Access to Quality Medicines in Low- and Middle-Income Countries

An informal selection of scientific literature

Elements added in April 2026 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 two decades, a growing attention has been being given to the need of assuring the quality of medicines, e.g. in the framework of strategies against resistance to anti-malarials[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 summarize the internationally accepted definitions and 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

By "appropriate standards", we mean those set by the World Health Organization (WHO) for pharmaceuticals in the *WHO Technical Report Series 992: WHO Expert Committee on Specifications for Pharmaceutical Preparations, Technical Report Series 996, 49th report, 2015*[7]; the *WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fiftieth Report, WHO 2016*[8]*;* the ***W****HO Expert Committee on Specifications for Pharmaceutical Preparations. Technical Report Series 1003 - Fifth first report. WHO 2017*[9], and further updates. The most recent one is *WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-eight report. Geneva: World Health Organization; 2025 (WHO Technical Report Series, No. 1060). Licence: CC BY-NC-SA 3.0 IGO, available at WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-eight report*.

Reference may also be done to *Global Fund Quality Assurance Policy for Pharmaceutical Products, amended and restated on 15/11/2023*; and *Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, amended and restated on 15 November 2023*.

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 definitions are as follows:

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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

[3] Macé C, *Access to essential asthma medicines: the response of the Asthma Drug Facility*. Ess Med Mon 2011;5:1-4

[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.globalforumljd.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/

- 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.
- “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 S*tringent Regulatory Authorities* toward *WHO-Listed Authorities*

The WHO Expert Committee- Technical Report Series 1003 (**2017)**, included 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 recognized term ‘Stringent Regulatory Authority’ (SRA) was developed to promote reliance and guide procurement decisions.

This classification is now being replaced by the one of “WHO-Listed Authority” (WLA), according to four “maturity levels”, and based on a “Global Benchmarking of Regulatory Systems”[10],[11],[12] to evaluate regulatory systems through a comprehensive and systematic benchmarking[13]. The 2021 “Evaluating and publicly designating regulatory authorities as WHO listed authorities: policy document” (Evaluating and publicly designating regulatory authorities as WHO listed authorities) 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. Please find relevant information here: WHO-Listed Authority (WLA).

3. Regulatory and policy documents in English

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- ICDRA 3rd International Conference of Drug Regulatory Authorities, Strategies to fight counterfeit medicines, WHO Drug Information Vol.22, N°4, **2008**,pp. 262-263.

[10] WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products, revision VI. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO
[11] Guzman J, O'Connell E, Kikule K, *et al*. The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity. *BMJ Global Health* 2020;5:e003181. doi:10.1136/bmjgh-2020-003181
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- United Nations Office Drug and Crime. At the Crossroads of Licit and Illicit: Tramadol and other pharmaceutical opioids trafficking in West Africa. **2021**
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4. Regulatory and policy documents in French

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