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Registration of health products for human use: Niger Republic case (from January 2018 to December 2020)

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Abstract

Objective: Our study aims to make a nomenclature of the pharmaceutical products having received an authorization of sale on the market (MA) in Niger Republic and to describe the profiles of the various applicant laboratories and or manufacturers. We had conducted a retrospective and descriptive study on new applications for registration of health products for human use examined in first intention only by the National Commission for Health Products Approval (NCHPA) from January 2018 to December 2020.

Material and methods: Over this period, 7 sessions of the NCHPA were held, including 3 in 2018, 2 in 2019, and 2 in 2020. In total, 951 dossiers for registration were reviewed in first intention.

Results: It was found that the majority of applicant laboratories (37.22%) as well as manufacturer laboratories (40.38%) were from India. The most represented therapeutic class was antibiotics (21.35%) followed by antimalarial (9.67%). However, the main route of administration was oral (79.28%) with a predominance of tablets (52.47%). Our study had also noted that only 10.10% of the dossiers have been accepted against 86.75% postponed due to lack of required information.

Summary ad conclusion: The national drug nomenclature remains the main document guiding the prescription and dispensing of products with a valid market authorization in the country. This is why all the actors in pharmaceutical logistics must have at hand all the information on the products approved in Niger.

Keywords: Pharmaceutical products, Registration, Regulations, Market Authorization (MA), Niger Republic, WAEMU, National Committee for Health Products Approval (NCHPA)

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1. Introduction

Medicines play a vital role in improving public health. They should therefore not be treated as ordinary commodities. This is why Niger Republic, like other countries in the sub-region, has a legislation to regulate health products for human use according to Ordinance n° 97-002 of January 10, 1997. (1)

In order to harmonize approval procedures, the member states of the West African Economic and Monetary Union (WAEMU) adopted Regulation n° 04/2020/CM/UEMOA relating to approval procedures for pharmaceutical products for human use in the member states of the Community. (2)

Registration is defined as all the procedures leading to the granting of a Market Authorization (MA) in a given country, namely: registration, renewal and variations. (2)

Its purpose is to guarantee the quality, safety and efficacy of products that have been granted authorization (MA) intended either for sale or distributed freely.

In Niger, the implementation of certain regulatory functions, in particular approval is carried out by the Pharmacy and Traditional Medicine Directorate, within the Ministry of Health.

Thus, in view of the increasing number of requests for marketing authorization on the one hand and the persistence and spread of substandard and falsified medical products on the other hand, a study of the approval system and the realization of a nomenclature of pharmaceutical products with an updated MA is necessary in order to reduce to the minimal level, the quantity of unapproved products circulating on the national territory.

To our knowledge and with reference to the literature consulted, no study has been conducted on the registration of pharmaceutical products for human use in Niger. The purpose of this work is to fill this gap.

2. Materials and Methods

- Type of study: this was a retrospective descriptive and analytical study of the MA application dossiers received and approved for review in the first instance by the National Commission for the Approval of Health Products from January 2018 to December 2020.
- Study location: the study was conducted within premise of the Pharmacy and Traditional Medicine Directorate of the Niger Republic Ministry of Health, Population and Social Affairs.
- Sampling: Were included in our study MA application dossiers reviewed by the National Committee for Health Products Approval (NCHPA) from January 2018 to December 2020 in first-line.
- Data entry, analysis, and processing: Our data were entered into Microsoft EXCEL version 2016 and analyzed using SPSS21 software. Microsoft Word version 2016 was used for writing.
- Studied variables:
  - ✓ Products information (INN, Dosage form, Route of administration, Pharmaco-therapeutic class, Product type).
  - ✓ Laboratory profiles (Countries/Continents of manufacturing laboratory, Countries/Continents of requesting laboratory)
  - ✓ NCHPA information (Number of cases from NCHPA's session opinion, Distribution of cases from NCHPA opinion).
- **Difficulties encountered**: Access to some archived documents;
- **Ethical and deontological considerations**: In the context of this work, a request for research authorization was issued. Health Minister had given his agreement through the general secretariat. The anonymity and confidentiality of the profile of the laboratories and that of the experts were guaranteed throughout our study.
- Statistical methods: The export of our Excel database to SPSS Statistics software, being a complete system of data analysis of almost any type of file to generate tabulated reports allowed us to achieve the following results.

3. Results

The largest numbers of dossiers reviewed were received in 2020 with a total of 474 dossiers compared to 299 in 2019 and 178 in 2018 (view figure1).

Table I shows us Distribution of applicant laboratories by country. Among all the countries of the applicant laboratories, India was the most represented country in our study with 354 application files, i.e. 37.22%.

The no determined (ND) correspond here to the MA applicant laboratories whose names have disappeared due to the SIAMED software bug. SIAMED is the software used in Niger to process the data from the laboratories applying for MA.

Table 2 shows the distribution by country of manufacturing laboratories. Among all the countries of the manufacturing laboratories, India was the most represented country in our study with 384 application files or 40.38%.

Table 3 summarizes the distribution by dosage form. Of the 951 registration applications, 499 were tablets, i.e. 52.47%.

Distribution by route of administration is summarized in table 4. Here, of the 951 registration applications, 754 were for health products for human use whose route of administration was oral, i.e. 79.28%.

Tables 5 and 6 summarize respectively the distribution of the dossiers according to the therapeutic class and the Committee opinion (NCHPA).

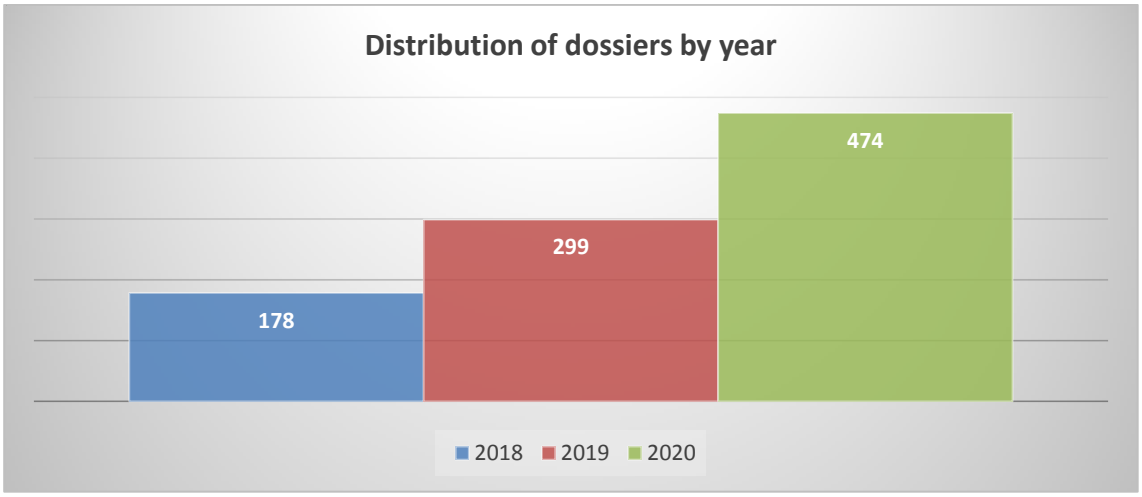

Figure 1. Number of Dossiers Reviewed by Year

Table 1. Distribution of applicant laboratories by country

Laboratory's applicants	Numbers	Percentage %
India	354	37,22
France	159	16,72
Egypt	61	6,41
Morocco	56	5,89
Tunisia	41	4,31
China	28	2,94
Belgium	27	2,84
Switzerland	27	2,84
Germany	21	2,21
Uganda	20	2,10
Niger	18	1,89
Kazakstan ?	16	1,68
Congo	15	1,58
Ivoy Cost	13	1,37
United Kingdom	12	1,26
Togo	12	1,26
Spain	10	1,05
NDs	2	0,21
Others	61	6,41
Nigeria	1	0,11
TOTAL	951	100

Others: New Zélande, Monaco, Italy, USA, Turkey, Corea, Canada, Arabie Saoudite, Senegal, Philippines, Algeria, Ghana, Sweden, South Africa, Portugal

Table 2. Distribution by country of manufacturing laboratories

Laboratory's applicants	Numbers	Percentage (%)
Inde	384	40,38
France	137	14,41
Chine	64	6,73
Egypte	61	6,41
Maroc	56	5,89
Tunisie	41	4,31
Suisse	22	2,31
Allemagne	20	2,10
Ouganda	20	2,10
Belgique	16	1,68
Congo	15	1,58
RCI	12	1,26

Espagne	11	1,16
ND	6	0,63
Others	86	9,05
TOTAL	951	100

Others: Nigeria, N Zélande, Monaco, Hongrie, Afrique du sud, USA, Togo, Pays Bas, Corée, Canada, Arabie Saoudite, Sénégal, Algérie, Portugal, Italie, Ghana, Angleterre, Caraïbes, Suède, Philippine, Niger, Turquie, Oman.

Table 3. Distribution by dosage form

Dosage form	2018	2019	2020	Total	Percentage (%)
Tablet	89	178	232	499	52,47
Injectable	22	35	67	124	13,03
Capsule	23	15	28	66	6,94
Oral suspension	11	15	39	65	6,83
Syrup	7	13	32	52	5,46
Powder for oral preparation	9	10	10	29	3,05
Powder nutritional supplement	0	1	28	29	3,05
Dermal cream	3	8	5	16	1,68
Suppository	4	3	5	12	1,26
Dermal gel	0	3	7	10	1,05
Others	10	18	21	49	5,08
TOTAL	178	299	474	951	100

Of the 951 registration applications, 499 were tablets, i.e. 52.47%.

Table 4. Distribution by route of administration

Route of administration	2018	2019	2020	Total	Percentage (%)
Oral route	140	241	373	754	79,28
Parenteral route	22	35	68	125	13,14
Mucosal route	13	7	13	33	3,47
Dermal route	3	13	16	32	3,26
Others	0	3	4	7	0,73
TOTAL	178	299	474	951	100

Other: RDT, manual suction kit, mosquito net.

Table 5. Distribution by therapeutic class

Therapeutic classes	2018	Years 2019	2020	Total	Percentage (%)
Antibacterials	**32**	**71**	**100**	**203**	**21,35**
Antimalarials	**20**	**29**	**43**	**92**	**9,67**
NSAIDS	7	17	32	56	5,89
Antalgics	11	19	23	53	5,57
Antihypertensives	9	20	22	51	5,36
Antiulcers	11	25	10	46	4,83
Vitamins	8	7	28	43	4,52
Antiparasitics	5	10	6	21	2,2
Antihistamines H1	3	13	13	29	3,04
Nutritional complements	0	0	28	28	2,94
Hypolipidemics	6	6	15	27	2,83
Antidiabetics	8	7	5	20	2,10
Antivirals	2	6	11	19	2
Antispasmodics	4	5	10	19	2
Others	52	64	126	244	25,66
TOTAL	178	299	474	951	100

Table 6. Distribution of dossiers by NCHPA opinion

Decision	Numbers	Percent (%)
Adjourned	**825**	**86,75**
Unreservedly accepted	79	8,31

Rejected	30	3,15
Reservedly accepted	17	1,79
Total	951	100

Of the 951 registration application products reviewed by NCHPA between 2018 and 2020, 825 were adjourned on first intent or 86.75% compared to 96 cases for accepted or 10.10%.

4. Discussion

At the end of our study, we found that over the past three years it covered (2018-2019-2020), there were a total of 7 sessions of the NCHPA for 951 registration application dossiers examined. Of these 7 sessions, NCHPA postponed 86.75%, accepted without reservation 8.31%, rejected 3.15% and accepted with reservation 1.79% of the files. We have thus noted an acceptance rate of 10.10%.

By comparing our results with those of the literature, we were able to determine that a study carried out in 2019 in Mali by Assissé-Nowoto *et al*, (3) had reported the holding of three sessions for 848 files examined, including 643 new applications, which was significantly higher than the 299 files we found. If the increase in the number of files observed each year can be translated into a better improvement of the regulatory system in Niger, the decrease in the number of NCHPA sessions in the last two years could be explained by an insufficient number of staff (experts) but also by the advent of the Covid-19 pandemic in 2020 in Niger.

Moreover, studies carried out by Ofirdam et al, (4) in Togo, Mounkoro et al, (5) in Mali and Assissé-Nowoto *et al*, (3) in Mali had, like us, found a predominance of India as a country requesting MA with respectively 35.16% in 2013, 46.44% in 2017 and 44.3% in 2019 in similar studies but also as a manufacturing country. These results could be explained by the difference between our sample sizes but also by the fact that India is full of large pharmaceutical companies and skilled and qualified manpower.

Studies carried out by Kouamba *et al*, in 2016 (6) and Bakabe *et al*, in 2008 (7) had also reported a predominance of the compressed form at respective rates of 48.16% and 43.80%, followed by the injectable form at respective rates of 23.08% and 20.00%. Moreover, Coulibaly *et al*, in their study conducted in Burkina Faso in 2012 had also reported a predominance of the oral route as a route of administration followed by the parenteral route and the dermal route with 73.66%, 13.33% and 6.59% respectively. (8) This means that the predominance of the tablet form could be explained by the galenic technology of their manufacture which is simple to implement. In addition, the dry galenic form of the tablet offers a better possibility of conservation of the product. In addition, looking at the therapeutic class, we note that our results overlap with those found by Assissé-Nowoto *et al*, in their study conducted in Mali in 2019 (3) which had also found a predominance of the antibacterial class with a rate of 21.8%. They were also similar with those obtained in the study of Ofirdam *et al*, in Togo in 2017 (4) which had shown that antibiotics 26.24% dominated in 2017 against 28.8% in 2010.

The predominance of antibacterial as the majority therapeutic class could be related to the fact that microbial infections are one of the major causes of morbidity and mortality in Niger. (9) Similarly, the national policy of infection control has extremely elaborate treatment strategies that ensure therapeutic success. The second place occupied by antimalarial was surely due to the fact that malaria represents more than 28% of all diseases and 50% of all deaths recorded in Niger. (10) Moreover, antimicrobials and antimalarial occupying the first two places in the ranking could be explained by the fact that the top ten morbidities in 2016 in reference to the Niger health statistical yearbook concern malaria, cough/cold, diarrhea, pneumonia, malnutrition, other digestive diseases, dermatological diseases, trauma-injuries, simple conjunctivitis and dysentery, all of which are essentially caused by microbes and parasites. (9)

At the end of our study, we found an acceptance rate of 10.10% of the applications for MSA, which was significantly lower than that reported by Assissé-Nowoto *et al*, in their study conducted in Mali in 2019 and Ofirdam *et al*, in their study conducted in Togo, who found respectively 70% and 25.23%. (3,4) These results could be explained by the fact that the authors Assissé-Nowoto *et al*, and Ofirdam *et al*, had included in their studies renewal requests which in most cases are granted by the regulatory authority except in cases of pharmacovigilance reported.

5. Conclusion

The national nomenclature of registered medicines thus remains the main document guiding the prescription and dispensing of products with valid MA. It is a core responsibility of the MOH to regularly edit and provide prescribers and importers the national nomenclature for rationale and effective prescribing act. More so, combination of awareness rising among prescribers, effective patient counseling and therapeutic education at dispensing point can significantly contribute to rationale drug use and general patient care.

As our study is the first to be conducted in Niger, it will serve as a reference for future studies.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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