UNDP Quality Assurance Policy

for Health Products

2 July 2018

Abbreviations and acronyms

AIDS	Acquired immunodeficiency syndrome
BMS	Bureau of Management Services (UNDP)
BP	British Pharmacopoeia
BPPS-HHD	Bureau for Policy and Programme Support – HIV, Health and Development Group (UNDP)
CAB	Conformity Assessment Body
EMA	European Medicines Agency
EML	Essential Medicines List
EOI	Expression of Interest
ERP	Expert Review Panel (WHO)
FDA	Food and Drug Administration (United States NRA in this document)
FPP	Finished Pharmaceutical Product
GDF	Global Drug Facility
GDP	Good Distribution Practices
GF	Global Fund
GF/HIST	Global Fund/Health Implementation Support Team (UNDP)
GHTF	Global Harmonization Task Force (on Medical Devices)
GMP	Good Manufacturing Practices
HEALTH CANADA	Canadian NRA
HIV	Human immunodeficiency virus
IAPQ	Inter-Agency Product Questionnaire
IMDRF	International Medical Devices Regulator Forum
IVD	In Vitro Diagnostic
MD	Medical Device
MHRA	Medicines and Healthcare products Regulatory Authority (UK NRA)
MIF	Manufacturer Information File
MQAS	Model Quality Assurance System (for Procurement Agencies) - WHO
MSF	Médecins Sans Frontières
NCD	Non-Communicable Diseases
NRA	National Regulatory Authority (Pharmaceutical Authority)
OOS	Out of Specification
PA	Procurement Agency
PAIF	Procurement Agency Information File
PQ	Pre-Qualification
PSM	Procurement and Supply Management
PSU	Procurement Support Unit (UNDP)
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SRA	Stringent Regulatory Authorities
STG	Standard Treatment Guidelines
SWISS MEDIC	Swiss NRA
TB	Tuberculosis
TGA	Therapeutic Goods Administration (Australian NRA)
TRS	Technical Report Series (WHO)
USP	United States Pharmacopoeia
WHOPES	WHO Pesticide Evaluation Scheme
WHOPIR	Public Inspection Report (as published on the WHO PQ website)
WHO PQT	WHO Pre-Qualification Team

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1. Introduction

In line with the UNDP Strategic Plan (2018-2021)[1] and UNDP's HIV, Health and Development Strategy – Connecting the Dots (2016-2021)[2], UNDP supports countries to implement large-scale health programmes for increasing access to inclusive basic services 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 World Health Organization (WHO[3]) and other UN agencies. More specifically, this helps countries to build a solid foundation for universal health coverage and ensuring no one is left behind.

Since 2003, UNDP has worked as interim Principal Recipient for funding from The Global Fund to Fight AIDS, TB and Malaria (Global Fund) 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/AIDS, tuberculosis and malaria (accounting for 50-60% of the budgets), which are complemented by longer-term capacity-building efforts which include strengthening procurement systems for health products.

A rapidly increasing number of governments are requesting UNDP to help strengthen national capacities and systems for the provision of health services, especially for the procurement and supply management of health products[4] for communicable and more recently for non-communicable diseases (NCD)[5]. In 2017 alone, UNDP procured over US$ 350 million of health products.

Conducting procurement of health products in a globalized pharmaceutical market places the organization at special risk of providing substandard products which could put patients' health at risk, expose UNDP to legal actions, cause loss of money and severely damage the reputation of the organization.

Consequently, and in line with established best practice, UNDP has taken the decision[6] to develop and implement a UNDP Quality Assurance (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 sub-standard or falsified health products to individuals (inefficacy or toxicity of medicines, inappropriateness of medical devices, lack of sterility, etc.) and to the community (risk of development of resistances to anti-infectious agents).

For HIV, tuberculosis and malaria, the UNDP QA Policy is consistent with the Global Fund QA policy, which has been the basis for UNDP procurement in the role of interim Principal Recipient. This UNDP policy will now extend to include all other health products procured by UNDP beyond these three diseases.[7]

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[1] UNDP Strategic Plan 2018-2021, Available at http://strategicplan.undp.org/.

[2] UNDP. HIV, Health and Development Strategy 2016-2021: *Connecting the Dots*.

[3] Memorandum of Understanding between UNDP and WHO. Signed 4 May 2018.

[4] "Health products" in the context of UNDP QA policy include medicines, medical devices, medical equipment and pesticides for public health.

[5] "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).

[6] OPG Decision, 16 November 2017

[7] It is to be noted UN and other international organizations procuring health products have a Quality Assurance Policy, and a specialized health procurement function at corporate level.

The UNDP QA Policy is based on international/WHO guidelines for medicines and health products and is aligned with QA policies from other UN organizations and other international organizations such as The Global Fund.

Consistent observance of this policy is essential to ensure UNDP health procurement is safe. Regular monitoring and oversight of the compliance of the QA policy, and support to its implementation, will be the responsibility of BPPS-HHD as part of its overall technical support to Country Offices and to the Procurement Support Unit (PSU)/Bureau of Management Services (BMS), as per OPG decision[8]. This policy will also serve as a guide for the development of national quality assurance systems through longer-term UNDP capacity-building activities in countries.

The UNDP Quality Assurance Policy is a key document for all parties involved in health procurement activities across UNDP as well as for national partners, suppliers and donors as it details UNDP's requirements for health procurement, in line with international best practice.

2. Scope

The UNDP Quality Assurance Policy applies to all health products[9] procured and/or supplied[10] by UNDP, whether through its specialized procurement services at corporate level, Country Offices or other business units.

3. Responsibilities

UNDP has established a QA system[11] that ensures that all health products procured and/or supplied by UNDP will be of appropriate quality and will not expose the consumer (patient) to avoidable risks. The QA system includes clear quality requirements for health products, manufacturing sites and all entities involved in the storage, distribution and transportation of such health products. The responsibility of UNDP under this QA Policy terminates when health products are delivered to the consignee in the recipient country.

In line with international best practices and WHO recommendations, the QA function will be independent from the health procurement function of UNDP. BPPS-HHD is responsible for the implementation, monitoring and the compliance to the QA policy.

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

The UNDP QA system includes provisions to prevent or mitigate potential or perceived conflicts of interest related to:
- UNDP staff involved in QA work and related activities
- UNDP staff involved in procurement and purchasing activities; and
- Individual Consultants, Service Providers who participate in the identification, evaluation and qualification of sources.

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[8] OPG Decision OPG-2017.11.19-4.4, November 2017

[9] "Health products" in the context of UNDP QA policy include medicines, medical devices, medical equipment and pesticides for public health

[10] In case of donations, they will be handled in accordance to WHO Guidelines for medicine donations (2011)

[11] "An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality." (WHO TRS 957 – Annex 4)

The QA system ensures that all information submitted to UNDP or observed by UNDP experts during the assessment of product dossiers and technical visits of procurement agencies premises and manufacturing sites is considered strictly confidential.

4. Norms and standards

4.1   Selection of health products to procure

For the selection of medicines to be procured, UNDP refers to the latest editions of the WHO Model Essential Medicines Lists (WHO EMLs for adults and for children)[12], WHO treatment guidelines and other institutional treatment guidelines.

Requests for medicines submitted to UNDP that are not included in the WHO EMLs should be supported by appropriate documents (e.g. National List of Essential Medicines, National Treatment Guidelines, etc.). Such requests are assessed by the **UNDP Experts Committee,** to determine compliance with UNDP's general principles for the procurement of medicines.

UNDP Experts Committee
The UNDP Experts Committee shall be comprised of the UNDP Senior Health PSM Advisor, UNDP QA expert, two UNDP pharmacists, one UNDP physician and external experts who can be consulted on specific quality issues on an ad hoc basis. Decisions of the Experts Committee are taken by consensus.

Requests for other health products (non-pharmaceutical) such as medical devices, insecticides, etc. should be submitted with specifications that are explicit and relevant to their intended use.

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

4.2   Quality Assurance

References

The UNDP QA system is based on the:
- WHO International Pharmacopoeia and WHO standards for pharmaceutical preparations, as published and regularly updated in the WHO Technical Report Series (TRS);
- Guidelines of the International Medical Devices Regulator Forum[13] (IMDRF) for Medical Devices; and
- WHO specifications for pesticides used in public health.[14]

UNDP also refers to the European Pharmacopoeia, the British Pharmacopoeia (BP) and the United States Pharmacopoeias (USP) and other reputed international guidelines (European Medicines Agency, US Food and Drug Administration, Australian Therapeutic Goods Administration, etc.) when appropriate.

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

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[12] www.who.int/selection_medicines/list/en/
[13] WHO is an official observer to the Management Committee of the IMDRF
[14] www.who.int/whopes/quality/newspecif/en/

Key principles:

UNDP will only purchase health products from suppliers (i.e. manufacturers and procurement agencies) that comply with WHO or equivalent good practice guidelines and WHO regulatory guidance.

Products are assessed and qualified in accordance with the rules and principles of the UNDP QA system.

As recommended by WHO, the UNDP qualification process includes the assessment of the manufacturing site **and** the product.

4.2.1. Finished Pharmaceutical Products[15] (FPP)

Manufacturing sites

All 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.

Suppliers must provide a valid copy of the manufacturing license issued by the NRA for each site involved in the production of the FPP that has been submitted to the UNDP qualification process.

UNDP recognizes the GMP inspections performed by the WHO Prequalification Team as well as the National Authorities members of the European Union (EU), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), US Food and Drug Administration (US FDA), Australian Therapeutic Goods Administration (TGA), Health Canada and Swiss Medic.

UNDP requires proof of GMP compliance which may be:
- A copy of a recent (< 3 years) inspection report written by one of the above-mentioned authorities; or
- A valid GMP certificate issued by one of the above-mentioned Regulatory Authorities; or
- A valid WHO Public Inspection Report (WHOPIR[16]).

UNDP reserves the right to commission qualified experts to perform GMP audits of manufacturing sites for qualification, verification or monitoring purposes.

Products

Any FPP procured and/or supplied by UNDP should comply with the guidelines for pharmaceutical preparations as published by WHO[17].

All FPPs that appear in the WHO PQ lists are de facto qualified by UNDP and directly purchasable.

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[15] "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)

[16] A "valid" WHOPIR is a WHOPIR published on the WHO PQT website.

[17] WHO Guidelines for Pharmaceutical Preparations (http://www.who.int/globalchange/publications/en/)

Those that received a positive opinion from the WHO Experts Review Panel (ERP) can be procured and supplied by UNDP within the period of time specified by the ERP.

UNDP recognizes the work of Stringent Regulatory Authorities (SRAs) as defined by the WHO[18].
All FPPs that are registered **and** marketed in countries with such SRAs are qualified by UNDP.

UNDP can decide to assess FPPs that are not WHO prequalified or recommended for use by the ERP or registered and marketed in countries with SRA. In such cases, the assessment will be conducted in accordance with WHO's Model Quality Assurance System (MQAS) guidelines.

Any FPP procured and/or supplied by UNDP must be authorized by the National Regulatory Authority in the recipient country.

4.2.2. Medical devices[19]

Manufacturing sites

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

A certified copy of the Manufacturing License(s) must be submitted to UNDP.

The manufacturing sites of medical devices must comply with the requirements of ISO 13485: 2003[20] or an equivalent Quality Management System (QMS).

Conformity to standards will be established by a Conformity Assessment Body (CAB) that is recognized by the regulatory authorities in one of the GHTF founding member countries, UNDP may request certified copies of valid certificates issued by CABs.

Certificates need to specify, as a minimum:
- The QMS standard; and
- The name of the CAB.

Regardless of the above-mentioned requirements, UNDP reserves the right to conduct an independent review or technical visit of the manufacturing sites involved in the production of any medical devises offered to UNDP.

Products

Medical devices, including in vitro diagnostics (IVDs), should comply with:
- The guidelines of the IMDRF and GHTF as appropriate
- The requirements and test methods set for them (as defined by the International Organization for Standardization).

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[18] Working document QAS/17.728/Rev.1

[19] WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices
Annex 4, WHO Technical Report Series 1003, 2017

[20] (* from 1st March 2019: 13485: 2016 will be applicable)

Medical devices classified B, C and D[21] according to GHTF classification principles[22] should have a market clearance in one of the GHTF founding members[23].

UNDP recognizes the work of the WHO: all IVDs and Male Circumcision Devices that appear in the WHO PQ lists are qualified by UNDP.

4.2.3. Pesticides for public health

Pesticides for public health must comply with the specifications defined by the WHO[24].

UNDP relies on the work of the WHO; long-lasting insecticidal nets that are recommended by WHO[25] are de facto qualified by UNDP.

4.2.4. Procurement Agencies (= Non-manufacturing suppliers)

> **WHO definition of "Procurement Agency"[26]**
> "Any organization purchasing pharmaceutical products, vaccines, or other health products or otherwise involved in their prequalification, purchasing, storage and distribution".

Procurement Agencies must:
- Be authorized by the National Regulatory Authority (NRA) of the country of location; and
- Comply with WHO (or equivalent[27]) Good Distribution Practices (GDP) guidelines and with the WHO Model Quality Assurance for Procurement Agencies (MQAS).

Applicants must provide a valid copy of the license issued by the NRA.

Any procurement agency that expresses its interest in submitting products for UNDP qualification will be assessed against WHO GDP and WHO MQAS guidelines[28].

The assessment will be performed by UNDP pharmacists and consultants under the responsibility of UNDP Head of QA.

5. Participation in the UNDP qualification process

The UNDP qualification process is open to any supplier (PAs and manufacturers) that wishes to sell medicines or other health products to the organization.

UNDP will periodically publish calls for qualification, in connection with international tender processes for specified health products.

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

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[21] B = Low-moderate hazard, C = Moderate-high hazard, D = High hazard

[22] GHTF/SG1/N77:2012

[23] GHTF founding members: EU, USA, Japan, Canada, Australia

[24] http://www.who.int/whopes/quality/newspecif/en/

[25] http://www.who.int/whopes/Long_lasting_insecticidal_nets_06_Feb_2014.pdf

[26] WHO TRS 986 – Annex 3

[27] EU EMA, Swiss Medic, Health Canada GDP guidelines are considered as equivalent to the WHO ones.

[28] Procedure for assessing the acceptability in principle of procurement agencies for use by United Nations agencies (WHO TR 917, Annexes 6 & 7).

Specific formats will be used to collect the technical information as appropriate:
- Manufacturer Information File (MIF)
- Procurement Agency Information File (PAIF)
- Inter-Agency Product Questionnaire (IAPQ)

Applicants' dossiers and product information will be assessed in accordance with UNDP Standard Operating Procedures and selection criteria as specified in the call for qualification.

6. Outcome of the UNDP qualification process

Suppliers that comply with the requirements as stated in the call for qualification will be considered as qualified for a period of three years and will be notified accordingly by UNDP.

Sources (i.e. pairs of FPPs and manufacturing sites) that are found to be compliant with UNDP quality criteria will remain qualified for a period of three years.

A list of qualified suppliers and sources will be maintained by the UNDP QA expert and updated regularly.

Only qualified suppliers will be eligible to participate in the tenders that UNDP launches on a regular basis.

7. Monitoring activities

7.1 Quality Control

The UNDP QA system includes provisions for Quality Control (QC) of health products.
- Sampling is based on an assessment of risks in accordance with WHO guidelines.[29,30]
- Samples may be taken at different points/levels in the supply chain.
- QC testing of samples is performed by independent QC laboratories.
- UNDP will preferably use QC laboratories that are prequalified by WHO; alternatively (when WHO PQ laboratories are not available or not able to comply with UNDP expected timeframes) ISO 17025 certified laboratories can be used.
- Any deviation (Out of Specifications [OOS] result) is investigated under the supervision of the Head of QA and in accordance with UNDP procedures.

7.2 Variations

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

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[29] WHO Guidelines for sampling of pharmaceutical products – TRS 929 (Annex 4)
[30] WHO Guidelines on the conduct of surveys of the quality of medicines – TRS 996 (Annex 7)

7.3 Traceability

The UNDP QA system ensures that all products supplied are traceable throughout the supply chain until the products reach the designated recipient in the country of destination.

7.4 Complaints

During the qualification validity period, qualified suppliers must inform UNDP of any complaint, alert or quality issue related to the product qualified (e.g. related to the manufacturing process and/or product characteristics).

The UNDP QA system includes a procedure for handling complaints related to the quality and safety of the products supplied. Any complaint will be investigated under the responsibility of the Head of QA and appropriate measures (including product recalls) will be taken based on an assessment of the risks for patients, the community and UNDP.

7.5 Re-assessment

UNDP periodically re-assesses its qualified suppliers and qualified sources to make sure that products and suppliers continue to comply with the standards.

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

7.6 Regulatory watch procedure

Any alert, notice of concern or warning letter issued by the WHO or SRAs will be considered and could lead to the disqualification of the product and the manufacturer(s) concerned.

8. Post-procurement Quality Assurance

The National Regulatory Authority of the recipient country is responsible for market surveillance and pharmacovigilance.
NRAs also set the standards for the storage, distribution and transportation of health products and inspect the supply chain for compliance with these standards.

In agreement with National Regulatory Authorities, UNDP may conduct joint Good Distribution Practices assessments of warehouses and other premises that are used to store health products. These assessments are conducted in accordance with WHO guidelines.

9. Implementation of the policy

The Policy will be implemented through the development and roll out of a Quality Assurance manual and Standard Operating Procedures and the development and roll out of training materials to build capacity of UNDP staff engaged in health procurement. Successful implementation of the QA Policy and monitoring of its compliance will require adequate resources from the organization.

10. Reporting

BPPS/HHD will submit an annual Quality Assurance Report to the Associate Administrator with copy to Regional Bureaux, Bureau of Management Services, and the Office of Audit and Investigations.

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 Country Offices and Regional Bureaux, a note will be sent by BPPS/HDD to inform the Associate Administrator.