Access to Quality Medicines in Developing Countries
An informal selection of scientific literature

Elements added in October 2022 are in red

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1. Introduction

Poor-quality medicines are mainly prevalent in low- and middle-income countries (LMICs), where they represent a serious threat to individual and public health. Even medicines the manufacturing process of which is not per se complex may present serious quality problems: for instance, paracetamol-containing products may be prone to develop the toxic contaminant 4-aminophenol, if manufactured in inappropriate conditions.

Over the last decade, a growing attention has been being given to the need of assuring the quality of medicines in LMICs, e.g. in the framework of strategies against resistance to antimalarials\(^1\) and antibiotics\(^2\), of strategies to improve access to asthma medicines\(^3\), and of general medicines’ procurement strategies\(^4\). The WHO set up a Member State Mechanism for Substandard and falsified medical products medical products (http://apps.who.int/gb/SF/).

Quality should not be pursued in isolation, but always in the frame of “access to quality-assured essential medicines", as it clearly appeared at the first-ever international conference on “Quality of Medicines and Public Health” that took place in Oxford, UK, in September 2018\(^5\).

In this informal working document, we try to summarize the internationally accepted definitions and to provide a non-exhaustive selection of scientific papers and regulatory documents addressing the subject of quality of medicine, with (non-exclusive) focus on resource-constrained settings.

2. Definitions\(^6\)

**Appropriate standards**


In addition, reference may be done to the Guide to Global Fund Policies on Procurement and Supply Management of Health Products, July 2016, Geneva, Switzerland.

**Substandard and falsified medical products**

On 29 May 2017, delegates at the World Health Assembly have reached new agreement on substandard and falsified medical products. The new definitions are as follows:

- The new name of “substandard and falsified” (SF) medical products will be used for what had previously been known as “substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC)” medical products.

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\(^1\) Chapter Removal of substandard and counterfeit drugs in the WHO document Global plan for artemisinin resistance containment, 2011

\(^2\) Section on Unassured drug quality and irrational use in the paper of Raviglione et al. The WHO policy package to combat antimicrobial resistance. Bulletin WHO 2011; 89:390-392


\(^4\) Chapters 1.3.2.3 and 1.4.4 in The World Medicine Situation 2011 - Procurement of Medicine. WHO, Geneva 2011

\(^5\) https://www.tropicalmedicine.ox.ac.uk/medicinequality2018/

\(^6\) Various resources on “Legal and Regulatory Aspects of Falsified and Substandard Medicines” are available at http://www.globalforumfid.org/legal-and-regulatory-aspects-falsified-and-substandard-medicines

\(^7\) http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

\(^8\) http://www.who.int/medicines/publications/pharmprep/trs_996/en/

\(^9\) http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_1003/en/
- “Substandard” medical products (also called “out of specification”): authorized by national regulatory authorities, but fail to meet either national or international quality standards or specifications – or in some cases, both.
- “Falsified” medical products: deliberately or fraudulently misrepresent their identity, composition or source.
- “Unregistered or unlicensed medical products”: have not been assessed or approved by the relevant national or regional regulatory authority for the market in which they are marketed, distributed or used.

From Stringent Regulatory Authorities toward WHO-Listed Authorities

The WHO Expert Committee on Specifications for Pharmaceutical Preparations - Technical Report Series 1003 (2017), includes an interim definition of Stringent Regulatory Authority: “A regulatory authority which is: a. a member of the ICH, being the European Commission, the US FDA and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or b. an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or c. a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015). The Expert Committee adopted the interim definition and noted the work being done towards developing a new approach to the assessment of national regulatory authorities….”. The widely used and recognized term ‘Stringent Regulatory Authority’ (SRA) had been developed to promote reliance and guide procurement decisions. This classification will future replaced by the one of “WHO-Listed Authority” (WLA), according to four “maturity levels”, and based on a “Global Benchmarking of Regulatory Systems” to evaluate regulatory systems through a comprehensive and systematic benchmarking.

In 2021, the Expert Committee adopted the definition of a WLA relevant as “a regulatory authority or a regional regulatory system which has been documented to comply with all the indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process”, in which “regulatory authority” is understood to cover all the institutions, working together in an integrated and effective manner, that are responsible for the regulatory oversight of medical products in a given country or region. The Expert Committee asked the WHO Secretariat to prepare a situation analysis and to propose ways to replace references to “stringent regulatory authorities” by “WLAs” in relevant WHO documents and guidance texts.

In 2021, the WHO published the policy document “Evaluating and publicly designating regulatory authorities as WHO listed authorities: policy document”, also available in Arabic, Chinese and Russian (Evaluating and publicly designating regulatory authorities as WHO listed authorities). It explains the concept of WHO Listed Authority (WLA), (i.e. it) is a regulatory authority or a regional regulatory system (RRS) which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope, and describes the principles based on which the WLA framework is to be implemented. The most updated lists should be checked at WHO-Listed Authority (WLA).

13 More details are available on the WHO website: https://www.who.int/tools/global-benchmarking
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R. Ravinetto October 2022
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