UNOPS

Quality Assurance Policy

Procurement of Medicines, Medical Devices and other Health Products

1 July 2021

Annex 2 to the
Procurement Manual

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Abbreviations

CAB	Conformity Assessment Body
DRiVE	Delivering Responsibility in Vendor Engagement
ERP	Expert Review Panel
GDP	Good Distribution Practice
GHTF	Global Harmonization Task Force
GF	Global Fund
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
EPP	Emergency Procurement Procedures
EUA, EUL	Emergency Use Authorization or Approval or Listing
FPP	Finished Pharmaceutical Product
HQCPC	Headquarters Contracts and Property Committee
IMDRF	International Medical Device Regulators Forum
IPMG	Infrastructure and Project Management Group
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostic
LTA	Long Term Agreement
MD	Medical Device
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, UN agencies, international organizations such as The Global Fund to Fight AIDS, TB and Malaria (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 other UN agencies and international organizations. In particular, this 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. To this end the UNOPS QA Policy is aligned with the Global Fund Quality Assurance Policy for Pharmaceuticals and Diagnostic Products, which is itself the product of extensive stakeholder consultation.

1.2. Purpose and scope of the QA policy

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

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

The QA Policy is structured to provide clear requirements to UNOPS personnel and partners, including suppliers. It is divided in 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: https://www.ungm.org/Shared/KnowledgeCenter/Pages/ASR

medicines, medical devices and other health products; requirements for medicines, 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 through 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, Medical Devices and other Health Products takes effect on 1st July 2021 and supersedes the Quality Assurance Manual for Pharmaceutical and Medical Device Procurement from 1st July 2012.

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 against 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 and in favour of the protection of the environment, of social progress and 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 medicines, medical devices and other health products can have to sustainable development and to the access to quality health care, 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 technical

[2] Sustainable Procurement Statement, adopted by the HLCM Procurement Network at its meeting in Vienna, February 2009

sustainability criteria, gender mainstreaming criteria or supplier sustainability requirements (further to the UNOPS 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, 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, pharmacists, biomedical engineers, regulatory affairs specialists) to enable 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 to this QA Policy should be channelled through the PG health advisors by email (procurement@unops.org).

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

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

UNOPS undertakes the procurement of medicines, medical devices and other health products on request of its partners. Wherever applicable, UNOPS will ensure that any needs assessment that may have been done is referenced or validated by technical experts; 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 validated with national capacity, in alignment with WHO, other relevant international guidelines and the UNOPS Procurement Manual.

2.2. Procurement methods and strategies

The overall aim of UNOPS is to procure medicines, medical devices and other health products which are safe, effective, and of appropriate quality with the aim of maximizing value for money; and appropriate for the economical, technical and socio-cultural 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' authorisations should be requested and checked so that no infringement of patents 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 medicines prequalification, it will do so in alignment with the guidance set out in the Model Quality Assurance System for Procurement Agencies (MQAS)[3].

2.2.2. Tender processes

Tender processes shall conform with 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, 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, 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 medicines, 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 WHO Guidelines for Medicines Donations[4] and the Guidelines for Health Care Equipment Donations[5].

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[3] WHO A Model Model Quality Assurance System for Procurement Agencies, 2007
https://apps.who.int/iris/bitstream/handle/10665/69721/WHO_PSM_PAR_2007.3_eng.pdf?sequence=1&isAllowed=y

[4] WHO Guidelines for Medicines Donations, 2010
http://apps.who.int/iris/bitstream/handle/10665/44647/9789241501989_eng.pdf?sequence=1

[5] Guidelines for Health Care Equipment Donations, 2000
https://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf?ua=1

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

3.1. Requirements for the procurement of medicines

All Finished Pharmaceutical Products (FPPs), biological products and vaccines purchased by UNOPS shall be authorised 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 authorisation including for special use. Where such authorisation has not been granted by the NRA, a waiver or exceptional permission to import/use the product shall be obtainable.

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

1. Prequalified by WHO under the WHO prequalification programme; or
2. Approved for use by a Stringent Regulatory Authority[6] (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. Recommended by the WHO-coordinated Expert Review Panel during the time frame stipulated, or
4. 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 and/or restrict procurement to 1-4 above in order to ensure full compliance to such requirements, in consultation with the Procurement Group if needed.

UNOPS can procure FPPs outside 1-4 above, following a decision by the Procurement Authority based on assessment and risk-based evaluation by the health technical team of the programme or project, in consultation with the Procurement Group if needed.

Relevant certifications and documentation issued by the national regulatory authority, as well as other NRAs and agencies listed in 1-4 above confirming the status of the product shall be provided by the supplier.

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

UNOPS recognises and adopts the definition of "Medical Device (MD)" and "In-Vitro Diagnostics (IVD)" according to the GHTF[7] and the WHO position on the subject matter[8]. Other health products meeting any of the medical purposes mentioned in the definitions above may be considered medical devices depending on the jurisdiction and the regulatory framework.

[6] https://www.who.int/medicines/regulation/sras/en/

[7] GHTF final document GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'
http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

[8] WHO definitions of Medical Devices and IVD https://www.who.int/medical_devices/definitions/en/

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 3.2 or 3.3 of this QA Policy.

3.2.1. General requirements

All Medical Devices (MDs), In-Vitro Diagnostics (IVD) and other health products falling under national MD and IVD regulations shall be authorised 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 authorisation including authorisation for special use. Where such authorisation has not been granted by the NRA, a waiver or exceptional permission to import/use the product shall be obtainable.

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 authorisation issued by one of the GHTF Founding Member countries or be prequalified by the WHO;
2. Are manufactured and distributed under a certified QMS, as per described in section 4, and according to the IMDRF and GHTF applicable requirements[9];
3. End products shall comply with specific standards (ISO and other technical standards) and have relevant QA documentation according to the available Regulatory Approval and Marketing Authorisation (point 1 above) and to the product classification in the Regulatory Framework, in line with the GHTF and IMDRF principles[10]; 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, Certificate of Analysis (CoA) and sterilisation, Declaration of Conformity (DoC), documentation issued by recognised Notified, Accredited or Conformity Assessment Bodies, Certificate of Origin (issued by the Chambers of Commerce), Material Safety Data Sheet (MSDS) and others;
4. Are compliant to the minimum technical requirements stated in the prequalification or in the tender process, including requirements for ancillary services and supplies and for specific languages;
5. Have a primary and secondary packaging and labelling according to the IMDRF and GHTF requirements[11], to the available regulatory approval and marketing authorisation and to the applicable regulations in the country of destination. For sterile products, the sterilisation method and the harmonised instructions and labelling information, according to the previous requirements, shall be clearly indicated in the primary and secondary packaging;
6. 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 any other special handling requirement, the procurement process shall include means of monitoring and validating the

[9] IMDRF repository http://www.imdrf.org/imdrf/imdrf-archives.asp
GHTF repository http://www.imdrf.org/ghtf/ghtf-archived-docs.asp
[10] Principles of Medical Devices Classification GHTF/SG1/N77:2012
http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification IMDRF/IVD WG/N64 FINAL:2021
http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-wng64.pdf
[11] Principles of Labelling for Medical Devices and IVD Medical Devices IMDRF/GRRP WG/N52 FINAL:2019
http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf

compliance with the requirements according to the manufacturer's instructions and to the applicable regulatory approval.

The last version in force of the applicable standards and certifications 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 and/or restrict procurement to selected regulatory approvals and marketing authorisations (point 1 above) in order to ensure full compliance to such requirements, in consultation with the Procurement Group if needed.

Any MD and IVD not meeting the requirements listed under Sections 3.2.1 and 3.2.2, or registered for "Research Use Only" or "For Export Only" shall not be procured, unless specifically requested by the Procurement Authority, based on an assessment and risk-based evaluation by the health technical team of the programme or project, and duly authorised as an exception by the Director, PG.

3.2.2. 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 Authorisations, Approvals or Listings (EUA, EUL), issued by the WHO or by an NRA in one of the GHTF Founding Member countries;
ii. Certain Medical Equipment[12] and health supplies may have an impact or depend on the health infrastructure and the utilities. Determinations on whether a specific requirement should be considered as works from a UNOPS process perspective, shall be done by the Procurement Group (PG) and the Infrastructure and Project Management Group (IPMG), in accordance with Procurement Manual, section 2.1.1. In such cases, UNOPS may have to perform an infrastructure design review process prior to initiating the tender process, in accordance with the Operational Instruction on Design Review and 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 Authorisations, such as, but not limited to, Personal Protective Equipment (PPE). If such products, depending on the specific jurisdiction and context, are classified also as Medical Devices, all the relevant provisions according to the classifications shall be implemented in a complementary manner besides, but not substituting, other Regulatory Frameworks applicable to the products.

3.3. Requirements for the procurement of other Health Products

All public health pesticides 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.

[12] WHO definition of Medical Equipment https://www.who.int/medical_devices/definitions/en/

UNOPS may procure health products, other than public health pesticides 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 authorisation accepted or issued by the NRA in the destination country; personal protective equipment (PPE) shall be authorised 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;
3. 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 Authorisation (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, Certificate of Analysis (CoA) and sterilisation, Declaration of Conformity (DoC), documentation issued by recognised Notified, Accredited or Conformity Assessment Bodies, Certificate of Origin (issued by the Chambers of Commerce), Material Safety Data Sheet (MSDS) and others;
4. Be compliant to the minimum technical requirements stated in the prequalification or in the tender process;
5. Have a primary and secondary packaging and labelling according to the available regulatory approval and marketing authorisation (point 1 above) and to the applicable regulations in the country of destination;
6. 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 any other special handling requirement, the procurement process shall include means of monitoring and validating the compliance with the requirements according to the Manufacturer's instructions and to the applicable Regulatory Approval.

4. Requirements for suppliers of medicines, 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 on 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 providing health products based on qualification or authorisation by third parties (WHO or SRAs) (section 3 of this QA Policy) may be required to confirm in writing that products conform in all aspects to those

approved. Suppliers shall also be required to submit to UNOPS on request, 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. Requirements for distributors

Distributors of medicines, 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 national regulatory authority or other relevant entity; and
2. Where relevant, have the manufacturer's authorisation for distributing 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 authorisations or other documents attesting compliance shall be provided as requested.

4.3. Requirements for manufacturers

All medicines manufacturers shall:

1. Be duly authorized by the NRA in the country where all relevant manufacturing sites are located and provide copies of valid licenses for all sites which unequivocally stipulate the types of activities that are authorized in the production facilities.
2. Supply medicines from sites deemed GMP compliant as inspected by WHO, an SRA, an NRA which is a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S)[13] or by other NRA considered acceptable following UNOPS internal assessment.

As proof of compliance, the manufacturer shall provide a valid WHO Public Inspection Report (WHOPIR), or a copy of the GMP certificate or other proof of approval issued by one of the mentioned regulatory authorities.

Manufacturers[14] of MDs, IVDs and other health products shall, subject to applicable regulations:

1. Have a duly authorised manufacturing license, 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 the following requirements:

[13] https://picscheme.org/en/members
[14] GHTF Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer SG1(PD)/N055R6
http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n055R6-definitions-of-the-terms-manufacturer-080226.pdf

   a. latest versions in force ISO 13485 or ISO 9001, when the first is not applicable, or an equivalent QMS standard (equivalence defined below from b. to c.); and
   b. the QMS shall include the scope and the locations and facilities where the relevant activities are performed;
   c. the QMS shall be issued by CABs, Notified or Accredited bodies recognised by the Regulatory Authority of one of the GHTF Founding Member countries and shall be recognised by such Authorities; and
3. Manufacturers of sterile products shall also have a valid and certified QMS, according to the previous point, covering the sterilisation plants and processes.

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

1. Have a duly authorised manufacturing license, 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, issued by a CAB, Notified or Accredited body;
   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, then the requirement for an independent QMS may apply to the contract manufacturer(s), conforming to the applicable Regulatory Approval.

Copies or proof of all above mentioned authorisations and certifications shall be requested and validated by UNOPS.

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 WHO prequalified/accredited or other competent ISO 17025 accredited labs or Conformity Assessment Body (CAB) 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 and UNOPS guidelines for conformity to specifications.

Where UNOPS is responsible for storage and distribution, systems shall be put in place that ensure that medicines 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 pharmacovigilance and technovigilance, 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, safety of the product or in agreed packaging or labelling, the supplier shall promptly and effectively replace the affected product at their 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, the 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. Whereneeded, complaints and disputes shall be escalated by the UNOPS business unit with responsibility over a process to a Legal Advisor, who shall, in consultation with the PG Health Advisors, take appropriate action based on 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 the creation of a Supplier Performance Evaluation record in the oneUNOPS system.

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