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Falsified drugs in the democratic republic of the Congo : still a long way to go

Les faux médicaments en République démocratique du Congo : encore un long chemin à parcourir

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Abstract. *Falsified medicines pose a significant threat to public health, particularly in low- and middle-income countries. The use of falsified pharmaceuticals can lead to poisoning, untreated illness, premature death, and treatment failure. They can also hinder the achievement of sustainable development goals. Particularly in the DRC, the level of knowledge about this problem is low. Therefore, the objective of this paper is to determine the extent of the problem of substandard and falsified medicines in the country. It is based on a retrospective review of drug alerts and scientific publications, based on a search of the Scopus, Google Scholar, PubMed databases and the Congolese Ministry of Health alerts issued between 2000 and 2021. It was found that four classes of drugs, namely: antimalarials, antibiotics, anti-inflammatories and antivirals, were the most falsified/counterfeited in the studies conducted. This highlights the need to overcome obstacles in the fight against falsified medicines in the DRC, including a lack of reliable and scalable technology to detect counterfeits before they reach patients, lack of consensus on definitions, weak national leadership and accountability systems, and manufacturing and regulatory challenges.*

Keywords: falsified drugs, substandard drugs, poor-quality drugs, low-income countries.

Résumé. *Les médicaments falsifiés constituent une menace importante pour la santé publique, en particulier dans les pays à revenu faible ou intermédiaire. L›utilisation de produits pharmaceutiques falsifiés peut entraîner des empoisonnements, des maladies non traitées, des décès prématurés et des échecs de traitement. Ils peuvent, par ailleurs, entraver la réalisation des objectifs de développement durable.*

S'agissant particulièrement de la RDC, le niveau de connaissance de ce problème est faible. Dès lors, l'objectif de ce papier est de déterminer l›ampleur de la problématique des médicaments de qualité inférieure et falsifiés dans le pays. Sa conception repose sur une revue rétrospective des alertes médicamenteuses et des publications scientifiques, sur la base d'une recherche dans les bases de données Scopus, Google Scholar, PubMed et les alertes du ministère congolais de la santé émises entre 2000 et 2021.

Il en ressort que quatre classes de médicaments, à savoir : les antipaludéens, les antibiotiques, les anti-inflammatoires et les antiviraux, ont été les plus falsifiés/contrefaits dans les études menées. D'où la nécessité de surmonter les obstacles dans sa lutte contre les médicaments falsifiés en RDC, notamment un manque de technologie fiable et évolutive pour détecter les contrefaçons avant qu'elles n'atteignent les patients, l'absence de consensus sur les définitions, la faiblesse des systèmes de leadership et de responsabilisation au niveau national, et les défis de fabrication et de réglementation.

Mots-clés : médicaments falsifiés, médicaments de qualité inférieure, pays à faible revenu.

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Introduction

In recent years, the issue of falsified drugs has been referred to a global pandemic, with worrisome reports on its scope and impact (G. M. L. Nayyar, Breman, et al., 2015). Traffic continues to expand exponentially. Patients without access to high-quality pharmaceuticals that are effective in treating their diseases have significant consequences everywhere, especially in underdeveloped countries. Nowadays, the sale of pharmaceuticals on the internet has increased the likelihood of this occurrence. A meta-analysis of 21 surveys in Sub-Saharan Africa found that 35% of antimalarial drugs failed chemical testing and 20% were falsified (G. M. Nayyar et al., 2012a). Falsified medicines represent a particularly large proportion of all medicines sold in Africa (Adepoju, 2020). Renschler et al. found that poor quality antimalarials may be linked to over 120.000 child deaths in sub-Saharan Africa each year (Renschler et al., 2015)substandard, or degraded. Taylor et al. investigated the quality of different drugs obtained from retail pharmacies in two urban areas of Nigeria. The study found that all antibiotic and antimalarial samples contained active pharmaceutical ingredient concentrations outside the officially specified limits (Taylor et al., 2001). In another study, approximately 40.5 % (n=116) of sulfadoxine-pyrimethamine and amodiaquine products (Kenya) failed the USP requirements for drug content and dissolution (Amin et al., 2005). Several other studies including those (Gaudiano et al.. (2007) and Hosseinipour et al. (27), ddemonstrateddrated al. (2008), and Minzi et al. (2003)"container-title":"Malaria Journal","DOI":"10.1186/1475-2875-6-22","language":"en","note":"publisher: BioMed Central\nPMID: 17316432","page":"22","source":"www.ncbi.nlm.nih.gov","title":"Medicines informal market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials","title-short":"Medicines informal market in Congo, Burundi and Angola","volume":"6","author":[{"family":"Gaudiano","given":"Maria Cristina"},{"family":"Maggio","given":"Anna Di"},{"family":"Cocchieri","given":"Emilia"},{"family":"Antoniella","given":"Eleonora"},{"family":"Bertocchi","given":"Paola"},{"family":"Alimonti","given":"Stefano"},{"family":"Valvo","given":"Luisa"}],"issued":{"date-parts":[["2007"]]}},"label":"page"},{"id":594,"uris":["http://zotero.org/users/8300523/items/7G3D5HG5"],"itemData":{"id":594,"type":"article-journal","abstract":"BACKGROUND: The Malawian antiretroviral program uses generic Triomune (stavudine, lamivudine, and nevirapine, have proven the circulation of falsified drugs in the African pharmaceutical market.

Low-income countries are particularly vulnerable to this problem because they frequently lack the resources, infrastructure, and trained personnel necessary to conduct regular surveillance for falsified medical products and to implement effective law enforcement measures against criminals (Petersen et al., 2017)especially in low- and middle-income countries. Their identification using pharmacopeial analysis is expensive and requires sophisticated equipment and highly trained personnel. Simple, low-cost technologies are required in addition to full pharmacopeial analysis in order to accomplish widespread routine surveillance for poor-quality medicines in low- and middle-income countries. Methods Ten faith-based drug supply organizations in seven countries of Africa and Asia were each equipped with a Minilab of the Global Pharma Health Fund (GPHF, Frankfurt, Germany. The Lancet Commission on Essential Medicines has acknowledged that "the scale of this issue remains unknown (Wirtz et al., 2017).

With more than 94 million inhabitants, the Democratic Republic of the Congo (DRC) is currently the fourth largest country in Africa (*DR Congo Population (2022) - Worldometer*, 2022). According to the WHO African regional office, the DRC recorded 207.500 deaths from non-communicable diseases in 2016 (*World Health Organization—WHO | 57 | v23 | The Europa Directory of Int*, s. d.). This is partly due to the changing demographics of the country, which has led to an increase in the demand for safe, effective, and inexpensive drugs that meet local needs. There is a lack of data on the extent of this epidemic in the DRC as little nationwide research has been conducted on this topic. This is due to many challenges faced by Congolese researchers, including insufficient academic capacity, lack of infrastructure, poor accessibility to educational resources, and lack of adequate

research data. Most published studies have focused on antimalarials, antiretrovirals, and antibiotics, which are commonly used by the population. Furthermore, the country's pharmaceutical manufacturing, import, supply, and distribution operations are poorly regulated, and even not at all, and the implementation of regulations is difficult, as evidenced by the absence or inadequacy of drug control, the random supply of pharmaceuticals, corruption, and vested interests (Tshilombo et al., 2018) adapted HPLC analytical USP methods were applied to evaluate the quality of the amoxicillin (with or without potassium clavulanate. The drug distribution system is completely out of control; a drug can be purchased on the street, on the market, or in charlatan-run pharmacies. Falsified drugs have various adverse effects and dangers, including therapeutic failure, drug poisoning, microbiological resistance, and death. It is a known fact that falsified drugs with erroneous chemicals may cause further ailments or necessitate the need for extra medical intervention (Newton et al., 2006; Rahman et al., 2018)mortality, and drug resistance, and leads to spurious reporting of resistance and toxicity and loss of confidence in health-care systems. Counterfeit drugs particularly affect the most disadvantaged people in poor countries. Although advances in forensic chemical analysis and simple field tests will enhance drug quality monitoring, improved access to inexpensive genuine medicines, support of drug regulatory authorities, more open reporting, vigorous law enforcement, and more international cooperation with determined political leadership will be essential to counter this threat.","container-title":"The Lancet Infectious Diseases","-DOI":"10.1016/S1473-3099(06. Poor clinical results associated with the use of falsified drugs gradually erode public confidence in the healthcare system and legitimate professionals who deliver it over time.

To the best of our knowledge, little is known about falsified medicines in the DRC. Therefore, this review aims to summarize published studies on this topic in a non-exhaustive manner. Furthermore, some recommendations will be provided to improve the quality of drug regulations in the country.

1. **Falsified or substandard drugs: What is this difference?**

In general, in high-income countries, the problem of poor-quality medicines is approached from one angle: the fight against falsified medicines, which are products intentionally and fraudulently modified and do not contain active pharmaceutical ingredients (API), the wrong dose of API, or the wrong API (G. M. L. Nayyar, Attaran, et al., 2015). Expensive (such as bevacizumab) and dramatic (such as death from using a falsified drug to treat erectile dysfunction) events are frequently mentioned in drug fraud reports. Therefore, identification of falsified drugs is of primary importance. However, in developing countries, the entire supply chain is of poor quality, with only one type of falsified drug. A more widespread problem may be that of substandard drugs, which are genuine drugs produced by legitimate manufacturers but do not meet the quality specifications that the producer claims they meet (Clift, 2010). For example, they may contain fewer (or more) active ingredients than those stated in the package.

2. **Studies reporting falsified drugs in the DRC**

Several scientific studies have revealed the presence of falsified drugs in the Congolese pharmaceutical market. Table 1 summarizes the studies found in the literature.

Table 1. Literature about falsified drugs in the Congolese pharmaceutical market

Drug name/class	Sampling site	Findings	Reference
Antibiotics and drugs against Noncommunicable Diseases	Ituri, North Kivu, South Kivu, and Tanganyika	Overall, 8.5% of the samples failed USP specifications for the content of the API and 11.7% failed dissolution testing. Three samples (0.6%) were identified as falsified	(Schäfermann et al., 2020)
Antimalarial: artemether-lumefantrine	Goma, Kikwit, Kinshasa, Kisangani, Lubumbashi, Matadi, Mbandaka, and Mbuji-Mayi	The result showed that 46 (30.7%) samples had artemether contents below 90% and 17 (11.3%) above 110% of the content claimed on the label. For lumefantrine, 32 (21.7%) samples had contents below 90%, and 8 (5.3%) had contents above 110%.	(Mufusama et al., 2018)the quality of antimalarial artemether-lumefantrine (AL
Antibiotics, antimalarials	Bukavu and Bunia	2.7 % of the tested samples were falsified	(Petersen et al., 2017)especially in low- and middle-income countries. Their identification using pharmacopeial analysis is expensive and requires sophisticated equipment and highly trained personnel. Simple, low-cost technologies are required in addition to full pharmacopeial analysis in order to accomplish widespread routine surveillance for poor-quality medicines in low- and middle-income countries. Methods Ten faith-based drug supply organizations in seven countries of Africa and Asia were each equipped with a Minilab of the Global Pharma Health Fund (GPHF, Frankfurt, Germany.
Opioid: tramadol	Kisangani	The study revealed that 25 samples out of 89 were not compliant in terms of manufacturing license, registration status in DRC and content as well.	(Amani et al., 2021)
Antiviral (covid-19); Chloroquine phosphate	Kinshasa	The results confirmed the falsified nature of the samples, highlighting the presence of metronidazole at low dose in four samples, too low levels of chloroquine in two samples, and substitution of chloroquine phosphate by paracetamol in one sample.	(Waffo Tchounga et al., 2021)
Antimalarial: artemether	Kinshasa	21% were found non-conform for the content in API and 48% were under-dosed in artemether.	(Ravinetto et al., 2015)

3. Economic and social impact of falsified drugs

Falsified drugs increase healthcare costs for both patients and the healthcare system. Drugs are expensive, and patients and governments waste money for ineffective treatment. This leads to persistent disease, thus reducing worker productivity. Falsified medicines shorten the effective shelf life of medicines by promoting antimicrobial resistance. They undermine public confidence in the healthcare system as well as in all other governmental institutions. Criminal cartels are frequently involved in the distribution of drugs that have been falsified (Rahman et al., 2006; Rahman et al., 2018)mortality, and drug resistance, and leads to spurious reporting of resistance and toxicity and loss of confidence in health-care systems. Counterfeit drugs particularly affect the most disadvantaged people in poor countries. Although advances in forensic chemical analysis and simple field tests will enhance drug quality monitoring, improved access to inexpensive genuine medicines, support of drug regulatory authorities, more open reporting, vigorous law enforcement, and more international cooperation with determined political leadership will be essential to counter this threat.»,»container-title»:»The Lancet Infectious Diseases»,»DOI»:»10.1016/S1473-3099(06. Selling them raises money for additional crimes, allows criminals to purchase weapons and ammunition, and allows corrupt officials to gain power. In most cases, victims of tainted and inadequate drugs are unaware that they have been wronged and, hence, do not have the opportunity to seek restitution. Illegal pharmaceutical trade contributes to the deterioration of the already precarious political infrastructure, thus contributing to the vicious cycle of poverty and criminality.

4. Consequences of falsified drugs

A reliable, good-quality drug supply is critical for health; however, it is frequently lacking in nations with poor regulatory regimes, such as the DRC. The use of falsified drugs can cause poisoning, untreated illnesses, early death, and treatment failure. One of the most dramatic cases of poisoning with falsified drugs occurred in Ituri, eastern DRC. In 2015, more than 1.000 people were admitted to the hospital after experiencing toxic effects from falsified and wrongly labeled drugs. Initially, the health staff suspected an outbreak of meningitis. However, further examination revealed that the symptoms were caused by the ingestion of toxic chemicals. After examining samples of pharmaceuticals routinely prescribed in the area, the toxicity was traced back to tablets sold locally as diazepam, which actually contained haloperidol, an antipsychotic drug used to treat schizophrenia (Peyraud et al., 2017).

5. Combating falsified drugs in the country

For decades, DRC has faced an overwhelmingly falsified drug problem. Street vendors across the country provide low-cost medication to those who otherwise cannot afford it. Therefore, it is not surprising that the most widespread falsified drugs are in high demand, such as antimalarials, antibiotics, and anti-inflammatory drugs. Currently, international public health organizations are at the forefront of developing strategies to combat falsified drugs (Gostin et al., 2013). One of these strategies is the WHO pre-qualification of manufacturers. WHO pre-qualification is a systematic process used to determine the capacity of a manufacturer to produce products of consistent quality in accordance with international standards and WHO specifications (Schäfermann et al., 2020). It provides a list of those who meet the WHO standards to countries and procurement agencies to promote the purchase of high-quality drugs in developing countries. This initiative initially concerned medicines for malaria, tuberculosis, and HIV/AIDS, and was extended to 316 medicines for priority diseases at the end of 2012. Currently, no manufacturing facilities in the DRC are pre-qualified by WHO.

Despite these efforts, the percentage of falsified drugs in the DRC is increasing. This was partly due to the non-application of recommendations issued by experts in the pharmaceutical field. The government's efforts to clean the pharmaceutical sector are weak. Since the main source of falsified medicines is imports, the government, through its specialized services, should rationalize the regulation and border control of the consignments

of medicines entering the country. Admittedly, these services exist (OCC, DPM, etc.), but their work is not tangible. The state must centralize the system of purchase and distribution of drugs, especially those for common diseases (malaria, tuberculosis, etc.), to exercise control over suppliers. Much work is also needed to regulate public pharmacies. Only well-identified establishments with responsible pharmacists should be authorized.

6. **Discussion and concluding remarks.**

Poor-quality medicines pose an immediate and urgent threat to healthcare facilities and expose patients, healthcare workers, and governments to increased morbidity, mortality, economic loss, and drug resistance. Poor quality drugs represent a significant share of the drugs consumed in the DRC, affecting the most vulnerable populations. Up to 80% of pharmaceuticals are imported, and most counterfeit pharmaceuticals are imported through illicit trade routes or channels (Karungamye, 2023)counterfeit and substandard pharmaceuticals are a severe public health concern. This is a global issue, but it is especially prevalent in African countries, where more than 30 % of the pharmaceuticals supplied are counterfeit or substandard. Many reasons contribute to the emergence of this issue, which differ from country to country. Online business, light sanctions for drug infringers, ignorance, and an absence of meaningful collaboration amongst players are all variables involved. The Tanzania Food and Drugs Authority (TFDA. In addition to imported drugs, some locally produced drugs are counterfeited. Poor quality problems are not limited to basic drugs and can be extended to other pharmaceutical drugs and personal care products. Available data on poor-quality medicines in the DRC have significant limitations, including a lack of data for packaging analysis, insufficient convenience sampling, and lack of data from provinces.

To detect poor-quality drugs accurately, standardized methods with good quality control, supporting technology, and trained and well-supervised personnel are essential (Nayyar et al., 2012b)which pose an urgent threat to vulnerable populations and jeopardise progress and investments in combating malaria. Emergence of artemisinin resistance or tolerance in Plasmodium falciparum on the Thailand–Cambodia border makes protection of the effectiveness of the drug supply imperative. We reviewed published and unpublished studies reporting chemical analyses and assessments of packaging of antimalarial drugs. Of 1437 samples of drugs in five classes from seven countries in southeast Asia, 497 (35%. Colorimetric tests, portable and battery-powered photometers, portable mass spectrometers, Raman spectroscopy, and near-infrared spectroscopy can allow pharmacy inspectors to monitor drug supply. Although the strengths and weaknesses of these tests are well known, conclusive comparative evaluations in the field are lacking.

In addition to their direct negative effects on patients and their families, poor-quality medicines harm health workers and services, pharmaceutical companies, and the economy by increasing patient medical care and expenditures and reducing the credibility of the health system (Antignac et al., 2019). Available data do not suggest definitive sources, supply chain entry points, or countries as major producers or distributors of substandard drugs. Poor quality drugs are widely available and can be purchased online. The mechanisms involved in the production and sale of substandard, falsified, and degraded drugs vary, as do the sources of these drugs. One of the challenges in the DRC may be the lack of enforcement and sanctions, as well as the absence of legislation and weak authorities that allow illegal counterfeiting businesses to thrive. Despite serious regulatory irregularities such as the sale of controlled pharmaceuticals, bulk tablets, and unregistered drugs, as well as an almost total shortage of qualified sales staff, research on pharmacies open to the public in the RDC revealed that these operate with the tacit authorization of the government or municipality.

There is an urgent need to improve the quality of drugs sold to Congolese patients. This will be done through several points, including: (1) conducting research to develop and select the most accurate and cost-effective tools to control the quality of medicines entering the country; (2) strengthening national legislation to facilitate the

emergence of high-quality medicines and protect the country against criminals and negligents who manufacture, distribute, and sell falsified medicines; (3) collaborating with highly qualified and recognized organizations (WHO, FDA, EMA) to establish training programs, guidelines, and drug quality monitoring in collaboration with local universities, pharmaceutical companies, and the agency of regulation; and (4) raising public awareness of the dangers associated with the use of falsified medicines.

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