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Review Article

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Pharmaceutical Regulation in Niger in 2021: Significant advances with the Harmonization Process

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Abstract

The pharmaceutical sector is governed in Niger by a number of scattered texts. After the independence, it was only in 1988 that the National Council of the Order of Medical doctors, Pharmacists and Dentists (CNO/MPCD) got created, then in 1995, the adoption of the national pharmaceutical policy (NPP). The NPP laid the foundations for the development of specific pharmacy and drug legislation and led to the adoption of the law and its subsequent implementing texts. This article aims to make an inventory, an analysis of texts relating to pharmacy and medicine in Niger, areas for improvement with regards to the application of these texts and the contributions of community texts in strengthening national regulations and the preservation of public health.

Keywords: Pharmaceutical law and regulation, Niger, Harmonization, WAEMU, ECOWAS, African Union (AU)

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1. Introduction

The Constitution of the 7th Republic of Niger, adopted by referendum on October 31st, 2010 and promulgated on November 25 of the same year, enshrines the right to health for all Nigerien citizens in its articles No. 12 and 13. (1)

This right implies the implicit recognition in the Constitution of the right of access to medical products and technologies by obliging the state to ensure the creation of conditions for providing medical services and medical assistance to all persons in case of illness. Pharmacy law and regulation, as a specialized branch of health law and regulation, contributes to the achievement of this provision of the Constitution by providing legal texts regulating health products, pharmaceutical institutions and personnel. The definition of a medicine encompasses pharmaceuticals for human use, health technologies including blood and biological products, vaccines and immunological products, cosmetics and personal care products, and medical devices. (2) Pharmaceutical law and regulation is now taking on a new dimension in the preservation of public health and the development of the pharmaceutical market, due to the harmonization within different regional economic communities but also at the international level with the signing of conventions and treaties.

Niger belongs to three sets of organizations, namely the West African Economic and Monetary Union (WAEMU), the Economic Community of West African States (ECOWAS) and the African Union (AU) and has resolutely followed the logic of continuity and implementation of community and international texts, thus reinforcing its legislation on health and particularly in the pharmaceutical field. This article will discuss the legal framework applicable in 2021 in Niger, the contribution of the community pharmaceutical regulation and the perspectives.

Niger's legal system is dualist in the sense that two categories of legal norms coexist: customary law, which is made up of unwritten rules originating from the social body (custom), in the domains circumscribed by the law, and Western law, which is made up of written rules expressly laid down by the public authorities at the various levels of the political and administrative hierarchy. (3–5)

Figure 1 schematizes the hierarchy of norms applicable in Niger. It derives from Law No. 2018-37 of 1 June 2018 establishing the organization and jurisdiction of the courts in the Republic of Niger. The place of custom in the legal system has been reaffirmed since the 1962 law establishing the judicial organization (articles 63 to 68) and law No. 2004-50 of 22 July 2004 on the judicial organization (articles 51 to 53). (6,7)

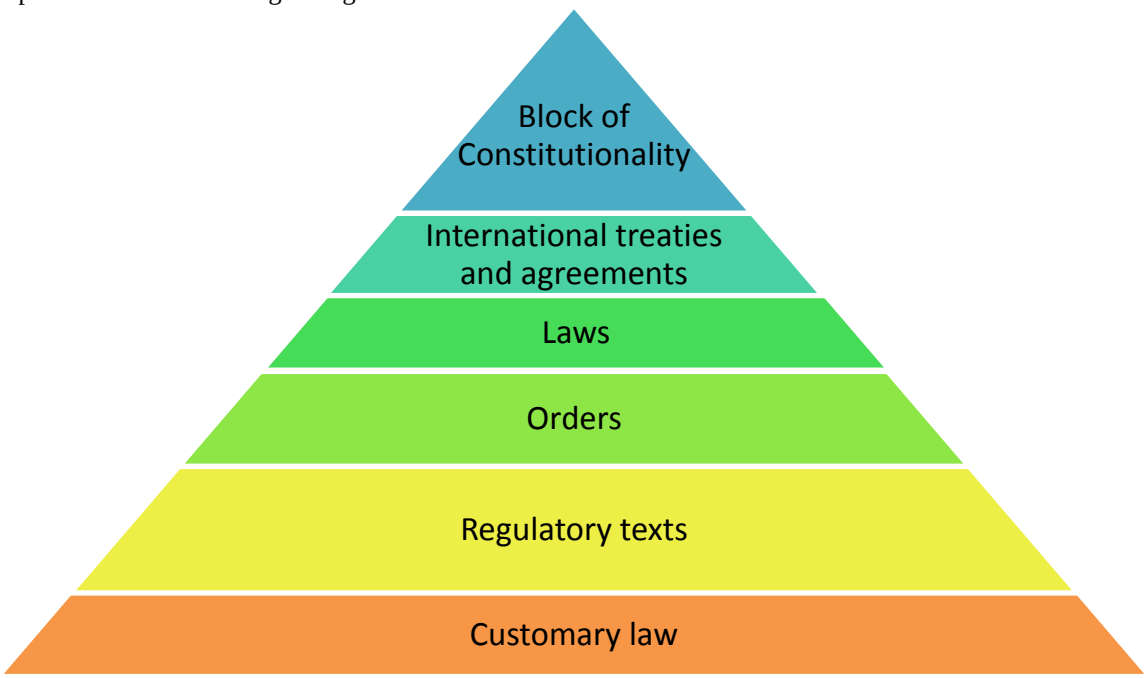

Figure 1. Hierarchy of norms applicable in Niger (based on Law No. 2018-37 of June 1, 2018 establishing the organization and jurisdiction of courts in the Republic of Niger)

2. The pharmaceutical legislative and regulatory framework applicable in Niger

The legislative framework governing the pharmaceutical sector and pharmaceutical activity in Niger includes Law No. 61-27 of July 15, 1961 establishing the penal code, (8) Ordinance No. 97-002 of January 10, 1997 on pharmaceutical legislation, (2) and ratified by law No. 97-05 of June 2, 1997. Other legal texts complete this system: those relating to the use of substances of human origin, (9) and the creation of structures for the implementation of the national pharmaceutical policy, namely the Office National des Produits Pharmaceutiques et Chimiques of Niger (ONPPC), (10) Société Nigérienne des Industries Pharmaceutiques (SONIPHAR), (11) the Laboratoire National de Santé Publique et d'Expertise (LANSPEX), (12) and the Centre National de Transfusion Sanguine (CNTS), (13) Other regulations are applicable to the pharmaceutical sector, such as Ordinance No. 99-42 of 23th September 1999 on the fight against drugs in Niger, (14) Law No. 2018-19 of 27 April 2018 on the National Customs Code, (15) and Order No. 0460/MF/DGD/DRRI of November 11, 2020 defining the list of goods referred to in Article No. 246 of the National Customs Code, (16) and Decree No. 2015-295/PRN/MISPD/ACR of June 5, 2015 determining the missions, organization and operation of the Central Office for the Repression of Illegal Drug Trafficking (OCRTIS). (17)

2.1 The basis of pharmaceutical legislation: an ambitious and proactive pharmaceutical policy

During the colonial era, in the last decade before independence, the field of pharmacy in the French colonies of Africa was mainly governed by the decree No. 51-1322 of November 6, 1951 relating to the pharmacy code, (18) the decree No. 53-591 of June 25, 1953 fixing the code of ethics of pharmacists, (19) law No. 53-662 of August 1, 1953 modifying and completing the provisions of the pharmacy code concerning the national order of pharmacists and making them applicable to the overseas territories, Togo and Cameroon (20) and the Public Health Code of 1954. (21) After Niger's independence in 1960, the very first regulatory text dealing with pharmaceutical law and regulation was decree No. 62-127/MTS of May 26, 1962 setting the reimbursement rate for the day of

hospitalization in the hospitals of the Republic of Niger and determining the reimbursement rate for certain medicines, examinations and laboratory analyses. (22) Products for which the price could not be fixed were sold at the management account price plus 25%. The previous texts did not take this aspect into account. (23)

Adopted in March 1995, Niger's pharmaceutical policy was the starting point for pharmaceutical law and regulation, covering the entire life of the drug as well as the pharmaceutical activity.

Thus, in terms of pharmaceutical legislation and regulation, its objective is to put in place an appropriate legal framework to govern the entire pharmaceutical sector.

In doing so, it already gives orientations as to the fields to be covered by the future law on pharmaceutical legislation of January 1997 and its subsequent texts of application.

2.2 The scope of the provisions of Law 97-05 of June 2, 1997, ratifying Ordinance 97-002 of January 10, 1997 on pharmaceutical legislation

Ordinance No. 97-002 of January 10, 1997 on pharmaceutical legislation is the reference text for the management of the sector and the application of pharmaceutical law in Niger.

It has remained unchanged since 1997, despite attempts to amend it, which have been initiated and documented with regard to its implementation and which will be largely addressed by the process of harmonization at the community and regional levels. Ordinance No. 97-002 is divided into two parts with four and three titles respectively and a total of 23 chapters.

The Ordinance addresses the following aspects:

General provisions relating to Pharmacy

This part of the law defines, in its article No. 2, the drug as being "any substance or composition presented as having curative or preventive properties with regard to human or animal diseases, as well as any product that can be administered to humans or animals, with a view to establishing a medical diagnosis or to restoring, correcting or modifying their organic functions", which is very close to that of the World Health Organization (WHO) (24) as well as the different categories of medicine mentioned. The definition has been extended to include medical and surgical devices and dressing objects, cosmetics and body hygiene products, as well as dietetic, diet products and products of human origin.
The registration of medicines intended to be distributed in the country, whether for sale or free of charge, has become compulsory and is subject to prior submission of files to the Ministry of Health for the purpose of obtaining a marketing authorization (MA).

The conditions for prescribing, preparing and dispensing medicines are defined with a classification of medicines containing poisonous substances according to lists I (toxic products), II (dangerous products) and the list of narcotics. These lists are based on the former tables A, C and B respectively, annexed to decree No. 77-168/PCMS/MSP/AS/DMR/MJ of December 8, 1977, implementing ordinance No. 74-30 of November 8, 1974, regulating the trade, possession and use of poisonous substances and narcotics, adopted within the framework of the international conventions ratified by Niger. This ordinance and its implementing decree were repealed by Ordinance No. 99-42 of September 23, 1999 on the fight against narcotic drugs in Niger. (25)

The latter includes the classification of narcotic drugs, psychotropic substances and their precursors in the four schedules I, II, III and IV according to the control measures to which they are subjected. It confirms the pharmacist's monopoly in the granting of licenses and authorizations with regard to the provisions applicable to retail trade and distribution, and to a lesser extent, to physicians and veterinary surgeons authorized to practice propharmacy.

In fact, the legislator has already explicitly introduced the concept of the pharmaceutical monopoly and implicitly the pharmaceutical responsibility and accountability in the management of medicines.

Advertising of medicines, other pharmaceutical products and pharmaceutical establishments is only allowed to health professionals, except for products that do not pose a risk to public health. The 'truthfulness and fairness' of the content of the advertisement is enforceable against the promoter.

Finally, this first title of Ordinance No. 97-002 ends with the conditions determining access to the profession of pharmacist in general and to private practice, and the possibility for nationals of a country that has concluded reciprocity agreements with Niger to practice in the territory. The pharmaceutical monopoly is confirmed by Article 37 and includes the products and acts contained in the monopoly as well as the exemptions granted and mentioned in Articles No. 19, 63 and 91.

These exemptions concern pharmacies established within public or private health facilities with a small capacity (less than 150 beds), private drugstores, doctors practicing in a locality that does not have a pharmacy open to the public, and veterinary pharmacies.

The various modes of practice of Pharmacy in Niger

The various modes of pharmacy practice provided for by Ordinance No. 97-002 are: private pharmacy, hospital, drugstores, manufacturing and preparation establishments, import and distribution establishments, herbalist's shop, and the pharmaceutical engineering company or business.

The pharmaceutical engineering company is any establishment whose purpose is to propose a set of plans and studies that allow determining the realization of a private pharmacy, a Laboratory of biomedical or physico-chemical analyses, a production unit or an investment program specific to the pharmaceutical field.

These establishments and structures exploit health products circulating in Niger, including those of the veterinary pharmacy, whether they are manufactured or imported and distributed for sale or free of charge. Other activities related to pharmacy include biomedical

analysis laboratories, optical eyewear and traditional medicine practices, products and remedies.

The administration of all these activities and establishments is the responsibility of the Ministry in charge of Public Health, with the exception of establishments for the manufacture and preparation of medicines, which is the responsibility of the Ministries of the Environment, Industry, Promotion of the Private Sector and Trade.

Restrictions on trade in certain substances and articles

The substances concerned here are poisonous substances, artificial radioelements, essences that can be used in the manufacture of alcoholic beverages and abortifacients, which are also the responsibility of the pharmacist with the same traceability and restrictions as narcotics.

The essences referred to here are those of anise, badian, fennel, hyssop, anethol as well as essences of wormwood and similar products or those likely to replace them.

Other products such as cosmetics and body hygiene products for therapeutic purposes, as well as related provisions such as the opening and operation of establishments and the extension of activity relating to these products, their safety and the formula for their manufacture are subject to a declaration to the competent administrative authorities, to whom a dossier is to be transmitted to the minister in charge of health.

These provisions also apply to insecticides and acaricides intended to be applied to humans and products intended for the maintenance or application of contact lenses.

Items such as fever thermometers, baby bottles, pacifiers and soothers are also covered. All these products can be marketed by non-pharmacists, but are also subject to the procedure of prior application for marketing authorization to the Ministry of Health.

Control and pharmaceutical inspection

Also devolved to the Ministry of Health, pharmaceutical inspection is carried out by pharmacist inspectors appointed by decree under the condition of having the grade of the 3rd step of the main class in the civil service grid.

In the exercise of their function, the pharmacist inspectors of health have the prerogative to control the pharmaceutical establishments, public and private, of manufacture, importation and wholesale distribution, dispensing of medicines and other pharmaceutical products and analysis laboratories as well as any other place where these products can be found. They carry their commission of employment which mentions their oath before the Court of Appeal, which they must show on request.

The inspectors may call on the police to assist them in the event of refusal or resistance to the inspection. In application of article No. 122 of the ordinance No. 97-002 of January 10, 1997 on pharmaceutical legislation and of the decree No. 0195/MSP/DPHL of July 8, 1998 fixing the conditions and the destination of a seizure of samples, (26) the inspectors in the exercise of their functions to carry out research, take samples and, if necessary, make seizures in pharmaceutical establishments and those where products and objects as defined in articles No. 2 and 29 of the law may be found. The samples taken or seized are sent by the inspector to the ministry in charge of health, which transmits them to the laboratory for analysis.

Inspectors are bound by professional secrecy in accordance with article No. 221 of the Penal Code, (8) They draw up a report on the violations observed, which is sent to the public prosecutor and the National Council of the Order of Pharmacists. Violations relating to the price of medicines are forwarded to the Ministry of Commerce, whose sworn agents draw up a report and send it to the Minister of Public Health. (27)

2.3 The regulations governing the pharmaceutical sector in Niger

The pharmaceutical regulatory system is composed of the unique decree No. 97-301/PRN/MSP of August 6, 1997 (28) setting out the terms of application of ordinance No. 97-002 of 10 January 1997 on pharmaceutical legislation. Decrees, circular letters and information notes, all taken either in the framework of the application of the aforementioned ordinance, the statutes of the various structures for the implementation of the national pharmaceutical policy, service requirements or in the process of harmonization of pharmaceutical regulations at the community level completes the system.
However, several of these provisions have been repealed or modified in the process of harmonization undertaken in the framework of the Economic Community of West African States (ECOWAS) and the West African Economic and Monetary Union (WAEMU).

3. Desirable areas of improvement in 2021 in light of the application of the texts:

After some 20 years of application and implementation, there are shortcomings and a need to improve the texts governing the pharmaceutical sector in Niger, despite an unsuccessful attempt in 2002. The NPP, which is the basis of the current legislation, has also been revised to take into account new public health challenges and to respond to the evolving international context governing health products and pharmacy practice.

The main areas for improvement should be the products included in the pharmaceutical monopoly and the pharmaceutical acts on the one hand, and the areas of regulation on the other.

3.1 Products and objects covered by the pharmaceutical monopoly

The pharmaceutical monopoly is enshrined in Article No. 37 of Law No. 97-002 of January 10, 1997 on pharmaceutical legislation, which defines the products, objects and acts included in it. Article 2 of the same law states that the pharmaceutical monopoly includes:

- Body hygiene products and cosmetic products containing a substance with a therapeutic action;

- Personal hygiene products and cosmetic products containing poisonous substances in doses and concentrations equal to or greater than those fixed for each substance and for each type of product by order of the Minister of Health.

- Dietetic products which contain in their composition chemical or biological substances which do not constitute foodstuffs themselves, but whose presence confers on these products either special property sought in dietetic therapy, or properties of test meals.

The items included in the pharmaceutical monopoly and listed in Article 37 of Law No. 97-002 of January 10, 1997, include dressing items, products intended for medical diagnosis or pregnancy and medical-surgical equipment.

The different categories of drugs mentioned are the pharmaceutical specialty, the essential drug, the generic drug, the official medicine, the magistral drug and the medicinal plant.

3.2 Products and objects not included in the pharmaceutical monopoly

The current categorization of medicines now needs to be updated in light of the considerable progress in science and public health issues. Thus, we are witnessing a diversity of terminology in terms of drugs that must be taken into account in the management and administration of the drug but also to allow a good decision making of the judge in case of litigation.

Hence, the following categories should be considered: other biological products in addition to blood products and their derivatives, homeopathic medicines, advanced therapy medicines, radiopharmaceutical products, immunological sera, generators, kits, precursors; but also preparations such as xenogeneic cell therapy preparations, gene therapy preparations and hospital or officinal preparations. And subject to intellectual property rights, similar biological drugs and the generic specialty of a reference specialty should also be considered. Similarly, should also be taken into account, medicines intended for clinical trials, including the experimental and authorized medicine, the auxiliary and authorized medicine and the experimental advanced therapy medicine.

Concerning medical-surgical and dressing materials, this designation is now restrictive in view of the range of products and objects included in this field, and of therapeutic advances in health technologies. Since the first draft of the work on these products under the lead of the WHO in 2007 with the resolution of the World Health Assembly WHA60.29, the new name for MD and diagnostics would be "Medical Devices (MD) and in vitro diagnostic MD (IVD)". (29) In 2014, Resolution WHA67-20 on Strengthening Regulatory Systems for Medical Products adopted the term "medical products" which now includes drugs, vaccines, diagnostics and MDs. The WHO equates these products with medicines and proposes their classification into four categories according to the severity of harm that may be inflicted on the patient or user "the risk class of a medical device is determined by factors such as the extent of invasiveness, the duration of use in the body, and the purpose for which a medicine or biological product is manufactured. The risk class of an IVD depends primarily on the impact of an incorrect result, either on public or individual health.

Specific regulations for MDs and IVDs have been incomplete or non-existent in Niger until 2020. In order to fill the gap in the regulation of health products for human use and to keep up with advances in the pharmaceutical field at the sub-regional, regional and international levels, two orders were issued. (30,31) The first, Order No. 884/MSP/SG/DGSP/DPH/MT of October 15, 2020, concerns the creation, missions, composition and operation of the national commission for approval of establishments manufacturing, importing, exporting, promoting, distributing and maintaining medical devices for human use (CNA-DM).

The second, Order No. 240/MSP/SG/DGSP/DPH/MT of March 11, 2021, deals with the regulation of MDs and brings together all aspects concerning classification, essential safety and performance requirements, the obligations of manufacturers, public authorities, conformity assessment bodies, importers, exporters, distributors, professional users, and the types of establishments manufacturing, importing, exporting and distributing MDs.

The decree also takes into account IVDs, market surveillance through import control, quality control, control of promotion and advertising, the fight against substandard and falsified MDs and their illegal sale, inspection of the various actors in the supply chain and materovigilance. Compliance with the provisions of these decrees will allow the introduction into the national territory and the circulation of medical devices that meet the norms and standards of quality and safety.

3.3 The concept of pharmacy activity in Niger

Pharmaceutical activity is usually defined as that relating to the development, production, import, export, exploitation, distribution and dispensing to users of a number of health products, including those included in the pharmaceutical monopoly. (32)

These activities, with the exception of export, are all mentioned in Article 37 of Law No. 97-002 of January 10, 1997 on pharmaceutical legislation, which is devoted to the pharmaceutical monopoly. The operations are mentioned in articles 92, 95 and 140. Quality control of medicines, carried out in the national laboratory, is also the responsibility of pharmacists. The exceptions to the monopoly are mentioned in articles 19, 63 and 91. Exportation of medicinal products from Niger is almost non-existent. This is due to the very low local production capacity, covering only 7.69% of national needs in 2005. (33)

The operation of pharmaceutical establishments is also devolved to pharmacists with some nuances. The opening and operation of pharmacies is reserved exclusively for pharmacists, and that of biomedical

analysis laboratories is shared between pharmacists, doctors and veterinary biologists. Establishments for importing and wholesale distribution, manufacturing and preparation, and the pharmaceutical engineering company or enterprise may be opened by lessors. However, Law No. 97-002 of January 10, 1997 requires that the management of these establishments be ensured by a pharmacist of Nigerien nationality. This pharmacist director is also the responsible pharmacist to the public authorities. The opening and operation of these pharmaceutical establishments are subject to the prior authorization of the Minister of Health, after consultation with the National Council of the Order of Pharmacists.

Despite the concept of the pharmacist in charge of pharmaceutical establishments, the legislation does not require the pharmacist to hold shares in these companies and this leads to a "deprofessionalization" of the activity, relegating the pharmacist to the background of the management of the establishment, without any precise and tangible task; and yet, in case of infringement of any provisions, the pharmacist is liable. This situation is one of the main causes of the large number of import and wholesale distribution establishments in the country, 12 private wholesalers and one national central purchasing office with its 3 zone depots, (34) but also of the difficulties in controlling and regulating the sector effectively, hence the development of the illicit market.

However, some provisions of the law still need to be regulated; these include Article 47 on pharmacy ownership agreements and Article 71 on in-house pharmacies, specifically with regard to supply between in-house pharmacies. There is also a need to clarify the category of health professional authorized to apply for a license to practice as a medical representative or laboratory representative for the promotion of pharmaceutical products.

3.4 Derogations from the monopoly and delegation of signature

In order to preserve public health, provisions derogating from the pharmaceutical monopoly were adopted by law n°97-02. In its articles 19, it allowed medicines dealers installed before the entry into force of the ordinance n° 97-002 to continue their activities; and in articles 72 to 75, the modalities of opening drug stores. Similarly, it allowed doctors in towns deprived of a pharmacy to dispense the medicines they prescribed to their patients (article 63) and allowed any authorized person to practice veterinary pharmacy (article 64).

Concerning the delegation of signature, Order n°149/MSP/LCE/DPS/ES/DPHL/MT of July 26, 1999, delegating signature to the Prefects of the Departments following consultation from the Regional Director of Public Health, mandated the Prefects of the Departments, now Governors of the Regions, to authorize the opening and operation of drug stores and certain health structures in their regional areas. This decree requires them to notify the Minister in charge of Public Health of any authorization granted as soon as possible. Authorizations for opening or renewal are granted every two (2) years after the Departmental Director of Health has established that the establishment is functioning properly. However, these provisions are not fully respected and it is common to see pharmaceutical warehouses in urban areas that do not respect the supply conditions imposed by the legislation, nor the list of medicines and devices authorized to be dispensed there.

3.5 Regulation of the pharmaceutical sector in Niger

The administration of the pharmaceutical sector in Niger is a shared responsibility between the Directorate of Pharmacy and Traditional Medicine (DPH/MT) and the Directorate of Health Laboratories (DLS), depending on the field of activity. The control of the application of the texts is the responsibility of the General Inspectorate of Services (IGS), by inspectors of the services in charge of pharmacy, laboratories, traditional medicine and pharmacopoeia. However, some areas of regulation also remain uncovered. These include the supervision of clinical trials, market surveillance and the fight against substandard and falsified medical products, and the transit of medicines, where there is a legal vacuum.

Other areas, however, are insufficiently covered. These are import controls and the modalities of quality control of medicines before they are released for consumption. In these cases, although there is a decree instituting a control of generic drugs before they are released for consumption, (35) there are no clear provisions on the responsibility for sampling and the presence of inspectors at the level of the customs cordon for the physical verification of conformity before the clearance of medicines consignements, nor the requirement for pharmaceutical specialties exempted from quality control to be accompanied by a certificate of analysis.

4. The National Order of Pharmacists (ONP): the guarantor of professional ethics

With financial autonomy and legal personality, the National Order of Pharmacists was created in 2017 by Decree No. 2017-765 /PRN/MSP of September 29. (36) Previously, there was a mixed Order called the National Council of the Order of Physicians, Pharmacists and Dentists of Niger, created by Order No. 88-31 of June 9, 1988, (37) with a code of ethics specific to each profession. (38) The Order ensures the defense of the honor and independence of the pharmaceutical profession as well as the defense of the practitioner in the exercise of his profession. It must also ensure that the principles of morality, probity and dedication essential to the practice of pharmacy in a public or private capacity are respected.

It gives its opinion to the public authorities on pharmaceutical legislation and regulations and on all matters concerning public health, on which it is consulted by the Government. The Order also hopes to improve the image of the pharmaceutical profession, which has been compromised by the development of the illicit drug market. In this fight, it is a major ally alongside the public services and other stakeholders. Table 1 summarizes the main legal texts applicable in Niger.

Table 1. Summary of the main legal texts applicable in Niger (39,40)

Pharmaceutical scope	Applicable legal text
Professional secrecy	Code pénal, loi nº 61-27 du 15 juillet 1961 portant institution du code pénal, article 221 relatif à la révélation du secret [Penal Code, Law No. 61-27 of July 15, 1961, establishing the Penal Code, Article No. 221 on the disclosure of secrets]. (8)
Administration of medicines and other health products, poisonous substances, different ways of practicing the profession, opening and operation of pharmaceutical establishments, traditional medicine and herbal medicine, activities related to pharmacy, vigilance	• Ordonnance nº 97-002 du 10 janvier 1997 portant Législation pharmaceutique ratifiée par la loi nº 97-005 du 02 juin 1997 [Ordinance No. 97-002 of January 10, 1997 on Pharmaceutical Legislation, ratified by Law No. 97-005 of June 2, 1997]. (2) • Décret nº 97-301/PRN/MSP du 06 août 1997 fixant les modalités d'application de l'ordonnance nº 97-002 du 10 janvier 1997 portant Législation Pharmaceutique [Decree No. 97-301/PRN/MSP of August 6, 1997, establishing the terms of application of Ordinance No. 97-002 of January 10, 1997 on Pharmaceutical Legislation]. (28) • Ordonnance n° 99-035 du 3 septembre 1999 relative à l'utilisation des substances d'origine humaine [Ordinance No. 99-035 of September 3, 1999 on the use of substances of human origin]. (9) • Arrêté n° 253 /MSP/DGSP/DPH/MT du 22/07/2014, portant création, missions et organisation des organes du Système National des Vigilances des produits de santé à usage humain [Order No. 253 /MSP/DGSP/DPH/MT of 22/07/2014, on the creation, missions and organization of the organs of the National System of Vigilances of health products for human use]. (41)
Fight against drugs in Niger	• Ordonnance n° 99-42 du 23 septembre 1999, relative à la lutte contre la drogue au Niger et annexes [Ordinance No. 99-42 of September 23, 1999 related to fight against drugs in Niger and annexes]. (25) • Arrêté n° 459/MSP/DGSP/DPHL/MT du 17 décembre 2013 portant inscription du Tramadol au groupe A du tableau II de l'ordonnance n° 99-42 du 23 septembre relative à la lutte contre les drogues au Niger [Order No. 459/MSP/DGSP/DPHL/MT of December 17, 2013 listing Tramadol in group A of Table II of Order No. 99-42 of September 23 on the fight against drugs in Niger]. (42)
Delegation of signature for drug stores	Arrêté n° 149/MSP/LCE/DPS/ES/DPHL/MT du 26 juillet 1999 [Order No. 149/MSP/LCE/DPS/ES/DPHL/MT of July 26, 1999]. (43)
Access to the pharmaceutical profession	• Décret n° 2017-765 /PRN/MSP du 29 septembre 2017 portant création de l'Ordre National des Pharmaciens [Decree No. 2017-765 /PRN/MSP of September 29, 2017 establishing the National Order of Pharmacists]. (36) • Arrêté nº 0996/MSP/SG/DL du 18 septembre 2019 portant modalités d'application du décret nº 2017-765/PRN/MSP du 29 septembre 2017 portant création de l'Ordre National des Pharmaciens [Order No. 0996/MSP/SG/DL of September 18, 2019 on the modalities of application of Decree No. 2017-765/PRN/MSP of September 29, 2017 creating the National Order of Pharmacists]. (44) • Décret n° 88-207/PCMS/MSP/AS du 9 juin 1988 portant approbation d'un code de Déontologie des pharmaciens [Decree No. 88-207/PCMS/MSP/AS of June 9, 1988 approving a code of ethics for pharmacists]. (38)
Illicit trafficking of drugs and pharmaceutical products	Décret nº 2015-295/PRN/MISPD/ACR du 5 juin 2015 déterminant les missions, l'organisation et le fonctionnement de l'Office Central de Répression du Trafic Illicite des Stupéfiants (OCRTIS) [Decree No. 2015-295/PRN/MISPD/ACR of June 5, 2015 determining the missions, organization and functioning of the Central Office for the Repression of Illegal Drug Trafficking (OCRTIS)]. (17)

In addition to these legislative and regulatory provisions governing medicines and other health products, the pharmaceutical sector and the exercise of the pharmaceutical profession in Niger, the harmonization of pharmaceutical regulations at the regional and sub-regional levels in which the country participates strengthens the provisions through various community acts of a mandatory nature.

5. The contribution of community regulations (AU, ECOWAS, WAEMU): strong and harmonized regulations for the sector

Niger is a member of ECOWAS and WAEMU, two regional economic communities (RECs), as well as the African Union (AU). Several actions are carried out by the different organizations in the pharmaceutical field, and Niger has voluntarily and resolutely joined the harmonization process.

5.1 At the regional level (AU)

For the various RECs on the African continent, the major challenge is to establish an effective National Pharmaceutical Regulatory Authority (NPRA) to ensure the effectiveness of interventions and of any health project or program involving health products and technologies. While this objective has been achieved in English-speaking countries, where all the functions of an NPRA are grouped together and carried out within a single entity with management autonomy and legal personality, this is not the case in French- and Portuguese-speaking countries, where the functions are shared between different entities and directorates within the Ministry of Health.

This pattern is not conducive to the effective implementation of regulatory functions because these departments are located at different levels within the Ministry of Health, resulting in a lack of coordination and the risk of a fragmented regulatory system. To remedy this situation, various initiatives are currently underway, all aimed at transforming the ANRP into a public entity, with legal personality and financial and management autonomy, placed under the technical supervision of the Minister of Health and the financial supervision of the Minister of Finance.

The work of the AU Commission (AUC, AU Secretariat) in the area of pharmaceuticals revolves around the adoption of the "Model Law" on the regulation of medical products in 2016 as well as the treaty on the establishment of the African Medicines Agency. (45)

5.1.1 The "Model Law" for African Union Member States on the Regulation of Medical Products

Adopted in January 2016, the model law aims to establish an effective and efficient system of regulation and control of medical products and to ensure that these products meet the required standards of safety, efficacy and quality, to serve as a model for member states in strengthening and harmonizing the regulation of medical products and is intended to be a framework for creating a harmonized regulatory environment on the continent.

Its scope covers all medical products (drugs, vaccines, diagnostic and medical devices), including those in veterinary medicine.

It establishes the National Agency/Authority as an autonomous structure responsible for the implementation and enforcement of all regulatory functions in accordance with the WHO Global Benchmarking Tool (GBT) for the assessment of national regulatory systems for medicines and vaccines. (46)

The Agency can institute administrative, civil and/or criminal procedures.

This law offers a great opportunity for countries to review their legislative and regulatory frameworks and it is within this framework that Niger has embarked on the revision of its texts in order to create the Agency, starting with the revision of the PPN in 2021. (47)

5.1.2 The Union treaty on the establishment of the African Medicines Agency (AMA)

Adopted on February 11, 2019, the Treaty establishing the African Medicines Agency (AMA) entered into force on November 5, 2021, thirty (30) days after the deposit of the 15th instrument of ratification, on October 5, 2021, by the Republic of Cameroon at the African Union Commission (Article 38, AMA Treaty), (48) Niger had signed the treaty on February 09, 2020 and ratified by Law No. 2021-17 of June 23, 2021. (49) AMA will act as a regulatory body at the continental level, responsible for providing leadership to ensure the existence of harmonized and strengthened regulatory systems that will govern the regulation of medicines and medical products on the African continent. In doing so, the Agency will regulate access to safe, effective, good quality and affordable essential medicines and health technologies. To achieve this goal, AMA will work to provide the necessary mechanism for effective coordination of existing regulatory systems, strengthening and harmonizing the efforts of the AUC, RECs and Member States. The funding mechanism of the agency will be established by the Conference of States Parties, which is also responsible for determining the contribution of each State and adopting the annual budget. (45)

The AU Commission's specialized body in the area of pharmaceutical regulation is the African Medicines Regulatory Harmonization (AMRH) Program. This program coordinates the implementation of regional and continental priority programs and projects, resource mobilization, and the establishment of partnerships with the international community and the Regional Economic Communities (RECs) and Member States. (50)

5.2 Sub-regional bodies (WAEMU and ECOWAS) in the harmonization process

5.2.1 The contributions of the Economic Community of West African States: ECOWAS

ECOWAS was created in 1975 following the elaboration of the Treaty of Lagos (Nigeria). With a population of more than 300 million inhabitants spread over an area of about 5.1 million km², ECOWAS constitutes an important pharmaceutical market. Its objective is to promote economic and political cooperation within its area. This objective led the member states to adopt the protocol establishing the West African Health Organization (WAHO) in 1987, which became the specialized body of ECOWAS in the area of health and whose objective is : "to provide the highest level of health care delivery to the populations of the sub-region on the basis of harmonization of Member States' policies, pooling of resources and cooperation between Member States and third countries, with a view to collectively and strategically finding solutions to the health problems of the sub-region". (51)

Since its creation, WAHO has made remarkable progress. WAHO also provides the training required to promote the local production of medicines, (52) capacity building for pharmaceutical regulatory authorities through specific training and evaluation. To accomplish

its missions, WAHO is assisted by technical working groups to work on the following areas: evaluation and registration of pharmaceutical dossiers, good manufacturing practices and inspection, clinical trials, pharmacovigilance and drug safety, drug quality control, quality management systems, information management systems, policy, legislation and regulation.

However, local production of medicines in the region is still limited, with a high concentration in English-speaking countries. (53) Because of the narrowness of national pharmaceutical markets, thought should be given to identifying a specific mechanism for manufacturing finished products, with priority given to essential medicines and public health products, so that a country identified on the basis of evaluations, feasibility studies, and internal potential can produce a given formulation for the entire region. This strategy would ideally allow the establishment of various specialized production units, and trade between countries within the framework of the African continental free trade area.

5.2.2 The jurisdiction of the West African Economic and Monetary Union: WAEMU

The implementation of the harmonization process is steered by the "Cellule d'Harmonisation de la Réglementation et de la Coopération Pharmaceutique" (CHRCP), created on July 4, 2005 by the adoption of Regulation No. 02/2005/CM/WAEMU. (54)

The objective assigned to the harmonization process within the WAEMU area is the promotion and protection of public health through the integration and mutual reinforcement of complementary pharmaceutical activities, through the adoption of measures to provide community procedures in the pharmaceutical field in general and medicines in particular.

The CHRCP is responsible for promoting and progressively monitoring the harmonization of pharmaceutical regulations in the member states of the Union in order to contribute to improving the quality of life of the population through access to medicines of guaranteed quality and safety. Regulation No. 02/2005/CM/WAEMU have identified eleven areas of common interest that will be subject to harmonization. These are: production, approval, quality assurance, inspection, supply, health monitoring, practice of the pharmaceutical profession, advertising of medicines, information exchange and technical cooperation, training, and traditional medicine and pharmacopoeia. The harmonization process led to the adoption of directives on the free movement and establishment of health professionals in the WAEMU area.

In 2010, texts whose implementation is mandatory (regulations, decisions and directives) for Member States were adopted. In addition to medicines, these texts concern nutritional supplements, vaccines, cosmetic products, advertising, and good practices for the importation and distribution of pharmaceutical products for human use. These texts have just been reinforced by the adoption of Regulation No. 04/2020/CM/UEMOA on the approval procedures for pharmaceutical products for human use in WAEMU member states (which repeals Regulation No. 06/2010/CM/UEMOA) and Directive No. 06/2020/CM/UEMOA on the status of the pharmaceutical regulatory authorities of WAEMU member states.

The CHRCP is assisted by committees and technical working groups composed of experts from member states, supported as needed by other expertise depending on the issues addressed. Table 2 summarizes the legal and regulatory provisions currently applicable in 2020 in Niger.

Table 2. Summary of legal and regulatory provisions in Niger and contribution of the different harmonization processes

Areas	Applicable provisions	Other standards, sources
Global legal framework	Ordonnance n° 97-002 du 10 janvier 1997 portant Législation pharmaceutique [Ordinance No. 97-002 of January 10, 1997 on pharmaceutical legislation]. (2) Décret nº 97-301 PRN/MSP du 06 août 1997 fixant les modalités d'application de l'ordonnance nº 97-002 [Decree No. 97-301 PRN/MSP of August 6, 1997 establishing the terms of application of Order No. 97-002]. (28)	--
Drug registration	Règlement n° 04/2020/CM/UEMOA relatif aux procédures d'homologation des produits pharmaceutiques à usage humain dans les Etats membres de l'UEMOA [Regulation n° 04/2020/CM/UEMOA relating to the procedures of approval of the pharmaceutical products for human use in the Member States of the UEMOA]. (55)	ECOWAS, (56–58) WHO (29)
Regulation of IVDs	Arrêté nº 0884/MSP/SG/DGSP/DPH/MT du 15 octobre 2020 portant création, missions, composition et fonctionnement de la commission nationale d'agréments des établissements de fabrication, d'importation, d'exportation, de promotion, de distribution et de maintenance des dispositifs médicaux (CNA-DM) à usage humain [Order No. 0884/MSP/SG/DGSP/DPH/MT of October 15, 2020 on the creation, missions, composition and operation of the national commission for the approval of establishments for the manufacture, import, export, promotion, distribution and maintenance of medical devices (CNA-DM) for human use]. (30) Arrêté nº 240/MSP/SG/DGSP/DPH/MT du 11 mars 2021 portant réglementation des dispositifs médicaux [Order No. 240/MSP/SG/DGSP/DPH/MT of March 11, 2021, on the regulation of medical	WHO (29)

Areas	Applicable provisions	Other standards, sources
	devices]. (31)	
Creation of NRAs	Directive n°06/2020/CM/UEMOA portant statut des Autorités Nationales de Règlementation Pharmaceutique dans les Etats membres de l'UEMOA [Directive No. 06/2020/CM/UEMOA on the status of National Pharmaceutical Regulatory Authorities in WAEMU Member States]. (59)	AU (60,61)
Market control and surveillance	Directive nationale applicable au plan de surveillance de la qualité des produits de santé à usage humain, 2013 [National Directive applicable to the quality monitoring plan for health products for human use, 2013]. (62) Arrêté n° 58 /MSP/DGSP/DPH/MT du 03 Février 2017 portant création de la Commission de Destruction des Produits Pharmaceutiques (CDPP) [Order No. 58 /MSP/DGSP/DPH/MT of February 03, 2017 establishing the Commission for the Destruction of Pharmaceutical Products (CDPP)]. (63)	ECOWAS, (64) WHO, (65)
Pharmacist Education and Practice	Arrêté n° 0131/rectorat du 29 février 2012, portant création et organisation des études de pharmacie à la Faculté des Sciences de la Santé de l'Université Abdou Moumouni de Niamey [Order No. 0131/rectorate of February 29, 2012, establishing and organizing pharmacy studies at the Faculty of Health Sciences of the Abdou Moumouni University of Niamey]. (66) Arrêté n° 00095/MESR/I/UDDKM du 18 aout 2014, fixant l'organisation, le fonctionnement des organes et des dispositions propres à la Faculté des Sciences de la Santé de l'Université de Maradi [Order n° 00095/MESR/I/UDDKM of August 18, 2014, fixing the organization, the functioning of the organs and provisions specific to the Faculty of Health Sciences of the University of Maradi]. (67)	WAEMU, (68) ECOWAS, (69–71)
Manufacturing, distribution and importation of drugs	Directives nationales applicables à la conservation et à la distribution des produits de santé, 2013 [National Guidelines for the Storage and Distribution of Health Products, 2013]. (72)	WAEMU, (73,74) ECOWAS, (75-78) AU, (79)

6. Conclusion:

The community texts have completed and strengthened the legal framework of the pharmaceutical sector in Niger.

Effective implementation of this legal arsenal and consideration of the recommendations made by regional and sub-regional organizations will make it possible to resolve key problems such as the increase in illicit sales and the circulation of substandard and falsified medical products.

Eventually, with the updating of the national pharmaceutical policy in 2021, the ongoing revision of pharmaceutical legislation and related standards and directives, the entire legal framework will be adapted to the current and future situation of the Nigerien pharmaceutical sector; in particular, the creation of an ANRP, as recommended by community texts.

These prospects are to be encouraged, as they will considerably facilitate the understanding and application of pharmaceutical law in Niger, both by the actors and by the decision-makers at the national level and the partners.

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Conflict of Interest

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