered as applicable and necessary:

- Are compliant with specific standards (International Organization for Standardization [ISO] and other technical standards) and have relevant QA documentation according to the available regulatory

⁴ Global Harmonization Task Force, [Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic \(IVD\) Medical Device’](#), GHTF/SG1/N071:2012, International Medical Device Regulators Forum, 16 May 2012.

⁵ Global Harmonization Task Force, [Principles of Medical Devices Classification](#), GHTF/SG1/N77:2012, International Medical Device Regulators Forum, 2 November 2012.

⁶ International Medical Device Regulators Forum, [Principles of In Vitro Diagnostic \(IVD\) Medical Devices Classification](#), IMDRF/IVD WG/N64FINAL:2021, IMDRF, 21 January 2021.

⁷ World Health Organization, ‘Medical devices: Definitions’, www.who.int/medical_devices/definitions/en/

⁸ Find the IMDRF repository at: International Medical Device Regulators Forum, ‘Documents’, www.imdrf.org/imdrf/imdrf-archives.asp

Find the GHTF repository at: International Medical Device Regulators Forum, ‘GHTF Archived Documents’, www.imdrf.org/ghtf/ghtf-archived-docs.asp

approval and marketing authorization (point 1 above) and to the product classification in the Regulatory Framework, in line with the IMDRF principles; such QA documentation shall be selected and requested based on an assessment and risk-based evaluation by the health technical team of the programme or project, and may include certifications, test reports, a Certificate of Analysis (CoA) and sterilization, a Declaration of Conformity (DoC), documentation issued by recognized Notified, Accredited or Conformity Assessment Bodies, a Certificate of Origin (issued by the Chambers of Commerce), a Material Safety Data Sheet (MSDS) and others;

- Are compliant with the minimum technical requirements stated in the prequalification or in the tender process, including requirements for ancillary services and supplies and for specific languages;
- Have primary and secondary packaging and labelling according to IMDRF requirements,⁹ the available regulatory approval and marketing authorization, and the applicable regulations in the country of destination. For sterile products, the sterilization method and the harmonized instructions and labelling information, according to the previous requirements, shall be clearly indicated in the primary and secondary packaging;
- Are accompanied by relevant manufacturer's and supplier's information on safety, transportation, storage, environmental conditions, shelf life, sterility, use, maintenance and disposal of the products. For products requiring special transport and storage conditions, or those with any other special handling requirements, the procurement process shall include means of monitoring and validating compliance with the requirements according to the manufacturer's instructions and to the applicable regulatory approval.

The last version of the applicable standards and certifications in force shall be considered.

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 regulatory approvals and marketing authorizations (point 1 above) in order to ensure full compliance with such requirements, in consultation with the Procurement Group if needed.

Requests for exceptions to procure medical devices outside the requirements outlined in sections 3.1.1 and 3.1.2, or those registered for "Research Use Only" or "For Export Only", shall be submitted to the UNOPS QA panel for medical devices following an established procedure. The panel shall make a recommendation to the PG Director, who will make the final decision.

3.1.2. Special requirements

The following special or additional requirements apply to the procurement of MDs and IVDs, depending on the nature of the product or on the context:

- i. Under emergency situations, including but not limited to when UNOPS has declared the use of Emergency Procurement Procedures (EPP), UNOPS may accept Emergency Use Authorizations, Approvals or Listings (EUA, EUL) issued by WHO or by an NRA in one of the GHTF Founding Member countries;
- ii. Certain Medical Devices¹⁰ and health supplies may have an impact or depend on health infrastructure and utilities. Determinations of whether a specific requirement should be considered as works from a

⁹ International Medical Device Regulators Forum, [Principles of Labelling for Medical Devices and IVD Medical Devices](#), IMDRF/GRRP WG/N52 FINAL:2019, IMDRF, 21 March 2019.

¹⁰ WHO, 'Medical devices: Definitions'.

UNOPS process perspective shall be done by the project, the Procurement Group (PG) and the Infrastructure and Project Management Group (IPMG), in accordance with the Procurement Manual, section 2.1.1. In such cases, the UNOPS project may have to conduct an infrastructure design review prior to initiating the tender process, in accordance with the Operational Instruction on Design Review, which may entail the use of a UNOPS works contract, in accordance with the Operational Instruction on Works Contracts.

- iii. Certain products may be subject to concurrent or overlying classifications, Regulatory Approvals and Marketing Authorizations, such as, but not limited to, personal protective equipment (PPE). If such products, depending on the specific jurisdiction and context, are also classified as Medical Devices, all the relevant provisions according to the classifications shall be implemented in a complementary manner together with, but not substituting, other Regulatory Frameworks applicable to the products.

3.2. Requirements for the procurement of other health products

All vector control products shall comply with applicable national policy, legislation and guidelines; and in addition, the products shall be pre-qualified under the WHO Vector Control Prequalification Programme.

UNOPS may procure health products other than medicines, vector control products, and MDs and IVDs based on a decision by the Procurement Authority, in consultation with the Procurement Group, if needed.

The following requirements shall be considered for these products based on a risk-based evaluation by the health technical team of the programme or project, taking into account the specific product and context:

1. The applicable regulatory approval and marketing authorization accepted or issued by the NRA in the destination country; personal protective equipment (PPE) shall be authorized for use by at least one of the Management Committee Members of the International Medical Device Regulators Forum (IMDRF);
2. Be manufactured and distributed under a certified QMS, according to section 4.

The following additional aspects should also be evaluated by the project team and considered as applicable and necessary. End products shall:

- Comply with specific standards (ISO and other applicable technical standards) and have relevant QA documentation according to the available regulatory approval and marketing authorization (point 1 above); such QA documentation shall be requested where applicable, based on an assessment and risk-based evaluation by the health technical team of the programme or project, and may include certifications, test reports, a Certificate of Analysis (CoA) and sterilization, a Declaration of Conformity (DoC), documentation issued by recognized Notified, Accredited or Conformity Assessment Bodies, a Certificate of Origin (issued by the Chambers of Commerce), a Material Safety Data Sheet (MSDS) and others;
- Be compliant with the minimum technical requirements stated in the prequalification or in the tender process;
- Have primary and secondary packaging and labelling according to the available regulatory approval and marketing authorization (point 1 above) and the applicable regulations in the country of destination;
- Be accompanied by relevant manufacturer's and supplier's information on safety, transportation, storage, environmental conditions, shelf life, sterility, use, maintenance and disposal of the products. For products requiring special transport and storage conditions, or those with any other special

handling requirements, the procurement process shall include means of monitoring and validating compliance with the requirements according to the manufacturer's instructions and the applicable Regulatory Approval.

Requests for exceptions to procure other health products outside the requirements outlined in section 3.2 shall be submitted to the UNOPS QA panel for medical devices following an established procedure. The panel shall make a recommendation to the PG Director, who will make the final decision.

4. Requirements for suppliers of medical devices and other health products

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 be required to submit to UNOPS, on request, written evidence of qualification or authorization by a competent body, requisite certifications, relevant product information, and product samples.

UNOPS further reserves the right to conduct, independently, including through a third party, an 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.

4.2. Additional requirements for distributors

Distributors of medical devices and health products shall:

1. Have all the licenses and authorizations required under national legislation of the country of operation, issued by the competent authority as applicable; and
2. Where relevant, have the manufacturer's authorization to distribute the product and applicable related services, or have a Free Sale Certificate; and
3. Where relevant, comply with national or WHO Good Distribution Practices (GDP)/Good Storage Practices (GSP) or have a certified QMS.

Relevant licenses, permits, authorizations, certifications or other documents attesting compliance shall be provided as requested and validated by UNOPS.

4.3. Additional requirements for manufacturers

Manufacturers¹¹ of MDs and IVDs shall, subject to applicable regulations:

1. Have a duly authorized manufacturing license, valid for all relevant manufacturing sites and activities performed, issued by the NRA of the country of manufacturing, and be compliant with Good Manufacturing Practice (GMP) (according to the applicable regulatory framework and national regulations);
2. Have a valid and certified QMS, according to the latest versions in force (ISO 13485 or ISO 9001 or equivalent), depending on the nature of the goods; the QMS certificate should:
 - a. include scope, locations and facilities where the relevant activities are performed; and
 - b. be issued by Conformity Assessment Bodies (CABs), Notified or Accredited bodies, or recognized by the Regulatory Authority of the relevant GHTF Founding Member country where the product is approved, or by the International Accreditation Forum (IAF).

Manufacturers of sterile products shall also have a valid and certified QMS, according to the previous point, covering the sterilization of plants and processes.

For manufacturers of health products not falling under the MD and IVD regulations, the following requirements apply:

1. Have a duly authorized manufacturing licence, valid for all relevant manufacturing sites and activities performed, issued by the NRA of the country of manufacturing, and be GMP-compliant (according to the applicable regulatory framework and national regulations); and
2. Have a valid and certified QMS, according to latest versions in force (ISO 13485 or ISO 9001), depending on the nature of the goods, issued by a CAB, Notified or Accredited body or recognized by the relevant regulatory framework where the product is approved, or by the IAF;
OR
3. Be approved by the Procurement Authority based on an assessment and a risk-based evaluation by the health technical team of the programme or project, in consultation with the Procurement Group, if needed.

If a significant part of the production processes is subcontracted by the legal manufacturer to a contractor, the requirement for an independent QMS may apply to the contract manufacturer(s), conforming to the applicable Regulatory Approval.

Relevant licences, permits, authorizations, certifications or other documents attesting compliance shall be provided as requested and validated by UNOPS.

Requests for exceptions to procure medical devices and other health products outside the requirements outlined in sections 4.1, 4.2 and 4.3 shall be submitted to the UNOPS QA panel for medical devices following an established procedure. The panel shall make a recommendation to the PG Director, who will make the final decision.

¹¹ Global Harmonization Task Force, [Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer](#), SG1(PD)/N055R6, International Medical Device Regulators Forum, 26 February 2008.

5. Quality monitoring activities

5.1. Quality control

UNOPS may monitor 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 informed by WHO technical guidance and internal risk assessment. UNOPS will use labs prequalified/accredited by WHO or those accredited by other competent ISO 17025 or Conformity Assessment Bodies (CABs) for independent quality testing of health products.

5.2. Receipt, storage and distribution

All health products will be subject, on receipt, to inspection and where applicable testing, installation and commissioning in accordance with 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 medical devices and other health products 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 relevant vigilance, 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. 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 on 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 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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