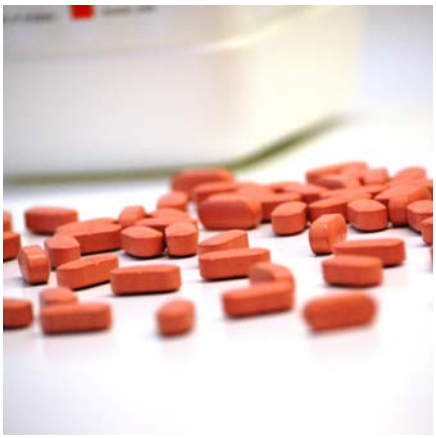
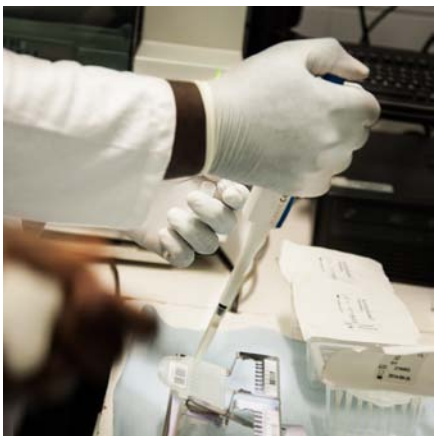
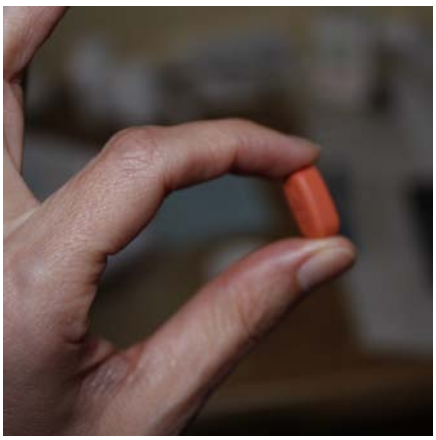
QUALITY ASSURANCE OF HEALTH PRODUCTS

Guideline for Project Implementers on Unitaid requirements for Quality Assurance of HIV, HCV, Tuberculosis and Malaria Health Products

Unitaid
Innovation in Global Health

1. INTRODUCTION

Unitaid uses innovative financing to increase funding for greater access to high quality medicines, diagnostics and related commodities for the prevention, diagnosis and treatment of HIV/AIDS, HCV, malaria and tuberculosis in low-income countries. Unitaid is the first global health organization to use buy-side market leverage to make life-saving health products better and more affordable for developing countries. Unitaid's interventions are based on its Strategy: 2013-2016 (www.unitaid. org/en/strategy) and adhere to its guiding principles: innovation, value for money, equity, sustainability, flexibility and transparency.

This document is intended to guide Unitaid's project implementers on the specific quality requirements which must be met by health products purchased with Unitaid resources to ensure the quality, safety and efficacy of the product across the full supply chain up to the point of use, for adequate prevention, diagnosis, treatment and monitoring in HIV, TB and malaria programmes.

The Unitaid secretariat is housed at the World Health Organization (WHO) headquarters in Geneva. For more information refer to: www.unitaid.org

2. BASIC PRINCIPLES

2.1 **Harmonization:** This Guideline recognizes that harmonization of the quality assurance standards and procedures related to HIV/AIDS, HCV, TB and malaria health products among United Nations agencies, international organizations, non-governmental organizations and initiatives (e.g. the Clinton Health Access Initiative, the Global Drug Facility) and major financing mechanisms/donors (e.g. the Global Fund to Fight AIDS, HCV, Tuberculosis and Malaria; USAID) is important in order to ensure consistency and increased compliance with global quality standards for procurement and supply of such health products. To this end the Guideline is aligned with the current Global Fund Quality Assurance Policy for Pharmaceuticals and Diagnostic Products[1] which is itself the product of extensive stakeholder consultation and buy-in and founded on, *inter alia*,[2] the quality assurance standards[3] of the World Health Organization's (WHO) Medicines and Diagnostics Prequalification Programmes and Stringent Regulatory Authorities.

2.2 **Quality assurance systems:** (a) Unitaid requires that its implementers shall handle all Unitaid funded health products, in accordance with the principles of the Interagency Guidelines on a Model Quality Assurance System for Procurement Agencies[4] and shall develop and fully maintain a quality assurance system in accordance with those principles. Unitaid's project implementers shall also ensure that all personnel involved in the selection of products are unbound by any real, potential or apparent conflict of interest; (b) Implementers shall further comply with, and shall ensure that each of its contractors, agents, and sub recipients comply with, **WHO Guidelines for Good Storage Practices and WHO Good Distribution Practices**[5]; (c) Implementers should use best efforts to ensure compliance with all relevant WHO guidance to ensure and monitor the quality and use of the health products procured with Unitaid funds is adequate.

1 www.theglobalfund.org/en/procurement/quality
2 Standards of other regulatory authorities and/or recognized quality management systems for specific pharmaceuticals and/or diagnostics are referenced and/or defined in sections 3 – 5 of this document.
3 Referenced and/or defined in sections 3 – 5 of this document.
4 Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies. Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products, WHO/ PSM/PAR/2007.3, available at www.who.int/medicines/publications/ModelQualityAssurance.pdf
5 See Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies.

2.3 Revisions to quality assurance requirements: This Guideline is not static and may be revised by Unitaid from time to time as needed, in consultation with other key stakeholders.

3. QUALITY STANDARDS FOR PHARMACEUTICALS

Unitaid funds may only be used to procure finished pharmaceutical products (FPP) that meet the following standards:

3.1 Compliance with national regulations: All FPPs must be authorized by the relevant authority in the country of use where applicable, following its standard practices for registration (or other forms of authorization, such as authorizations for special use).

3.1.1 For FPPs that have been prequalified by the WHO Prequalification Programme, authorities of the country of use are encouraged to expedite the process for authorizing the use of such FPPs by accepting the prequalification approval letter and supporting documentation, including WHO prequalification reports and the manufacturer's summary of information relating to the quality, safety and efficacy of the FPP, together with all the necessary information to perform quality control testing of products and necessary reference standards.

3.1.2 For FPPs that have been authorized for use by a Stringent Regulatory Authority (SRA)[6], National Drug Regulatory Authorities (NDRAs) are encouraged to expedite the process for authorizing the use of such FPPs in the relevant country by accepting the executive summary of the Common Technical Document for the Registration of Pharmaceutical Products for Human Use (CTD) or sections of the CTD relating to the quality, safety and efficacy of the FPP, together with all necessary information to perform quality control testing of products and necessary reference standards, to fulfill national requirements.

3.2 Quality standards: In addition, all FPPs must meet the following standards:

a) Prequalified by the WHO Prequalification Programme **(Option A)**; AND/OR

b) Authorized for use by a SRA **(Option B)**; OR

c) Reviewed and permitted for use by the Expert Review Panel (ERP)[7] for a time limited period not exceeding 12 months, if there is only one or no Option A or Option B FPP available[8].

3.3 Selection process

a) If there are two or more Option A or Option B FPPs available, Unitaid's project implementers will only select these products, based on a competitive selection and/or negotiation process acceptable to Unitaid;

b) If there is only one or no Option A or Option B FPP available, and one or more ERP recommended FPPs are available, implementers can select an FPP recommended by the ERP based on a competitive selection and/or negotiation process acceptable to Unitaid.

6 Authorized by an authority member, observer or associate of ICH, or approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004, or United States FDA tentative approval

7 The ERP, hosted by WHO, consists of a group of independent external technical experts that review the potential risk/benefits associated with the use of a finished pharmaceutical product that is yet to be WHO prequalified or SRA-authorized. The Global Fund is responsible for issuing periodic Invitations to manufacturers to submit an Expression of Interest (EoI) for product evaluations by the ERP Please see further details about the ERP, including Terms of Reference, at the following link: www.theglobalfund.org/en/procurement/quality/pharmaceutical/

8 "Available" means the manufacturer can supply the requested quantity of the FPP within not more than 90 days of the requested delivery date.

3.4 **Eligibility criteria for ERP review:** FPPs are eligible for review by the ERP if the following conditions are met:

a) Product prequalification or approval is pending as follows:

I. The manufacturer of the FPP has submitted an application for Prequalification of the product by the WHO PQ Programme and it has been accepted for assessment; OR

II. The manufacturer of the FPP has submitted an application for marketing authorization to a SRA and it has been accepted by the SRA.

AND

b) The FPP must be manufactured at a site that is compliant with the standards of Good Manufacturing Practices (GMP) as verified after inspection by:

I. the WHO prequalification programme; OR

II. a SRA; OR

III. a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)[9]

All FPP recommendations by an ERP shall be valid for a maximum of 12 months, or until the FPP is WHO-prequalified or SRA-authorized, whichever is earlier.

3.5 **Quality control requirements for FPPs Recommended for use by the ERP:** When an implementer procures, directly or through a third party, an FPP that has been recommended for use by the ERP, the implementer must make the necessary arrangements to randomly selected samples of the FPP to be tested for quality control purposes, in accordance with advice provided by the ERP, prior to the delivery of that FPP to the designated recipient. The cost of the sampling and testing of the FPP will only be borne by Unitaid subject to an approved budget line for such costs specified in the Grant Agreement between the implementer and Unitaid; otherwise all such costs must be borne by the implementer.

4. QUALITY STANDARDS FOR DIAGNOSTIC PRODUCTS

Unitaid funds will only be used to procure diagnostic products that meet the applicable following standards:

4.1 **Compliance with national regulations:** All diagnostic products must meet national requirements and laws as relevant.

4.2 **Quality standards:**

4.2.1 IVDs and imaging, or measuring, equipment shall be manufactured at a site compliant with the requirements of ISO 13485:2012, ISO 13485:2003or an equivalent Quality

9 List of PIC/S members is available on the PIC/S website: www.picscheme.org

Management System(QMS) recognized by one of the Stringent Regulatory Authorities of the Founding Members[10] of Global Harmonization Task Force (GHTF)[11], and

4.2.2. Any Diagnostic Products for which section 4.2.1 above does not apply, such as microscopes, must be manufactured at a site compliant with all applicable requirements of the ISO 9000 series.

4.2.3. In addition to the requirements of Section 4.2.1 and 4.2.2. above, Diagnostics Products for HIV Immunoassays, HIV Virological Technologies, CD4 technologies; tuberculosis Diagnostic Products and malaria Rapid Diagnostic Tests shall meet any one of the following[12]:

a) Shall be recommended by WHO for use in HIV, TB and malaria programs as applicable, based on a technical review of quality and performance indicators (as applicable to the specific type of diagnostic product, as published by the Global Fund on its website from time to time); or

b) Shall be authorized for use by a Regulatory Authority when stringently assessed (high risk classification). This option is only applicable to HIV Immunoassays and HIV Virological Technologies; or

c) Shall be acceptable for procurement, as determined by Unitaid, based on the advice of a Unitaid/GF Expert Review Panel (Unitaid/GF ERPD). At its discretion, for Diagnostic Products for which there is a public health need and which are not yet compliant with the above, Unitaid may request advice from the ERP to determine the acceptability for procurement of such Diagnostic Products for a time-limited period as recommended by the ERP, pending full assessment by one of the processes listed in 4.2.3(a) and 4.2.3(b) above.

The additional quality requirements under point 4.2.3 above shall only be applied from 2015. Unitaid reserves the right to apply these specific requirements at an earlier or later date at its discretion and will notify all relevant stakeholders if the date changes.

Manufacturers of Diagnostic Products are actively encouraged to submit their applications for full product review to the WHO Prequalification of Diagnostics Programme or for stringently regulated products types to one of the Regulatory Authorities of the Founding Members of GHTF.

5. QUALITY STANDARDS FOR OTHER HEALTH PRODUCTS[13]

When implementers are exceptionally permitted by Unitaid to procure health products other than HIV, TB and malaria pharmaceuticals and diagnostics, the quality standards specified in the Guide to Global Fund Policies on Procurement and Supply Management of Health products (June 2012)[14] shall apply.

10 European Union, USA, Canada, Australia, and Japan.
11 www.who.int/medical_devices/collaborations/force/en/
12 These standards will be applicable to other diagnostic tests (HIV viral load and CD4 tests and TB molecular tests) at a future date as determined by Unitaid in consultation with the WHO, the Global Fund and other relevant partners.
13 Other than pharmaceuticals and diagnostics
14 Section VII, Page 17, Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2012) and complementary information as updated at the following link: www.theglobalfund.org/en/procurement/quality/health/

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