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Survey Results on the Risk-Based Quality of Selected Medicines Available in ECOWAS Countries in Mali

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ABSTRACT

Background and Objectives: Medicines are not ordinary commercial products. In most cases, consumers are unable to decide when and how to use drugs and weigh the potential benefits against the risks, because no drug is completely safe. The use of ineffective, poor quality and harmful drugs leads to treatment failure, exacerbation of disease, drug resistance and sometimes even death. It also contributes to reducing consumer confidence in health systems, healthcare providers, manufacturers and distributors of pharmaceutical products.

Methods: The survey focused on establishments identified in cross-border areas selected by the ECOWAS PMS technical working group. These can be manufacturers, importers, central purchasing bodies, wholesalers, hospital distribution centers, health centers, retail outlets. It took place from September to November 2022 and aimed to conduct quality risk-based post-marketing survey of antimalarials, antibiotics and COVID-19 drugs circulating at selected distribution levels in Mali.

Results: A total of 33 samples were taken and analyzed according to a risk-based protocol, of which 27 were compliant with a rate of 82% against 06 were non-compliant or 22%. Non-compliant drugs were from both the public and private sectors. We found that 79% of drugs were unregistered among which antimicrobials were the least registered drugs with a rate of 73% and came mainly from India and China.

Conclusion: This study with its cross-border character allowed us to take samples in certain areas often not covered by routine PMS. It allowed us to detect 6 non-compliant products that were withdrawn from the market and regulatory measures were taken to ensure health and guarantee access to quality medicines for health and the well-being of populations.

KEYWORDS: Antimalarials, Antibiotics, quality control, RB-PMS.

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INTRODUCTION

Medicines are not ordinary commercial products. In most cases, consumers are unable to decide when and how to use drugs and weigh the potential benefits against the risks, because no drug is completely safe. The use of ineffective, poor quality and harmful drugs leads to treatment failure, exacerbation of disease, drug resistance and sometimes even death. It also contributes to reducing consumer confidence in health systems, healthcare providers, manufacturers and distributors of pharmaceutical products. Money spent on ineffective, unsafe and poor quality drugs is thus wasted – whether by patients/consumers or by insurance schemes/governments. Governments have a responsibility to protect their citizens in areas where citizens themselves are unable to do so. The success of a government's efforts to provide effective health care to the population depends to a large extent on the availability of quality, safe and effective medicines. A government's effort can be threatened by the presence of substandard and falsified medicines in the supply chain, putting the public at risk.

Product quality control is a very important part of the regulations which ensures that registered products (allopathic

medicines, herbal medicines and nutritional supplements) after receiving marketing authorization maintain their quality specifications /power throughout their shelf life as stipulated in the approved application package.

Product quality monitoring is carried out through different approaches such as random or scheduled sampling and testing, investigation of consumer complaints, cases of suspected treatment failure and general market surveillance exercises to determine the regulatory status of the products on the market.

In order to document the presence and level of spread of falsified/substandard medicines and the extent of the illicit trade in medicines in the ECOWAS sub-region, WAHO in collaboration with its Technical and Financial Partners (TFPs) has initiated the meeting of members of the ECOWAS Medicines Counterfeiting Committee (EMACCOM) and other stakeholders for the preparation of the analysis of the counterfeiting situation in West Africa.

In addition to these drugs, in addition to quality issues, others were also chosen due to storage issues that impacted stability and treatment trends observed through the MedRS tool.(1)

MATERIAL AND METHODS

Scope and Duration of the Survey: The survey focused on establishments identified in cross-border areas selected by the PMS technical working group. On this basis, samples were collected from public, private, faith-based organizations, nongovernmental and unofficial health care facilities that stock the drugs in question. These can be manufacturers, importers, central purchasing bodies, wholesalers, hospital distribution centers, health centers, retail outlets (pharmacy and over-the-counter drug sellers), unauthorized outlets and online retailers, where applicable.

The survey will be conducted between September 2022 and November 2022.(1)

Selection of drugs and geographical areas

Drugs were selected based on risk analysis using a series of risk factors through the Drug Risk Assessment Tool (MedRS) developed by USP/PQM Plus (2). This tool helps to identify medicines based on risk analysis according to the guideline for the implementation of risk-based post-marketing surveillance in (LMIC).(3)

In addition to these drugs, in addition to quality issues, others were also chosen due to storage issues that impacted stability and treatment trends

Table 1. Drugs to be covered in the survey

N	Antimalarials	Antibiotics	COVID-19
1	Sulfadoxine/Pyrimethamine Tablet	Amoxicilline DT	Dexamethasone injection
2	Artésunate/Amodiaquine Tablet	Cefuroxime Tablet	Hydroxychloroquine Tablet

Sample analysis in the laboratory

Sample analysis was performed using a risk-based 3-step testing approach in accordance with the document Guidance for Implementing Risk-Based Post-Marketing Surveillance in LMICs (1). It is based on the use of three levels of drug quality assessment, using methodologies different from each other, increasing complexity and complementary to each other:

Level 1: Visual and physical inspection

- Labeling and packaging
- Appearance, conditions and physical characteristics of the drug

Level 2: Basic analytical tests

- Disintegration:
- Physical process required for dissolution of solid dosage forms
- Thin Layer Chromatography (TLC)
- Identification of the active pharmaceutical ingredient (API)
- Presence of impurities
- Semi-quantitative assessment of content (20% range)

Level 3: pharmacy/validated tests

- According to recording specifications
- Assessment of all critical quality attributes
-

RESULTS

Samples situation

33 samples were collected in the region of Kayes in the Health Districts of Yelimane and Kita which border respectively Mauritania and Guinea. (Table 2) at some levels of the drug distribution chain described in the methodology.

Table 2. Proportion of samples by localities

Indication	Localities		Total
	Kita	Yelimane	
Analgesic	2	0	2
Antibiotic	4	6	10
Antimalarial	5	4	9
Antiparasitic	2	3	5
Covid19	4	3	7
Total	**17**	**16**	**33**

Situation of products collected according to the manufacturer

Most of the products came from China (54.5%) followed by India (27.3%) or 81.8% of the products. This rate is similar to previous PMS results.(4,5)

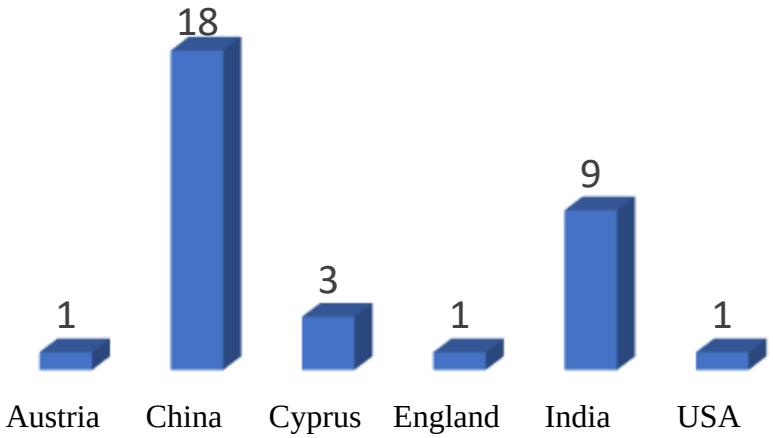
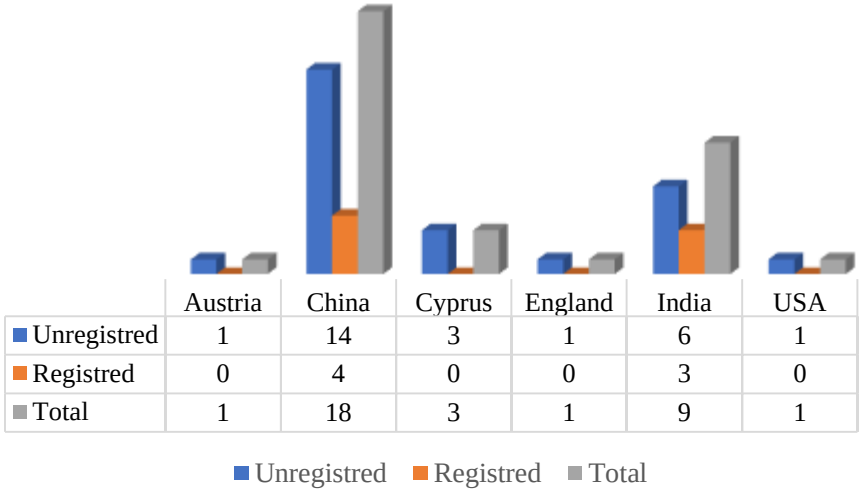


Figure 1: Situation of products by manufacturer.

The majority of unregistered products came from China (42.4%) and India (18.2%) constituting 60.6% of our samples were unregistered.



	Austria	China	Cyprus	England	India	USA
Unregistred	1	14	3	1	6	1
Registred	0	4	0	0	3	0
Total	1	18	3	1	9	1

Figure 2: Situation of unregistered products by origin.

Samples registration status

In this work, only 21% of the medicines collected were registered. This rate is similar to that of PMS2 which was 26% and slightly lower than that of PMS1 which was 31%.(4,6)

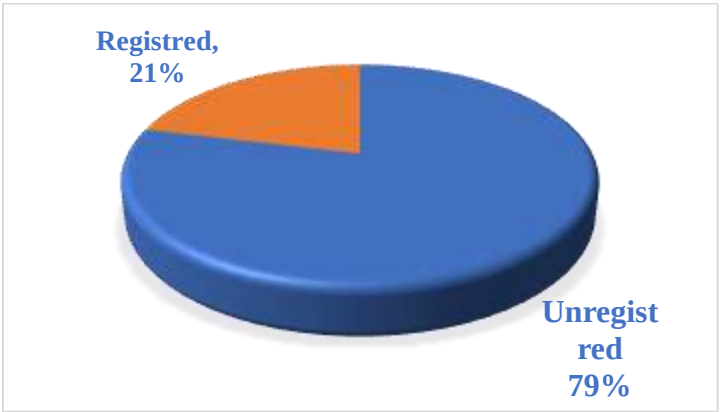


Figure 3: General registration status of the products.

Products registration status by active pharmaceutical ingredient

We found that 79% of drugs were unregistered among which antimicrobials were the least registered drugs with a rate of 73%.

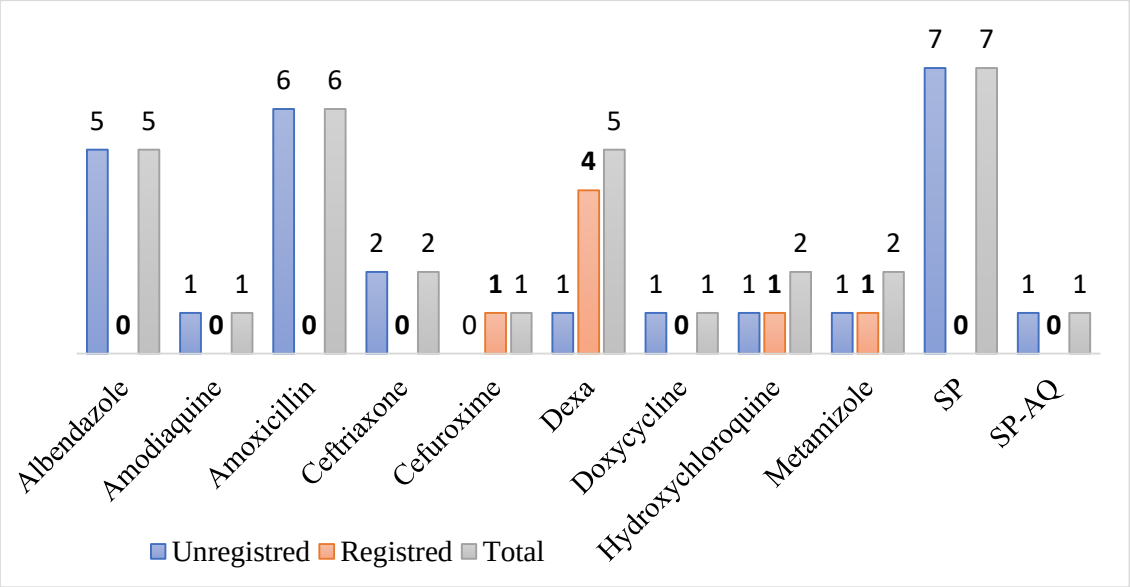


Figure 4: Product registration status by active pharmaceutical ingredient.

Situation of products by active pharmaceutical ingredient

In this study, antimicrobials were the most represented with 73%. Antibiotics were the most represented pharmacological class with 31%, followed by antimalarials and antiparasitics with 27% and 15% respectively. Sulfadoxine-Pyrimethamine was the most represented active ingredient with 21% followed by amoxicillin (18%).

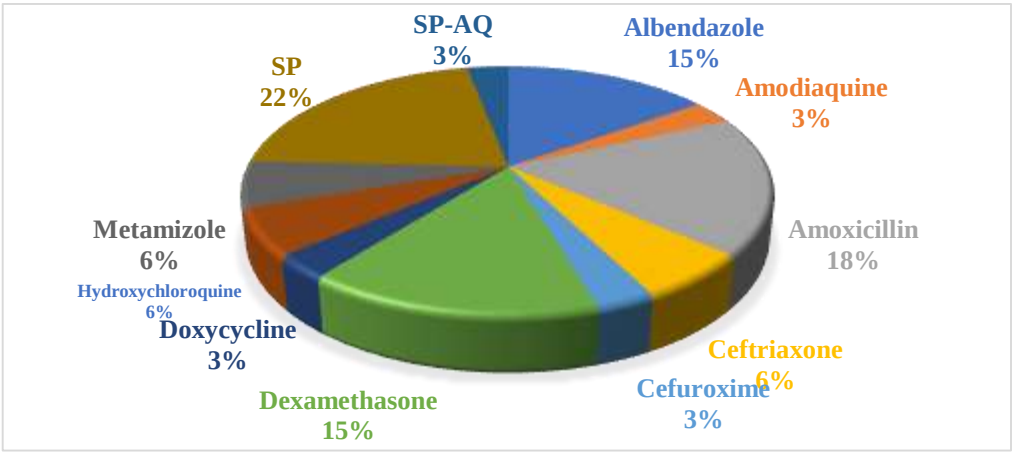


Figure 5: Situation of products by active pharmaceutical ingredient.

Compliance with Specifications

Global Results

Out of 33 samples tested, 27 were compliant, i.e. a rate of 82% and 6 non-compliant, corresponding to a rate of 18%.

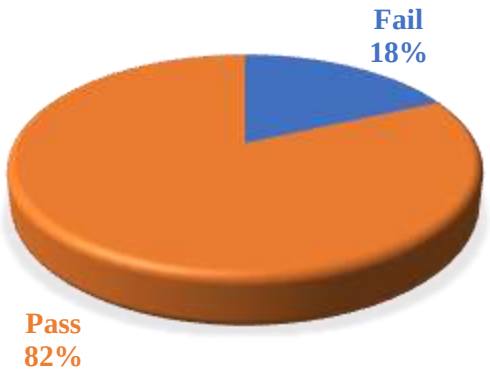
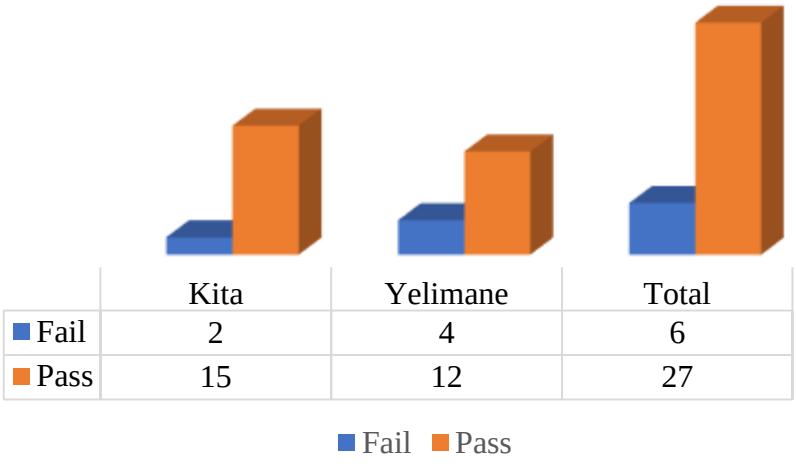


Figure 6: Global situation of products according to compliance

Situation of non-conformities by District

The District of Yelimane had the highest number with 4 samples and Kita District had 2 samples.



	Kita	Yelimane	Total
Fail	2	4	6
Pass	15	12	27

Figure 7: Situation of non-conpliances by District.

DISCUSSION

Test methods and data quality

In accordance with the Guidance document for implementing risk-based post-marketing quality surveillance in low- and middle-income countries, we conducted sample analysis by step using a risk-based testing approach that is done in 3 levels. Non-compliant samples were subject to OOS processing in accordance with LNS's procedure. All data has been submitted for review and approval by the laboratory's quality control functions and a certificate of analysis was issued for each sample.

Results interpretation

Out of 33 samples tested, 27 were compliant, i.e. a rate of 82% and 6 non-compliant, corresponding to a rate of 18%. This result is much higher than those of previous years which are around 4%.(6,7). All the cases of non-compliance encountered were antibiotics (Amoxicillin). The causes of non-compliance were due to an under-dosage of active ingredient (API). The District of Yelimane had the highest number with 4 samples and Kita District had 2 samples. All samples were from the public sector. This is explained by the nature of the study which is a cross-border study and these areas are covered only by the public unlike previous studies which covered the 2 sectors.(8)

We found that a large majority of products came from China (54.5%) followed by India (27.3%) or 81.8% of the products. This rate is similar to previous PMS results.(4,5)

Only 21% of the medicines collected were registered. This rate is similar to that of PMS2 which was 26% and slightly lower than that of PMS1 which was 31%.(4,6)

CONCLUSION

This study allowed us to detect 6 non-compliant products that were withdrawn from the market and regulatory measures were taken to ensure health and guarantee access to quality medicines for health and the well-being of populations. This study with its cross-border character allowed us to take samples in certain areas often not covered by routine PMS. In view of the scarcity of resources, this risk-based sampling and analysis technique (RB-PMS) must be continued, optimized and sustained to ensure health and guarantee access to quality medicines for health and the well-being of populations.

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CONFLICTS OF INTEREST

No conflict of interest.

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