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Substandard and falsified medicines in the Democratic Republic of the Congo: Situational analysis and future perspetives

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ABSTRACT

Introduction

The circulation of counterfeit medicines in the Democratic Republic of the Congo (DRC) and elsewhere is driven by several factors, including regulatory weaknesses, inadequate inspections, and porous borders. This issue is frequently highlighted in case reports and scientific publications, demonstrating the link between regulatory capacity—particularly the maturity level of the National Regulatory Authority (NRA)—and the prevalence of substandard and falsified medicines.

Purpose

To assess the extent of counterfeit medicines in the DRC and propose future perspectives.

Methods

Publications related to counterfeit medicines were collected from databases such as ScienceDirect, PubMed, Google, Google Scholar, ACOREP, the World Health Organization (WHO), websites of major organizations, case reports, and alerts. Searches were conducted using the keywords "falsified," "substandard," "counterfeit," and "alert" (in both English and French). References were managed using Zotero software and analyzed through a structured literature review flowchart. Inclusion criteria comprised articles published between 2010 and 2025, including case reports, alerts, and study summaries focusing on the prevention, detection, and response to counterfeit medicines for human use in the DRC or other low- and middle-income countries.

Results

Of the 238 articles and documents identified, 62 met the inclusion criteria. The average prevalence of counterfeit medicines in Africa was estimated at 18.7% (range: 12.9%–24.5%), with 34.6% classified as unregistered. In the DRC, the consolidated average prevalence rates were 22.4% for counterfeit medicines, 22.2% for substandard medicines, and 35% for unregistered medicines.

Conclusion

The Congolese Pharmaceutical Regulatory Authority (ACOREP) has not yet achieved WHO maturity level 3 (ML3) in accordance with good regulatory practices. The Congolese government is therefore encouraged to strengthen its commitment to establishing a robust and deterrent national regulatory system (NRA) to combat the circulation of counterfeit medicines, particularly given the high proportion (approximately 35%) of unregistered products.

INTRODUCTION

Access to high-quality, safe, effective, and affordable medicines is a fundamental pillar of Universal Health Coverage (UHC) and a key determinant of health system performance (Nana, 2025). The Democratic Republic of the Congo (DRC), a low-income country, faces not only communicable and non-communicable diseases but also the growing problem of substandard and falsified medicines (PNDS-RDC-SPA30, 2016–2020).

The phenomenon of falsified medicines is now considered a major public health scourge and remains a persistent threat to patient safety and the credibility of healthcare systems (Nduu et al., 2023). In its Strategic Plan for Universal Health Coverage (Plan UHC, 2020), the DRC acknowledges that, despite efforts made by the government and its technical and financial partners (TFPs), significant structural deficiencies persist. National procurement centers continue to supply less than 50% of the medicines listed on the National List of Essential Medicines (NLEM), while the availability of generic essential medicines in health facilities averages only 29%, according to the Service Availability and Readiness Assessment (SARA) survey (OpenAFRICA, 2015).

These low availability levels contribute to chronic stockouts (Sabiti et al., n.d.) and facilitate the infiltration of substandard and falsified medicines into both formal and informal supply chains (Fryze & Naughton, 2025; Pinel, 2017). Available data highlight the magnitude of this issue in the DRC. Two studies conducted in Lubumbashi—one in 2015 (Tshilumba et al., 2015) focusing on anti-infectives and another in 2023 (Tshilumba et al., 2023)—reported that 31.7% (n = 60) and 25% (n = 95, $p < .05$), respectively, of samples were suspected to be substandard or falsified according to World Health Organization (WHO) criteria.

Similarly, concerns regarding the quality of azithromycin in Kisangani have been reported (Ngwato et al., 2025). In Kinshasa, Mavungu Landu et al. (2019) found that 19% of antimalarial medicines were non-compliant and 47% were unregistered. Pharmaceutical market surveillance reports (Rounds 1 and 2–3) published by the Congolese Pharmaceutical Regulatory Authority (ACOREP) indicate that the proportion of unregistered antimalarial medicines increased from approximately 24.4% in 2022 to 32% in 2024 (ACOREP PMS Report, 2022–2024). Additionally, Muya et al. (2025) reported a prevalence of 41.7% (n = 12) of substandard doxycycline samples in Kinshasa. These findings extend across multiple therapeutic categories, confirming the systemic nature of the problem (UNCTAD, 2019; PSI, n.d.).

At the regional level, Pinel (2017) reports that nearly 90% of National Regulatory Authorities (NRAs) in Africa lack the capacity to ensure effective pharmaceutical market surveillance, particularly for the quality control of imported medicines (estimated at 80–90%). The DRC is among these countries, as its regulatory authority (ACOREP) is currently classified at maturity level 1 according to the WHO Global Benchmarking Tool (Report cGBT, 2024), with market surveillance activities still largely dependent on technical and financial partners.

In this context of regulatory vulnerability (Nduu et al., 2015), pharmaceutical quality assurance—both during manufacturing and post-marketing—is more critical than ever and requires strict compliance with good regulatory practices (Valentin, 2022). Since the 1950s, countries with well-established regulatory systems have progressively strengthened requirements related to the quality, safety, and efficacy of medicines (Abraham, 2010a).

The World Health Organization estimates that approximately 10% of medicines circulating globally are substandard or falsified (WHO, 2017), with this proportion rising to between 30% and 70% in certain regions of sub-Saharan Africa (Monneret, 2017). This situation is particularly alarming in settings affected by priority diseases such as malaria, which remains endemic in nearly 100 countries and places approximately 3 billion people at risk (WHO, 2022). Illicit pharmaceutical networks have increasingly infiltrated official distribution systems, introducing falsified and substandard products (Fryze et al., 2025; Persson et al., 2024).

This article aims to assess the current scale of substandard and falsified medicines in the DRC and to propose future perspectives. This issue represents a major public health challenge, contributing to treatment failures, increased morbidity and mortality, antimicrobial resistance (Cavany et al., 2023), significant economic losses, and the weakening of health systems (Beargie et al., 2019).

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METHODS

Data were collected through a comprehensive review of multiple sources, including PubMed, ScienceDirect, the World Health Organization (WHO), the Congolese Pharmaceutical Regulatory Authority (ACOREP), Google Scholar, and Google, as well as websites of organizations involved in combating substandard and falsified products (SFPs). All retrieved references were managed using Zotero software.

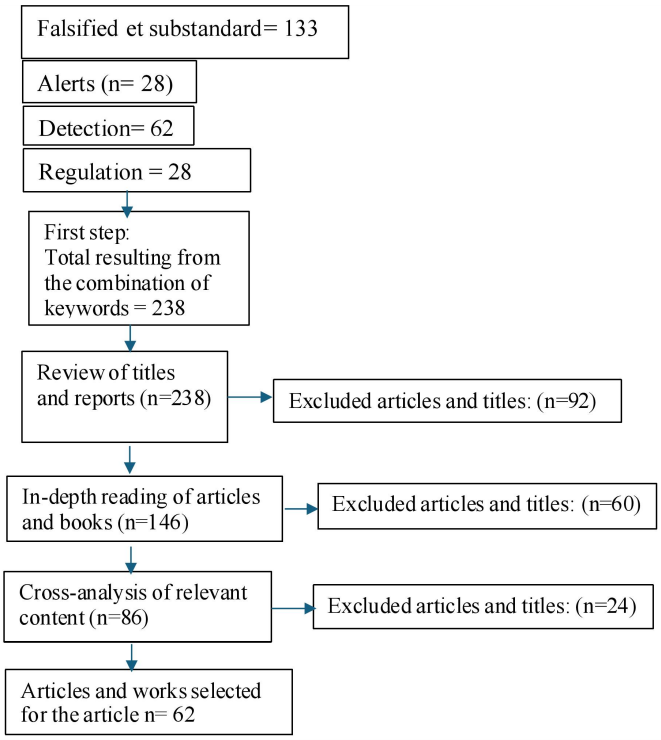
A structured literature review flowchart was used to select relevant studies based on predefined inclusion criteria.

Literature Review Flowchart

- Substandard and falsified medicines: 133
- Detection: 62
- Regulations, intellectual property rights, and DRC reports: 12 + 4 + 12 = 28
- WHO alerts and miscellaneous: 15

Total identified records: 238

Figure 1:
Literature review flowchart used for study selection



This diagram illustrates the screening process for article selection (238 − 92 = 146; 146 − 60 = 86; 86 − 24 = 62).

Inclusion Criteria

The inclusion criteria comprised published articles, case reports, and study summaries on medicine quality; government reports; legislative documents; and alerts related to the detection and seizure of substandard and falsified medicines for human use in the DRC or sub-Saharan Africa.

Analytical Framework

The analytical framework adopted for combating substandard and falsified medicines is based on the consensus model of prevention–detection–response (Kniazkov et al., 2020). This framework is aligned with the resolutions of the World Health Assembly (WHO, 2017).

Classification and Definitions of Substandard and Falsified Medicines

The WHO classifies poor-quality medicines into three main categories:

- Falsified (counterfeit) medicines: Products deliberately and fraudulently misrepresented, often associated with violations of intellectual property rights.
- Substandard medicines: Authorized medical products that fail to meet quality standards or specifications due to errors in manufacturing, storage, or distribution, or non-compliance with Good Manufacturing Practices (GMP) (WHO, 2010).
- Unregistered/unlicensed medicines: Products for which no marketing authorization has been granted and whose manufacturer or applicant may be unknown (Hauk et al., 2021).

The term *adulterated* is sometimes used broadly to describe products that have undergone deliberate alteration.

Definitions

Falsified medicines:

The WHO formally adopted the term *falsified medicines* in May 2017 during the World Health Assembly, replacing the term *counterfeit* (WHO, 2017). These are defined as "*medical products that deliberately or fraudulently misrepresent their identity, composition, or source.*" This definition distinguishes falsified medicines from other categories of poor-quality products.

Substandard medicines:

Substandard medicines are authorized products that do not meet established quality specifications. They may contain incorrect amounts of active or inactive ingredients and are often ineffective or potentially harmful (Cavany et al., 2023; Hauk et al., 2021).

Unregistered or unlicensed medicines:

These are products that have not undergone regulatory evaluation for quality, safety, and efficacy and are therefore considered high-risk (Khurelbat et al., 2020).

Table 1:
Comparison of Characteristics of Falsified and Substandard Medicines (WHO, 20171; WHO, 2017b)

Characteristic	Falsified/Counterfeit Medicines	Substandard/Poor-Quality Medicines
Intention	Fraudulent and deliberate	Unintentional error or negligence
Origin	Imitation of an authentic product intended to deceive	Genuine product from an authorized manufacturer but of poor quality
Objective	Financial gain through deception of consumers, distributors, and authorities	No intention to deceive
Product quality	May contain incorrect ingredients or harmful substances	May follow the intended formulation but fails to meet required quality standards (GMP)
Regulatory status	Often outside regulatory control	Can be identified and removed through traceability and batch recall systems

Note: Adapted from WHO definitions.

Prevention and Initiatives to Combat Substandard and Falsified Medicines

Strengthening Border Controls

Advanced technologies play a crucial role in surveillance. Customs authorities must be equipped with practical detection tools to identify suspicious pharmaceutical products.

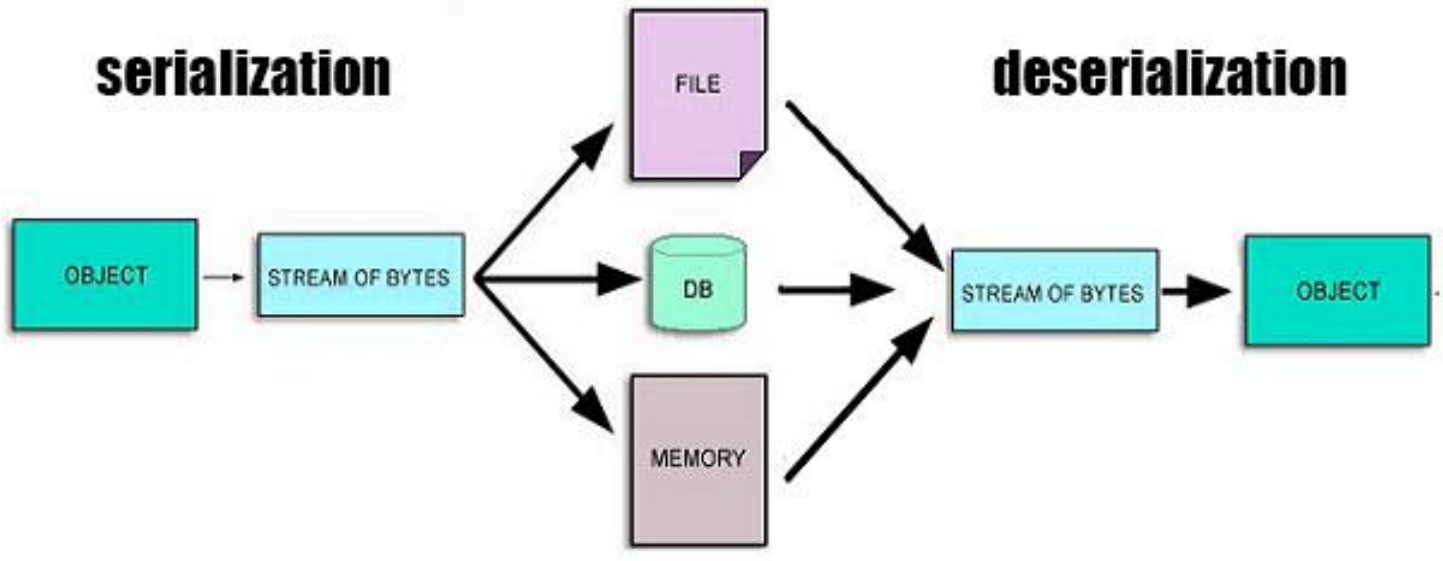
Expanding Healthcare Coverage, Including Medicines

Universal health coverage aligns with Sustainable Development Goal (SDG) target 3.8, although progress remains uneven (Guterres, 2023). According to the DRC's UHC Strategic Plan (Plan UHC, 2020), strengthening governance in the pharmaceutical sector is essential to reduce the circulation of falsified medicines.

Serialization

Serialization ensures traceability at the individual package level, enabling verification of authenticity throughout the supply chain. Information is encoded in a two-dimensional Data Matrix code and printed in human-readable form on packaging (Serialization Guide, 2018).

Figure 2:
Illustration of the authentication and traceability process (Eshce, 2007)



Anti-Tampering Devices

Tamper-evident devices, such as seals or closures, ensure that packaging has not been altered. These features are integrated into serialization systems and must be verified by healthcare professionals (Leem, 2020).

Figure 3:
Generic image, same medication (press release) (PharmaliZr, n.d.)

Regulation of Online Sales

The rise of online pharmacies presents regulatory challenges, including the proliferation of unauthorized websites and falsified medicines (Delforge, 2017; Persson et al., 2024).

Technical Monitoring by Healthcare Professionals

Healthcare professionals play a key role in detecting and preventing the circulation of falsified medicines by implementing risk-based monitoring strategies (Ahmed et al., 2022).

Guidelines and Regulations

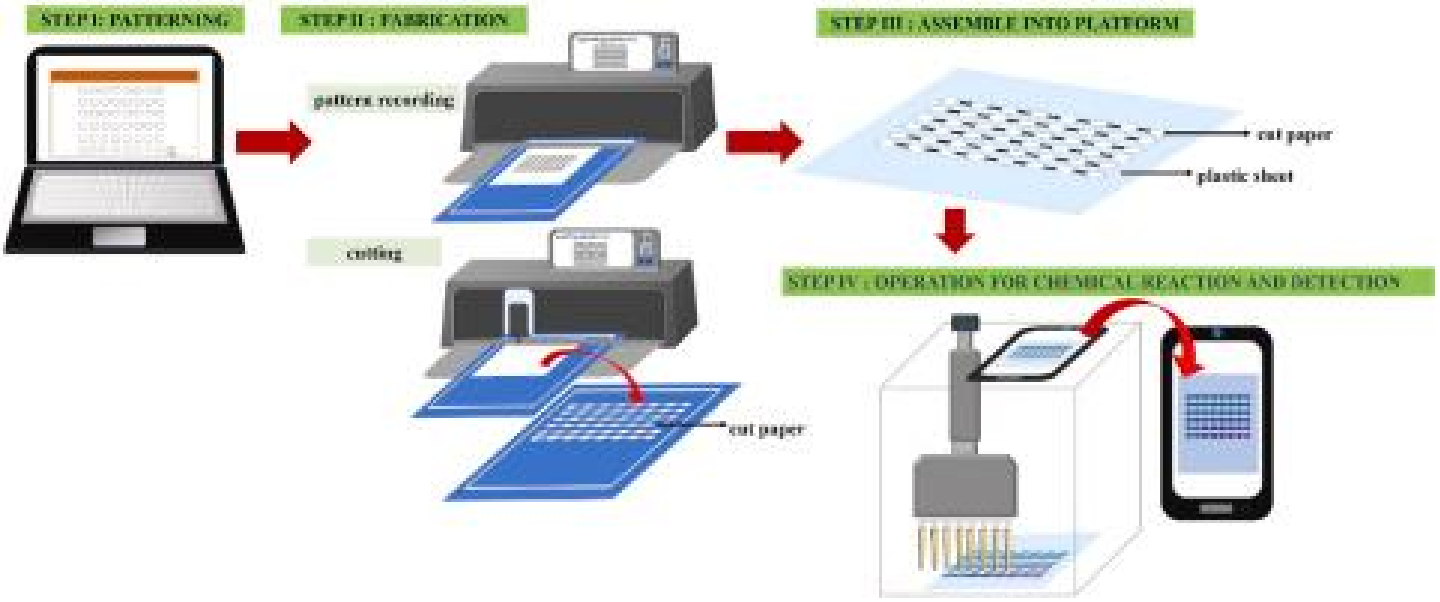
Countries with strong regulatory systems enforce strict pharmaceutical legislation. In the DRC, regulatory functions have not yet reached WHO maturity level 3 (ML3) (WHO, 2018).

Detection

Detection involves monitoring medicines throughout the supply chain using various methods:

1. Tamper-evident systems to prevent manipulation (Leem, 2020).
2. Product authentication techniques (e.g., holograms, special inks, microscopic markers) (Hauk et al., 2021).
3. Paper Analytical Devices (PADs) for rapid screening of antibiotics (Kiwfo et al., 2022).
4. Chromatographic techniques with detectors such as UV, MS, fluorescence, and FID (Suárez-González et al., 2022).
5. Portable Raman spectroscopy for rapid identification (Mosca et al., 2023; Sanada et al., 2020).
6. Use of Minilabs for screening in low-income settings (Lächele et al., n.d.).
7. Combined analytical methods (Opuni et al., 2019).
8. Mobile authentication systems (MAS) (Ciapponi et al., 2021).

Figure 4:
Example of a paper-based analytical device used for detecting counterfeit medicines (Kiwfo et al., 2021)



Response

Following detection, responses include legal prosecution of offenders and strengthened pharmaceutical market surveillance. Measures include batch recalls, sanctions, and regulatory enforcement coordinated by national authorities. These actions aim to combat illegal manufacturing, distribution, and sale of medicines (DRC, 2015).

Drug Lifecycle Monitoring (Pre-Marketing and Post-Marketing Authorization)

The lifecycle of medicinal products in the DRC must be rigorously monitored before and after marketing authorization (MA). According to Leem (2017), this lifecycle includes:

- Pre-marketing phase: Research and development, production, and regulatory approval
- Post-marketing phase: Distribution (pharmacies, hospitals) and continuous monitoring (pharmacovigilance and post-marketing studies)

In the DRC, this process is governed by national legislation and regulatory decrees related to drug approval and commercialization (Official Journal of the DRC, 2015).

RESULTS

International Regulations

Good Manufacturing Practice (GMP) Guidelines

Good Manufacturing Practice (GMP) guidelines established by the International Council for Harmonisation (ICH) and the World Health Organization (WHO) emphasize the importance of maintaining records of complaints and their trends to enable the implementation of corrective and preventive actions (CAPA) (Abraham, 2010b; WHO, 2010). Regulatory authorities harmonize technical standards related to medicines before and after marketing authorization, covering quality, safety, efficacy, and multidisciplinary aspects, thereby reducing duplication of testing and regulatory disparities.

ICH guidelines are organized into the following categories:

- Quality (Q): Product stability, manufacturing processes, etc.
- Safety (S): Toxicology and safety studies (e.g., S1A)
- Efficacy (E): Clinical trials and Good Clinical Practice (e.g., E6)
- Multidisciplinary (M): Cross-cutting topics not specific to a single domain

Role of Pharmacovigilance and Post-Market Quality Monitoring

The fight against poor-quality medicines requires an integrated and multidimensional approach, including pharmacovigilance and incident reporting systems (Pozsgai et al., 2022).

For example, WHO Medical Product Alerts have highlighted serious public health risks:

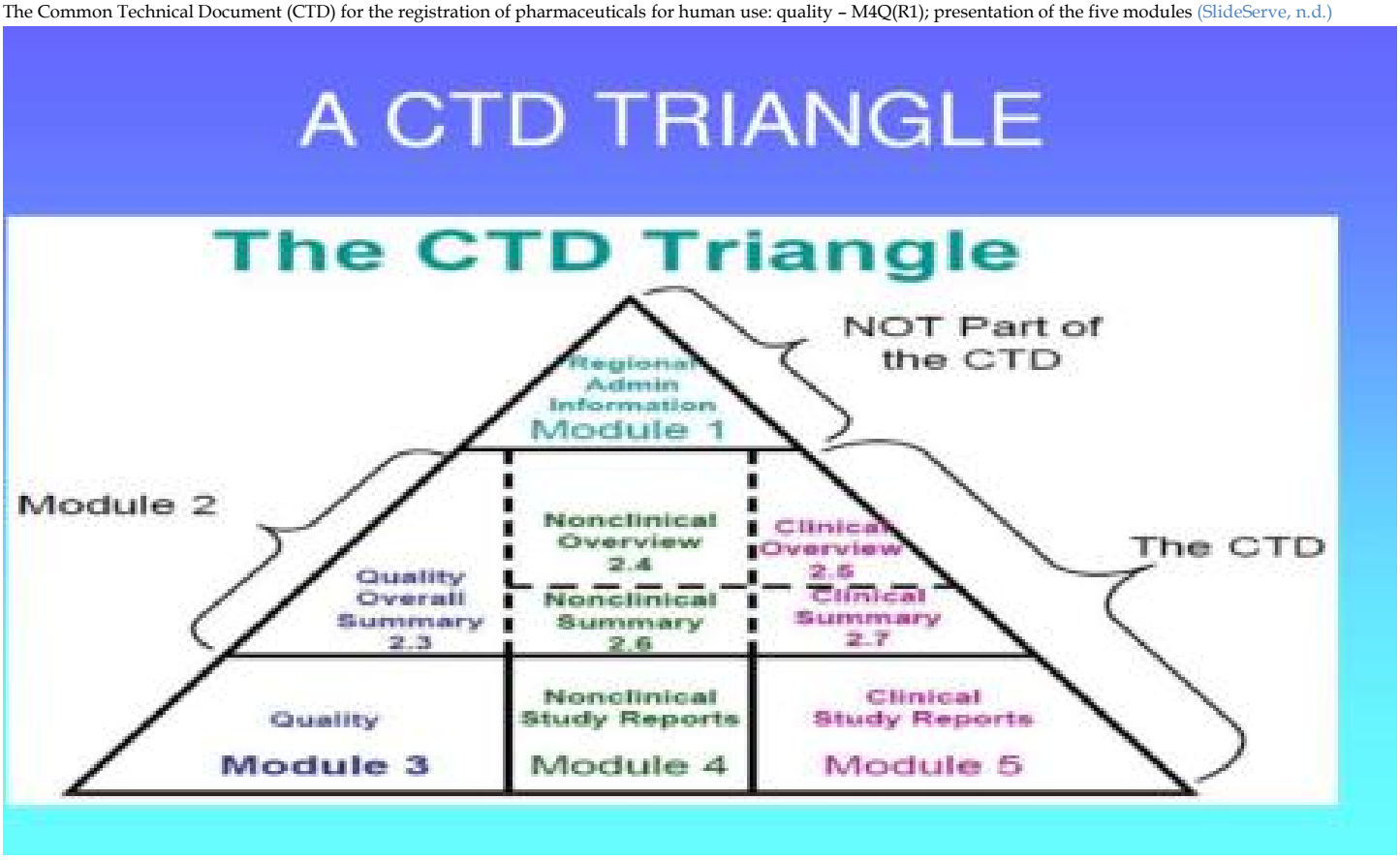
- Medical Product Alert No. 1/2023: Contamination of Ambronol syrup and DOK-1 Max syrup with diethylene glycol and/or ethylene glycol (WHO, 2023).
- Medical Product Alert No. 2/2025**:** Identification of falsified HEALMOXY (amoxicillin 500 mg) capsules in the WHO African Region (WHO, 2025).

These alerts underscore the importance of rapid detection and international information-sharing systems.

Role of the Common Technical Document (CTD) in Quality Assurance

The Common Technical Document (CTD) is an internationally harmonized format used for marketing authorization applications (Abraham, 2010a). It provides a structured presentation of scientific and technical data, facilitating evaluation by regulatory authorities across countries. The CTD ensures consistency in the assessment of a medicine's quality, safety, and efficacy.

Figure 5:
The Common Technical Document (CTD) for the registration of pharmaceuticals for human use: quality – M4Q(R1); presentation of the five modules (SlideServe, n.d.)



WHO Global Benchmarking Tool and Maturity Level (ML)

DRC Positioning

According to the ACOREP self-assessment conducted in March 2024, the Democratic Republic of the Congo remains at maturity level 1 (ML1), despite progress in certain regulatory functions (Report cGBT, 2024).

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Table 2:
ACOREP Self-Assessment Results (March 12–15, 2024)

NRA Function	Sub-indicator Score	Indicator Result	% Sub-indicators	Maturity Level (ML)
National Regulatory System (RS)	25.5 / 60.0	3 / 10	43%	1
Registration & Marketing Authorization (MA)	26.25 / 35.0	4 / 6	75%	1
Vigilance (VL)	13.5 / 26.0	3 / 6	52%	1
Market Surveillance & Control (MSC)	24.25 / 27.0	6 / 6	90%	2
Licensing of Establishments (LI)	12.75 / 19.0	4 / 6	67%	2
Regulatory Inspections (RI)	12.25 / 26.0	3 / 6	47%	1
Laboratory Testing (LT)	27.0 / 27.0	10 / 10	100%	4
Clinical Trial Oversight (CT)	6.25 / 30.0	1 / 6	21%	1
Lot Release (LR)	0.0 / 17.0	0 / 6	0%	1

Note: Results of the ACOREP self-assessment conducted in Kinshasa (WHO-supported evaluation (Congolese Pharmaceutical Regulatory Authority, 2024))

Overall, laboratory testing (ML4), market surveillance (ML2), and licensing (ML2) show progress, while most other regulatory functions remain at ML1.

Situational Analysis of Substandard and Falsified Medicines in the DRC and Africa

According to a report by Okapi (2013), the Congolese National Police (PNC), in collaboration with INTERPOL, seized approximately 30 tons of pharmaceutical products unfit for consumption in Kinshasa. This operation was part of a broader regional initiative targeting pharmaceutical crime across Central Africa.

Table 3
Summary of Selected Studies on Substandard and Falsified Medicines

Author (Year)	Therapeutic Group	Location / Sector	Sample Size (n)	Falsified (%)	Substandard (%)	Unregistered (%)
Tshilumba et al. (2015)	Antibiotics	DRC (Lubumbashi, informal sector)	60	31.7	–	–
Tshilumba et al. (2023)	Antibacterials	DRC (Haut-Katanga)	95	–	25.0	37.0
Nduu et al. (2015)	Review	DRC	–	–	–	–
Waffo Tchounga et al. (2020)	Antimalarials	DRC/Niger/Cameroon	8	75.0	12.5	75.0
Schiavetti et al. (2018)	Pediatric antimalarials	DRC (Kinshasa)	239	27.2	59.5	–
Ngwato et al. (2025)	Azithromycin	DRC (Kisangani)	14	–	20.0	–
Muya et al. (2025)	Doxycycline	DRC (Kinshasa)	12	41.7	41.7	16.6
Waffo Tchounga et al. (2023)	Antibiotics	Cameroon	150	0.7	7.9	–
Schäfermann et al. (2020)	Mixed drugs	Cameroon/DRC	506	0.6	20.2	–
Ngum et al. (2025)	Systematic review	West & Central Africa	–	26.9	26.9	–
ACOREP/USAID-PQM+	Antimalarials	DRC (7 provinces)	303	3.6	7.14	22.4
ACOREP/USAID-PQM+	Antimalarials	DRC (7 provinces)	272	1.1	6.25	32.0

Overall estimates (DRC):

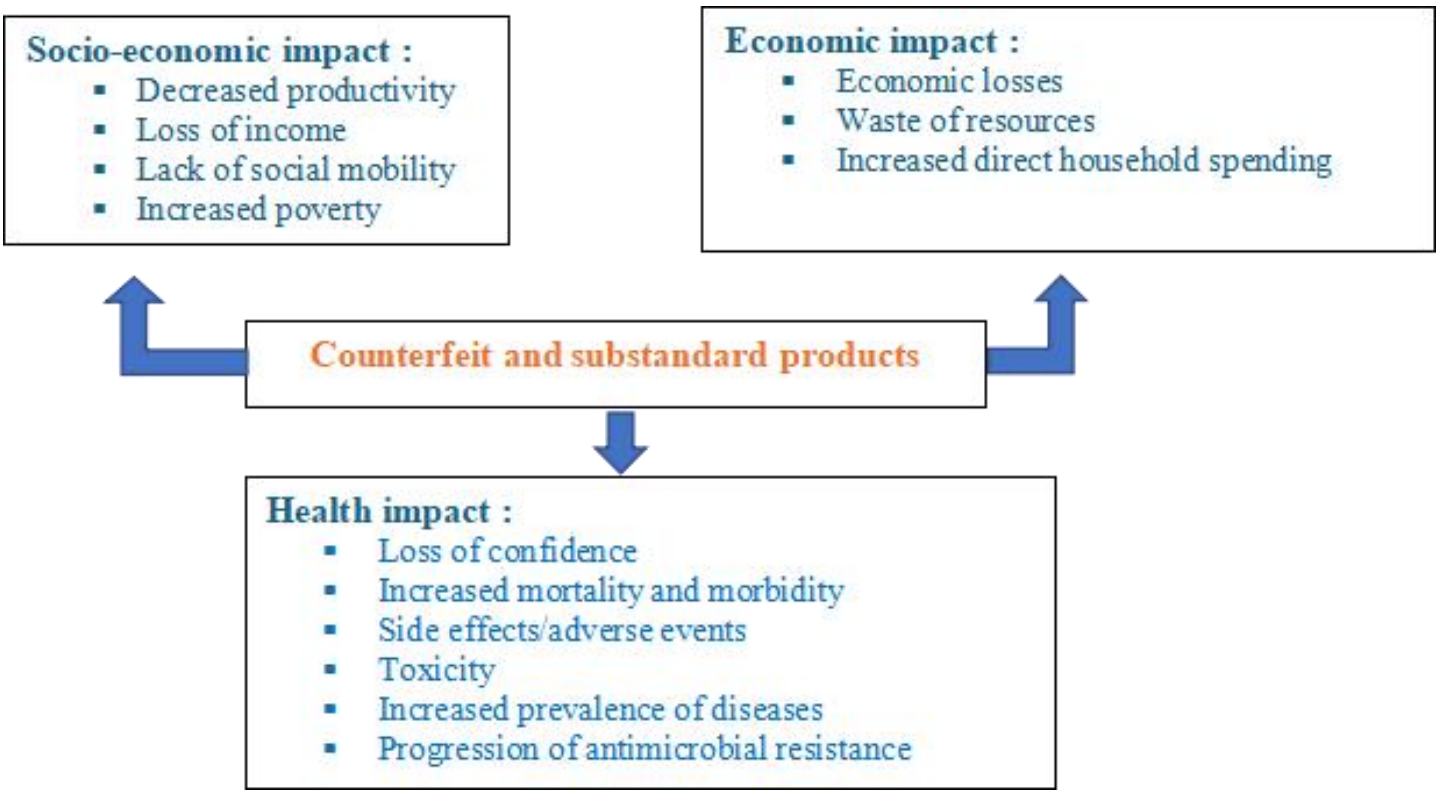
- Falsified medicines: 22.4%
- Substandard medicines: 22.2%
- Unregistered medicines: ~35.0%

These findings highlight a strong association between falsification and socioeconomic vulnerability, forming a vicious cycle in which poverty both contributes to and results from the circulation of poor-quality medicines.

Summary of the Impact of Falsified Medicines

Substandard and falsified medicines have far-reaching consequences, including treatment failure, increased morbidity and mortality, antimicrobial resistance, economic losses, and weakened health systems (Kniazkov et al., 2020; WHO, 2017).

Figure 6:
Summary of the impact of falsified medicines (Kniazkov et al., 2020b; WHO-Global Surveillance, 2017)



Future Prospects and Policy Implications

The falsification of medicines represents a complex and evolving challenge. Over the past two decades, this illegal activity has adapted to technological advances, globalization, and the expansion of e-commerce. Addressing this issue requires a multisectoral approach supported by a robust regulatory and management framework (WHO, 2017).

International and Multisectoral Collaboration

Technological innovation and collaboration among stakeholders in the pharmaceutical supply chain are essential to effectively combat substandard and falsified medicines. Strengthening partnerships between governments, regulatory authorities, healthcare professionals, and international organizations is critical to ensuring medicine quality and patient safety.

DISCUSSION

The present study provides an analysis of the situation in the Democratic Republic of the Congo (DRC), which is broadly comparable to findings reported across the African region regarding the prevalence of substandard and falsified medicines. Bhandari and Rayamajhi (2022) reported a prevalence of 13.6% (11.0%–16.3%) in low- and middle-income countries, with a regional average of 18.7% (12.9%–24.5%) in Africa and 13.7% (8.2%–19.1%) in Asia.

Similarly, Landu et al. (2019) found that 19% (14/75) of antimalarial medicines were non-compliant, followed by antibiotics (12.4%). These findings are consistent with those of Mekonnen et al. (2024), who reported an overall prevalence of 22.6% (1,718/7,592) for substandard or falsified medicines in Africa, along with 34.6% (108/312) of unregistered medicines.

According to the Congolese Pharmaceutical Regulatory Authority (ACOREP), the proportion of unregistered antimalarial medicines ranges from 24.4% to 32% (n = 303 and n = 272), while the rate of non-compliance remains relatively low (6.25%–7.14%) (ACOREP PMS Report, 2022–2024). However, earlier findings by Benedetta Schiavetti et al. (2018) reported a higher rate of 27.2% within the same pediatric therapeutic group.

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In addition, Muya et al. (2025) observed that 41.7% of doxycycline samples (n = 12) were non-compliant. In contrast, studies conducted in Cameroon reported lower rates, approximately 7.9% (n = 150) (Tchounga et al., 2023).

The most frequently targeted therapeutic groups include antibiotics, antimalarials, and antihypertensive drugs, which are consistently reported as the most affected categories in low- and middle-income countries. Approximately 60.7% (91/150) of falsified medicines were anthelmintics and antiprotozoals (Mekonnen et al., 2024), a category that includes antimalarials. In contrast, in high-income countries, the most affected therapeutic classes are genitourinary, central nervous system (CNS), and metabolic drugs (PSI, n.d.).

A common feature across health systems with high levels of substandard and falsified medicines is the presence of weak regulatory frameworks. These weaknesses result in insufficient inspections and audits throughout the supply chain and are often associated with low regulatory maturity levels (WHO, 2017). This observation is consistent with the situation in the DRC.

Study Limitations

Counterfeiting of medicines remains a major public health concern. This study has several limitations. First, not all relevant publications could be identified or accessed. Second, the analysis is based on probabilistic estimates, limiting the generalizability of findings to the entire population. Finally, the data used are secondary and often underreported, particularly in contexts where detailed local studies are lacking.

CONCLUSION

In the DRC, where local pharmaceutical production accounts for approximately 10%–20% of supply, ACOREP and other relevant institutions can leverage the tools outlined in this study to strengthen control over the pharmaceutical supply chain.

The reported prevalence rates—22.4% for falsified medicines, 22.2% for substandard medicines, and approximately 35% for unregistered products—highlight a critical public health concern. These findings underscore the urgent need for strengthened regulatory systems and improved health policy interventions.

Recommendations

The Congolese government is strongly encouraged to develop a comprehensive contingency plan to address the proliferation of substandard and falsified medicines. This should include:

- A strategic roadmap to achieve WHO Maturity Level 3 (ML3) for the national regulatory system
- Strengthening of supply chain control mechanisms
- Promotion of local pharmaceutical production
- Expansion of access to quality-assured medicines through subsidies and universal health coverage

A multisectoral approach involving all relevant stakeholders is essential to ensure sustainable progress.

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Marini, D. R.[4,5]:	Nil identified.
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