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Marketing Authorisation for Medicines in Mali: Issues and Prospects

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Abstract **Original Research Article**

Introduction: Medicines are special products, and their marketing requires an evaluation of the benefit-risk ratio, which leads to the granting of a marketing authorisation (MA). The objective was to study the conditions for issuing marketing authorisations in Mali. ***Materials and methods:*** This was a retro prospective cross-sectional descriptive study conducted from 01 January to 31 December 2019 at the Directorate of Pharmacy and Medicines. It included registration applications examined in 2019 and marketing authorisation applications for medicines for human use. Data entry and analysis was done with SPSS 21.0. ***Results:*** Of the 848 dossiers reviewed, 594 were favourable and 254 were unfavourable to the national marketing authorisation commission. Among the 254 refusals, 162 were due to price non-competitiveness, 91 to package insert defects, and only one to an inconclusive clinical study. ***Conclusion:*** This study allowed us to note a high number of references for the molecules amoxicillin, amoxicillin-clavulanic acid, artemether-lumefantrine, omeprazole, paracetamol, ceftriaxone.

Keywords: Regulation, MA, Medicines, Mali.

INTRODUCTION

Medicines are not like other goods, from their conception to their manufacture and marketing, they are subject to specific and rigorous legislation aimed at guaranteeing the required quality, efficacy and safety. This is why the production, distribution and dispensing of health products are subject to strict regulation. Medicines must have a positive benefit-risk ratio, and their quality, efficacy and safety must be monitored in the interest of human health [1].

The Marketing Authorisation for a medicine (MA) is, as its name indicates, an authorisation decision. It results from the fact that the State, via the legislator, has arrogated to itself a power of prior approval. This authorisation decision is based on the evaluation of a dossier proposed by the manufacturer [2].

In the United States, in 1938, legislation recommended that pharmaceutical companies submit an application for a new product to the competent authority, namely the Food and Drug Administration (FDA), with proof of its safe use and quality [3].

In Europe, following the thalidomide tragedy in the early 1960s, various states decided to tighten laws, regulations and directives to record and evaluate data on the safety, quality and efficacy of new pharmaceutical products, in order to ensure that defective products are not available to the patient [4].

In Mali, the marketing of medicines is governed by Decree No. 04-55/P-RM and Inter-ministerial Order No. 05- 2203/MS-MEP-SG on the modalities for requesting marketing authorisations for medicines for human and veterinary use. The purpose of this framework is to verify that the medicine meets the necessary quality, efficacy and safety requirements. A complete file drawn up by the manufacturer, including all the characteristics of the product as well as the analytical, toxico-pharmacological and clinical expertise reports is submitted to the Ministry of Health (Directorate of Pharmacy and Medicines).

The objectives of this modest work are to determine the number of MA applications examined and products registered in 2019; to list the products that have been registered; and to establish the profile of the

various laboratories (MA applicants in Mali and product manufacturers).

MATERIALS AND METHOD

This was a retrospective, descriptive study conducted at the Directorate of Pharmacy and Medicines and more specifically at the Regulation and Monitoring of the Pharmaceutical Profession Division. It covered the MA application files examined at the DPM from 01 January to 31 December 2019. It included the files of registration applications examined in 2019 for medicines for human use. Files were selected on the basis of a comprehensive sampling where all applications that met the inclusion criteria were analysed for the study period considered.

The data collection was based on an anonymous questionnaire with closed and open questions on the identification of the laboratory applying for authorisation, the legal requirements for the application for authorisation, and the opinion of the Ministry of Health on the application for marketing authorisation.

Data Analysis and Ethical Considerations

The data were analysed using SPSS 21 software. The results were presented as numbers and percentages. The study was conducted with the consent of the DPM administration.

RESULTS

A total of 848 dossiers were examined from 1 January to 31 December 2019, of which 812 were for specialities/generics and 36 for INN generics. For applicant companies, the Asian continent outperforms the other continents. India tops the list of applicant countries.

The most represented pharmaceutical form was tablets (44.3%) followed by injectable solutions (13.2%). Antibiotics were the most represented therapeutic class at 21.1%.

Of the 848 applications, the commission accepted 594 (70%), against 9 rejections (1.1%). In relation to the acceptances with reservations, it can be explained by poor formulation or the non-conformity of the drug's indication. For those pending, they required an expert opinion; details are given in Table I.

Table I: Distribution of marketing authorisation applications according to the decision of the national marketing authorisation commission

Decision of the Commission	Frequency	Percentage %
Accepted	594	70,0
Accepted with reservation	64	7,7
Pending	15	1,7
Rejection	166	19,6
Final rejection	9	1,1
Total	**848**	**100**

It should be noted that out of the 166 applications rejected, 162 were for the high Overall Taxable Price (ATP), i.e. 97.6%; 1 case (0.6%) respectively for an inconclusive clinical study, and lack of package leaflet. And the Fisher test carried out showed the existence of a statistically significant relationship between the decision of the national marketing authorisation commission and the GTP of the products compared to that of similar products on the market (Fisher test = 330.375 ddl = 8 p = 0.000). The table below gives the different reasons for the rejection.

Table II: Distribution of MA application files according to reasons for rejection

Reasons for rejection	Frequency	Percentage %
Non-competitive TPBT	162	97,6
Notice	1	0,6
Inconclusive clinical study	1	0,6
Others	2	1,2
Total	**166**	**100**

Out of 166 rejected applications, 162 were for high Total Price before Tax (TPBT), i.e. 97.6% of the cases. Only one (0.6%) application was rejected for inconclusive clinical study and lack of package insert respectively.

Other: errors of indication, inappropriate dosage, etc.

DISCUSSION

We carried out a retro prospective study over a period of one year. It consisted of studying the conditions for issuing marketing authorisations for medicines in Mali.

In total, the commission evaluated 848 marketing authorisation application files. Branded specialities/generics were the most represented with 84.3% and simple generics 15.7%. This result is comparable to that reported by Kouamba G A. in 2017 who in his study found a rate of 74.25% for branded generics [5]. This increase in the number of branded generics would be in line with the country's national pharmaceutical policy whose general objective is to guarantee universal access to quality generic essential medicines at an affordable cost to the population. Indeed, quality and lower cost generic medicines are an interesting solution to the problem of access to medicines in our developing countries.

Our study revealed that 44.3% of the laboratories applying for MAs were from India. This result is different from that reported by Kouam K F. in 2014 where China ranked 1st (61.09%) followed by India (20.30%) [6].

From our study, it was found that the compressed form was the most represented with 44.3%. It is followed by injectable solutions 13.2%, capsules 10% and syrup 7.7%. This result is comparable to that reported by Bakabe M R. in 2008, with the tablet form leading the way at 43.8%, followed by injectables at 20.0%, and oral suspensions and syrups at 14.2% [7].

The most represented therapeutic classes were antibiotics (21.1%), followed by antihypertensives (9.7%), antimalarials (9.2%) and analgesics (7.8%). This result is close to the one obtained by Ofirdan A. who showed that antibiotics dominated in 2017 against 28.8% in 2010[8].

The national marketing authorisation commission accepted 70% of applications for marketing authorisation. This rate is higher than that obtained in the study by OFIRDAN A., which gave 25.23% of accepted applications [8]. It should be noted that our rate is also much higher than that reported by the Senegalese National Medicines Commission in 2017, with only 26% of applications accepted. On the other hand, 19.6% of the MA applications were rejected and the most common reason given was a non-competitive HMP.

CONCLUSION

At the end of our study, we had the following results; out of a total of 848 dossiers reviewed in 2019. India was the dominant country of MA applicants. Antibiotics were the most represented. The main reason for rejections was the non-competitiveness of the HGMP. These results raised concerns about the non-availability of registered products from wholesalers and the lack of post-marketing control. A limitation is the lack of impact of the national market authorisation commission's decision on the quality of prescriptions and dispensing of medicines.

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