World Health Organization

WHO QUALITY ASSURANCE POLICY

FOR THE PROCUREMENT OF ESSENTIAL MEDICINES AND OTHER HEALTH PRODUCTS

Corporate procurement policy
and coordination programme

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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

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.