World Health Organization

WHO QUALITY ASSURANCE POLICY

FOR THE PROCUREMENT OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS

Corporate procurement policy
and coordination programme

World Health Organization

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WHO quality assurance policy for the procurement of essential medicines and other health products

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CONTENTS

ACRONYMS iv

1. INTRODUCTION 1
   - 1.1. Procurement by WHO and responsibilities within WHO 2
   - 1.2. Conflict of interest and confidentiality considerations in WHO procurement 2
   - 1.3. The WHO Quality Assurance Group 2

2. REQUIREMENTS FOR THE PROCUREMENT OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS 3
   - 2.1. General principles, norms and standards applicable to WHO's procurement of essential medicines and other health products 3
   - 2.2. Specific requirements for the procurement of certain types of essential medicines and other health products 4

3. REQUIREMENTS FOR SUPPLIERS OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS TO WHO 8
   - 3.1. Definitions of supplier and requirements for all suppliers 8
   - 3.2. Requirements for wholesale distributors 8
   - 3.3. Requirements for manufacturers 10
   - 3.4. Accepting a potential supplier of essential medicines and other health products which is not prequalified under the WHO Prequalification Programme 11
   - 3.5. Removal of Suppliers 11

4. MONITORING THE QUALITY OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS PROCURED BY WHO, AND SUPPLIERS THEREOF 12
   - 4.1. Monitoring of suppliers' performance 12
   - 4.2. Quality testing of essential medicines and other health products 12
   - 4.3. Managing quality non-conformity 13
   - 4.4. Suppliers' responsibility for rejected or returned products 13

ACRONYMS

CPP	Certificate of a pharmaceutical product
EMA	European Medicines Agency
EML	Essential Medicines List
ERP	Expert Review Panel
ECSPP	WHO Expert Committee on Specifications for Pharmaceutical Preparations
EU	European Union
EUAL	Emergency Use Assessment and Listing procedure (EUAL)
FPP	finished pharmaceutical product(s)
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
GHTF	Global Harmonization Task Force
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardization
IVD	In vitro diagnostic medical device
MQAS	Model Quality Assurance System for procurement agencies
NRA	National Regulatory Authority
PIC/S	Pharmaceutical Inspection Co-operation Scheme
QA	Quality Assurance
QA Group	WHO Quality Assurance Group
QL	Quality Control Laboratory
SMF	site master file
SRA	Stringent Regulatory Authority
TGF	The Global Fund to Fight Aids, Tuberculosis, and Malaria
UN	United Nations
UNGM	United Nations Global Marketplace
USFDA	United States Food and Drug Administration
WHO	World Health Organization
WHO PQ	WHO Prequalification

1. INTRODUCTION

The procurement of essential medicines and other health products is a critical function in support of the effective discharge of WHO's mandate, and WHO values the importance of the quality of essential medicines and health products that are supplied to countries. The first World Health Assembly in 1948 recognized the need to establish a procurement service at WHO, and recommended setting up an office "to give advice on the procurement of essential drugs, biological products and other medical supplies".

This WHO Quality Assurance Policy for the Procurement of Essential Medicines and other Health Products (the Policy) sets out the principles and requirements regulating WHO procurement of essential medicines and health products, including a set of clear and transparent criteria on which potential sources and suppliers are selected and engaged. The Policy functions to update and consolidate existing internal quality procedures into a single document. Reference should also be made to the WHO procurement rules as described on the WHO website at http://www.who.int/about/finances-accountability/procurement/en/ and as modified from time to time.

This Policy aims for harmonization, where appropriate, with the quality assurance policies of other United Nations (UN) agencies and international organizations procuring essential medicines and other health products. WHO intends to continue to collaborate with relevant technical partners to ensure consistent application of quality assessment tools and procedures within the UN system. Suppliers (manufacturers and wholesale distributors) of essential medicines and other health products to WHO must accept the provisions of this Policy as part of the WHO procurement process and their contractual relationship with WHO.

1.1. Procurement by WHO and responsibilities within WHO

All WHO procurement must be in line with the Organization's rules and regulations. When WHO procures essential medicines and other health products, the procuring entity or unit collaborates with other WHO technical departments as appropriate. This could include those departments responsible for creating treatment guidelines, demand planning, prequalification of medicines, vaccines an in vitro diagnostic medical devices (IVDs), as well as departments with administrative, financial and legal oversight. Externally, WHO may choose to collaborate with other UN organizations which are procuring essential medicines and other health products for similar projects and/or activities.

Although WHO primarily acquires goods and services to enable the implementation of its own programme needs, it may also conduct procurement for various government health programmes and occasionally for parallel activities undertaken by United Nations agencies and nongovernmental organizations, subject to the Organization's rules and regulations.

1.2. Conflict of interest and confidentiality considerations in WHO procurement

WHO staff and WHO experts involved in the procurement of essential medicines and other health products, including any and all qualification and/or procurement of products or suppliers, must disclose any real, potential or apparent conflicts of interest, in accordance with WHO's rules and procedures. Information submitted to WHO related to the procurement of essential medicines and other health products, including any and all qualification and/or procurement of products or suppliers may be subject to confidentiality obligations and undertakings, which must be respected by WHO.

1.3. The WHO Quality Assurance Group

The WHO Quality Assurance Group (QA Group) is an internal WHO group with a technical focus which aims to ensure the safety, efficacy and quality of essential medicines and health products procured by WHO. The QA Group, chaired by the Director of WHO's Department of Essential Medicines (EMP), is composed of in-house technical experts and operates in accordance with its established terms of reference.

2. REQUIREMENTS FOR THE PROCUREMENT OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS

2.1. General principles, norms and standards applicable to WHO's procurement of essential medicines and other health products

This Policy incorporates by reference the quality standards and guidelines established by the WHO Technical Report Series, including the following:

- The current WHO Model List of Essential Medicines (EML)[1]
- The WHO Global Atlas of Medical Devices;[2]
- The WHO Model List of Essential In Vitro Diagnostics (EDL);[3]
- WHO technical guidelines as approved by the WHO Expert Committee on Specifications for Pharmaceutical Preparations[4,5] and the Expert Committee on Biological Standardization[6], and the WHO International Pharmacopoeia[7];
- WHO testing and treatment guidelines;[8]
- WHO guidance on procurement of IVDs and other laboratory items[9]; and
- WHO Medical device technical series – procurement process resource guide.[10]

1 - WHO Model List of Essential Medicines, 20th list. Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/essentialmedicines/en/, accessed 23 January 2018)

2 - Global atlas of medical devices. Geneva: World Health Organization; 2017. (http://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/, accessed 23 January 2018)

3 - Proposal for a WHO Model List of Essential In Vitro Diagnostics (or the EDL). Proposed by the Department of Essential Medicines and Health Products, World Health Organization and submitted to the WHO Expert Committee on the Selection and Use of Essential Medicines for comments and recommendations, 26 January 2017. (http://www.who.int/selection_medicines/committees/expert/21/applications/Proposal_for_a_WHOModelListofEssential_In_Vitro_DXs_2017.pdf?ua=1, accessed 23 January 2018).

4 - Guidelines. In: Essential Medicines and Health Products [website]. Geneva: World Health Organization; 2018 (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/, accessed 23 January 2018).

5 - Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP). In: Essential medicines and health products [website]. Geneva: World Health Organization; 2018 (http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/en/, accessed 23 January 2018).

6 - WHO Expert Committee on Biological Standardization (ECBS). In: Biologicals [website]. Geneva: World Health Organization; 2018 (http://www.who.int/biologicals/WHO_ECBS/en/, accessed 23 January 2018).

7 - The International Pharmacopeia (17th edition). Geneva: World Health Organization; 2017 (http://www.who.int/medicines/publications/pharmacopoeia/en/, accessed 23 January 2018).

8 - See, for example, Consolidated Guidelines on HIV Testing Services. Geneva: World Health Organization; 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/, accessed 24 January 2018) and Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017

9 - Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. (http://apps.who.int/iris/bitstream/10665/255577/1/9789241512558-eng.pdf?ua=1, accessed 23 January 2018).

10 - Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. (http://apps.who.int/iris/bitstream/10665/255577/1/9789241512558-eng.pdf?ua=1, accessed 23 January 2018).

WHO mainly procures pharmaceutical products which are included in the above listed documents. When purchasing pharmaceutical products not included in the above-listed documents, the QA Group must review and endorse the technical justifications for such a purchase.

In principle, all essential medicines and other health products procured by WHO should be authorized (or exceptionally authorized) for importation and use by the relevant National Regulatory Authority (NRA) in the country of destination. In specific contexts, for example, emergencies, WHO may choose to accept government waivers or other exceptional market authorizations to this requirement, consistent with its rules and regulations.

2.2. Specific requirements for the procurement of certain types of essential medicines and other health products

In addition to the requirements set forth in Section 2.1 above, the following requirements and criteria apply to WHO's procurement of the specified products/items.

2.2.1. Criteria for the procurement of finished pharmaceutical products (FPP)

WHO procures only FPPs which are (listed in order of priority):

A. **Prequalified by WHO,** through its Programme for Prequalification of Medicines;[11] or

B. **Approved by a Stringent Regulatory Authority (SRA)**[12] as currently defined by WHO, including those FPPs which are tentatively approved [by the US Food and Drug Administration (USFDA)] or have an Article 58 positive opinion [issued by the European Medicines Agency (EMA)]; or

C. **Recommended by the Expert Review Panel (ERP)**[13], as coordinated by the WHO Prequalification team for TGF, UNFPA or UNICEF; or

D. **Considered acceptable in principle for procurement by WHO based on technical data collected**, the product dossier and expert risk assessment, on the basis of the information obtained and available from other sources and the GMP inspection; or

11 - Medicines/Finished pharmaceutical products. In: Essential Medicines and Health Products: Prequalification of medicines [website]. Geneva: World Health Organization; 2018 (https://extranet.who.int/prequal/content/prequalified-lists/medicines, accessed 23 January 2018).

12 - Fifty-first report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2017 (WHO technical report series ; no. 1003). Licence: CC BY-NC-SA 3.0 IGO. (http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1003/en/, accessed 23 January 2018).

13 - The Expert Review Panel [Information Note 09 Feb 2016]. Geneva: World Health Organization; 2016 (https://extranet.who.int/prequal/sites/default/files/documents/73%20ERP_Feb2016_1.pdf, accessed 23 January 2018).

E. **Listed under the WHO Emergency Use Assessment and Listing procedure (EUAL)** for candidate medicines for use in the context of a public health emergency.

The following documents shall be submitted by the supplier to WHO as evidence:

- Reference to the WHO-PQ list and copy of the letter sent by WHO-PQ to the manufacturer; or
- A Certificate of a Pharmaceutical Product (CPP)[14] issued by a SRA, together with a summary of product characteristics (SmPC), or proof of the official registration of the product; or
- Reference to the ERP list of recommended products and/or the letter issued by TGF or the relevant ERP client; or
- A certification that the proposed product is exactly the same as the prequalified/ approved one. If differences exist between the proposed product and the approved/ registered one (e.g. differences in formulation, strength, shelf-life or other specifications including packaging), they shall be identified and justified. WHO will, at its sole discretion, determine the eligibility of such a product for procurement by WHO.

All FPPs not captured by the above listed categories (A-E) will be managed by WHO through a technical review conducted by the QA Group using the Interagency finished pharmaceutical product questionnaire. This questionnaire is based on the model qualityassurance system for procurement agencies (MQAS)[15]. WHO will, at its sole discretion, determine whether such products are eligible for procurement by WHO.

In all cases, certificates of analysis, product samples and product information including packaging and labelling shall be made available to WHO upon request.

2.2.2. Criteria for the procurement of biological products and vaccines

WHO procures primarily WHO prequalified vaccines.[16]

In exceptional circumstances, WHO may procure vaccines which are not prequalified by WHO. In such cases, in addition to a full assessment of the technical requirements by the QA Group, preference is given to:

A. Products **approved by an SRA;** or

B. **Manufacturers already WHO prequalified for at least one (1) biological or vaccine product**; or

C. Products **listed under the Emergency Use Assessment and Listing Procedure (EUAL)** for candidate vaccines for use in the context of a public health emergency.

14 - Certification scheme on the quality of pharmaceutical products moving in international commerce. In: Essential medicines and health products [website]. Geneva: World Health Organization; 2018 (http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/, accessed 23 January 2018).

15 - Appendix 6 (Interagency finished pharmaceutical product questionnaire based on the model quality assurance system for procurement agencies). (http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/MQAS-Appendix-6.docx?ua=1, accessed 24 January 2018).

16 - http://www.who.int/immunization_standards/vaccine_quality/pq_suppliers/en/index.html WHO Prequalified Vaccines [online databse]. Geneva: World Health Organization; 2018 (https://extranet.who.int/gavi/PQ_Web/, accessed 24 January 2018).

Any non-pre-qualified product will be subject to the final written acceptance of the biological product / vaccine and source (manufacturer) by the recipient country prior to the WHO final procurement procedure.

For biological products (if applicable), a formal declaration is required indicating the NRA responsible for the lot release of the finished product. When the product is a human-derived blood product, the formal declaration must also include the NRA responsible for the plasma pool release.

2.2.3. Criteria for the procurement of medical devices

WHO procures medical devices only if the product is:

A. **Listed as WHO prequalified**; or

B. **Considered acceptable in principle for procurement by WHO based on technical data collected, the product dossier and expert risk assessment** (if the product is not within the scope of WHO prequalification).

Currently, few medical device categories fall within the scope of WHO prequalification. Some within this scope include male circumcision devices and immunization-related equipment.

For products in category A, a WHO Prequalification Public Report shall be submitted by the supplier as proof of the PQ listing.

For products in category B, a WHO Assessment Report shall be submitted as proof of the WHO assessment.

2.2.4. Criteria for the procurement of in vitro diagnostic medical devices (IVDs) and other laboratory items

WHO procures IVDs only if the product is:

A. **Listed as WHO prequalified**;[17] or

B. **Recommended by the Expert Review Panel for Diagnostics[18] (ERPD), as coordinated by WHO Pre-qualification Team for TGF and Unitaid;** or

C. **Listed under the WHO Emergency Use Assessment and Listing procedure** for use in the context of a public health emergency; or

D. **Considered acceptable in principle for procurement by WHO based on technical data collected, the product dossier and expert risk assessment** (if the product is not within the scope of WHO prequalification).

The WHO prequalification focusses on assessment of IVDs for certain priority diseases and their suitability for use in resource-limited settings. Therefore, the WHO prequalification assessment is limited to certain categories of IVDs. When the IVD category is subject to the WHO prequalification assessment, only WHO prequalified IVDs should be sourced.

17 - WHO list of prequalified in vitro diagnostic products. In: In vitro diagnostics and laboratory technology [website]. Geneva: World Health Organization; 2018 (http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/, accessed 23 January 2018).

18 - The Expert Review Panel [Information Note 09 Feb 2016]. Geneva: World Health Organization; 2016 (https://extranet.who.int/prequal/sites/default/files/documents/73%20ERP_Feb2016_1.pdf, accessed 23 January 2018).

When the IVD category does not fall within the scope of PQ or EUAL, an assessment shall be made by the relevant WHO technical unit. Such an assessment shall follow WHO guidance for procurement of diagnostics[19] through technical review of selected quality, performance and operational characteristics.

For products in category A, a WHO Prequalification Public Report shall be submitted by the supplier as proof of the PQ listing.

For products in category B, a WHO Assessment Report shall be submitted as proof of the relevant WHO technical unit's assessment.

For products in category C, a WHO EUAL Report shall be submitted as proof of EUAL.

As a minimum requirement, IVDs and other laboratory items procured by WHO must be manufactured at a site in compliance with ISO 13485 or an equivalent quality management system (QMS) recognized by a regulatory authority of the founding members of the Global Harmonization Workforce (GHTF) [20].

19 - Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. (http://apps.who.int/iris/bitstream/10665/255577/1/9789241512558-eng.pdf?ua=1, accessed 23 January 2018).

20 - Global harmonization task force (GHTF). In: Medical Devices [website]. Geneva: World Health Organization; 2018 (http://www.who.int/medical_devices/collaborations/force/en/, accessed 23 January 2018).

3. REQUIREMENTS FOR SUPPLIERS OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS TO WHO

3.1. Definitions of supplier and requirements for all suppliers

For the purposes of this Policy, a supplier of essential medicines or other health products to WHO is either (i) a wholesale distributor, which is an intermediary which does not manufacture the product, or (ii) the manufacturer of the product. Specific requirements for wholesale distributors and manufacturers, respectively, follow.

In order to be a potential supplier of essential medicines and other health products to WHO, suppliers must:

i. abide by the UN Supplier Code of Conduct [21];
ii. accept the terms of the relevant procurement solicitation documents (RFP or otherwise);
iii. be registered in the United Nations Global Marketplace (UNGM); and
iv. comply with this Policy, as applicable.

3.2. Requirements for wholesale distributors

In addition to the provisions in Section 3.1 above, wholesale distributors supplying essential medicines and other health products to WHO must:

A. **have all requisite authorizations in their country of operation, delivered by their NRA or other entity as required by local legislation.** A copy of any valid license, permit, or authorization shall be provided[22]; and

B. **comply with the WHO Good Distribution Practices (GDP) / Good Storage Practices (GSP)[23] and with the requirements of the WHO MQAS.**[24] This requirement also includes the concerned premises of the wholesale distributor. For GDP and GSP, standards from USFDA and EU are accepted.
A valid copy of the certificate or document attesting of this compliance shall be provided. Such certificate/document shall be issued by a SRA; and

C. complete the WHO wholesaler distributor information questionnaire for review and approval by WHO QA Group.

21 - UN Supplier Code of Conduct. New York: UN Procurement Division; 2017 (https://www.un.org/Depts/ptd/about-us/un-supplier-code-conduct).

22 - Wholesale distributors can have multiple premises, located in different sites or even different countries. All premises shall be duly authorized and a copy of the license, permit etc. for each of the operating premises engaged in any function of the proposed procurement must be provided.

23 - Guidelines. In: Essential medicines and health products [website]. Geneva: World Health Organization; 2018 (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/, accessed 23 January 2018).

24 - A model quality assurance system for procurement agencies. Geneva: World Health Organization; 2007 (WHO/PSM/PAR/2007.3) (http://www.who.int/medicines/publications/ModelQualityAssurance.pdf, accessed 23 January 2018)

WHO reserves the right to audit the site(s) of the wholesale distributor to verify the compliance of their QA system with the standards in this Policy. The observations and conclusions of the audit pertain exclusively to the audited premises and cannot be extrapolated to other premises (as per the MQAS[25]).

For special cases, such as approval of a wholesale distributor for kit supply, the audits also address the ability of the wholesale distributor to perform the proposed activities according to applicable standards, such as WHO GSP/GDP. A list of the audited wholesale distributors is maintained by the WHO QA officer.

WHO's waiver of audits of wholesale distributors

WHO reserves the right to accept the audit of a wholesale distributor performed by another UN system organization. In such cases, the whole-saler's compliance will be accepted by WHO if WHO determines that the audit:

- Is conducted less than three years from the date of the proposed procurement;
- Assesses the same premises and similar products supplied to WHO by the wholesale distributor (name and address shall be identified with no ambiguity);
- Satisfies the requirements of WHO regarding the selection of the auditor (expertise and independence), the standards used [WHO (or equivalent GDP/ GSP and WHO MQAS)] and the audit management (according to its written SOPs);
- Concludes that the wholesale distributor operates at an acceptable level of compliance with the WHO GDP and/or the WHO MQAS (the report or at least the conclusions and the list of the observations noted during the audit must be made available to WHO); and
- Includes a signed statement from the wholesale distributor that no major changes have been made to premises, equipment and key personnel since the audit.

25 - Annex Three. In: Model Quality Assurance System for Procurement Agencies. Geneva: World Health Organization; 2014 (WHO technical report series; no. 986). (http://apps.who.int/medicinedocs/en/m/abstract/Js21492en/, accessed 23 January 2018).

3.3. Requirements for manufacturers

In addition to the provisions in Section 3.1 above, the following requirements apply to manufacturers supplying essential medicines and other health products to WHO:

A. **Manufacturers must be duly authorized by the NRA in the country of origin.** A copy of the valid license must be provided. The license must unequivocally stipulate the types of activities that are authorized in the production facilities. A copy of the license for each production site where proposed products are produced must also be provided; **AND**

B. Manufacturing sites must be GMP compliant as inspected by WHO, an SRA or a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). As proof of compliance, the manufacturer shall provide reference to the WHO Public Inspection Report (WHOPIR) published on the WHO PQP website, or a copy of the GMP certificateor approval letter (for USFDA) delivered by a SRA/PICs member.

In addition, the manufacturers (or their representatives) shall submit information about each concerned manufacturing site and production unit, by sharing a copy of a recent site master file (SMF) or a completing a technical questionnaire (see Annex 4 of the Technical Questionnaire for pharmaceutical manufacturers, WHO MQAS 2014).

In absence of proof of compliance with WHO (or equivalent) GMP compliance, WHO reserves the right to organize a GMP audit against the WHO guidelines. WHO will contract independent qualified experts to perform an audit.

WHO waivers of audits of suppliers

WHO reserves the right to accept the audit of a supplier performed by another UN system organization. In such cases, the manufacturer's GMP compliance will be accepted by WHO if WHO determines that the audit:

- Is conducted less than three years from the date of the proposed procurement;
- Assesses the same premises and similar products proposed by the manufacturer (name and address shall be identified with no ambiguity);
- Satisfies the requirements of WHO regarding the selection of auditors in terms of expertise, independence and the standards used (i.e. WHO or EU, USFDA) standards for GDP/GSP and MQAS);
- Concludes that the manufacturing site operates at an acceptable level of compliance with the WHO GMP (the report or at least the conclusions and the list of the observations noted during the audit must be made available to WHO); and
- Includes a signed statement from the manufacturer that no major changes have been made to premises, equipment and key personnel since the audit.

3.4. Accepting a potential supplier of essential medicines and other health products which is not pre-qualified under the WHO Prequalification Programme

In the event that a manufacturer or wholesale distributor is not prequalified under the WHO Prequalification Programme, it may be accepted as compliant with this Policy if the QA Group has performed a risk assessment of the supplier, based on audit reports and relevant information collected from WHO or recognised organizations (other UN agencies and member of the Interagency Pharmaceutical Group), and determined that the manufacturer/wholesale distributor meets the qualification standards as set forth in this Policy.

When the manufacturer/wholesale distributor is found by WHO to meet the qualification standards, it is included in the list of potential WHO suppliers for the range of products for which the supplier was assessed.

Suppliers who have been accepted in principle under this Policy must agree to the following:

- To inform WHO in case of any change in the safety profile (specifications, stability, quality management system, etc.) of the supplied product(s);
- To request WHO's acceptance of any change in the products source as agreed in the qualification process before making such changes;
- To inform WHO, through its Procurement Department, immediately about any serious quality and/or safety concerns about the manufacture, control or use of the supplied products, and suspension or cancellation of marketing authorizations; and, in the case of IVDs, to conduct field safety corrective actions (field safety notices);[26]
- To work with WHO to minimize potential public health risks by actively organizing product recalls of defective products by either replacing the defective product or covering the direct and related costs related to the replacing and destroying of the defective product.

3.5. Removal of Suppliers

WHO may, at its discretion, remove a supplier from the WHO list of accepted-in-principle suppliers of essential medicines and other health products, including due to the supplier's failure to comply with this Policy.

26 - Post-market surveillance for in vitro diagnostics (IVDs). In: In vitro diagnostics and laboratory technology [website]. Geneva: World Health Organization; 2018. (http://www.who.int/diagnostics_laboratory/postmarket/en, accessed 23 January 2018).

4. MONITORING THE QUALITY OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS PROCURED BY WHO, AND SUPPLIERS THEREOF

4.1. Monitoring of suppliers' performance

At least every three years, WHO will conduct the technical monitoring of suppliers considered acceptable in principle for procurement by WHO. This includes a review of updated documentation and a technical visit or re-audit of the supplier's premises in accordance with the WHO guidelines (GMP, GDP, MQAS). The work and findings of SRA/WHO-PQ and other recognized organizations (Other UN Agencies and member of the Interagency Pharmaceutical Group) will be considered. In addition, WHO closely monitors the performance of the suppliers against a set of meaningful and measurable key performance indicators (KPIs) when such KPIs are defined in the contract between the supplier and WHO.

4.2. Quality testing of essential medicines and other health products

Suppliers considered acceptable in principle for procurement by WHO shall submit to WHO the results of their own quality control laboratory tests for each batch of essential medicines and health products procured by WHO.

4.2.1. Pre-shipment and post-shipment quality monitoring

WHO independently monitors the quality of the essential medicines and health products procured by the Organization at different points of the supply chain. The quality control testing is carried out according to sampling and testing protocols and standard operating procedures.[27]

WHO reserves the right to assign an independent WHO Quality Control Laboratory (QCL) to test batches. The testing may occur at any stage of the supply chain and is aimed at assessing the quality of essential medicines and health products. To ensure the quality of independent quality control testing, WHO only uses QCL services that are WHO prequalified[28] or accredited in accordance with ISO 17025.

In addition, suppliers shall report to WHO any information available to them regarding a change in safety profile of the supplied pharmaceutical products. WHO reserves the right to be in contact with NRAs concerning issues related to quality, safety and efficacy of procured pharmaceutical or other health products, and may participate in post-delivery monitoring activities in collaboration with NRAs and other recognized organisations (other UN Agencies and member of the Interagency Pharmaceutical Group) as needed.

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27 - Annex 4 (Considerations for requesting analysis of drug samples). In: Thirty-sixth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2002 (WHO technical report series; no 902) (http://www.who.int/medicines/areas/quality_safety/quality_assurance/ConsiderationsRequestingAnalysesDrug-SamplesTRS902Annex4.pdf?ua=1, accessed 24 January 2018).

28 - Medicines Quality Control Laboratories. In: Essential Medicines and Health Products: Prequalification of medicines [website]. Geneva: World Health Organization; 2018 (https://extranet.who.int/prequal/content/medicines-quality-control-laboratories-list, accessed 24 January 2018).

4.2.2. Criteria for the sampling plan

The sampling plan is established in line with relevant WHO technical references[29] and risk assessment. The sampling will depend on the following:

- The level of GMP compliance of the manufacturer;
- The criticality of the products (anti-infective, injections, Fixed Dose Combinations (FDC), products with known stability problems, etc.);
- The potential risk for falsification;
- The quality problems reported during the past two years;
- Any specific requirements from the local authorities;
- Recently approved products; and/or
- Products purchased in high quantities.

4.3. Managing quality non-conformity

In the event that WHO-designated independent QCLs, either during pre-shipment or post-shipment testing, return results that are non-conforming to specifications as per indicated pharmacopoeia standards, the manufacturer will be required to investigate the discrepancy and provide a report. The investigations shall include testing of the retained sample.

4.4. Suppliers' responsibility for rejected or returned products

In case of confirmed non-compliance, either in the quality, performance, safety of the product or in agreed packaging or labelling, the supplier must replace promptly and effectively the complete batch at the supplier's own cost (including product recall, and other field safety corrective actions, product replacement, freight and re-inspection cost) and take appropriate actions to eliminate risks to the health of users.

Depending on the nature of non-compliance, the replacement from the same source may no longer be acceptable. In such a case, WHO reserves the right to cancel or terminate the contract with the supplier (in addition to other rights, such as the right to claim damages) and/or remove the supplier from the WHO list of accepted-in-principle suppliers of essential medicines and other health products

29 - Annex 4 (WHO guidelines for sampling of pharmaceutical products and related materials). In: Thirty-ninth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Geneva: World Health Organization; 2005 (WHO technical report series; no 929) (http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesSamplingPharmProductsTRS929Annex4.pdf?ua=1, accessed 24 January 2018).

For more information:
http://www.who.int/about/finances-accountability/procurement/en/

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