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# Evaluation of the Pharmaceutical Quality Assurance of Selected Veterinary Medicines at the National Health Laboratory of Mali

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**ABSTRACT**

**Background and objectives**: Livestock play a pivotal role in Mali's economy, contributing approximately 15% to GDP and supporting the livelihoods of over 30% of the population. However, the proliferation of substandard and falsified veterinary medicines undermines animal health, productivity, and food security while increasing risks of antimicrobial resistance and drug residues. This study evaluated the pharmaceutical quality of 50 veterinary medicine samples (mainly ivermectin injectables and albendazole boluses/tablets) collected from four regions in Mali.

**Methods**: Samples underwent organoleptic evaluation, packaging inspection, pH determination, thin-layer chromatography (TLC), UV-Vis spectrophotometry, HPLC and other pharmacopoeial tests per USP and BP standards.

**Results:** Of the 50 samples, 40 complied with specifications, while 10 were non-compliant, due to a total absence of active ingredient but also to under-dosing of the active ingredient (API) and identification failures. Non-compliance was highest in Bamako (6 cases) the majority of which came from France, which was also the largest country of origin of the products. Many non-compliant products were unregistered.

**Conclusion:** These findings highlight the urgent need to strengthen pre- and post-marketing surveillance of veterinary medicines in Mali, similar to measures for human pharmaceuticals, to safeguard animal health, public health, and livestock productivity.

**ARTICLE DETAILS**

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**KEYWORDS:** Veterinary medicines, substandard and falsified drugs (SF), Ivermectin, Albendazole, PMS-Mali.

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## INTRODUCTION

Livestock farming holds a significant place in the national economy due to the high demand for animal products and its contribution to GDP. It is the primary source of livelihood for more than 30% of the Malian population and contributes approximately 15% to GDP, 24% to rural sector production, about 80% to rural incomes, and nearly 20% to export revenues [1].

The livestock herd plays a crucial role in the country's economic development, the formation and distribution of income in rural areas, food and nutritional security, poverty reduction, and the overall well-being of the population. However, the persistence of major livestock diseases represents a significant barrier to the development of livestock farming and the improvement of its productivity.

In response to the proliferation of counterfeits and the uncontrolled growth of informal distribution networks, the regulation and control of the medicine market has become an increasing political concern in most African countries, particularly in Sahel nations. Veterinary medicines are especially affected, as some studies and surveys indicate that more than 50% of veterinary medicines distributed in the Sahel region are counterfeits or even fake drugs, and the illegal practice of veterinary pharmacy is common in most

countries [2], [3]. These illicit practices are responsible for significant productivity losses in the livestock sector as well as increased health risks for animals and consumers (residues and antimicrobial resistance) [4], [5], [6].

The distribution of veterinary medicines in Mali occurs through two channels: one authorized, known as the official circuit, and the other clandestine, known as the illicit circuit [7].

Quality control of products is a very important element of regulation that ensures health products (allopathic medicines, herbal medicines, and nutritional supplements), after receiving marketing authorization, maintain their quality and efficacy specifications throughout their shelf life, as stipulated in the approved application dossier.

Product quality monitoring is achieved through various approaches such as random or scheduled sampling and testing, consumer complaint investigations, suspected therapeutic failure cases, and general market surveillance exercises aimed at determining the regulatory status of products on the market.

The National Health Laboratory (LNS), has the mission to control the quality of medicines, foods, beverages, or any other substances imported or produced in the Republic of Mali and intended for therapeutic, dietary, or food purposes to safeguard human and animal health.

This work aims to contribute i) to Mali's food and nutritional security by improving the productivity of the livestock sub-sector, ii) to the health safety of populations by controlling the use of medicinal substances, and iii) to improve animal welfare.

## MATERIALS AND METHODS

### Sample collection

Samples were collected from establishments selling veterinary medicines.

### Material

The pure standard of Ivermectin and Albendazole sample was obtained from United States Pharmacopeial Convention, USA, while the samples were collected from veterinary pharmacies and outlets in Mali. These samples were stored at a temperature < 25°C, in a cool place, without direct access to light, and then tested within the expiry times.

### Packaging and labeling inspection

The primary and secondary packaging of the different samples was carefully examined to verify the required information, such as the product name, manufacturer's address, manufacturing dates, batch numbers, expiry date, and dosage.

### Organoleptic properties test

The organoleptic properties of the different samples, such as appearance, color, and odor of the drug, were determined by inspection. These properties are directly related to the chemistry of the drug and can thus serve as a non-specific identification test.

### Average volume determination

The United States Pharmacopeia [8] specifies that the average volume is used to ensure that oral solutions, once transferred from their original container, deliver the volume of the pharmaceutical form indicated on the label. The average volume of liquid obtained from 10 containers is greater than or equal to 100%, and the volume of each container is not less than 95% of the volume indicated on the labeling.

### Average weight determination

Uniformity of Dosage Units refers to the degree of uniformity in the amount of medicinal substance among dosage units.

To ensure consistency of dosage units, each unit in a batch must have a medicinal substance content within a narrow range around the label claim. Uniformity of dosage units can be demonstrated by two methods: content uniformity or weight variation. The content uniformity test for dosage forms is based on the assay of the individual content of the active substance(s) in a number of dosage units to determine whether the individual content is within the limits set. The content uniformity method can be applied in all cases [9].

### Disintegration

This test aims to verify whether tablets, capsules, or granules disintegrate within a prescribed time when placed in a liquid medium under the described conditions. It does not imply complete dissolution of the unit or its active ingredient. It is achieved when any residue remaining on the screen of the apparatus (or adhering to the disk, if used), except for fragments of insoluble coating or capsule shell, forms a soft mass without a palpable firm core [10].

### Colorimetric tests

Colorimetric tests involve reactions generated by a chemical function or a set of functions. It consists of adding a determined amount of an appropriate reagent to a determined amount of the substance to be analyzed in a test tube, resulting in a coloration instantly or after a certain time [11].

### pH determination

According to the United States Pharmacopeia, pH, a characteristic number of a solution, is defined as the value given by an appropriate and properly calibrated potentiometric sensor and measurement system. It conventionally represents its acidity or alkalinity [12].

### Thin-Layer Chromatography (TLC)-GPHF Minilab®

Routine quality control of medicines in resource-limited settings has been tested through the design and implementation of simple, autonomous mobile testing kits, such as the GPHF Minilab®. The spot obtained from the test solution must match, in terms of color, size, intensity, shape, and distance, that of the chromatogram obtained with the standard solution, according to the formula: %Rf = (RfStd - RfEch) / RfStd * 100 ≤ 5% [13], [14].

**Assay: UV-vis spectroscopy**

The ultraviolet-visible spectrophotometer is an instrument that measures the amount of light absorbed by the sample. The sample to be analyzed is traversed by light radiation ranging from 100-800 nm. The photons from the radiation transfer energy to the analyzed compounds, exciting the molecules, atoms, or ions traversed. Thus, part of the incident radiation is absorbed. Studying the radiation after passing through the analyzed substance provides information about its nature [15].

**Assay: HPLC**

Chromatography is a physical separation method based on differences in affinities of the substances to be analyzed toward two phases: one stationary or fixed, the other mobile. High-performance liquid chromatography (HPLC) is an analytical and/or preparative separation technique for molecules in a liquid mixture. The sample to be analyzed is pushed by a liquid (called the mobile phase) into a column filled with a fine-grained stationary phase; the mobile phases used are mixtures of water and a miscible organic solvent (acetonitrile, methanol) [16].

**Data analysis and statistics**

The data were analyzed using SPSS software. A statistical significance threshold of $P \leq 0.05$ was adopted.

## RESULTS

**Sample distribution**

In total, 50 samples were collected from 4 regions of Mali (Figure 1). These samples were collected by veterinary service agents and also during post-marketing surveillance missions of medicines by LNS agents. The samples consist of 2 pharmaceutical forms.

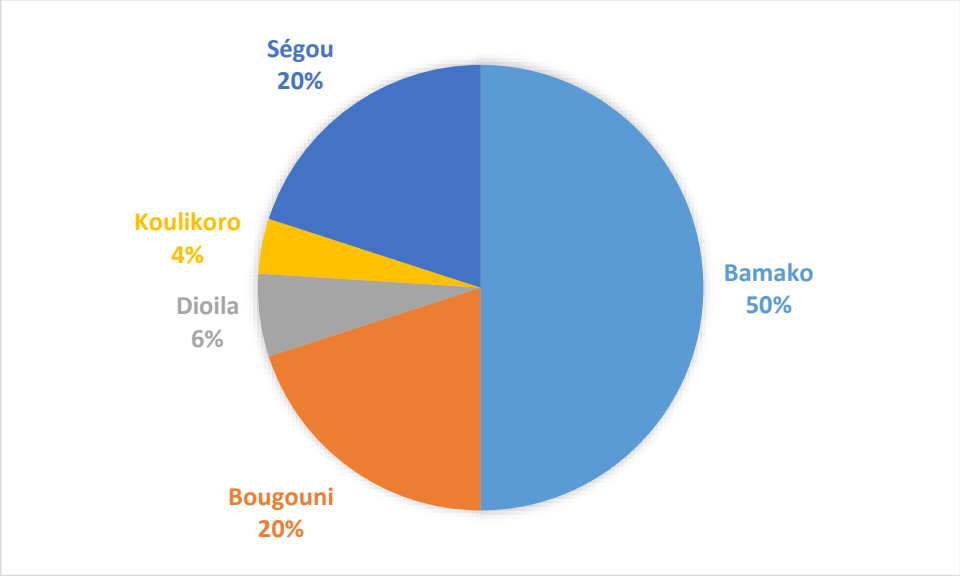


**Figure 1. Distribution of samples by collection region**

Half of the products were collected in Bamako (50%).

**Distribution of samples according to active ingredient**

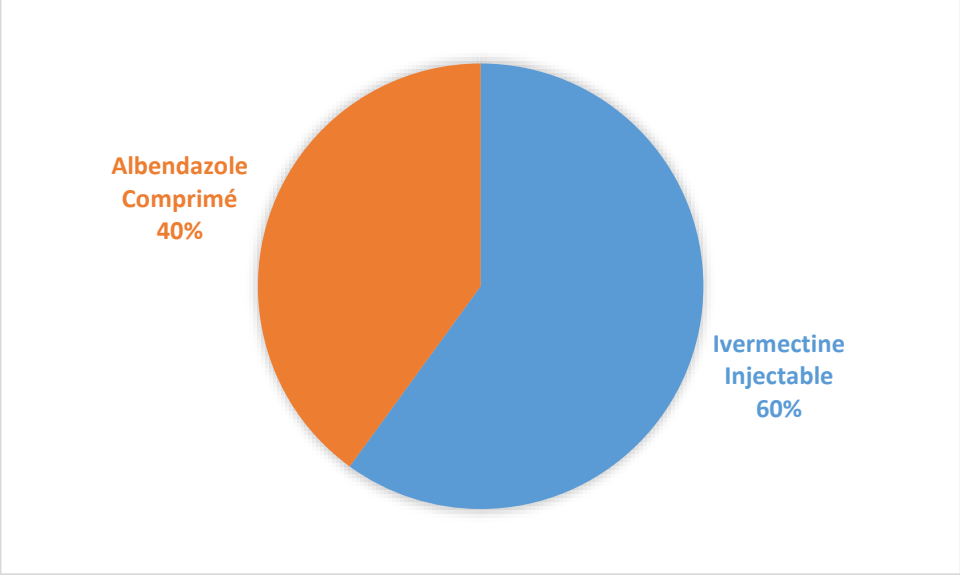


**Figure 2. Distribution of samples according to active ingredient**

The majority of products consisted of Ivermectin (60%) compared to Albendazole tablets (40%), which were the 2 molecules in this study.

**Distribution of samples according to country of origin**

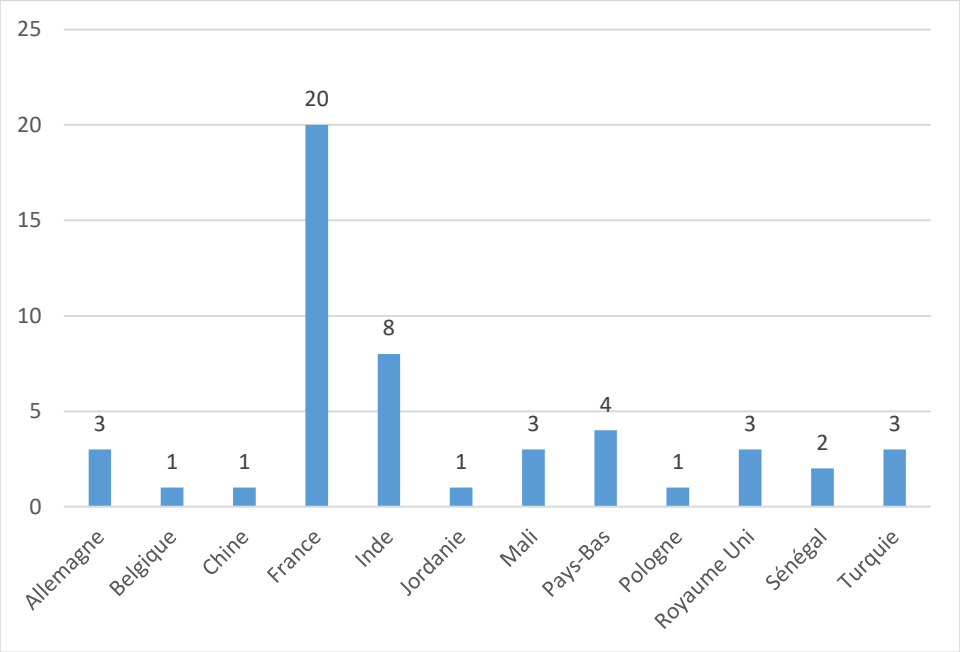


**Figure 3. Distribution of samples according to country of origin**

France is by far the main supplier of samples with 50%, followed distantly by India, while other origins remain marginal.

**Compliance with specifications – Overall results**

Of the 50 samples tested, 40 were compliant (80%) and 10 non-compliant (20%).

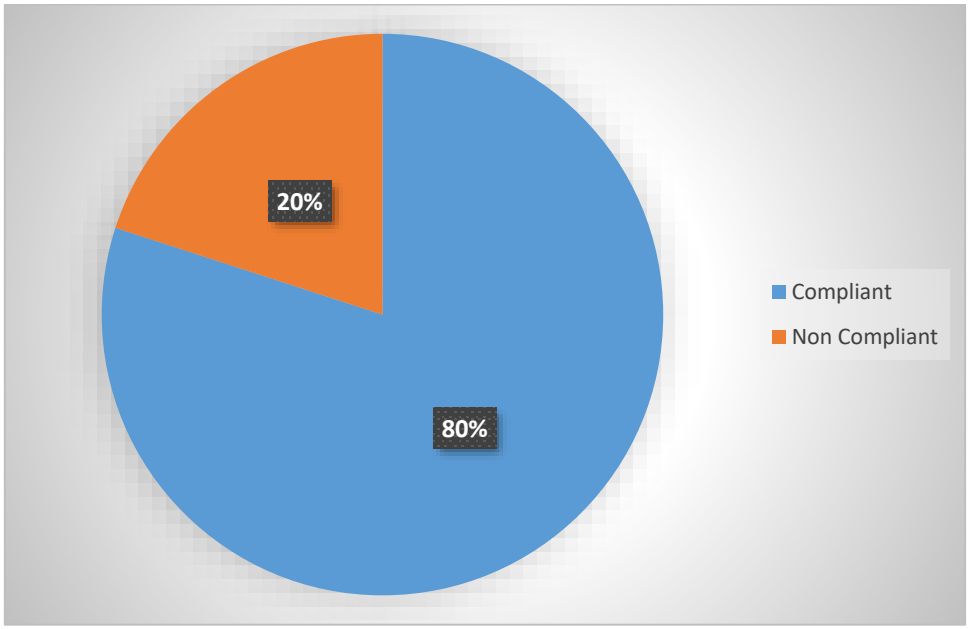


**Figure 4. Distribution of samples according to compliance**

**Situation of non-compliant samples by origin**

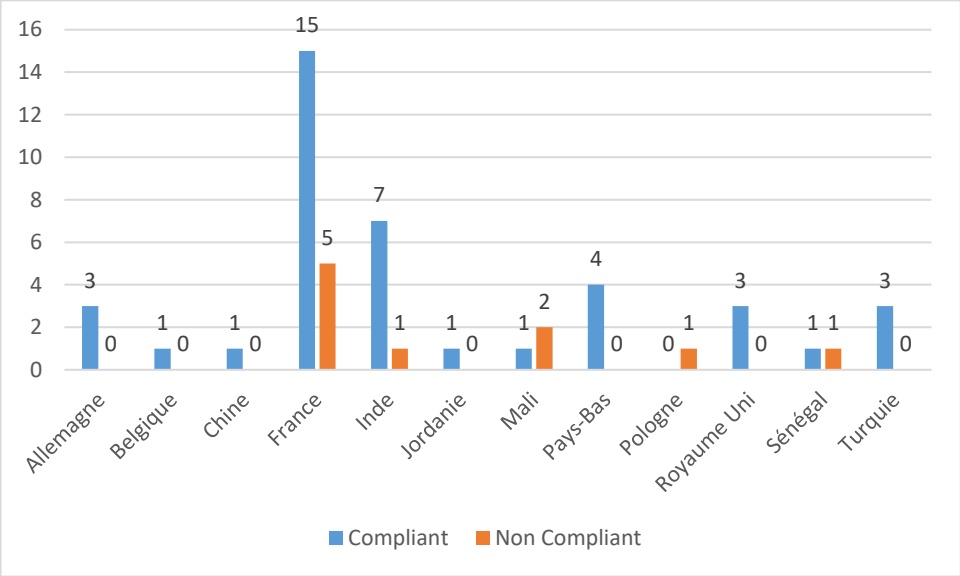


**Figure 5. Distribution of samples according to compliance**

Overall, 10% of non-compliant samples came from France. More specifically, 33.33% of samples from this country are non-compliant.
This rate could be explained by the fact that 50% of all samples came from this same country.

**Compliance by region**

The Bamako region recorded the highest number of non-compliances (6 samples). Cases of non-compliance were observed in each region.

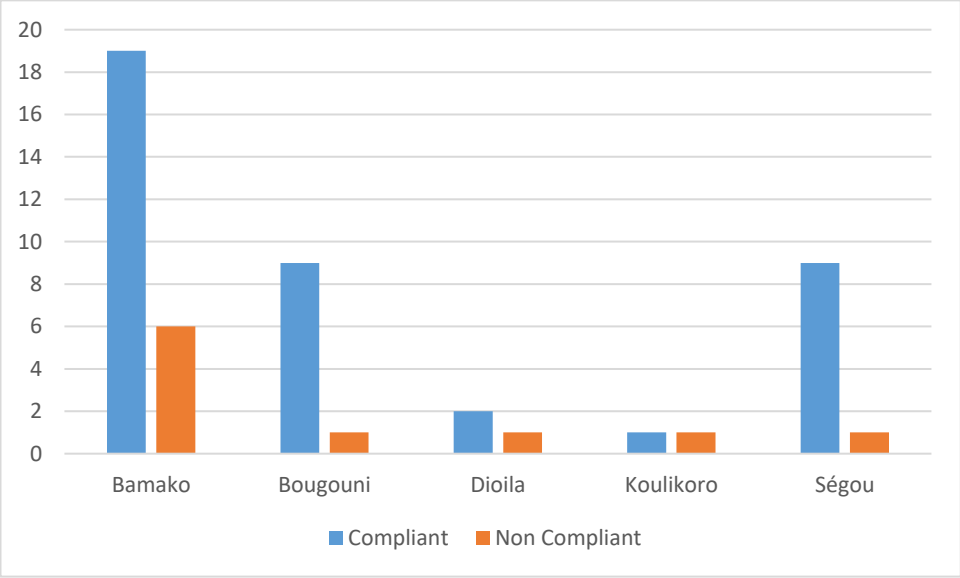


**Figure 6. Distribution of samples according to compliance**

**Test methods and data quality**

Non-compliant samples underwent Out-Of-Specification (OOS) processing in accordance with the laboratory procedure describing the management of out-of-specification results. All data were submitted for review and approval by the laboratory's quality control department, in accordance with our technical records control procedure. This procedure describes the specific provisions for analysis and required controls before final approval.

**Pharmaceutical quality analysis**

Results obtained for physicochemical analysis, pH, and TLC were analyzed against USP and BP specifications. The average volume of all tested samples complied with the United States Pharmacopeia specifications [17] regarding volume uniformity of single-dose preparations. The values ranged between 90 and 110%. The active ingredient content showed that all samples complied with the required

specifications, with active ingredient content between 90 and 110%.

**Results interpretation**

In this study, France is by far the main supplier of samples with 40%, suggesting strong dependence or marked preference for French products/manufacturers. India follows at 16%. These results contrast with those from previous PMS where India and China constitute the countries of origin for the majority of medicines. This difference is explained by the product category. While for human medicines India and China seem to be the major suppliers, for veterinary medicines, this does not appear to be the case [18], [19]. The majority of products consisted of Ivermectin (60%) compared to Albendazole tablets (40%), which were the 2 molecules in this study.

Among the samples, 2 were non-compliant in identification, and among them, 1 had no batch number. This suggests falsification because we observed that all samples non-compliant in identification also had active ingredient content out of specifications.

We also found that 3 samples were manufactured in Mali, among which 2 were non-compliant, including the sample without a batch number.

This study revealed that many products were not registered, which explains the high non-compliance rate observed. The causes of non-compliance were due to a total absence of active ingredient but also to under-dosing of the active ingredient.

## CONCLUSION

Ivermectin and albendazole are two major antiparasitics in veterinary medicine, widely used for controlling parasitic infections in animals. The quality of these medicines is essential to prevent productivity losses and reduce the spread of parasites in the herd.

The quality assurance tests performed on these samples revealed that 10 out of 50 samples were non-compliant. These results clearly underscore the need to strengthen pre- and post-marketing control of these medicines, as is done for human medicines.

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