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

Elements added on 14/06/17 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\(^1\). Even medicines whose manufacturing process 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 recent years, 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\(^2\) and antibiotics\(^3\), of strategies to improve access to asthma medicines\(^4\), and of general medicines’ procurement strategies\(^5\). The WHO set up a Member State Mechanism for Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit medical products or SSFFC ([http://apps.who.int/gb/ssffc/](http://apps.who.int/gb/ssffc/)).

Quality of essential medicines should not be pursued in isolation, but always in conjunction with access to essential medicines\(^6\).

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\(^7\)

**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:

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2. Chapter Removal of substandard and counterfeit drugs in the WHO document *Global plan for artemisinin resistance containment, 2011*
5. Chapters 1.3.2.3 and 1.4.4 in *The World Medicine Situation 2011 - Procurement of Medicine*. WHO, Geneva 2011
3. Regulatory and policy documents in English

- WHO. Assessment of medicines regulatory systems in Sub-Saharan African countries: an overview of findings from 26 assessment reports. WHO 2010
- Addis Ababa Declaration on Combating Pharmaceutical Crime. 12 December 2013


11 http://www.interpol.int/News-and-media/News/2013/N20131216
4. Regulatory and policy documents in French

- WHO. Guide pour l’élaboration de mesures visant à éliminer les médicaments contrefaits. WHO/EDM/QSM/99.1

5. WHO Alerts14 and other Regulatory Alerts

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- WHO Information Exchange System. Alert No. 125. Contaminated Isotab® (isosorbide mononitrate) incident in Lahore Pakistan. 3rd February 2012. QSM/MC/IEA.125
- WHO Information Exchange System Alert No. 127. QSM/MC/IEA.127. Falsified batches of Coartem recently circulating in Western and Central Africa. 3 May 2013
- WHO Information Exchange System Alert No. 128. QSM/MC/IEA.128. Falsified batches of Postinor 2 recently discovered in Nigeria. 26 July 2013
- WHO Information Exchange System Alert No. 129. RHT/SAV/MD//IEA.130. Falsified batches of Coartem recently circulating in Cameroon. 8 November 2013

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13 www.fondationchirac.eu
14 All available in English and French at http://www.who.int/medicines/publications/drugalerts/en/


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R. Ravinetto 14/06/2017
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