

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 anti-malarials¹ and antibiotics², of strategies to improve access to asthma medicines³, and of general medicines' procurement strategies⁴. 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 2018⁵.

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. Definitions⁶

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 *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Technical Report Series 1003 - Fifth first report. WHO 2017*⁹, and further updates.

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.

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.globalforumijd.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”^{10,11,12} to evaluate regulatory systems through a comprehensive and systematic benchmarking¹³.

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 \(WLA\)](#).**

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

¹² Macé C, Rågo L, Ravinetto R. How the concept of WHO-listed Authorities will change international procurement policies for medicines. *BMJ Global Health* 2022;6:e008109. doi:10.1136/bmjgh-2021-008109

¹³ More details are available on the WHO website: [https://www.who.int/tools/global-benchmarking-tools#:~:text=The%20Global%20Benchmarking%20Tool%20\(GBT,System%20Strengthening%20for%20medical%20products](https://www.who.int/tools/global-benchmarking-tools#:~:text=The%20Global%20Benchmarking%20Tool%20(GBT,System%20Strengthening%20for%20medical%20products)

3. Regulatory and policy documents in English

- WHO-IMPACT. Declaration of Roma, 18th February **2006**. Conclusions and recommendations of the WHO “Combating Counterfeit Drugs: Building Effective International Collaboration” International Conference
- Pan-American Network for Drug Regulation Harmonization Anti-Counterfeiting Group, WHO Drug Information Vol.22, N°4, **2008**, p.278.
- ICDRA 3rd International Conference of Drug Regulatory Authorities, Strategies to fight counterfeit medicines, WHO Drug Information Vol.22, N°4, **2008**, pp. 262-263.
- WHO Legal aspects of defining counterfeit medicines: a discussion paper. WHO **2009**. Regional Office for South East Asia, New Delhi.
- WHO Regulatory Harmonization. Updating medicines regulatory systems in sub-Saharan African countries. WHO Drug Information Vol. 24, No. 1, **2010**
- WHO. Assessment of medicines regulatory systems in Sub-Saharan African countries: an overview of findings from 26 assessment reports. WHO **2010**
- WHO. Report of the working group of member states on substandard/spurious/falsely labeled/falsified/counterfeit medical products. A/SSFFC/WG/5, 11th March **2011**¹⁴.
- Moore T et al. Assuring the quality of essential medicines procured with donor funds. Health Nutrition and Population Discussion Paper **2011**. The International Bank for Reconstruction and Development / The World Bank
- Parliament of India –Rajya Sabha. Department-related parliamentary standing committee on health and family welfare. 59th report on the functioning of the Central Drugs Standard Control Organization (CDSCO). 8th May **2012**.
- WHO Quality Assurance and Safety Medicines (QSM) Team. Regulator prequalification of medicines: a future concept for networking. WHO Drug Information Vol. 26, No. 3, **2012**
- Addis Ababa Declaration on Combating Pharmaceutical Crime. 12 December **2013**¹⁵.
- India releases medicines quality survey results. WHO Drug Information **2017**; 31(1): 37-38 (full report available at <http://www.cdscsco.nic.in/forms/list.aspx?lid=2254&ld=23>)
- Chowdhury P et al. Indian Council for Research on International Economic Relations. Policy Brief # 1. Administrative Structure & Functions of Drug Regulatory Authorities in India. **2015**
- Chokshi M et al. Indian Council for Research on International Economic Relations. Policy Brief # 2. Drug Quality and Safety Issues in India. **2015**
- Norms and standards. 70 years of WHO standards on medicines quality Expert Committee on Specifications for Pharmaceutical Preparations, 1947-2017: Addressing changing public health challenges. Who Drug Info **2017**; 31(1): 15-26
- United Nations Office Drug and Crime. Combating falsified medical product-related crime. A guide to good legislative practices. UNODC **2019**; Vienna, Austria
- WHO Member State Mechanism on Substandard and Falsified Medical Products. WHO/MVP/EMP/SAV/2019.04. WHO Geneva, Switzerland **2020**
- UNODC. At the Crossroads of Licit and Illicit: Tramadol and other pharmaceutical opioids trafficking in West Africa. **2021**

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
- XIIIe Conférence des Chefs d'État et de gouvernement des pays ayant le français en partage. Montreux (Suisse), 23-24 octobre **2010**. Résolution sur le renforcement de la coopération entre les États pour lutter contre les faux médicaments et les produits médicaux falsifiés.

¹⁴ http://apps.who.int/gb/ssffc/pdf_files/A_SSFFC_WG5-en.pdf

¹⁵ <http://www.interpol.int/News-and-media/News/2013/N20131216>

- ACP Résolution de la 92eme session du conseil des ministres ACP (African Caribbean Pacific), Bruxelles 8-10 novembre **2010**. Lutte contre la production et la commercialisation des faux médicaments et des produits médicinaux falsifiés¹⁶.
- Fondation Chirac. Accès à des médicaments et une santé de qualité - Mobilisation contre les faux. Médicaments. Actes de la conférence sur les faux médicaments - 7 décembre **2010**, Journées européennes du Développement¹⁷.
- Communauté Economique et Monétaire de l'Afrique Centrale (CEMAC). Conférence des Ministres de la Santé des Etats membres de la CEMAC. Déclaration de Douala. « Mettre un ferme au trafic des faux médicaments et aux circuits illicites des médicaments en Afrique Centrale ». Douala, Cameroun, 23 juin 2016
- Duteil Q et Chemtob-Comc é MC. Le trafic des faux médicaments : état des lieux et moyens d'action. *Panorama de droit pharmaceutique* **2017**; 4 :97-117

5. Poor-quality medicines: viewpoints and papers of general interest

- Penn RG. The state control of medicines: the first 3000 years. *Br J Clin Pharmac* **1979**; 8: 293-305
- Braithwaite J. Unsafe manufacturing practices. Chapter 4 in the *Book Corporate crime in the pharmaceutical industry*. Routledge & Kegan Paul London, Boston, Melbourne and Henley **1984**
- Shakoor O et al. Assessment of the incidence of substandard drugs in developing countries. *Tropical Medicine and International Health* **1997**; 2(9): 839–845
- McGregor A. Counterfeits drugs flood developing world. *The Lancet* **1997**; 350 (9092): 1690
- Andriollo O et al. Supplies for humanitarian aid and development countries: the quality of essential multi-sources drugs. *STP Pharma pratique* **1998**; 8 (2):137-155
- MM Reidenberg et al., Counterfeit and substandard drugs. *Clinical Pharmacology & Therapeutics*. Vol. 69, number 4, pp 189-193, April **2001**
- Videau JV. Editorial: Making Medicines Safe. *Bulletin of the World Health Organization*, **2001**, 79 (2)
- Issack MI. Substandard drugs. *Lancet* **2001**; 358: 1563
- Newton PN et al. Murder by fake drugs Time for international action *BMJ* **2002**;324:800–1
- R. Cockburn et al., The global threat of counterfeit drugs: why industry and governments must communicate the dangers. *PLOS Medicine* **2005**; 2(4).
- Andreotti F, Crea F. Substandard life-saving drugs: a global concern. *European Heart Journal* **2005** ; 26, 858–860 doi:10.1093/eurheartj/ehi219
- USP Drug Quality and Information Program. Ensuring the quality of medicines in resource-limited countries: an operational guide. Published in **2007**¹⁸.
- M. Loewy, Deadly Imitations. Perspectives in Health, the Magazine of PAHO, Vol.11, No 1, **2007**. Available at <http://www.paho.org/>
- A. Jack, Counterfeit medicines. Bitter pills. *BMJ* **2007**; 335: 1120-1121.
- J.-M. Caudron, N. Ford, M. Henkens, C. Mace´, R. Kiddle-Monroe and J. Pinel. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *TMIH* **2008**; 13(8): 1062–1072
- I.A. Dhalla et A.S. Detsky, Risks and Benefits of Importing Prescription Medications From Lower-Income Countries, *JAMA* **2008**; 300 (12): 1453-1455.
- Senior K. Global health-care implications of substandard medicines. *The Lancet ID* **2008**; 8: 666
- Swaminath G. Faking it – The menace of counterfeit Drugs. *Indian J Psychiatry*. **2008**; 50(4): 238–240. doi: 10.4103/0019-5545.44743

¹⁶ <http://www.fondationchirac.eu/le-conseil-des-ministres-acp-a-adopte-une-resolution-contre-les-faux-medicaments/>

¹⁷ www.fondationchirac.eu

¹⁸ <http://www.usp.org/pdf/EN/dqi/ensuringQualityOperationalGuide.pdf>

- R. Ravinetto et al., Poor-quality medicines in developing countries. *Lancet Inf.Dis.* **2009**; 9: 267-268.
- Keugoung B., The availability of drugs for rich and poor people in developing Countries. *Lancet* **2009**;9; 586-587
- Okie S., Multinational Medicines: Ensuring Drug Quality in an Era of Global Manufacturing. *NEMJ* **2009** 361:8; 737-740
- Mondialisation Contrefaçons de médicaments: vrais et faux problèmes. *La Revue Prescrire.* **2009.** 29 (306): 298 – 303
- J Harris et al., Keeping it real: combating the spread of fake drugs in poor countries. *International Policy Network* **2009.**
- P.N. Newton et al., Guidelines for Field Surveys of the Quality of Medicines: A Proposal. *PLoS Medicine* **2009**; 6 (3): 252 – 257.
- Katsnelson, Substandard drugs overshadowed by focus on fakes. *Nature Medicine* **2010**: 16 (4), p. 364
- Newton PN 2010, Impact of poor-quality medicines in the ‘developing’ World. *Trends in Pharmacological Sciences* **2010**; 31 (3). 10.1016/j.tips.2009.11.005
- Siva N. Tackling the booming trade in counterfeit drugs. *Lancet* **2010**; 376: 1725-1726
- Burki T. The real cost of counterfeit medicines. *Lancet Inf. Dis.* **2010**; 10: 585-586
- Bates et al. The danger of substandard drugs in emerging markets: an assessment of basic product quality. *Pharmacologia* **2011**; 3 (2): 46-51
- Bates et al. Dangerous substandard medicines: an increasing global problem. *American Enterprise Institute for Public Policy Research* **2011**; 6: 1-7
- Kuehn BM. As production goes global, drug supply faces greater risks to safety, quality. *JAMA* **2011**; 306(8): 811-813
- PEW Health Group. After Heparin: protecting Consumers from the Risks of Substandard and Counterfeit Drugs. *PEW Trusts* **2011**¹⁹.
- Editorial. Fighting fake drugs: the role of WHO and pharma. *The Lancet* **2011**; 377: 1626
- Baxerre C et Le Hesran JY. Where do pharmaceuticals on the market originate? An analysis of the informal drug supply in Cotonou, Benin. *Social Science & Medicine* **2011**; 73: 1249e1256
- Newton PN, Amin AA, Bird C, Passmore P, Dukes G, et al. The Primacy of Public Health. Considerations in Defining Poor Quality Medicines. *PLoS Med* **2011**; 8(12): e1001139. doi:10.1371/journal.pmed.1001139
- Attaran A, Bate R, Kendall M. Why and how to make an international crime of medicine counterfeiting. *J Int Crim Justice* **2011**; 9: 325-354
- Bate R., Zhe Jin G, Mathur A. Does price reveal poor-quality drugs? Evidence from 17 countries. *National Bureau Economic Research Working Paper N. 16854*; March **2011**
- Interview with Dr Paul Newton, Head, Wellcome Trust–Mahosot Hospital–Oxford Tropical Medicine Research Collaboration, Vientiane, Laos. *Pathogens and Global Health* **2012**; 106 (2): 69-71
- Wise J. Global operation tackles internet trade in fake drugs. *BMJ* **2012**;345:e6724
- Jack A. Faking it. *BMJ* **2012**;345:e7836
- Dorlo TPC, Boelaert M. , Beijnen JH, Ravinetto RM. Universal access to quality medicines: prioritisation of a-priori solutions. *Lancet Inf. Dis.* **2012**; 12: 829-830
- Attaran A., Barry D., Basheer S. et al. How to achieve international action on falsified and substandard medicines. *BMJ* **2012**;345:e7381
- Godlee F. Time for global action on fake and substandard drugs. *BMJ* **2012**;345:e7917
- Marc Gentilini. *Médecine Tropicale*, 6eme édition **2012**. Chapitre 9 : Accès aux Médicaments Essentiels de Qualité, de Carinne Bruneton, Jacques Pinel et Marc Gentilini.
- Editorial. Counterfeit drugs: a growing global threat. *The Lancet* **2012**; 379: 685

¹⁹ http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Health/Pew_Heparin_Final_HR.pdf

- Bate R. et al. The danger of substandard drugs in emerging markets: an assessment of basic product quality. *Pharmacologia* **2012**; 3(2): 46-51
- Rowland K. International groups move to criminalize fake drugs. *Nature* **2012**; doi:10.1038/nature.2012.10159
- 2011 drug packaging review: too many dangers and too many patients overlooked. *Prescrire International* **2012**; 21 (127): 133-138
- Seear M. Pharmaceutical quality: an urgent and unresolved issue. *Lancet Infect Dis* **2012**; 12: 428-429
- Editorial. Drug regulation in India – the time is ripe for change. *The Lancet* **2012**; 379: 1852
- Avorn J. Two centuries of assessing drug risks. *NEJM* **2012**; 367 (3): 193-197
- Ravinetto R, Boelaert M, Jacobs J, Pouget C, Luyckx C. Poor-quality medical products: time to address substandards, not only counterfeits. *Trop Med Int Health* **2012**; 17(11):1412-6.
- Christina Y. Chang, M.D., M.P.H., and Lesley-Anne Furlong, M.D. Editorial. Strengthening global action against poor quality drugs. *The Lancet* **2013** (381): 599
- Gostin L, Buckley G., Kelley P. Stemming the Global Trade in Falsified and Substandard Medicines. *JAMA*, Published online April 11, **2013**.
- UNODC. Fraudulent essential medicines from East Asia to Southeast Asia and Africa. Chapter 12 of the Report *Transnational Organized Crime in West Africa*. February **2013**²⁰.
- J Wise. Record number of fake drugs are seized in crackdown. *BMJ* **2013**;346:f4204
- RM Ravinetto, TPC Dorlo, JM Caudron, NS Prashanth. The global impact of Indian generics on access to health. *Indian Journal of Medical Ethics* **2013**; X (2): 118-120
- Weigmann K. Elixirs of death. International organizations are working towards a global solution to address the problem of falsified and substandard medicines, but progress has stagnated. *EMBO Rep.* **2013** Jul 1;14(7):597-600.
- Kuehn BM. IOM: Curbing fake drugs will require national tracking and global teamwork. *JAMA*. **2013** Apr 3;309(13):1333-4.
- IOM (Institute of Medicine). **2013**. Countering the problem of falsified and substandard drugs. Washington, DC: The National Academies Press. http://www.nap.edu/catalog.php?record_id=18272
- Seear M. The need for coordinated action against falsified and substandard medicines. *Int J Tuberc Lung Dis.* **2013** Mar;17(3):286.
- Roehr B. US body demands tougher global response to "bad drugs". *BMJ.* **2013** Feb 19;346:f1115.
- GJ Buckley, JE Riviere, LO Gostin. What to do about unsafe medicines? *BMJ* **2013**; 347:f5064
- Editorial. What is Quality of Medicines? *Int Med J* **2013**; 43: 1057-1058
- Johnston A, Holt DW. Substandard drugs: a potential crisis for public health. *Br J Clin Pharmacol.* **2013**.
- 't Hoen EFM, Hogerzeil HV, Quick JD, Sillo H. A quiet revolution in global public health: the World Health Organization's Prequalification of Medicines Programme. *Journal of Public Health Policy* **2014**; doi:10.1057/jphp.2013.53
- Binagwaho A, Bate R, Gasana M, Karema C, Mucyo Y, et al. (2013) Combatting Substandard and Falsified Medicines: A View from Rwanda. *PLoS Med* **2013**. 10(7): e1001476. doi:10.1371/journal.pmed.1001476
- Dyer O. Drugs exported from India to Africa are poorer quality than those sent elsewhere. *BMJ* **2014**;349:g6017
- RM Ravinetto, Commentary. Poor-quality medicines: from knowledge to control and prevention. *Path Glob Health* **2014**; 108 (4): 171-172.
- Rago L. et al. Review. Regulatory framework for access to safe, effective, quality medicines. *Antiviral Therapy* (**2014**); 19 Suppl 3: 69-77

²⁰ http://www.unodc.org/documents/data-and-analysis/tocta/West_Africa_TOCTA_2013_EN.pdf

- Newton PN et al. Falsified medicines in Africa: all talk, no action. *Lancet GH* **2014**; 2: e509-e510
- Goyal A. "Pharmacy of the world" is ill? *Developing World Bioethics* **2015**; 1471-8731. doi:10.1111/dewb.12077
- Ziemer T. Falsified medicines in Africa. *The Lancet Global Health* **2015**;3: e82
- Khan A.N and Khar RK. Current scenarios of spurious and substandard medicines in India. A systematic review. *Indian Journal of Pharmaceutical Sciences* **2015**; 77 (1): 2-7
- El-Jardali F, Akl EA, Fadlallah R, et al. Interventions to combat or prevent drug counterfeiting: a systematic review. *BMJ Open* **2015**;5:e006290. doi:10.1136/bmjopen-2014-006290
- Nayyar GML, Breman JG, Herrington J. The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives: Summary. *AJTMH* **2015**; Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives. *Am J Trop Med Hyg* **2015**; 9 (6): 2-7 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- t' Hoen E and Pascual F. Counterfeit medicines and substandard medicines: Different problems requiring different solutions. *J Pub J Health Pol* **2015**; advance online publication 16th July 2015
- Newton PN, Schellenberg D, Ashley EA et al. Quality assurance of drugs used in clinical trials: proposal for adapting guidelines. *BMJ*. **2015** Feb 25;350:h602.
- Ravinetto R and Schiavetti B. The quality of medicines: an ethical issue? *Indian J Med Ethics* **2015**; 12(4):232-234
- Drug packaging in 2015: risky industry choices and lax regulation. Translated from *Rev Prescrire* March **2016**; 36 (389): 218-224
- IDLO, UNICRI, O'Neill Institute, World Bank Group. Strengthening the Legal Environment for the Elimination of Falsified and Substandard Medicines: Uganda Report. 15th February **2016**²¹.
- Liu R and Lundin S. Falsified medicines: literature review. Working papers in medical humanities 'published by Lund University Libraries) **2016**; 2(1): 1-25; <http://journals.lub.lu.se/index.php/medhum/index>
- McEwen J, Vestergaard LS and Sanburg ALC. Pacific Island Pharmacovigilance: The Need for a Different Approach. *Drug Safety* **2016**; DOI 10.1007/s40264-016-0439-4
- Fatokun O. Curbing the circulation of counterfeit medicines in Nigeria. *Lancet* **2016**; 388: 2603
- Taberner P, Parker M, Ravinetto R et al. Ethical challenges in designing and conducting medicine quality surveys. *Trop Med Int Health* **2016**; 21(6): 799-806
- Jacques Pinel. Falsified and Sub-standard Medicines: Danger of Death -Unusual in the industrialized countries -Commonplace in the developing countries. 2016. Available at <http://www.itg.be/E/Article/final-work-of-quamed-pioneer-completed>
- Ravinetto R, Vandenberg D, Macé C, Pouget C, Renchon B, Rigal J, Schiavetti B, Caudron JM. Fighting poor-quality medicines in low- and middle-income countries: the importance of advocacy and pedagogy. *Journal Pharm Policy Practice* **2016**; 9:36; DOI: 10.1186/s40545-016-0088-0
- Ministry of Health and Family Welfare, Government of India. Survey of extent of problems of spurious and not of standard quality drugs in the country. National drug survey **2014-2016**.
- Nebot Giralt A, Schiavetti B, Meessen B, Pouget C, Caudron JM, Marchal B, Massat P, Thys T, Ravinetto R. Quality assurance of medicines supplied to low income and middle-income countries: poor products in shiny boxes? *BMJ Global Health* **2017**;2:e000172. doi:10.1136/bmjgh-2016-000172
- WHO. A study on the public health and socioeconomic impact of substandard and falsified products: executive summary: Geneva: World Health Organization; **2017** (WHO/EMP/RHT/SAV/2017.02)

- WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization; **2017**.
- Editorial. Fake Medicines; fighting on all fronts. *Lancet Respiratory Med* **2018**; 6: 315
- Ravinetto R, Roosen T, Dujardin C. The Belgian commitment to pharmaceutical quality: a model policy to improve quality assurance of medicines available through humanitarian and development programs. *Journal of Pharmaceutical Policy and Practice* **2018**; 11:12: 1
- Breman JG. Eliminating poor quality medicines: ‘Caveat emptor, Caveat venditor’ (buyer beware, seller beware). *Int Health* **2018**; 10: 321–323
- Ozawa S et al. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries. A Systematic Review and Meta-analysis. *JAMA Network Open*. **2018**;1(4):e181662.
- Vickers S, Bernier M, Zambrzycki S, et al. Field detection devices for screening the quality of medicines: a systematic review. *BMJ Glob Health* **2018**;3:e000725.
- Ravinetto R, Pinxten W, Rago L. Quality of medicines in resource-limited settings: need for ethical guidance. *Global Bioethics* **2018**; 29:1, 81-94
- Roth et al. Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems *Globalization and Health* (**2018**) 14:102
- Coyne PE. The World Health Organization Prequalification Programme, playing an essential role in assuring quality medical products. *Int Health* **2018**. doi:10.1093/inthealth/ihy095
- Mohammad Sofiqur Rahman. The health consequences of falsified medicines. A study of the published literature. *Tropical Medicine and International Health* **2018**. doi:10.1111/tmi.13161
- Tuck et al. Editorial: Medicines pricing, access and safety in Morocco. *Trop Med Int H* 2019. doi:10.1111/tmi.13191
- Ghanem N. Substandard and falsified medicines: global and local efforts to address a growing problem. *The pharmaceutical Journal*. Published online 8 May **2019**; available at <https://pharmaceutical-journal.com/article/research/substandard-and-falsified-medicines-global-and-local-efforts-to-address-a-growing-problem>
- Gaurvika M. L. Nayyar et al. Review Article Falsified and Substandard Drugs: Stopping the Pandemic. *Am. J. Trop. Med. Hyg.*, 00(0), **2019**, pp. 1–8
- Olliaro E, Olliaro P, Ho CWL, Ravinetto R. Perspective Piece Legal Uncertainty—The Gray Area around Substandard Medicines: Where Public Health Meets Law. *Am. J. Trop. Med. Hyg.*, 00(0), **2019**, pp. 1–6 doi:10.4269/ajtmh.19-0645
- Kingori P, Peeters Grietens K, Abimbola S, Ravinetto R. Poor- quality medical products: social and ethical issues in accessing ‘quality’ in global health. *BMJ Global Health* **2019**;4:e002151. doi:10.1136/ bmjgh-2019-002151
- Paul N Newton, Katherine C Bond, on behalf of the Oxford Statement signatories. Global access to quality-assured medical products: the Oxford Statement and call to action. *Lancet GH* **2019**; e1609-11.
- Paul Adepoju. African nations to criminalise falsified medicine trafficking. *Lancet* **2020**; 395: 10221
- Nebot Giralt A, Ronse M, Ravinetto R. A survey of nongovernmental organizations on their use of WHO’s prequalification program. *Bull World Health Organ* **2020**; 98:413–419
- Orubu et al. Tackling the blind spot of poor-quality medicines in Universal Health Coverage. *Journal of Pharmaceutical Policy and Practice* (**2020**) 13:40
- Ozawa S, Higgins CR, Yemeke TT, Nwokike JI, Evans L, Hajjou M, et al. (**2020**). Importance of medicine quality in achieving universal health coverage. *PLoS ONE* 15(7):e0232966.
- Perrin C, Cloez S, Dujardin C, Ravinetto R. Europe should lead in coordinated procurement of quality- assured medicines for programmes in low- income and middle- income countries. *BMJ Global Health* **2020**;5:e003283. doi:10.1136/ bmjgh-2020-003283
- Nebot Giralt A, Bourasseau A, White G, et al. Quality assurance systems of pharmaceutical distributors in low-income and middle-income countries: weaknesses and ways forward. *BMJ Global Health* 2020;5:e003147. doi:10.1136/bmjgh-2020-003147

- The Interacademy Partnership (IAP). A Call to Action: Furthering the fight against falsified and substandard medical products. Published in September **2020**.
- Enright K. Elusive quality: the challenges and ethical dilemmas faced by international non-governmental organisations in sourcing quality assured medical products. *BMJ Global Health* 2021;6:e004339. doi:10.1136/bmjgh-2020-004339
- Waleed M. Sweileh. Substandard and falsified medical products: bibliometric analysis and mapping of scientific research. *Sweileh Globalization and Health* (2021) 17:114
- Masini T, Macé C, Heide L, Hamill H, Hampshire K, Newton PN, Ravinetto R. Out of the boxes, out of the silos: The need of interdisciplinary collaboration to reduce poor-quality medical products in the supply chain. *Res Social Adm Pharm.* **2022** Mar 17:S1551-7411(22)00061-4. doi: 10.1016/j.sapharm.2022.03.006. Epub ahead of print. PMID: 35317978.\
- Yusuf Hassan Wada, Abdullahi Abdulrahman, Musabu Ibrahim Muhammad, Vivian Chiemerie Owanta, Pearl Udoka Chimelumeze, Garba M. Khalid. Falsified and substandard medicines trafficking: A wakeup call for the African continent. *Public Health in Practice*, 233; 3, 100240. ISSN 2666-5352
- Pyzik, O.Z., Abubakar, I. Fighting the fakes: tackling substandard and falsified medicines. *Nat Rev Dis Primers* **8**, 55 (2022). <https://doi.org/10.1038/s41572-022-00387-1>

6. Cases of poor quality medicines: non-product specific

- OMS. La qualité des médicaments sur le marché pharmaceutique africain. Etude analytique dans trois pays: Cameroun, Madagascar, Tchad. Programme d'Action pour les Médicaments Essentiels, OMS **1995**.
- WHO 1999. Counterfeit and Substandard Drugs in Myanmar and Viet Nam. Report of a study carried out in cooperation with the Governments of Myanmar and Viet Nam. E. Wondemagegnehu, WHO Essential Drugs and Other Medicines. WHO **1999** (WHO/EDM/QSM/99.3)
- RB Taylor et al., Pharmacopoeial quality of drugs supplied by Nigerian pharmacies. *The Lancet.* **2001**; 357: 1933-1936
- J.-M. Caudron, N. Ford, M. Henkens, C. Mace´, R. Kiddle-Monroe and J. Pinel. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *TMIH* **2008**; 13(8): 1062–1072
- Matrix of Drug Quality Reports in USAID-assisted Countries. By the U.S. Pharmacopeia Drug Quality and Information Program. July 1st, **2008**. Available at www.uspdqi.org
- Matrix of Drug Quality Reports Affecting USAID-assisted Countries. By the U.S. Pharmacopeia Drug Quality and Information Program. June 1st, **2009**. Available at www.uspdqi.org
- Bate R, Tren R, Mooney L, Hess K, Mitra B, et al. (2009) Pilot Study of Essential Drug Quality in Two Major Cities in India. *PLoS ONE* **2009** 4(6): e6003.
- Bate et al. Drug Use in Nigeria An informal survey of doctors, pharmacists, healthcare workers in Lagos, Ondo, and Ogun, and a pilot quality assessment of essential drugs from Lagos pharmacies. *Africa Fighting Malaria, the American Enterprise Institute and the Initiative for Public Policy Analysis Working Paper August* **2009**
- Bate R et al. Medicine registration and medicine quality: a preliminary analysis of key cities in emerging markets. *Research and Reports in Tropical Medicine* **2010**:1 89–93
- Matrix of Drug Quality Reports Affecting USAID-assisted Countries. By the U.S. Pharmacopeia Drug Quality and Information Program. Updated April-May **2010**. Available at www.uspdqi.org
- USAID-USP. Media Reports on Medicine Quality Focusing on USAID-assisted Countries by the Promoting the Quality of Medicines Program December 1, **2011**. Website: <http://www.usp.org/worldwide/>
- Srinivasan S., Jesani A. Standing committee report on CDSCO: hard facts confirm an open secret. *Indian Journal of Medical Ethics* **2012**; Vol IX No 3 July-September
- Conway J, Bero L, Ondari C, Wasan KM. Review of the quality of pediatric medications in developing countries. *J Pharm Sci.* **2013** May;102(5):1419-33. doi: 10.1002/jps.23474.

- Almuzaini T, Choonara I, Sammons H. Substandard and counterfeit medicines: a systematic review of the literature. *BMJ Open* **2013**;3:e002923. doi:10.1136/bmjopen-2013-002923
- Conway J, Bero L, Ondari C, Wasan KM. Global Health Commentary. Review of the quality of pediatric medications in developing countries. *Journal of Pharmaceutical Sciences* **2013**, 102: 1419–1433
- Yoshida et al. A cross-sectional investigation of the quality of selected medicines in Cambodia in 2010. *BMC Pharmacology and Toxicology* **2014**, 15:13
- Almuzaini T, Sammons H, Choonara I. Quality of medicines in Canada: a retrospective review of risk communication documents (2005–2013). *BMJ Open* **2014**
- WHO Information Exchange System Alert No. 133. RHT/SAV/MD//IEA.132. Falsified medicines in West and Central Africa. 10 October **2014**
- Editorial. Indian generic drug manufacturers in the spotlight. *Lancet*. **2014**; 383: 2186
- Baggchi S. Indian generic drugs debate heats up. *Lancet* (2014); 384: 1334
- Travasso C. Canada bans import of drugs from three Indian facilities. *BMJ* **2014**;349:g6153
- Combating unsafe medical products: outcomes of a survey on testing of suspect medicines. *WHO Drug Information* Vol. 28, No. 3, **2014**
- Johnston A and Holt DW. Substandard drugs: a potential crisis for public health. *Br J Clin Pharm* **2014**; 78(2): 218-243
- Mc Ginnis M. USAID-USP Media Reports on Medicine Quality: Focusing on USAID-assisted Countries. U.S. (2014) Agency for International Development and United States Pharmacopeia
- Krech LA, El-Hadri L, Evans L, Fouche T et al. The medicines Quality Database : a free public resource. *Bull World Health Organ* **2014**;92:2–2A
- Ratanawijitrasin S and Phanouvong S. The state of medicine quality in the Mekong sub_region in the 2000s and the challenges ahead. Occasional Paper. Observatories Series 07. IRASEC November **2014**. ISBN 978-616-7571-19-5
- Clark F. Rise in online pharmacies sees counterfeit drugs so global. *Lancet* **2015**; 386:1327-1328
- Limb M. Regulators seize 6.2 million doses of illegally traded medicines in the UK. *BMJ* **2015**; 350:h3365
- Mackey TK, Liang BA, York P, Kubic T. Counterfeit Drug Penetration into Global Legitimate Supply Chains: a Global Assessment. *Am J Trop Med Hyg* **2015**; 9 (6): 59-67 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Hajjou M, Lane-Barlow C, Roth L, Pribluda VS, et al. Monitoring the Quality of Medicines: Results from Africa, Asia, and South America. *Am J Trop Med Hyg* **2015**; 9 (6): 68-74 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Counterfeit medicines in Peru: a retrospective review (1997–2014). *BMJ Open* **2016**;6: e010387.
- Kaale E, Manyanga V, Chambuso M, Liana J, Rutta E, Embrey M, et al. (2016) The Quality of Selected Essential Medicines Sold in Accredited Drug Dispensing Outlets and Pharmacies in Tanzania. *PLoS ONE* 11(11):e0165785.
- Gyanwali P, Humagain BR, Aryal KK, Pandit A, Acharya T, Bista B, Dhimal M, Karki KB. Surveillance of Quality of Medicines Available in the Nepalese Market: A Study from Kathmandu. *J Nepal Health Res Counc* 2015 Sep - Dec;13(31): 233-40
- Editorial staff. Drug packaging in 2016: marketing takes precedence over public health. *Prescrire International* 2017; 26 (183): 161-165
- Khuluza F et al. Low Prevalence of Substandard and Falsified Antimalarial and Antibiotic Medicines in Public and Faith-Based Health Facilities of Southern Malawi. *AJTMH* **2017**; 96(5): 1124–35
- Petersen A, Held N, Heide L, on behalf of the DifaEm-EPN Minilab Survey Group (2017). Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. *PLoS ONE* 12(9):e0184165

- Schiavetti B et al. The Quality of Medicines Used in Children and Supplied by Private Pharmaceutical Wholesalers in Kinshasa, Democratic Republic of Congo: A Prospective Survey. *Am J Trop Med Hyg* 2018. Published online ahead of print. DOI: <https://doi.org/10.4269/ajtmh.17-0732>. Cited as “Children’s medicines in the DRC” in WHO Drug Information **2018**; 32(1): 38-39
- Frimpong G et al. Quality Assessment of Some Essential Children’s Medicines Sold in Licensed Outlets in Ashanti Region, Ghana. *J Trop Med* **2018**; Article ID 1494957
- Poudel et al. Assessment of primary labeling of medicines manufactured by Nepalese pharmaceutical industries. *J Pharmaceutical Pol Practice* **2018**; 11:13
- Van Assche K, Nebot Giralto A, Caudron JM, Schiavetti B, Pouget C, Tsoumanis A, Meessen B, Ravinetto R. Pharmaceutical quality assurance of local private distributors: a secondary analysis in 13 low-and middle-income countries. *BMJ Glob Health* **2018**;3:e000771. doi:10.1136/bmjgh-2018-000771
- Lehmann A et al. Drug Quality In South Africa: A Field Test. *J Pharm Sci.* **2018** Jun 21. pii: S0022-3549(18)30345-9. doi: 10.1016/j.xphs.2018.06.012. [Epub ahead of print]
- Lehmann A et al. Differences in drug quality between South Africa and Germany. *J Pharm Pharmacol* **2018**; doi: 10.1111/jphp.12985
- Rauf A. Microbiological quality control of some non-sterile preparations commonly used in Pakistan. *Pak J Pharm Sci* **2018**; 31(4): 1237-42
- Moreno-Exebio L et al. Características de los medicamentos de baja calidad en el Perú del 2005-2014 - Characteristics of poor quality medicines in Peru from 2005-2014. *Ciencia e Investigación* **2018**; 21(1):27-34
- Khurelbar et al. A cross-sectional analysis of falsified, counterfeit and substandard medicines in a low-middle income country. *BMC Public Health* (**2020**) 20:743
- McManus D, Naughton BD. A systematic review of substandard, falsified, unlicensed and unregistered medicine sampling studies: a focus on context, prevalence, and quality. *BMJ Global Health* 2020;5:e002393
- Rojas-Cortés R. Substandard, falsified and unregistered medicines in Latin America, 2017-2018. *Rev Panam Salud Publica.* **2020**;44:e125 <https://doi.org/10.26633/RPSP.2020.125>
- Waffo Tchounga CA et al. Review Article Poor-Quality Medicines in Cameroon: A Critical Review. *Am. J. Trop. Med. Hyg.*, **2021**, 105(2), 2021, pp. 284–294
- Mayra Bruna Fedalto et al. Reports of substandard medicines: a lexicographic analysis of the Brazilian Health Surveillance Report System. *Rev Ciênc Farm Básica Apl.* **2021**;42:e753
- The Medical Product Quality Report - COVID-19 Issues hold reports from scientific literature, public alerts/warnings, and lay press. **Please check the most recent update** at <https://www.iddo.org/mq/research/medical-product-quality-reports>
- Rahman MS, Yoshida N, Tsuboi H, Karmoker JR, Kabir N, Schaefermann S, Akimoto Y, Bhuiyan MA, Reza MS, Kimura K. A comprehensive analysis of selected medicines collected from private drug outlets of Dhaka city, Bangladesh in a simple random survey. *Sci Rep.* **2022** Jan 7;12(1):234. doi: 10.1038/s41598-021-04309-1. PMID: 34997152; PMCID: PMC8741935.
- Ozawa S, Chen HH, Lee YA, Higgins CR, Yemeke TT. Characterizing Medicine Quality by Active Pharmaceutical Ingredient Levels: A Systematic Review and Meta-Analysis across Low-and Middle-Income Countries. *Am J Trop Med Hyg.* **2022** Jun 15;106(6):1778-1790. doi: 10.4269/ajtmh.21-1123.
- Gnegel G, Häfele-Abah C, Neci R; Difâm-EPN Minilab Network, Heide L. Surveillance for substandard and falsified medicines by local faith-based organizations in 13 low- and middle-income countries using the GPHF Minilab. *Sci Rep.* **2022** Jul 30;12(1):13095. doi: 10.1038/s41598-022-17123-0.

7. Cases of poor quality medicines: malaria

- Cong LD et al. Use and quality of antimalarial drugs in the private sector in Viet Nam. *Bulletin of the World Health Organization*, **1998**, 76 (Suppl. 1): 51-68
- Rozendaal J. Fake antimalaria drugs in Cambodia. *The Lancet* **2001**; 357: 890

- C. Maponga and C. Ondari, The quality of antimalarials. A study in selected African countries. WHO/EDM/PAR/2003.4, May **2003**. Available at WHO website
- Minzi OMS et al. Evaluation of the quality of amodiaquine and sulphadoxine/pyrimethamine tablets sold by private wholesale pharmacies in Dar Es Salaam Tanzania. *Journal of Clinical Pharmacy and Therapeutics* **2003**; 28, 117–122
- Kayumba PC et al. The quality of essential antimicrobial and antimalarial drugs marketed in Rwanda and Tanzania: influence of tropical storage conditions on in vitro dissolution *Journal of Clinical Pharmacy and Therapeutics* **2004**; 29: 331–338
- Dondorp AM et al. Fake antimalarials in Southeast Asia are a major impediment to malaria control: multinational cross-sectional survey on the prevalence of fake antimalarials. *Tropical Medicine and International Health* **2004**; 9 (12): 1241–1246
- Abdo-Rabbo et al. The quality of anti-malarials available in Yemen. *Malaria Journal* **2005**, 4:28.
- Amin AA et al. The quality of sulphadoxine-pyrimethamine and amodiaquine products in the Kenyan retail sector. *Journal of Clinical Pharmacy and Therapeutics* **2005**; 30, 559–565
- Alfadl AA et al. Quality of antimalarial drugs in Sudan: results of post-marketing surveillance. *Sudanese Journal of Public Health* **2006**. Vol 1 (2)
- P. Newton et al., Manslaughter by fake artesunate in Asia – Will Africa be next? *PLOS Medicine*, **2006**; 3 (6).
- P. Newton, Fake artesunate warning sheet N. 5, July **2006** (and any subsequent updates).
- Lon CT et al. Counterfeit and substandard antimalarial drugs in Cambodia. *Transactions of the Royal Society of Tropical Medicine and Hygiene* (**2006**) 100, 1019–1024
- A.A. Amin et al. Antimalarial drug quality in Africa. *Journal of Clinical Pharmacy and Therapeutics* **2007**, 32; 429-440
- MA Atemnkeng et al., Quality control of active ingredients in artemisinin-derivative antimalarials within Kenya and R Congo. *Tropical Medicine and International Health*. **2007**; 12 (1): 68-74
- MC Gaudio et al. Informal medicine market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials. *Malaria Journal* **2007**, 6:22 doi:10.1186/1475-2875-6-22
- Tipke et al. Substandard anti-malarial drugs in Burkina Faso. *Malaria Journal* **2008**, 7:95 doi:10.1186/1475-2875-7-95.
- Kaur H, Goodman C, Thompson E, Thompson KA, Masanja I, et al. A Nationwide Survey of the Quality of Antimalarials in Retail Outlets in Tanzania. *PLoS ONE* **2008** 3(10): e3403.
- Bate R, Coticelli P, Tren R, Attaran A (2008) Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study. *PLoS ONE* **2008** 3(5): e2132.
- P.N. Newton et al., A Collaborative Epidemiological Investigation into the Criminal Fake Artesunate Trade in South East Asia. *PLOS Medicine* **2008**; 5 (2): e32
- Sixteen types of counterfeit artesunate circulating in South-east Asia. *WHO Drug Information* **2008**; 22(1): 24.
- Counterfeit medicines. Regulatory tackles incident of fake Vicks Kingo. *WHO Pharmaceuticals Newsletter* **2008**; 4
- Nsimba S.. Problems Associated with Substandard and Counterfeit Drugs in Developing Countries: A Review Article on Global Implications of Counterfeit Drugs in the Era of Anti-retroviral (ARVS) Drugs in a Free Market Economy. *East African Journal of Public Health* **2008**; 5 (3): 205-210.
- Ofori-Kwakye K et al. Quality of artesunate tablets sold in pharmacies in Kumasi, Ghana. *Trop J Pharm Res* **2008**; 7 (4).
- USP-USAID. Survey of the Quality of Selected Antimalarial Medicines Circulating in Madagascar, Senegal, and Uganda. November **2009**. Available at USP on request (Francine Pierson: fp@usp.org).
- Leslie T et al., Epidemics of Plasmodium Falciparum malaria involving substandard antimalarial drugs, Pakistan 2003. *Emerging Infectious Diseases* www.cdc.gov/eid **2009**; 15 (11)
- Sengaloundeth et al., A stratified random survey of the proportion of poor quality oral artesunate sold at medicine outlets in the Lao PDR – implications for therapeutic failure and drug resistance. *Malaria Journal* **2009**, 8:172

- Onwujekwe O et al. Quality of anti-malarial drugs provided by public and private healthcare providers in south-east Nigeria. *Malaria Journal* **2009**, 8:22 doi:10.1186/1475-2875-8-22
- Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa. WHO (Quality Assurance and Safety of Medicines, Department of Essential Medicines and Pharmaceutical Policies), January **2011**
- Newton PN et al. Poor quality vital anti-malarials in Africa - an urgent neglected public health priority *Malaria Journal* **2011**, 10:352 doi:10.1186/1475-2875-10-352
- Gaurvika M L Nayyar, Joel G Breman, Paul N Newton, James Herrington. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. *Lancet Infect Dis* **2012**; 12: 488–96
- WHO Pre-qualification of Medicines Programme. Briefing note. Investigation into compliance with quality specifications of artemisinin-based combination products procured during the pilot phase of the Affordable Medicines Facility – malaria. December **2012**²².
- Chaccour C.J et al. Travel and fake artesunate: a risky business. *Lancet* **2012**; 380 (9847): 1120
- Evans et al.: Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname. *Malaria Journal* **2012**; 11:203.
- Affum AO, Lowor S, Osae SD et al. A pilot study on quality of artesunate and amodiaquine tablets used in the fishing community of Tema, Ghana. *Malar J.* **2013** Jun 28;12:220. doi: 10.1186/1475-2875-12-220.
- 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. 129. RHT/SAV/MD//IEA.130. Falsified batches of Coartem recently circulating in Cameroon. 8 November **2013**
- WHO Information Exchange System Alert No. 131. RHT/SAV/MD//IEA.131. Falsified antimalarial medicines in West and Central Africa. 25 March **2014**
- Taberner P, Fernandez FM, Green M, Guerin P and Newton PN, Mind the gaps – the epidemiology of poor-quality anti-malarials in the malarious world – analysis of the WorldWide Antimalarial Resistance Network database. *Mal J* **2014**, 13:19
- Hetzel MW, Page-Sharp M, Bala N, Pulford J, Betuela I, et al. (2014) Quality of Antimalarial Drugs and Antibiotics in Papua New Guinea: A Survey of the Health Facility Supply Chain. *PLoS ONE* 9(5): e96810. doi:10.1371/journal.pone.0096810
- D Osei-Safo, A Agbonon, DY Konadu, et al. Evaluation of the Quality of Artemisinin-Based Antimalarial Medicines Distributed in Ghana and Togo. *Malaria Research and Treatment* **2014**, Article ID 806416, 12 pages
- ACT Consortium Drug Quality Project Team and the IMPACT2 Study Team. Quality of Artemisinin-Containing Antimalarials in Tanzania’s Private Sector. Results from a Nationally Representative Outlet Survey. *Am J Trop Med Hyg* **2015**; 9 (6): 75-86 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Lin Yong Y, Plancon A, Hui Lau Y et al. Collaborative Health and Enforcement Operations on the Quality of Antimalarials and Antibiotics in Southeast Asia. *Am J Trop Med Hyg* **2015**; 9 (6): 105-112 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Yeung S, Lawford HLS, Taberner P et al. Quality of Antimalarials at the Epicenter of Antimalarial Drug Resistance: Results from an Overt and Mystery Client Survey in Cambodia. *Am J Trop Med Hyg* **2015**; 9 (6) Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Taberner P, Mayxay M, Culzoni MJ et al. A Repeat Random Survey of the Prevalence of Falsified and Substandard Antimalarials in the Lao PDR: A Change for the Better. *Am J Trop Med Hyg* **2015**; 9 (6): 95-104 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.

²² http://apps.who.int/prequal/info_press/documents/AMFm_medicines_testing.pdf

- Lalani M, Kaur H, Mohammed N et al. Substandard Antimalarials Available in Afghanistan: A Case for Assessing the Quality of Drugs in Resource Poor Settings. *Am J Trop Med Hyg* **2015**; 9 (6): 51-58 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- T. Dorlo. Falsified and substandard antimalarials. A fatal threat to malaria control. *Mtb. Bull Nederlands Soc Trop Med Int Health* **2015**; 53(3); 13-19
- Bassat Q, Tanner M, Guerin PJ, Stricker K and Hamed K. Combating poor-quality anti-malarial medicines: a call to action. *Malar J* **2016**; 15:302
- Hall Z, Allan EL, van Schalkwyk DA, van Wyk A, Kaur H. Degradation of Artemisinin-Based Combination therapies under tropical conditions. *Am J Trop Med Hyg* **2016**; 94(5): 993-1001
- Kaur H, Allan EL, Mamadu I, Hall Z, et al. Quality of Artemisinin-Based Combination Formulations for Malaria Treatment: Prevalence and Risk Factors for Poor Quality Medicines in Public Facilities and Private Sector Drug Outlets in Enugu, Nigeria. *PLoS ONE* **2015**; 10(5): e0125577. doi:10.1371/journal.pone.0125577
- Tivura M, Asante I, van Wyk A et al. Quality of Artemisinin-based Combination Therapy for malaria found in Ghanaian markets and public health implications of their use. *BMC Pharmacology and Toxicology* **2016**; 17:48
- Kaur H, Clarke S; Lalani M, et al. Fake anti-malarials: start with the facts. *Kaur et al. Malar J* (**2016**) 15:86
- WHO Information Exchange System Alert No. 4/2016. RHT/SAV/Alert 4.2016. Falsified quinine sulphate circulating in West and Central Africa. August **2016**
- PN.Newton, C Caillet & PJ.Guerin (**2016**) A link between poor quality antimalarials and malaria drug resistance?, *Expert Review of Anti-infective Therapy*, 14:6, 531-533
- Izevbekhai O et al. Quality of artemisinin-based antimalarial drugs marketed in Nigeria. *Trans R Soc Trop Med Hyg* **2017**; 111: 90–96
- Hodel EM e al. Stability of Dihydroartemisinin–Piperazine Tablet Halves during Prolonged Storage under Tropical Conditions. *Am. J. Trop. Med. Hyg.*, 96(2), **2017**, pp. 338–340
- Guo S. et al. RDTs, ARTEMISININ MONOTHERAPIES, AND FALSIFIED ARTESUNATE. Quality Testing of Artemisinin-Based Antimalarial Drugs in Myanmar. *American Journal of Tropical Medicine and Hygiene* **2017**, posted online ahead of print publication.
- WHO Information Exchange System Alert No. 2/2017. RHT/SAV/Alert 2.2017. Falsified Quinine Sulphate circulating in Africa. July **2017**
- ACTwatch Group et al. Do anti-malarials in Africa meet quality standards? The market penetration of non quality-assured artemisinin combination therapy in eight African countries. *Malar J* (**2017**) 16:204
- Kaur H, Allan EL, Mamadu I, et al. Prevalence of substandard and falsified artemisinin-based combination antimalarial medicines on Bioko Island, Equatorial Guinea. *BMJ Glob Health* **2017**;2:e000409
- Yemoa A et al. Detection of poor-quality artemisinin-based combination therapy (QCT) medicines marketed in Benin using simple and advanced analytical techniques. *Current Drug Safety* **2017**; 12: 178-186
- Walker et al. Are we doing enough to prevent poor-quality antimalarial medicines in the developing world? *BMC Public Health* (**2018**) 18:630
- Mufusame JP et al. Quality of the antimalarial medicine artemether - lumefantrine in eight cities of the Democratic Republic of the Congo. *Drug Test Anal. Drug Test Anal.* **2018**;1–8.
- Ndwigah S et al. The quality of anti-malarial medicines in Embu County, Kenya. *Malar J* (**2018**) 17:330
- The Global Fund QA Information Notice. Falsified Combiart: temether 20 mg + Lumefantrine 120 mg tablet. IN No **2018-05**. Version: 20/11/2018
- Walker et al. Are we doing enough to prevent poor-quality antimalarial medicines in the developing world? *BMC Public Health* (**2018**) 18:630

- Ozawa et al. Development of an agent-based model to assess the impact of substandard and falsified anti-malarials: Uganda case study. *Malar J* (2019) 18:5
- DJ Mavungu Landu et al. Quality of antimalarials in Kinshasa peri-urban areas with regard to local pharmaceutical legislation and regulation. *Int Health* 2019; 00: 1–11. doi:10.1093/inthealth/ihz070
- WHO Information Exchange System Alert No.10/2019. EMP/SAV/Alert 10.2019. Falsified Quinine Bisulphate circulating in Uganda and Quinine Sulphate circulating in Central African Republic and Chad. 1 October 2019
- Belew et al. Quality of fixed dose artemether/lumefantrine products in Jimma Zone, Ethiopia. *Malar J* 2019; 18:236. <https://doi.org/10.1186/s12936-019-2872-1>
- Opuni et al. Usefulness of combined screening methods for rapid detection of falsified and/or substandard medicines in the absence of a confirmatory method. *Malar J* 2019 ; 18:403
- Habtamu Abuye et al. Physicochemical Quality Assessment of Antimalarial Medicines: Chloroquine Phosphate and Quinine Sulfate Tablets from Drug Retail Outlets of South-West Ethiopia. *Infection and Drug Resistance* 2020:13 691–701
- Jackson et al. Impact of substandard and falsified antimalarials in Zambia: application of the SAFARI model. *BMC Public Health* (2020) 20:1083
- Hassett MR, Roepe PD (2021) *In vitro* growth competition experiments that suggest consequences of the substandard artemisinin epidemic that may be accelerating drug resistance in *P. falciparum* malaria. *PLoS ONE* 16(3): e0248057.
- WHO Information Exchange System Alert N8/2021. Ref. R PQ/REG/ISF/Alert N°8.2021. Medical Product Alert N°8/2021 Falsified Combiart identified in WHO region of Africa. 21 December 2021
- Aladin Ombeni Mahano et al. Pharmaceutical quality of antimalarial drugs: quinine sulfate and Artemether/ Lumefantrine tablets sold on Bukavu Market. *Journal of Pharmaceutical Sciences* (2021) 7:131 <https://doi.org/10.1186/s43094-021-00290-8>

8. Cases of poor quality medicines: antibiotics

- GI convicted of illegal penicillin sales. *The Washington Post*, 16th March 1950
- Three indicted in drug sales. *The Washington Post*, 5th April 1951
- US probing illegal cargo to China. *The Washington Post*, 1st August 1953
- A review of drug quality in Asia with focus on anti-infective. The USP Drug Quality and Information Program. February 2004. Available at www.uspdqi.org
- Kayumba PC et al. The quality of essential antimicrobial and antimalarial drugs marketed in Rwanda and Tanzania: influence of tropical storage conditions on in vitro dissolution *Journal of Clinical Pharmacy and Therapeutics* 2004; 29: 331–338
- P Newton et al, Counterfeit anti-infective drugs, *Lancet Infect. Dis.* 2006; 6: 602-13.
- Kelisidis T et al. Counterfeit or substandard antimicrobial drugs: a review of the scientific evidence. *Journal of Antimicrobial Chemotherapy* 2007. doi:10.1093/jac/dkm109
- J. van den Boogaard et al., Sale of fluoroquinolones in northern Tanzania: a potential threat for fluoroquinolone use in tuberculosis treatment. *J Antimicrob Chemother* 2010; 65: 145–147 doi:10.1093/jac/dkp413
- Hadi U et al. Cross-sectional study of availability and pharmaceutical quality of antibiotics requested with or without prescription (Over the Counter) in Surabaya, Indonesia. *BMC Infectious Diseases* 2010, 10:203 doi:10.1186/1471-2334-10-203
- Newton PN et al. Counterfeit and sub-standard anti-infectives in developing countries. Chapter 24 of the Springer book —Antimicrobial resistance in developing countriesII, 2010. DOI 10.1007/978-0-387-89370-9_24
- Delepierre, A. Gayot, A. Carpentier. Update on counterfeit antibiotics worldwide; Public health risks. *Med Mal Infect* 2012; 42 (6): 247-255
- Khan MH, Hatanaka K, Sovannarith T et al. Effects of packaging and storage conditions on the quality of amoxicillin-clavulanic acid - an analysis of Cambodian samples. *BMC Pharmacol Toxicol.* 2013 Jun 18;14:33. doi: 10.1186/2050-6511-14-33.

- Fadeyi I, Lalani M, Mailk N et al. Quality of the Antibiotics—Amoxicillin and Co-Trimoxazole from Ghana, Nigeria, and the UK. *Am J Trop Med Hyg* **2015**; 9 (6): 87-94 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Lin Yong Y, Plancon A, Hui Lau Y et al. Collaborative Health and Enforcement Operations on the Quality of Antimalarials and Antibiotics in Southeast Asia. *Am J Trop Med Hyg* **2015**; 9 (6): 105-112 Supplement: The pandemic of falsified medicines: laboratory and field innovations and policy perspectives.
- Antimicrobial resistance: What does medicine quality have to do with it? Paper prepared by Dr. Elizabeth Pisani, Visiting Senior Research Fellow, Policy Institute, King's College London and Director of Ternyata Ltd. for the Review on Antimicrobial Resistance. September 22, **2015**. Available at <http://apps.who.int/medicinedocs/en/m/abstract/Js22186en/>
- WHO Information Exchange System Alert No. 1/2015. RHT/SAV/MD/1/2015. Falsified antimalarial medicines circulating in West Africa. February **2015**
- Holmes AH, Moore LSP, Sundsfjord A et al. Understanding the mechanisms and drivers of antimicrobial resistance. *Lancet* **2016**; 387: 176–87
- Mendelson M, Rottingen JA, Gopinathan U et al. Maximizing access to achieve appropriate human antimicrobial use in Low- and Middle-Income Countries. *Lancet* **2016**; 387: 188-98
- Hy Pan et al. Pharmacopoeial quality of antimicrobial drugs in southern China. *Lancet GH* 2016; 4: e300-1
- Ravinetto R, Dujardin C. The threat of poor quality antibiotics in increasing antimicrobial resistance. *BMJ* 2016;353:i3618 doi: 10.1136/bmj.i3618 (Published 6 July **2016**)
- Newton PN and Timmermann B. Fake penicillin, The Third Man, and Operation Claptrap. *BMJ* **2016**;355:i6494
- WHO Information Exchange System Alert No. 4/2017. RHT/SAV/Alert 4.2017. Falsified Penicillin V circulating in Cameroon. November **2017**
- WHO Information Exchange System Alert No.1/2018. RHT/SAV/Alert 1.2018. Falsified cefixime products circulating in the Democratic Republic of Congo. January **2018**
- Khojah HM et al. The Quality of Medicines in Community Pharmacies in Riyadh, Saudi Arabia: A Lot Quality Assurance Sampling Based Survey. *Pharmacol & Pharmacy*, 2013, 4, 511-519
- Kakio T et al. Survey to Identify Substandard and Falsified Tablets in Several Asian Countries with Pharmacopoeial Quality Control Tests and Principal Component Analysis of Handheld Raman Spectroscopy. *Am J Trop Med Hyg* **2018**; published online ahead of print.
- Nwokike J et al. Medicines quality assurance to fight antimicrobial resistance. *Bull World Health Organ* **2018**; 96:135–137
- Chicowe I et al. Amoxicillin Quality and Selling Practices in Urban Pharmacies and Drug Stores of Blantyre, Malawi. *Am J Trop Med H*; **2018**, published online ahead of printing
- Md. Rafiqul Islam et al. An Investigation into the Quality of Medicines in Yangon, Myanmar. *Pharmacy* **2018**, 6, 96
- Humuli P et al. Investigation of the Quality of Antibiotics-Based Amoxicillin for Monitoring of Some Different Medicine Markets of Democratic Republic of Congo. *Am J Anal Chem* **2018**; 9: 366-85
- Schafermann Set al. Quality of medicines in southern Togo: Investigation of antibiotics and of medicines for non-communicable diseases from pharmacies and informal vendors. *PLoS ONE* **2018**; 13(11): e0207911.
- Microbiological and physicochemical assessment of some brands of gentamicin eye drops marketed in registered retail pharmacies in Port Harcourt, Nigeria. *J Pharmacy Bioresources* **2018**; 15(1): 27-36
- Yaxin Tie et al. Development and validation of chromatographic methods for screening and subsequent quantification of suspected illegal antimicrobial drugs encountered on the Belgian market. *Talanta* 194 (**2019**) 876–887
- WHO Information Exchange System Alert No.9/2019. EMP/SAV/Alert 9.2019. Falsified Augmentin found in Uganda and Kenya. 20 August **2019**

- WHO Information Exchange System Alert No.11/2019. EMP/SAV/Alert 11.2019. Falsified Amoxicillin + Clavulanic Acid products circulating in Haiti. 16 October **2019**
- Schafermann et al. Substandard and Falsified Antibiotics and Medicines against Noncommunicable Diseases in Western Cameroon and Northeastern Democratic Republic of Congo. *Am. J. Trop. Med. Hyg.*, 00(0), **2020**, pp. 1–15
- WHO Information Exchange System Alert No.1/2020. RPQ/REG/ISF/Alert 1.2020. Falsified antimalarials in West and Central Africa. January **2020**
- Koech LC et al Quality and Brands of Amoxicillin Formulations in Nairobi, Kenya. *BioMed Research International* Volume **2020**, Article ID 7091278, 14 pages
- Oppong Bekoe et al. Exposure of consumers to substandard antibiotics from selected authorized and unauthorized medicine sales outlets in Ghana. *TMIH* **2020**; 17 May 2020; <https://doi.org/10.1111/tmi.13442>
- Theodule JB et al. Substandard Quality of the Antimicrobials Sold in the Street Markets in Haiti. *Antibiotics* **2020**, 9; 407
- Woldemichael A et al. In Vitro Comparative Quality Assessment of Different Brands of Doxycycline Hyclate Finished DosageForms: Capsule and Tablet in Jimma Town, South-West Ethiopia. *Advances in Pharmacological and Pharmaceutical Sciences*. Volume **2021**, Article ID 6645876
- Rahman, M.S., Yoshida, N., Tsuboi, H. *et al.* A comprehensive analysis of selected medicines collected from private drug outlets of Dhaka city, Bangladesh in a simple random survey. *Sci Rep* **12**, 234 (**2022**). <https://doi.org/10.1038/s41598-021-04309-1>
- Zabala GA, Bellingham K, Vidhamaly V, *et al.* Substandard and falsified antibiotics: neglected drivers of antimicrobial resistance? *BMJ Global Health* **2022**;7:e008587. doi:10.1136/bmjgh-2022-008587
- Busha et al. Contents of Amoxicillin Drugs Dispensed in Goma, Democratic Republic of Congo. *Afr. J. Pharm. Sci.* 2(1) (**2022**) 14-22
- Bizimana T, Kagisha V, Nyandwi JB, Nyirimigabo AK, Muganga R, Mukanyangezi MF, Kayitare E. Investigation of the Quality of the 12 Most-Used Antibiotics Available in Retail Private Pharmacies in Rwanda. *Antibiotics (Basel)*. **2022** Mar 2;11(3):329.

9. Cases of poor quality medicines: diethylene glycol **contamination**

- Geiling EMK and Cannon PR. Pathologic effects of elixir of sulfanilamide (diethylene glycol) poisoning. A clinical and experimental correlation: final report. *JAMA* **1938**; 111: 919–26.
- Bowie MD and McKenzie D, Diethylene glycol poisoning in children. *SAMJ* **1972**; 46 (27): 931-934
- Ballentine V. Taste of Raspberries, Taste of Death. The 1937 Elixir Sulfanilamide Incident FDA Consumer magazine - June **1981** Issue
- Cantarell M.C. et al. Acute intoxication due to topical application of diethylene glycol. *Annals of Internal Medicine*. **1987**. Vol. 106 pp. 478-479
- Pandya SK Letter from Bombay - An unmitigated tragedy. *BMJ* **1988**; 297: 117-119
- Okuonghae HO, Ighogboja IS, Lawson JO and Nwana EJC; Diethylene glycol poisoning in Nigerian children **1992**. *Annals of Tropical Pediatrics* 12,235-238
- Wax PM. Elixirs, diluents, and the passage of the 1938 Federal Food, Drug and Cosmetic Act. *Annals of Internal Medicine*, **1995**,122: 456–461
- Mohammed Hanif, M Reaz Mobarak, Anne Ronan et al. Fatal renal failure caused by diethylene glycol in paracetamol elixir: the Bangladesh epidemic. *BMJ* **1995**; 311: 88-91
- Scalzo AJ. The 1996 Haitian epidemic. *Journal of Toxicology: Clinical Toxicology* **1996**; 34 (5): 513-516.
- Woolf A.D. The Haitian Diethylene Glycol Poisoning Tragedy. *JAMA* **1998**; 279 (15): 1215-1216
- O' Brien K et al. Epidemic of Pediatric Deaths From Acute Renal Failure Caused by Diethylene Glycol Poisoning. *JAMA* **1998**; 279: 1175-1180
- White Junod S. Diethylene glycol deaths in Haiti. *Public Health Reports* **2000**; 115: 78-86

- Baffi P and Elsener S., Quantitative Determination of Diethylene Glycol Contamination in Pharmaceutical Products. *J AOAC Intern* **2000**; 83(4): 793-801 (mentioning the Maracaibo accident in Venezuela)
- Singh J et al. Diethylene glycol poisoning in Gurgaon, India. *WHO Bull* **2001**; 79 (2): 88-95
- Kumar A. Diethylene glycol poisoning in Gurgaon, Haryana, India 1998. *WHO Bull* **2001**; 79 (7): 686
- P Hari, Yogesh Jain and Sushil Kumar Kabra. Case Report Fatal Encephalopathy and Renal Failure Caused by Diethylene Glycol Poisoning. *J Trop Pediatr* **2006**; 52: 442
- Barr D et al. Identification and Quantification of Diethylene Glycol in Pharmaceuticals Implicated in Poisoning Epidemics: An Historical Laboratory Perspective. *Journal of Analytical Toxicology* **2007**; 31 (6): 295-303
- E Danielle Rentz et al., Outbreak of acute renal failure in Panama in 2006: a case-control study. *Bulletin of the World Health Organization* **2008**; 86: 749-756. Available at WHO website
- Abubukar A et al. Fatal poisoning among young children from diethylene glycol-contaminated acetaminophen - Nigeria, 2008-2009. *Morbidity and Mortality Weekly Report* 2009; 58 (48): 1345-1347
- Schier J.G et al. Medication-associated diethylene glycol mass poisoning. A review and discussion on origin of contamination. *J Pub Health Pol* **2009**; 30: 127-143
- Bonati M. Drug therapy. Once again, children are the main victims of fake drugs. *Arch Dis Child* **2009**; 94:468
- Saad Alkahtani S, Sammons H and Choonara I. Epidemics of acute renal failure in children (diethylene glycol toxicity) *Arch. Dis. Child* **2010**; 95: 1062
- Oshikoya KA and Senbajo I.O. Medicines turned poison for children in Nigeria. *West Afr J Med* **2010**; 29 (4): 278-279
- **WHO Information Exchange System Alert N6/2022. Ref. RPQ/REG/ISF/Alert N°6.2022. Substandard (contaminated) paediatric medicines identified in WHO region of Africa. 5 October 2022**

10. Cases of poor quality medicines: neglected tropical diseases

- Sundar S, Sinha PR, Agrawal NK, Srivastava R, Rainey PM, Berman JD, Murray HW, Singh VP. A cluster of cases of severe cardiotoxicity among kala-azar patients treated with a high-osmolarity lot of sodium antimony gluconate. *Am J Trop Med Hyg.* **1998** Jul;59(1):139-43.
- Boelaert M, Le Ray D, Van Der Stuyft P. How better drugs could change kala-azar control. Lessons from a cost-effectiveness analysis. *Trop Med Int Health* **2002**; 7: 955–9.
- Rijal S, Chappuis F, Singh R, Boelaert M, Loutan L, Koirala S. Sodium stibogluconate cardiotoxicity and safety of generics. *Trans R Soc Trop Med Hyg.* **2003** Sep-Oct;97(5):597-8.
- Dorlo TPC, Eggelte TA, de Vries PJ, Beijnen JH. Characterization and identification of suspected counterfeit miltefosine capsules. *Analyst* **2012**; 137: 1265–74.
- Dorlo TPC et al. A poor-quality generic drug for the treatment of visceral leishmaniasis: a case report and appeal. *PLoS Negl Trop Dis* **2012**; 6(5): e1544. doi:10.1371/journal.pntd.0001544
- Dorlo TPC, Ravinetto RM, Beijnen JH, Boelaert M. Commentary: Substandard medicines are the priority for neglected tropical diseases. *BMJ* **2012**;345:e7518
- Arya SC and Agarwal N. Miltefosine Drug Concerns. *Clinical Infectious Diseases* **2013**;57(6):917 **AND** Dorlo TPC et al. Reply to Arya and Agarwal. *Clinical Infectious Diseases* **2013**;57(6):917–8
- Barbe B, Verdonck K, El-Safi S et al. Rapid Diagnostic Tests for Neglected Infectious Diseases: Case Study Highlights Need for Customer Awareness and Postmarket Surveillance. *PLoS Negl Trop Dis* **2016** ; 10(11): e0004655. doi:10.1371/journal.pntd.0004655
- WHO Information Exchange System Alert No.7/2019. EMP/SAV/Alert 7.2019. Falsified meglumine antimoniate ampoules in Iran and Pakistan. 24 April **2019**
- Seitzer M, Klapper S, Mazigo HD, Holzgrave U, Mueller A (**2021**) Quality and composition of Albendazole, Mebendazole and Praziquantel available in Burkina Faso, Cote d'Ivoire, Ghana and Tanzania. *PLoS Negl Trop Dis* 15(1): e0009038.

11. Cases of poor quality medicines: TB

- Laserson KF et al. Substandard tuberculosis drugs on the global market and their simple detection *Int J Tuberc Lung Dis* **2001**; 5(5):448–454
- Laing R, Vrakking H, Fourie B. Quality and stability of TB medicines: let the buyer beware. *Int J Tuberc Lung Dis* **2004**; 8 (9): 1043-1044
- R van Crevel et al. Bioavailability of rifampicin in Indonesian subjects a comparison of different local drug manufacturers. *Int J Tuberc Lung Dis* **2004**; 8(4): 500-503
- Rookkapan et al. Deteriorated tuberculosis drugs and management system problems in lower southern Thailand. *INT J TUBERC LUNG DIS* **2005**; 9(6):654–660
- Sidley, P. South Africa withdraws TB drugs because of quality concerns. *British Medical Journal* **2008**; 337:a1385
- SL Barber et al, Multidrug-resistant tuberculosis and quality-assured medicines. *Lancet* **2009**; 374: 292
- WHO. Survey of the quality of anti-tuberculosis medicines circulating in selected newly independent states of the former Soviet Union. WHO (Quality Assurance and Safety of Medicines, Department of Essential Medicines and Pharmaceutical Policies. WHO Regional Office for Europe), November **2011**
- Bate R et al. Substandard and falsified anti-tuberculosis drugs: a preliminary field analysis. *Int J Tuberc Lung Dis*. e-publication ahead of print 14 January **2013**. © 2013 The Union; 1–4
- Luther Gwaza, John Gordon, Jan Welink et al. Adjusted indirect treatment comparison of the bioavailability of WHO-prequalified first-line generic antituberculosis medicines, *Clinical Pharmacology & Therapeutics* accepted article preview online 02 July **2014**
- Pouplin T, Phuong PN, Toi PV, Nguyen Pouplin J, Farrar J (2014) Isoniazid, Pyrazinamide and Rifampicin Content Variation in Split Fixed-Dose Combination Tablets. *PLoS ONE* **2014**; 9(7): e102047. doi:10.1371/journal.pone.0102047
- Editorial. Making up the difference: ensuring the bioequivalence of fixed dose combinations for tuberculosis. *INT J TUBERC LUNG DIS* **2018**; 22(5):473–474
- Nabirova D and coll. Assessment of the quality of anti-tuberculosis medicines in Almaty, Kazakhstan, 2014. *Int J Tuberc Lung Dis*. **2017** October 01; 21(10): 1161–1168
- Court R et al. Quality assurance of rifampicin-containing fixed-drug combinations in South Africa: dosing implications. *INT J TUBERC LUNG DIS* **2018**; 22(5):537–543
- Hauk C, Schafermann S, Martus P, Muzafarova N, Babaley M, Waning B, et al. Quality assurance in anti-tuberculosis drug procurement by the Stop TB Partnership—Global Drug Facility: Procedures, costs, time requirements, and comparison of assay and dissolution results by manufacturers and by external analysis. *PLoS ONE* **2020**; 15(12): e0243428.
- Sandrine Cloez and Mike Frick. FAQ Nitrosamines and TB Medicines: What People Taking TB Treatment Need to Know. Treatment Action Group. February **2021**
- Sandrine Cloez and Mike Frick. Information note: N-nitrosamines and Tuberculosis Medicines Rifampicin and Rifapentine. Treatment Action Group. February **2021**

12. Cases of poor quality medicines: HIV

- J.J. Amon, Dangerous medicine. Unproven AIDS cures and counterfeit antiretroviral drugs. *Globalization and health*, **2008**, 4:5
- Musoke D et al. Assessment of the Drugs Storage Facilities and Quality of Generic co-Formulation Tablets (Stavudine, Lamivudine, Nevirapine) at HIV Treatment Centres in Uganda. *Res J Med Sci* **2008**; 2(3): 159-62
- WHO Pre-qualification Programme. Falsified lamivudine, zidovudine and nevirapine tablets (Zidolam-N) in Kenya. Alert, 22 and 23 September **2011**
- Cohn J., Von Schoenen-Angerer T., Jambert E., Arreghini G and Childs M. When falsified medicines enter the supply chain: Description of an incident in Kenya and lessons learned for rapid response. *J Pub Health Pol* **2012**; 1-9. doi:10.1057/jphp.2012.53

- Zucman D, Camara S, Gravisse J et al. Generic antiretroviral drugs in developing countries: friends or foes? *AIDS* **2014**, 28: 607-612
- Survey of the quality of selected antiretroviral medicines circulating in five African countries. *WHO Drug Information* Vol. 31, No. 2, **2017**
- WHO Information Exchange System Alert No.2/2020. RPQ/REG/ISF/Alert 2.2020. Falsified HIV rapid diagnostic test circulating in the WHO regions of the Americas and Africa. 27 March **2020**
- Mziray et al. Quality of selected anti-retroviral medicines: Tanzania Mainland market as a case study. *BMC Pharmacology and Toxicology* (**2021**) 22:46
- **WHO Review of product information for selected antiretroviral medicines circulating in five African countries. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.**

13. Cases of poor quality medicines: noncommunicable diseases

- Laroche ML et al., Quality of Phenobarbital Solid-dosage Forms in the Urban Community of Nouakchott (Mauritania). *Epilepsia* **2005**; 46(8):1293–1296
- Twagirumukiza M, Cosijns A, Pringelset E al. Influence of Tropical Climate Conditions on the Quality of Antihypertensive Drugs from Rwandan Pharmacies. *Am. J. Trop. Med. Hyg.*, **2009**; 81 (5): 776–781
- Tomic S. et al., Identification of counterfeit medicines for erectile dysfunction from an illegal supply chain. *Arh Hig Rada Toksikol* **2010**;61:69-75.
- WHO Information Exchange System. Alert No. 125. Contaminated Isotab® (isosorbide mononitrate) incident in Lahore Pakistan. 3rd February **2012**. QSM/MC/IEA.125
- Arie S. Contaminated drugs are held responsible for 120 deaths in Pakistan. *BMJ* **2012**;344:e951 doi: 10.1136/bmj.e951
- Nishtar S. Pakistan's deadly cocktail of substandard drugs. *The Lancet* **2012**; 379: 1084-1085
- Batch JO93. The pathology of negligence. Report of the Judicial Inquiry Tribunal to determine the causes of death of patients of the Punjab Institute of Cardiology, Lahore, in **2011-2012**.
- Kuehn BM. FDA warning: New batch of fake bevacizumab found. *JAMA*. **2013** Mar 6;309(9):864.
- Wang F, Yu S, Liu K, Chen FE et al. Acute intraocular inflammation caused by endotoxin after intravitreal injection of counterfeit bevacizumab in Shanghai, China. *Ophthalmology*. **2013** Feb;120(2):355-61.
- J Correale, E Chiquete, S Milojevic et al. Assessing the potential impact of non-proprietary drug copies on quality of medicine and treatment in patients with relapsing multiple sclerosis: the experience with fingolimod. *Drug Design, Development and Therapy* **2014**;8 859–867
- Otte WM et al. Counterfeit antiepileptic drugs threaten community services in Guinea-Bissau and Nigeria. *Lancet Neurol* **2015**; 14: 1075-1076
- WHO Information Exchange System Alert No. 4/2015. RHT/SAV/MD/4/2015. Adverse reactions caused by Falsified Diazepam in Central Africa. July **2015**
- WHO Information Exchange System Alert No. 1/2016. RHT/SAV/Alert 1.2016. Falsified phenobarbitone tablets circulating in West Africa. February **2016**
- Arens AM et al. Research letter. Adverse Effects From Counterfeit Alprazolam Tablets. *JAMA* **2016**; published on line 8th August.
- Yang YT, Nagai S, Chen BK, et al. Generic oncology drugs: are they all safe? *Lancet Oncology* **2016**; 17: e493-501
- Stewart M et al. Perspective. Counterfeit Avastin in India: Punish the Criminals, Not the Patients. *Am J Ophthalmol* **2016**;170:228–231.
- Peyraud N, Rafael F, Parker LA et al. An epidemic of dystonic reactions in central Africa. *Lancet GH* **2017**; 5: e137-8
- WHO Information Exchange System Alert No. 3/2017. RHT/SAV/Alert 3.2017. Falsified Avastin (bevacizumab) and Sutent (sunitinib maleate) circulating in East Africa. August **2017**

- Rahman et al. Erroneous formulation of delayed-release omeprazole capsules: alert for importing countries *BMC Pharmacology and Toxicology*; **2017**; 18:31:1-11
- Xiaodong Sun et al. Counterfeit Bevacizumab and Endophthalmitis. *NEJM* **2017**; 365 (4): 378-9
- Addendum to Perspective entitled “Counterfeit Avastin in India: Punish the Criminals, Not the Patients”. <http://dx.doi.org/10.1016/j.ajo.2016.09.001>
- M. Antignac, et al., Fighting fake medicines: First quality evaluation of cardiac drugs in Africa, *Int J Cardiol* (**2017**) <http://dx.doi.org/10.1016/j.ijcard.2017.04.099>
- Mattar M, et al, Letter to the Editor On the use of substandard medicines in hematology: An emerging concern in the Middle East and North Africa region , *Eur J Intern Med* (**2017**), <https://doi.org/10.1016/j.ejim.2017.08.003>
- Veenhuis BJ. Oncology drugs in the crosshairs of pharmaceutical crime. *Lancet Oncol* **2018**; 19: e209–17
- Steyn M et al., A herbal treatment for type 2 diabetes adulterated with undisclosed drugs. *Lancet* **2018**; 391: 2411
- Joost J et al. Quality of antiepileptic drugs in sub-Saharan Africa: A study in Gabon, Kenya, and Madagascar. *Epilepsia*. **2018**;59:1351–1361.
- Schafermann Set al. Quality of medicines in southern Togo: Investigation of antibiotics and of medicines for non-communicable diseases from pharmacies and informal vendors. *PLoS ONE* **2018**; 13(11): e0207911.
- WHO Information Exchange System Alert No.2/2018. RHT/SAV/Alert 2.2018. Falsified “Augmentin” circulating in Cameroon. March **2018**
- Diane Macquart de Terline et al. Substandard drugs among five common antihypertensive generic medications: an analysis from 10 African countries. *Journal of Hypertension* **2018**, 36:395–401
- WHO Information Exchange System Alert No.2/2019. EMP/SAV/Alert 2.2019. Falsified ICLUSIG traded globally. 31 January, updated 5 February **2019**
- WHO Information Exchange System Alert No3/2019. EMP/SAV/Alert 3.2019. Falsified ICLUSIG traded in Asian at patient level and globally. 21 February **2019**
- EMA/231394/2020. Suspension of ranitidine medicines in the EU. 30 April **2020**
- Ndichu ET, Ohiri K, Sekoni O, Makinde O, Schulman K (**2019**) Evaluating the quality of antihypertensive drugs in Lagos State, Nigeria. *PLoS ONE* 14(2): e0211567.
- Mohammad Sofiqur Rahman et al. A Cross-Sectional Investigation of the Quality of Selected Medicines for Noncommunicable Diseases in Private Community Drug Outlets in Cambodia during 2011–2013. , *Am. J. Trop. Med. Hyg* **2019**, 00(0): 1–9
- Saraswati K, Sichanh C, Newton PN, *et al.* Quality of medical products for diabetes management: a systematic review. *BMJ Global Health* **2019**;4:e001636.
- Redfern J et al. Equivalence in Active Pharmaceutical Ingredient of Generic Antihypertensive Medicines Available in Nigeria (EQUIMEDS). A Case for Further Surveillance *Glob Heart* **2019**; 14 (3): 327-333
- Tamargo J, Rosano G. Low quality of some generic medicinal products represents a matter for growing concern. *European Society of Cardiology* **2019**.
- WHO Information Exchange System Alert No.6/2019. EMP/SAV/Alert 6.2019. Falsified Hydrochlorothiazide (containing glibenclamide) in Cameroon. 16 April **2019**
- Schafermann et al. Substandard and Falsified Antibiotics and Medicines against Noncommunicable Diseases in Western Cameroon and Northeastern Democratic Republic of Congo. *Am. J. Trop. Med. Hyg.*, 00(0), **2020**, pp. 1–15
- Secretan P-H, Antignac M, Yagoubi N, *et al.* Post hoc study to investigate the potential causes of poor quality of cardiovascular medicines collected in sub-Saharan countries. *BMJ Open* **2020**;10:e039252.
- Chloe Tuck, Kwame Peprah Boaitey, Amy Hai Yan Chan. Quality assurance and cancer medicines in low-income and middle-income countries. *Lancet Oncology* **2021**; 22: 301-3

- Madeline S. Eberle et al. Substandard Cisplatin Found While Screening the Quality of Anticancer Drugs From Addis Ababa, Ethiopia. *JCO Global Oncol* 6:407-413.
- Rahman, M.S., Yoshida, N., Tsuboi, H. *et al.* A comprehensive analysis of selected medicines collected from private drug outlets of Dhaka city, Bangladesh in a simple random survey. *Sci Rep* 12, 234 (2022). <https://doi.org/10.1038/s41598-021-04309-1>
- Do NT, Bellingham K, Newton PN, et al. The quality of medical products for cardiovascular diseases: a gap in global cardiac care. *BMJ Global Health* 2021;6:e006523. doi:10.1136/bmjgh-2021-006523

14. Cases of poor quality medicines: sexual reproductive health

- 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. 5/2015. RHT/SAV/Alert 5.2015. Falsified emergency contraceptive circulating in East Africa. November 2015
- World Health Organization. Survey of the quality of medicines identified by the United Nations commission on life saving commodities for women and children. 2015 WHO. Geneva, Switzerland. ISBN 978 92 4 151111 7
- Briefing note. Quality of misoprostol products. *WHO Drug Information* 2016; 30(1): 35-39
- Torloni MR et al. Quality of oxytocin available in low- and middle-income countries: a systematic review of the literature. *BJOG* 2016;123: 2076-86
- Chimezie Anyakora et al. Quality medicines in maternal health: results of oxytocin, misoprostol magnesium sulfate and calcium gluconate quality audits. *BMC Pregnancy and Childbirth* (2018) 18:44
- Lambert P et al. Quality of oxytocin ampoules available in health care facilities in the Democratic Republic of Congo: an exploratory study in five provinces. *Journal of Global Health* 2018; 8(2): 020415
- Tremelling J, All A, Lleras L, Cancel A, Jenkins D, Pina C, et al. (2019) Poor quality male latex condoms found in Dominican Republic: Quality assurance evaluation and public health impact. *PLoS ONE* 14(1): e0210150.
- Ejekam CS, Okafor IP, Anyakora C, et al.. Clinical experiences with the use of oxytocin injection by healthcare providers in a southwestern state of Nigeria: A cross-sectional study. *PLoS ONE* 2019; 14(10): e0208367. <https://doi.org/10.1371/journal.pone.0208367>
- Hagen et al. Quality, availability and storage conditions of oxytocin and misoprostol in Malawi. *BMC Pregnancy and Childbirth* 2020; 20:184
- Lambert P et al. Oxytocin quality: evidence to support updated global recommendations on oxytocin for postpartum hemorrhage. *Journal of Pharmaceutical Policy and Practice* (2020) 13:14
- Nhomsai Hagen et al. Stability of Oxytocin Preparations in Malawi and Rwanda: Stabilizing Effect of Chlorobutanol. *AmJTropMedHyg* 2020; 00(0): 1–13
- Torloni MR, Bonet M, Betrán AP, Ribero-Valle CC, Widmer M (2020) Quality of medicines for life-threatening pregnancy complications in low- and middle-income countries: A systematic review. *PLoS ONE* 15(7):e0236060.
- Hagen N, Bizimana T, Kayumba PC, Khuluza F, Heide L (2020) Stability of misoprostol tablets collected in Malawi and Rwanda: Importance of intact primary packaging. *PLoS ONE* 15(9): e0238628.
- Hand RM et al. Quality of benzathine penicillin G: A multinational cross-sectional study *Pharmacol Res Perspect.* 2020;e00668.
- WHO Information Exchange System Alert No.3/2020. RPQ/REG/ISF/Alert 3.2020. Falsified medical products, including in vitro diagnostics, that claim to prevent, detect, treat or cure COVID-19. 31 March 2020
- WHO Information Exchange System Alert No.4/2020. RPQ/REG/ISF/Alert 4.2020. Falsified chloroquine products circulating in the WHO region of Africa. 9 April 2020

- Unidad de Información y Vigilancia de Medicamentos, BOLIVIA. Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos. (CECMED). LA AGEMED ALERTA SOBRE LA FALSIFICACIÓN DEL PRODUCTO LEVONOGESTREL. 26/10/2020. Available at <https://www.agemed.gob.bo/>
- Bizimana T, Hagen N, Gnegel G, Kayumba PC, Heide L (2021) Quality of oxytocin and misoprostol in health facilities of Rwanda. PLoS ONE 16(1): e0245054.
- WHO. Regulatory guidance for assessment and management of applications for marketing authorization of oxytocin 2021. ISBN 978-92-4-002213-3 (electronic version). ISBN 978-92-4-002214-0 (print version)
- WHO Information Exchange System Alert N3/2021. Ref. RPQ/REG/ISF/Alert N°3.2021. Falsified Misoprostol in WHO region of the Africa. August 2021

15. Cases of poor-quality products: COVID19

- Gnesel G et al. Identification of Falsified Chloroquine Tablets in Africa at the Time of the COVID-19 Pandemic. Am. J. Trop. Med. Hyg., 00(00), 2020, pp. 1–4.
- Newton PN, Bond K, on behalf of 53 signatories from 20 countries. COVID-19 and risks to the supply and quality of tests, drugs, and vaccines. Lancet GH 2020; published online April 9, 2020. [https://doi.org/10.1016/S2214-109X\(20\)30136-4](https://doi.org/10.1016/S2214-109X(20)30136-4)
- Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford. Medical Product Quality Report – COVID-19 Issues. Issue 1. January to June 2020. **Check monthly updates at <https://www.iddo.org/mg/research/medical-product-quality-reports>**
- WHO INFORMATION NOTICE FOR USERS OF MEDICAL DEVICES. Substandard/Falsified medical devices and personal protective equipment (PPE) used in the context of the COVID-19 pandemic. 2020/3, version 1. 7 August 2020
- United Nations Office Drug and Crime. Report on COVID-19-related Trafficking of Medical Products as a Threat to Public Health. UNODC Vienna, Austria, 2020
- Wubshet Tesfaye et al. Perspective Piece. How Do We Combat Bogus Medicines in the Age of the COVID-19 Pandemic? Am. J. Trop. Med. Hyg., 00(0), 2020, pp. 1–4
- Waffo Tchounga CA, Sacre PY, Ciza P, Ngono R, Ziemons E, Hubert P, Marini RD, Composition analysis of falsified chloroquine phosphate samples seized during the COVID-19 pandemic, *Journal of Pharmaceutical and Biomedical Analysis* (2020), doi: <https://doi.org/10.1016/j.jpba.2020.113761>
- Jairoun *et al.* Online medication purchasing during the Covid-19 pandemic: potential risks to patient safety and the urgent need to develop more rigorous controls for purchasing online medications, a pilot study from the United Arab Emirates. J of Pharm Policy and Pract (2021) 14:38
- Division of Enforcement and Inspection, Israel Ministry of Health. (2021). Vaccine scams, miracle cures, spurious supplements, and counterfeit medical devices during the COVID-19 pandemic in Israel.
- WHO Information Exchange System Alert N4/2021. Ref. RPQ/REG/ISF/Alert N°4.2021. Falsified Remdesivir identified in WHO region of the Americas. August 2021
- WHO Information Exchange System Alert N2/2022. Ref. RPQ/REG/ISF/Alert N°2.2022. Falsified DESREM (Remdesivir) identified in the WHO Region of the Americas and South Asia. 28 February 2022
- Plata G. The black market for COVID19 antiviral drugs. BMJ 2022; 377: o1282. Doi: 10.1136/bmj.o1282

16. Cases of poor quality medicines: vaccines

- WHO Information Exchange System Alert No. 2/2015. RHT/SAV/MD/2/2015. Falsified meningitis vaccines circulating in West Africa. May 2015

- WHO Information Exchange System Alert No. 3/2015. RHT/SAV/MD/3/2015. Falsified meningitis vaccines circulating in West Africa. UPDATE. May **2015**
- WHO Information Exchange System Alert No. 2/2016. RHT/SAV/Alert 2.2016. Falsified AMARIL yellow fever vaccines circulating in South East Asia. February **2016**
- WHO Information Exchange System Alert No. 1/2017. RHT/SAV/Alert 1.2017. Falsified meningococcal ACWY vaccine circulating in West Africa. June **2017**
- WHO Information Exchange System Alert No.3/2018. RHT/SAV/Alert 3.2018. Falsified Hepatitis B Vaccines circulating in Uganda. March **2018**
- WHO Information Exchange System Alert No.1/2019. EMP/SAV/Alert 1.2019. Falsified Rabies Vaccines circulating in the Philippines. 30 January **2019**
- WHO Information Exchange System Alert No.4/2019. EMP/SAV/Alert 4.2019. Falsified Oral Cholera Vaccines circulating in Bangladesh. 21 March **2019**
- WHO Information Exchange System Alert No.5/2019. EMP/SAV/Alert 5.2019. Falsified Meningitis Vaccines circulating in Niger. 28 March **2019**
- WHO Information Exchange System Alert No.8/2019. Falsified Rabies Vaccines and Anti-Rabies Serum circulating in the Philippines EMP/SAV/Alert 8.2019. 16 July **2019**
- WHO Information Exchange System Alert No.6/2020. Ref. RPQ/REG/ISF/Alert N°6.2020 Falsified Fluzone® Quadrivalent Influenza Vaccine identified in WHO region of the Americas. 29 October **2020**
- UNODC. COVID-19 VACCINES AND CORRUPTION RISKS: PREVENTING CORRUPTION IN THE MANUFACTURE, ALLOCATION AND DISTRIBUTION OF VACCINES. United Nations Office for Drugs and Crime, Vienna, **2021**
- WHO Information Exchange System Alert N2/2021. Ref. RPQ/REG/ISF/Alert N°2.2021. Falsified COVID-19 Vaccine BNT162b2 identified in WHO region of the Americas. 26 March **2021**
- WHO Information Exchange System Alert N5/2021. Ref. RPQ/REG/ISF/Alert N°5.2021. Falsified COVISHIELD vaccine identified in the WHO regions of Africa and South-East Asia . 20 August **2021**
- WHO Information Exchange System Alert N6/2021. Ref. RPQ/REG/ISF/Alert N°6.2021. Falsified Pfizer-BioNTech COVID-19 Vaccine identified in WHO region of the Eastern Mediterranean. 4 November **2021**
- WHO Information Exchange System Alert N7/2021. Ref. RPQ/REG/ISF/Alert N°7.2021. Medical Product Alert N°7/2021 Falsified COVID-19 VACCINE AstraZeneca identified in WHO region of the Eastern Mediterranean. 4 November **2021**

17. Cases of poor quality medicines: other products

- Csillag C. Epidemics of counterfeit drugs causes concern in Brazil. *The Lancet* **1998**; 352: 553
- Sulaiman SL et al. Counterfeit praziquantel. *The Lancet* **2001**; 358 (9282): 666-667
- Janice Hopkins Tanne. Four deaths and 350 adverse events lead to US recall of heparin. *BMJ* **2008**; 336:412-413
- M. Mitka, Contaminated Heparin seized by FDA. *JAMA* **2008**; 300 (22): 2597.
- FE Eichie et al., In-vitro evaluation of the pharmaceutical quality of some ibuprofen tablets dispensed in Nigeria. *African Journal of Pharmacy and Pharmacology* **2009**; 3(10): 491-495.
- Hussain Khan M et al., Prevalence of counterfeit anthelmintic medicines: a cross-sectional survey in Cambodia. *Tropical Medicine and International Health* **2010**; 15 (5): 639–644.
- Heparin contamination. *JAMA* **2010**; 303 (22): 2241
- Ali GKM, et al. Newspapers' coverage of contaminated intravenous fluids from an Indian manufacturer distributed by Public Central Medical Supplies in Sudan: Lessons to be learned. *Health Policy* **2011**, doi:10.1016/j.healthpol.2010.12.004
- Kauffman A et al. Fungal Infections Associated with Contaminated Methylprednisolone Injections — Preliminary Report. *N Engl J Med* **2012**. DOI: 10.1056/NEJMra1212617

- Chang CY, Furlon LA. Microbial Stowaways in Topical Antiseptic Products. *NEJM* **2012**; 367 (23): 2170-2173
- McCarthy M. FDA inspections find unsafe practices in compounding Pharmacies. *BMJ* **2013**;346:f2414
- WHO Information Exchange System Alert No. 126. QSM/MC/IEA.126. Contaminated Dextromethorphan Active Pharmaceutical Ingredient. 24 January **2013**
- WHO Information Exchange System Alert No. 129. RHT/SAV/MD//IEA.127. Contaminated Dextromethorphan active pharmaceutical ingredient. 17 October **2013**
- Monge ME, Dwivedi P, Zhou M, Payne M, Harris C, et al. (2014) A Tiered Analytical Approach for Investigating Poor Quality Emergency Contraceptives. *PLoS ONE* 9(4): e95353.
- Suleman S, Zeleke G, Deti H, et al. (2014) Quality of Medicines Commonly Used in the Treatment of Soil Transmitted Helminths and Giardia in Ethiopia: A Nationwide Survey. *PLoS Negl Trop Dis* 8(12): e3345.
- Khuluza F. In-vitro evaluation of the quality of Paracetamol and Co-trimoxazole tablets used in Malawi based on pharmacopoeial standards. *Malawi Medical Journal* (2014); 26 (2) 38-41
- FDA Warning: Phony Ebola Treatments Being Sold Online. *JAMA* (2014); 312 (12): 1185
- Cousins S. Contaminated vaccine deaths a serious setback for Syria. *Lancet* **2014**; 384: 1172
- Pakenham-Walsh, Ana. Confusing drug packaging contributes to death of 15 children. *Lancet GH* **2014**; 2: e634
- Axel Orozco-Hernández1. Acute sterile endophthalmitis following intravitreal bevacizumab: case series. *Clinical Ophthalmology* **2014**:8 1793–1799
- Bagcchi S. Medical negligence and substandard drugs caused deaths in Indian sterilisation programme, report finds. *BMJ* **2015**;351:h4813
- Belew S, Getachew M, Suleman Set al. Assessment of Efficacy and Quality of Two Albendazole Brands Commonly Used against Soil-Transmitted Helminth Infections in School Children in Jimma Town, Ethiopia. *PLoS Negl Trop Dis* **2015** ; 9(9):e0004057
- Williams DJ. Snake bite: a global failure to act costs thousands of lives each year. *BMJ* **2015**;351:h5378
- Vo KT et al. Counterfeit Norco Poisoning Outbreak — San Francisco Bay Area, California, March 25–April 5, **2016**. *MMWR* 2016; (16): 420-3
- Green TC and Gilbert M. Invited commentary. Counterfeit Medications and Fentanyl. *JAMA Int Med* **2016**; published on line 8th August.
- Ravinetto, R., Weggheleire, A. D., Dorlo, et al. Predictable threats to public health through delaying universal access to innovative medicines for Hepatitis C: A pharmaceutical standpoint. *Trop Med Int Health* **2016**; doi:10.1111/tmi.12784
- Hepatitis medicines: Warning concerning Harvoni® packs with counterfeit contents. Alert of the Swiss Regulatory Authority. 4th March **2016**²³.
- Torrie J, Cumin D, Sheridan J, Merry AF. Fake and expired medications in simulation-based education: an underappreciated risk to patient safety. *BMJ Qual Saf* **2016**; 25: 917-920
- McLaughlin K. Scandal clouds China's global vaccine ambitions. *Science* **2016**; 352: 6285
- DEA Intelligence Brief. Counterfeit Prescription Pills Containing Fentanyls: A Global Threat. DEA-DCT-DIB-021-16. July **2016**
- Abbasi J. Amid Reports of Infant Deaths, FTC Cracks Down on Homeopathy While FDA Investigates. *JAMA* **2017**; published online February 8, 2017
- Tanimoto T, Tsuda K, Kurokawa T et al. Essential medicines for universal health coverage. *Lancet* **2017**; 389: 1880-1
- Cyranoski D. The secret war against counterfeit science. China has a lucrative market for fake research reagents. Now some scientist are fighting back. *Nature* **2017**; 454: 148-150
- Mumphansa H, Nickerson JW, Attaran A et al. An Analysis of Substandard Propofol Detected in Use in Zambian Anesthesia. *Anesthesia Analgesia* **2017**; 125 (2): 1-4

²³ <https://www.swissmedic.ch/aktuell/00673/03287/index.html?lang=en>

- Nicolas Peyraud et al. An epidemic of dystonic reactions in central Africa. *Lancet GH* **2017**; 5: e137-8
- Mzer-Amirshahi M et al. Saline Shortages — Many Causes, No Simple Solution. *NEJM* **2018**; DOI: 10.1056/NEJMp1800347
- Belew S et al. Quality of anthelmintic medicines available in Jimma Ethiopia. *Acta Tropica* **2018** 177 (2018) 157–163
- Janvier S et al. Falsification of biotechnology drugs: current dangers and/or future disasters? *J Pharm Biomed Analysis* **2018** 161 (2018) 175–191
- Lawson G, Ogwu J, Tanna S (2018) Quantitative screening of the pharmaceutical ingredient for the rapid identification of substandard and falsified medicines using reflectance infrared spectroscopy. *PLoS ONE* **13** (8): e0202059.
- Yuan X. China's vaccine production scare. *Lancet* **2018**; 392: 371
- Editorial. Vaccine scandal and confidence crisis in China. *Lancet* **2018**; 392: 360
- Clifford K et al. Antimicrobial resistance in livestock and poor quality veterinary medicines. *Bull World Health Organ* **2018**; 96: 662-4
- Tekle T et al. Aberrant use and poor quality of trypanocides: a risk for drug resistance in south western Ethiopia. *BMC Veterinary Research* (2018) 14:4
- Ponte H et al. Quality control programmes for veterinary antimicrobial medicines. *Regulatory Toxicology and Pharmacology* **2018**; 99: 1–4
- WHO Information Note: UPDATE ON NITROSAMINE IMPURITIES. EMP/RHT/Information Note_Nitrosamine impurities 20 Nov. **2019**
- WHO Information Exchange System Alert No. 3/2016. RHT/SAV/Alert 3.2016. Falsified Hepatitis C medicines circulating in South East Asia. February **2016**
- Sartan medicines: contamination by impurities which are probable carcinogens. *Prescrire International* **2019**; 28 (207): 220-1
- WHO Information Exchange System Alert No.7/2020. Ref. RPQ/REG/ISF/Alert N°7.2020. Falsified HARVONI (Ledipasvir/sofosbuvir) identified in the WHO regions of the Americas and Europe. 8 December **2020**
- Shu Zhu et al. Falsified vardenafil tablets available online. *Journal of Pharmaceutical and Biomedical Analysis* **2020**; 177: 112872
- WHO Information Exchange System Alert No.5/2020. RPQ/REG/ISF/Alert 5.2020. Falsified and contaminated Defibrotide identified in WHO regions of Western Pacific, Europe and Eastern Mediterranean. 7 May **2020**
- WHO Information Exchange System Alert N1/2021. Ref. RPQ/REG/ISF/Alert N°1.2021. Falsified Vitamin A (Retinol) identified in the WHO Africa region. 5 March **2021**
- Kabedi NN et al. Quality of timolol eye drops marketed in Kinshasa, Democratic Republic of the Congo. *Qualité du timolol collyre vendu à Kinshasa, République Démocratique du Congo. Journal Français d'Ophthalmologie*. Available online 26 July **2021**
- WHO Information Exchange System Alert N9/2021. Ref. RPQ/REG/ISF/Alert N°9.2021. Medical Product Alert N°9/2021 Falsified Soliris identified in WHO regions of the Americas, Europe and South East Asia. 21 December **2021**
- Saliou P, Duteil Q, Plotkin SA, Gentilini M. The scourge of vaccine falsification. *Vaccine*. **2022** Mar 25;40(14):2126-2128. doi: 10.1016/j.vaccine.2022.01.063. Epub 2022 Feb 26. PMID: 35232595; PMCID: PMC8881974.
- Schwartzman GH, Dekker PK, Silverstein AS, Fontecilla NM, Norton SA. Dermatologic Consequences of Substandard, Spurious, Falsely Labeled, Falsified, and Counterfeit Medications. *Dermatol Clin*. **2022** Apr;40(2):227-236. doi: 10.1016/j.det.2021.12.008. Epub 2022 Mar 4. PMID: 35366975.
- Zheng Y, Tang Y, Tseng HC, Chang TH, Li L, Chen P, Tang Y, Lin XB, Chen X, Tang KJ. Evaluation of quality and readability of over-the-counter medication package inserts. *Res Social Adm Pharm*. **2022** Mar 25:S1551-7411(22)00088-2. doi: 10.1016/j.sapharm.2022.03.012. Epub ahead of print. PMID: 35379561.

- Vidhamaly V, Bellingham K, Newton PN, *et al.* The quality of veterinary medicines and their implications for One Health. *BMJ Global Health* **2022**;7:e008564. doi:10.1136/bmjgh-2022-008564
- Myemba DT *et al.* Microbiological Quality of Selected Local and Imported Non-Sterile Pharmaceutical Products in Dar es Salaam, Tanzania. *Infection and Drug Resistance* **2022**:15 2021–2034
- WHO Information Exchange System Alert N3/2022. Ref. RPQ/REG/ISF/Alert N°3.2022. Falsified Intratect (Human normal immunoglobulin) identified in the WHO Regions of the Americas, Eastern Mediterranean and South-East Asia. 27 May **2022**
- WHO Information Exchange System Alert N4/2022. Ref. RPQ/REG/ISF/Alert N°4.2022. Falsified DYSPORT (Clostridium botulinum type A toxin-haemagglutinin complex) identified in the WHO Regions of Europe and Eastern Mediterranean. 19 August **2022**
- WHO Information Exchange System Alert N5/2022. Ref. RPQ/REG/ISF/Alert N°5.2022. Falsified DIPRIVAN (Propofol) identified in WHO region of the Americas. 25 August **2022**