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Poor-quality medical products in the Democratic Republic of Congo: A ten-year retrospective study in Kinshasa (2012–2021)

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ABSTRACT

Introduction

Substandard and falsified (SF) medical products continue to threaten public health worldwide, particularly in developing countries. Unfortunately, the available literature primarily focuses on anti-infective drugs.

Purpose

The aim of this study is to review data on the quality of medical products to contribute to the development of future field studies.

Methods

A ten-year retrospective study in Kinshasa, DRC, analyzed data on poor-quality medical products from 2012 to 2021. The study identified international non-proprietary names, pharmaceutical forms, countries of origin, causes of non-compliance, therapeutic classes, batch numbers, and labeling.

Results

Although the descriptive statistics derived from these data show a rate of non-compliance ranging from 0.45% to 1.34%, well below recent World Health Organization estimates, the current study reveals that quality problems with medical products also affect therapeutic classes other than antimalarials and antibiotics.

Conclusion

This study aimed to analyze data on the quality of medical products in Kinshasa to contribute to future studies. The study involved 59,961 samples analyzed over a decade, with 258 non-compliant samples in the first laboratory, 670 in the second laboratory, and 7,681 in the third laboratory. Factors such as the country and continent of manufacture, therapeutic classes, non-compliant drugs, and pharmacological forms were considered. These results highlight the need for regulatory authorities to implement effective surveillance and monitoring policies for all establishments involved in the quality control of medicines and health products. Such efforts are essential for ensuring consumer safety and reflecting the quality of regulatory activities, which must encompass all parameters that contribute to the development of an exemplary quality model.

INTRODUCTION

The internationalization of the pharmaceutical industry has the potential to rapidly spread poor-quality medicines around the world before adequate detection and intervention are possible (Newton et al., 2010). To combat this spread, the United Nations declared access to "safe, effective, quality, and affordable essential medicines" as one of the Sustainable Development Goals of its 2030 Agenda (United Nations, 2015; United Nations Department of Economic and Social Affairs [DESA], 2017). Moreover, substandard and falsified medical products represent a dual crime: a crime against health and a crime against society, particularly in Africa, Southeast Asia, and Latin America (Nayyar et al., 2015; République, 2000; Wirtz et al., 2017).

According to the World Health Organization (WHO), falsified medicines are those that deliberately or fraudulently misrepresent their identity, composition, or source. Substandard medicines, also called "out of specification," are authorized medicines that do not meet their quality standards or specifications, or both (World Health Organization, n.d.). Substandard products result from a lack of expertise, poor manufacturing practices, or insufficient infrastructure, while counterfeits are the products of criminals (Caudron et al., 2008; Newton et al., 2006).

Counterfeits may contain no active ingredients, incorrect ingredients, or toxins. The amount of active ingredient does not provide enough information to accurately determine whether a medicine is counterfeit; visual inspection of packaging is also required, as mislabeling is a key part of the definition. Counterfeits with false packaging but the correct amount of active ingredient have been described.

In addition, this phenomenon generates serious societal problems linked to socio-economic and financial damage, including loss of competitiveness in the market, loss of credibility with pharmaceutical industries, loss of jobs, and impoverishment of the population (Bakker-'t Hart et al., 2021; Peltier-Rivest & Pacini, 2019; Waffo Tchounga et al., 2023). Moreover, it contributes to therapeutic resistances to essential drugs, as well as an increase in morbidity and mortality (Brower, 2017).

The problem of falsified medicines varies by continent but represents an estimated 10% of the global medicines market. In sub-Saharan countries, it is estimated that more than 30% of marketed medicines are of substandard quality, most of which are substandard or degraded drugs. Although all pharmacological classes are affected, antibiotics and antimalarials remain the most commonly reported (Rahman et al., 2018; Tie et al., 2019). Furthermore, each year, 120,000 deaths of children under five years old could be associated with the consumption of poor-quality antimalarials in sub-Saharan Africa alone, particularly in the Democratic Republic of Congo (Hamilton et al., 2016; Mbinze et al., 2015).

Low- and middle-income countries (LMICs) are particularly affected by this problem, as they often lack the resources, infrastructure, and trained personnel (Caudron et al., 2008; World Health Organization, n.d.) to ensure the quality of locally produced and imported medicines and to carry out regular monitoring of substandard and falsified medicines. The Democratic Republic of Congo (DRC) is not exempt from this issue, as the vastness of the country is compounded by the uncontrollable porosity of its borders with various neighboring countries.

To reduce the extent of this phenomenon, strengthening pharmaceutical inspections and developing easy-to-use technologies are necessary at both national and international levels. Pharmaceutical industries and agencies in LMICs have limited resources, leading to a lack of convergence toward new modern technologies and strict regulations (Mayer, n.d.; Praussello, 2006; World Health Organization, 2011). Therefore, preventive and corrective measures need to be implemented in the DRC to ensure the availability of quality-assured medicines without risking public health. This study serves as a preliminary effort to shed light on the state of affairs regarding the quality of medicines circulating in the DRC, particularly in Kinshasa, the capital. Based on the results obtained, we aim to raise awareness and advocate for the redefinition of pharmaceutical quality control practices at various levels, from the entry of imported products or the release of locally produced products from laboratories to the final consumer level—patients.

Ensuring the quality of pharmaceutical products, whether manufactured locally or imported, is fundamental to any healthcare system, as poor-quality products endanger citizens' lives. Therefore, there is a need for quality-assured medicines and a management system for all medicines confirmed to be non-compliant.

Previously, the Directorate of Pharmacy and Medicines (DPM) of the Ministry of Public Health in the DRC was the regulatory authority responsible for ensuring the quality of medicines circulating in the country. Since 2020, the DPM has been transformed into an independent national agency, named the Autorité Congolaise de Réglementation Pharmaceutique (Acorep).

In light of the situation described above, this study was designed to conduct a ten-year quality survey using data from three reference laboratories in Kinshasa, DRC. The results described and discussed below are intended to help shape future field studies, moving beyond the traditional focus on antimalarials and antibiotics, which have been the main focus in recent literature.

METHODS

Reference Laboratories Location

This retrospective study focused on medical products declared non-compliant by three reference laboratories: L1, L2, and L3, located in the Township of Gombe, Barumbu, and Lemba, respectively, all in Kinshasa, Democratic Republic of the Congo. These laboratories were selected because they are approved by the Congolese Ministry of Public Health to monitor the quality of medical products.

Materials

For the collection, processing, analysis, and interpretation of data, the following materials were used: survey sheets and registers of non-compliant medical products as provided by the selected three reference laboratories. Microsoft Word 2016 and Excel 2016 were used as software tools.

Methods

A ten-year retrospective study was conducted using data from the reference laboratories (L1, L2, and L3) in Kinshasa, the capital of the DRC, with detailed descriptive statistics on poor-quality medical products recorded between 2012 and 2021. The following parameters were included in the data analysis: the international non-proprietary names (INN) of the medicines, the pharmaceutical form, the country of origin, the continent of origin, the cause of non-compliance, the therapeutic class, the batch number, and labeling. This simple yet effective method has the advantage of rapid detection of falsification. According to the World Health Organization (WHO), the identification of potentially falsified medical products first involves careful visual inspection of the product and labeling (Dégardin et al., 2014; Mackey & Liang, 2011; WHO, 1999; Peltier-Rivest & Pacini, 2019).

Statistical Analysis

Descriptive statistics were used to identify the criteria associated with drug non-compliance. Excel 2016 (Microsoft, Redmond, WA) was used for statistical data processing.

RESULTS

During the period under review (2012–2021), the three reference laboratories in Kinshasa reported 422 cases of non-compliance out of the 74,312 samples analysed, representing a non-compliance rate of 0.57%. The following illustrations present the analysed samples and the corresponding cases of non-compliance recorded by the reference laboratories in Kinshasa.

Figure 1:
Distribution of analysed samples by reference laboratory

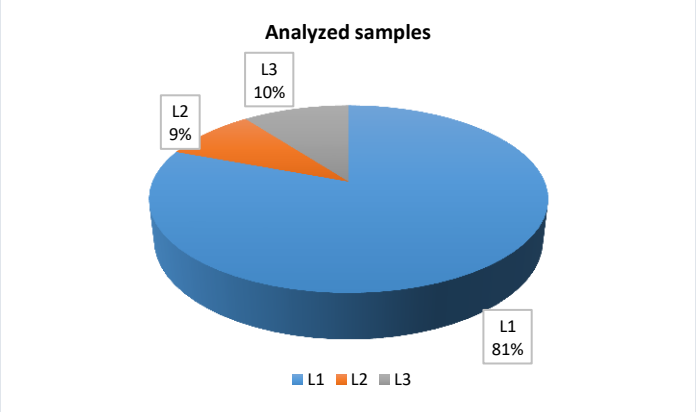
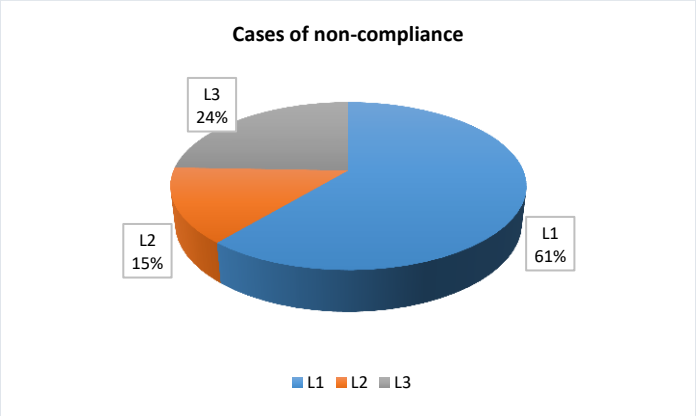


Figure 2:
Distribution of non-compliance cases by reference laboratory



The samples analysed in the Kinshasa reference laboratories were categorised according to several criteria:

- Continent of manufacture
- Country of manufacture
- Therapeutic class
- Cause of non-compliance
- Pharmaceutical dosage form

The Tables below illustrate the findings.

Table 1:
Distribution of non-compliant medicines by continent of manufacture

Continent	Frequency	Percentage (%)
Africa	6,424	44.00
America	451	3.08
Asia	6,121	41.90
Europe	1,495	10.23
Oceania	–	–
Not indicated	115	0.79
Total	**14,606**	**100**

Of all medicines declared non-compliant, Africa accounted for the highest proportion (44%), followed by Asia (41.90%).

Table 2:
Distribution of non-compliant medicines by country of manufacture

Country	Frequency	Percentage (%)
South Africa	1	0.0065
Germany	152	1.00
England	4	0.026
Belgium	3	0.019
Canada	1	0.0065
China	1,966	12.95
Denmark	1	0.0065
United Arab Emirates (Dubai)	298	1.96
Spain	2	0.013
United States	450	2.96
France	15	0.098
Greece	1	0.0065
India	6,172	40.68
Italy	3	0.019
Malaysia	300	1.97
Morocco	2	0.013
Not indicated	115	0.75
The Netherlands	1	0.0065
Democratic Republic of the Congo (DRC)	5,233	34.49
Sweden	1	0.0065
Switzerland	150	0.98
Tanzania	298	1.96
Türkiye	3	0.019
Total	**15,172**	**100**

India accounted for the highest number of non-compliant medicines (40.68%), followed by the DRC (34.49%).

Table 3:
Distribution of non-compliant medicines by therapeutic class

Therapeutic Class	Frequency	Percentage (%)
Analgesic, antipyretic, and anti-inflammatory	2,393	16.38
Anesthetic	186	1.27
Antacid	120	0.82
Hypo-allergenic	481	3.29
Antianemic	2	0.013
Antibiotic	1,527	10.45
Wound healing agents	219	1.49
Anticancer	1	0.0068
Anticoagulant	1	0.0068
Antidiabetic	185	1.26
Antiemetic	5	0.034
Antiepileptic	299	2.05
Antifungal	228	1.56
Antiglaucoma	149	1.02
Anthelminthic	3	0.020
Antihypertensive	2	0.013
Anti-infective	149	1.02
Antimalarial	1,237	8.46
Antiparasitic	1,367	9.35

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Therapeutic Class	Frequency	Percentage (%)
Antiseptic	270	1.84
Antispasmodic musculotropic	219	1.49
Cough suppressant	84	0.57
Antiviral	1	0.0068
Anxiolytic	109	0.74
Dye	75	0.51
Medical consumable	333	2.27
Detergent	149	1.02
Sweetener	2	0.013
Hormone	4	0.027
Ocular hypotensive	1	0.0068
Mucolytic	219	1.49
Psychotropic	153	1.05
Laboratory reagent	5	0.034
Mineral salt	15	0.10
Solute	1,178	8.06
Solvent	219	1.49
Caustic welding agent	219	1.49
Sexual stimulant	409	2.79
Vitamin	2,391	16.36
Total	**14,609**	**100**

Analgesics, antipyretics, and anti-inflammatories accounted for the largest therapeutic class of non-compliant medicines (16.38%), followed closely by vitamins (16.36%).

Table 4:
Distribution of non-compliant medicines by cause of non-compliance

Cause of Non-compliance	Frequency	Percentage (%)
Underdosed	84	20.89
Overdosed	2	0.49
Absence of active ingredient (API)	4	1.00
Others	312	77.61
Total	**402**	**100**

Among non-compliant medicines, 77.61% had causes other than those specified, followed by underdosed products (20.89%).

Table 5:
Distribution of non-compliant medicines by dosage form

Dosage Form	Frequency	Percentage (%)
Drinkable ampoule	1	0.23
Capsule	9	2.13
Catheter	8	1.89
Eye drops	8	1.89
Tablet	138	32.70
Cream	6	1.42
Elixir	1	0.23
Epicranial	7	1.65
Suture thread	3	0.71
Surgical gloves	4	0.94
Hydrophilic gauze	9	2.13
Gel	2	0.47
Capsule (duplicate)	7	1.65
Drops	3	0.71
Granule	1	0.23
Infusion	20	4.73
Ovule	2	0.47
Ointment	15	3.55
Powder for injection	58	13.74
Powder for suspension	23	5.45
Laboratory reagent	6	1.42
Syringe	6	1.42
Syrup	26	6.16
Solution	16	3.79
Solution for injection	10	2.36
Solvent	7	1.65
Spray	2	0.47
Suspension	24	5.68
Total	**422**	**100**

Tablets accounted for the highest number of non-compliant medicines (32.70%), followed by powders for injection (13.74%).

DISCUSSION

Out of 422 non-compliant samples in our study, 44.68% of these drugs were sourced from India. This differs from Koumaré's (2018) study, which recorded that 72.22% of non-compliant samples came from China. Furthermore, in our study, we found that Oceania, Europe, and America had low non-compliance rates, while Africa represented a high rate of 44%, compared to 41.90% for Asia. These data contrast with those from Koumaré (2018), where Asia had a rate of 88.89%, compared to 11.11% for Europe. Konaté (2013) and Madingar (Djim-Madjim, 2008) also recorded rates of 55.19% and 22.98%, and 63.04% and 5.43%, respectively, in Asia and Europe.

Regarding therapeutic classes, the majority of non-compliant samples came from analgesics, antipyretics,

anti-inflammatories, and vitamins, with 16.38% and 16.36%, respectively. This differs from the Koumaré (2018) study, which recorded four classes: antiseptics (44.43%), antibiotics (16.67%), antimalarials (16.67%), and non-steroidal anti-inflammatory drugs (11.11%). This discrepancy is likely because these two therapeutic classes are among the most consumed and falsified classes (Ciza et al., 2019).

The causes of non-compliance noted in our study are numerous. For non-compliant samples, we observed underdosing, overdosing, absence of the active ingredient, and other causes, with respective rates of 20.89%, 0.49%, 1.00%, and 77.61%. It is evident that non-compliant drugs with other causes had a higher rate of occurrence. These data are lower than those obtained in a study by the World Health Organization (WHO) titled "Quality of Drugs on the African Pharmaceutical Market" (Akiny, 2013), which recorded 34 underdosed samples out of 162 samples (20.98%), and a study conducted in Mali by Dicko (2007), which recorded 2 underdosed samples out of 12 samples (20% underdosage). These data also differ from those obtained during a study conducted in Senegal by Diop (n.d.), which recorded 10.30% of underdosed samples, whereas in our study, underdosed cases were more prevalent. This issue exposes patients to treatment failure and the development of resistance, which are among the consequences of substandard drugs circulating in the market.

Overdoses of medications and health products can cause serious accidents and dangerous toxic effects. Our data show lower rates of overdose compared to a study by Mbadinga and Géralde (2005), which recorded 11 overdosed samples out of 109 samples (1.00%), and are comparable to a study conducted in Burkina Faso by Madingar (Djim-Madjim, 2008), which did not observe any cases of overdose.

As mentioned earlier, the circulation of drugs that do not contain the active ingredients can lead to therapeutic failure, impoverishment of the population, and cases of poisoning. The rate of absence of active ingredients in our study differs from Koumaré's (2018) study, which recorded 3 cases out of 18 non-compliant samples (16.66%), and from Kouonang Komguep's (2005) study, which noted no cases of non-compliance out of a total of 101 antimalarial samples between October 2003 and November 2004. Similarly, the study by Mbadinga and Géralde (2005) noted only one case of non-compliance out of 109 samples, and the WHO study "Quality of Medicines on the African Pharmaceutical Market: Analytical Study in Three African Countries (Cameroon, Chad, and Madagascar)" (Akiny, 2013) recorded 12 antibiotic samples without active ingredients out of a total of 62 non-compliant samples (19.35%).

The tablet form was the most prevalent in our study, with 32.70% of non-compliant samples. This rate differs from those observed in the studies by Konaté (2013) and Koumaré (2018), which recorded 55.55% and 11.59%, respectively, for the non-conformity of the solution form.

CONCLUSIONS

The objective of this study was to review the quality data of medical products to help shape future field studies. Our study involved samples from Kinshasa, as part of a conformity analysis at three reference laboratories: L1, L2, and L3. A total of 59,961 samples were analyzed over ten years, including 258 non-compliant cases (0.45%) from the first laboratory, 6,670 samples with 61 non-compliant cases (0.92%) from the second laboratory, and 7,681 samples with 103 non-compliant cases (1.34%) from the third laboratory. The samples were studied according to several criteria: the country and continent of manufacture, therapeutic classes, non-compliant drugs based on their cause of non-compliance, and pharmaceutical forms. For instance, the therapeutic classes with higher non-compliance rates were vitamins and analgesics, antipyretics, and anti-inflammatory drugs.

Therefore, we recommend that the regulatory authorities in the pharmaceutical sector in the DRC take appropriate measures to monitor the various control laboratories to ensure that only products meeting the quality standards established by the laws in force are released. This will help ensure patient safety and guarantee the quality of state services.

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Conflicts of Interest: None declared.

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