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RESEARCH ARTICLE

PRE- AND POST-MARKETING CONTROL OF DRUG QUALITY AT THE NATIONAL HEALTH LABORATORY, BAMAKO-MALI

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Abstract

Background and Objectives: In a world marked by the spread of counterfeiting and substandard drugs, often without active ingredients or falsified active ingredients, greater vigilance by pharmaceutical regulatory authorities is necessary. The National Health Laboratory (LNS), in accordance with its mission, takes samples throughout the country in order to ensure their quality control.
Methods: Samples were taken in certain regions and the district of Bamako and analyzed according to the standards of the United State Pharmacopoeia (USP), British Pharmacopoeia (BP) and International Pharmacopoeia (IP)by identification and assay methods. Products that do not meet the required specifications described by these pharmacopoeias are declared non-compliant.
Results: This allowed us to analyze a total of 617 samples with 11 cases of non-compliance for a rate of 2%. The causes of the non-conformities were due to the absence of an active ingredient, an under-dosage of the active ingredient and technical and regulatory defects.
Conclusions: After one year of activity, our results showed that out of a total of 617 drug samples collected and analyzed, 606 were compliant with a rate of 98% against 11 cases of non-compliance or 2% ($p \leq 0.05$). The causes of the non-compliance were due to the absence of an active ingredient, an under-dosage of the active ingredient and technical and regulatory defects.
Keywords: non-compliance, quality control, post-marketing, pre-marketing.

INTRODUCTION

In a world marked by several challenges including, among others, the increase in chemo resistance leading to the adoption of therapeutic combinations, the advent of multi-source generic drugs, the spread of counterfeiting and substandard drugs, often without active ingredients or falsified active ingredients, greater vigilance by pharmaceutical regulatory authorities is necessary[1]. Good quality drugs are essential for effective disease management. Substandard and falsified drugs can cause treatment failure and side effects, increase morbidity and mortality, and contribute to the development of drug resistance. Vulnerable populations and patients with co-morbidities are particularly at risk of being affected by receiving substandard or falsified drugs. Poor quality drugs also increase health care costs for patients and the health system as a whole, wasting resources that could otherwise be used for the benefit of public health.[1] Medicines regulation is a complex process that includes various regulatory instruments, such as authorization /registration for marketing. It also implies product documentation, inspection to verify manufacturer's compliance with the principles of good manufacturing practices (GMP) and approval of product information. It may also include Post-Marketing Surveillance (PMS) activities, such as maintaining product authorization and/or registration through variations or renewals, regular inspections of manufacturers, quality control tests, pharmacovigilance and the implementation of regulatory measures in case a quality problem is found. When a product is made available to the public, it is not possible to predict every conceivable side effect or adverse event that could occur in large and diverse populations[1,2].

The quality of drugs can easily deteriorate through improper handling during distribution or storage before they reach patients[3]. Quality control/quality assurance (QC/QA) of drugs in the distribution system to appropriate specifications is therefore an important prerequisite to ensure optimal results. It is therefore essential to carry out regular monitoring of the quality of medicinal products through sampling missions and

pre-marketing controls to guarantee their quality[3]. Post-market surveillance of drugs therefore plays an important role in uncovering the actual state of products in terms of safety, quality and efficacy that could pose a risk to users. It allows regulatory authorities to take appropriate measures for the withdrawal of falsified and substandard medicines from the market[4].

The National Health Laboratory (LNS) in accordance with its mission and as part of the pre- and post-marketing quality control of drugs, periodic samples are taken throughout the territory by LNS agents with the aim of to ensure the monitoring of drugs by their quality control at the laboratory with a view to safeguarding the health of populations.

MATERIALS AND METHODS

The material consisted of all the drugs analyzed from January 2020 to December 2020 at the LNS. In this study, data was collected using analytical certificates of drugs subject to quality control. The following information was collected: origin, place of collection, galenic form, therapeutic class, analytical methods, analytical equipment, and analytical results. Various analytical methods and tests are important for the development and manufacture of pharmaceutical formulations but also for their quality control. The evaluation was carried out according to the standards of the United State Pharmacopoeia (USP), the British Pharmacopoeia (BP) and the International Pharmacopoeia (IP) by test methods (Friability, Disaggregation, Dissolution, pH, Average Volume, Coefficient of Variation of Weight, Loss on Desiccation), identifications (Thin Layer Chromatography, Minilab®, FTIR, RAMAN and assays (High Performance Liquid Chromatography, UV-Visible Spectrophotometry, Titrimetry)[5-8].

RESULTS AND DISCUSSION

Out of a total of 617 drug samples taken and analyzed, 606 comply with the required specifications, therefore compliants, a rate of 98% against 11 cases of non-compliance with 2%.These data are similar to those of Konaté *et al.*, who found 6.9% of non-compliance[9].

Galenic forms

In this study, the most represented dosage form was the compressed form with 41.3% followed by the injectable form 36.1% which is similar to that of Konaté *et al.*, who found 57.05%. We found that the syrup form represented the greatest number of non-compliance, i.e. 54.54% of the total number of non-compliant products, followed by the syrup/suspension form with 36.36%[9] (Table 1).

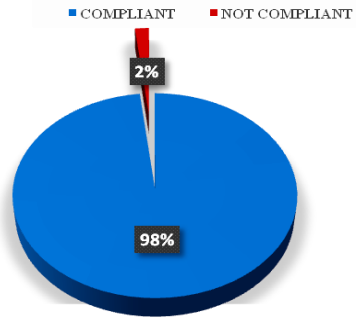

Figure 1: Global situation of samples according to their quality.

Pharmacological classes

In this study, the predominant pharmacological class was antimalarials 24%, followed by antibiotics 19.4%. These results are contrary to those of Konaté *et al.*, who found 34.84% for antibiotics followed by 16.89% for antimalarials. Total 45.45% of the total number of non-compliance products were found. This is different from that of the same study which found a high rate of non-compliance in antiseptics with 48.59%[9] (Table 2).

Quality and manufacturer's country

These results showed that the samples analyzed came mainly from India with 57.4% followed by China 16%. These results confirm those of Sidibé *et al.*, who found 45% and 17% respectively for India and China[10].

It was also found that 13.1% of our samples were of unknown origin, these were mainly products of the Central Purchasing of Medicines (PPM) (Table 3).

Distribution/sampling circuit

In order to control the quality of our drugs by touching the entire distribution chain, samples were taken at all levels of the distribution circuit. Samples were taken in large part from the Pharmacy Popular of Mali (PPM) 67.1% which is the local purchasing center, followed by samples taken during LNS post-marketing surveillance missions with 11.3%, unlike those of Harira *et al.*, who found that 59.4% came from Hospitals/Health centers[11] (Table 4).

Assay methods

In this study among the assay methods, the HPLC technique was the most used, followed by UV-Visible spectroscopy and titrimetry with 38%, 36% and 26% respectively (Figure 2).

Table 1: Distribution of molecules according to the galenic form.

S.N.	Galenic forms	Numbers (%)
1	Eye drops	1(0.2)
2	Tablets	255(41.3)
3	Capsules	24(3.9)
4	Injection	223(36.1)
5	Ointment /cream /lotion	7(1.1)
6	Syrup/suspension	52(8.4)
7	Solution	55(8.9)
	Total	617(100.0)

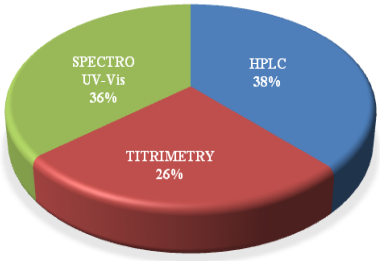

Figure 2: Distribution of assay methods.

Test and identification methods

In this study of the test methods, the uniformity of dosage units (UDU), pH and volume were the most used test methods. The colored test was the most widely used identification technique followed by TLC and FTIR (Figure 3).

Statistical analysis

After entering the data into an Excel file (database), it was exported to SPSS version 20 software for statistical analysis.

Table 2: Distribution of molecules according to pharmacological class.

S.N.	Pharmacological class	Numbers (%)
1	Corticosteroids	5(0.8)
2	Anesthesia	16(2.6)
3	Analgesic / NSAID	51(8.3)
4	Antihemorrhoid	1(0.2)
5	Antihistamine	3(0.5)
6	Antihypertensive	5(0.8)
7	Antimicrobial	120(19.4)
8	Antimalarial	148(24.0)
9	Antiseptic	54(8.8)
10	Anti-tuberculosis	7(1.1)
11	Cough suppressant	7(1.1)
12	Antiulcer	5(0.8)
13	Antiretrovirals (ARV)	77(12.5)
14	Benzodiazepine	1(0.2)
15	Others[1]	117(19.0)
	Total	617(100.0)

Table 3: Distribution of samples according to the country of origin.

S.N.	Country	Numbers (%)
1	Germany	1(0.2)
2	Austria	1(0.2)
3	China	99(16)
4	France	1(0.2)
5	Ghana	24(3.9)
6	India	354(57.4)
7	Italy	1(0.2)
8	Unknown	81(13.1)
9	Nigeria	1(0.2)
10	Mali	42(6.8)
11	Swiss	9(1.5)
12	United Kingdom	3(0.5)
	Total	617(100.0)

Table 4: Distribution of samples according to customer.

S.N.	Customer	Numbers (%)
1	CAMEG BURKINA	14(2.3)
2	Directorate of Pharmacy and Medicines (DPM)	3(0.5)
3	Mali Hospital	4(0.6)
4	Islamic Relief	21(3.4)
5	LNS missions	70(11.3)
6	Pharma Etoile Sarl	3(0.5)
7	Popular Pharmacy of Mali (PPM)	414(67.1)
8	SE/HCNLS	67(10.9)
9	SVPP	9(1.5)
10	UFCP	2(0.3)
11	UNIMED SARL	3(0.5)
12	USAID/GHSC-PSM	7(1.1)
	Total	617(100.0)

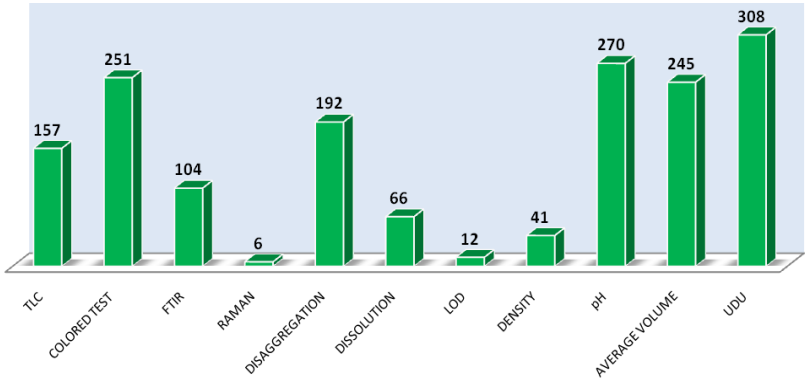

Figure 3: **Distribution of testing and identification methods.**

CONCLUSIONS

The proliferation of sources of supply and illicit sale of drugs as well as the inadequate conditions of their storage and the non-observance of good manufacturing practices can cause, with acuteness, problems at the level of the quality of the drugs available on the market. The LNS National Health Laboratory, in accordance with its mission and as part of the pre- and post-marketing quality control of drugs, takes periodic samples throughout the country for their quality control at the Laboratory. After one year of activity, our results showed that out of a total of 617 drug samples collected and analyzed, 606 were compliant, a rate of 98% against 11 cases of non-compliance or 2%. The causes of the non-conformities were due to the absence of an active ingredient, an under-dosage of the active ingredient and technical-regulatory defects and mainly affected antimalarials 24%, followed by antibiotics 19.4%. The results of these analyzes were transmitted to the socio-health authorities who proceeded with the withdrawals of these poor quality drugs thus safeguarding the health of the populations and advice was given in order to maintain the quality of the drugs at the points of sale and storage.Emphasis was also placed on the need to respect the master plan for the supply and distribution of Medicines which guarantees the safety of products up to the patient.

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AUTHOR'S CONTRIBUTION

Dembélé O: writing original draft, literature survey. **Coulibaly SM:** methodology, conceptualization. **Dakouo J:** formal analysis, review. **Koumaré BY:** investigation, data interpretation.

DATA AVAILABILITY

Data will be made available on reasonable request.

CONFLICT OF INTEREST

None to declare.

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