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Biosafety in the Pharmaceutical Industry in Cameroon: A Holistic-Legal Approach

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Abstract

This paper examines the extent at which the laws in the pharmaceutical industry address biosafety concerns in Cameroon. Of the findings of this study, it was discovered that the government of Cameroon has put in place regulatory frameworks to help address biosafety concerns in the pharmaceutical industry. The efforts of the government however still remain inadequate to tackle the continuous production and marketing of substandard pharmaceutical products. Helping in finding a solution to the problems, it is recommended that the regulatory authority and medicines registration processes be strengthened.

Keywords: Biosafety; Pharmaceutical; Holistic

Introduction

Background and justification to the study, research questions, and objectives of the study and statement of the research problems are what makes up the introductory aspects of this paper.

Background and Justification to the Study

The rapid innovation of modern technology has given rise to new legislative needs, in order to safeguard human health and the environment while at the same time taking advantage of the opportunities offered by technology. Biosafety which are polices or procedures adopted with the view of guaranteeing its application without environmental risks, has also become a point of interest in the pharmaceutical medicines and industry as a whole. Biosafety therefore is a concept that is linked to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. They are measures which have been put into place to prevent and to reduce the dangers of handling and using biological materials in diagnostic, teaching, industrial and even in research in the pharmaceutical laboratories.

The public sector, private sector, and traditional pharmacopoeia are the dominate actors involved in pharmaceutical activities in Cameroon. Centrale National d'Approvisionnement en Medicaments Essentiels (CENAME) is the main public actor involved in the pharmaceutical industry in Cameroon after the Ministry of Health (MoH). The private pharmaceutical sector is made up of the private firms who are out for-profit. They are dominated by distributor wholesalers such as PHARMACAM, BIOPHARM, LABOREX, UCPHARM, and SDPP, and approximately 500 private pharmacies; and the private non-profit, made up reformed, catholic, and Islamic organizations and NGOs [1].

Statement of the Research Problem

Pharmaceutical medicines generally speaking are devoted to the discovery, development and ethical promotion of safe use of pharmaceuticals, vaccines, medical devices and diagnostics [5]. Pharmaceutical products are substances or combination of substances which are presented for the purpose of treating or preventing diseases in human beings or animals with a view of making a diagnosis, correcting or modifying physiological functions in human beings or animals [6]. Since this industry is human centered, a lot of caution has to be followed to ensure that safety measures relating to human health and the environment are adhered to. Access to quality pharmaceuticals products remains a significant constraint to the industry. The industry has been proliferated by hawkers who sell drugs of unknown origin in the markets. Control of these drugs and other pharmaceutical products have become a problem due to the limited capacity of the institutions mandated for such purposes in Cameroon. Against this backdrop, there is a growing need for regulations to govern the conducts of the various actors involved in this industry.

Research Questions

This research is based on the following questions: To what extent the law in the pharmaceutical industry addresses biosafety concerns in Cameroon? Are there biosafety measures that pharmaceutical industry must conform to during/after the production of pharmaceutical products in Cameroon?

Research Objectives

To answer these questions as aforementioned, the researcher formulated the objectives of the study as follows: To examine how biosafety concerns are addressed in the laws relating to the pharmaceutical industry in Cameroon; to discuss the biosafety measures that the pharmaceutical industry must conform to during/after the production of pharmaceutical products in Cameroon.

1. The legal basis in addressing biosafety concerns in the pharmaceutical industry in Cameroon

The issue of biosafety in relation to the pharmaceutical industry has been addressed differently in the different legislative texts promulgated by the parliament in Cameroon Law No. 90-036 of 10th August, 1990 relating to the Organization and Practice of Medicine can be considered as a starting point. This framework law is made of 63 sections, divided into three parts. Part one vividly spelt out the conditions of practice of medicine in Cameroon. In this light, for anyone to engage in the practice of medicine in Cameroon it is a condition unavoidable that he registered with the Medical Association [7].

The law also gives opportunity for physicians of foreign nationality to engage in the practice of medicine in Cameroon after fulfilling certain conditions [8]. The law clearly incorporates the principle of Professional secrecy by those involved in the practice of medicines [9]. Civil servants and government contract employees who are in active service or employed persons are incompatible to practice medicine on a private basis [10].

Though the law does not address biosafety strict census, Section 16 addresses the issues of unlawful practice of medicines in Cameroon. The practice of medicine under an assumed physician name of another is unlawful as well as those who have been banned temporarily or permanently. Persons found guilty of unlawful practice of medicine are punishable with imprisonment of from 6 (six) days to 6 (six) months or with fine of from 2,00,000 to 2,000,000 million francs or with both such imprisonment and fine [11]. The institution of the aforementioned penalties goes a long to ensure safe practice in the medical field and pharmaceutical industry as a whole.

The safety, development, use including contained use, manipulation and cross border movement, including the transit of any genetically modified organism that may negatively affect human and animal health, biodiversity and the environment falls under the coverage of Law N° 2003/006 of 21 April 2003 to lay down safety regulations governing modern biotechnology in Cameroon [12]. This law is followed by its applicable Decree No 2007/0737/PM of 31ST May 2007. The law provides a mechanism for assessing, managing, communicating and controlling the risks inherent in the use, release and cross border movement of genetically modified organisms or those having new traits as a result modern biotechnological activity that may negatively affect the environment, and by extension the conservation and sustainable use of biological resources [13].

Classification of safety levels, advance informed agreement, risk assessment, risk management, raising public awareness and precautionary principle are important concepts covered by the text. Directly related to biosafety is the applicable Decree which provides that the authorization for the fabrication, importation and distribution of the ADN vaccines and other pharmaceutical products related to genetic modified organisms must be issued by the competent administrative authority [14].

Decree No.98/405/PM of 22nd October 1998 lays down conditions for Approving and Marketing Pharmaceutical Products. Approval for pharmaceutical product is a statutory prerequisite for putting a pharmaceutical product in the market. This authorization is granted by the Minster of public health. The Decree holds that any new pharmaceutical product will have a marketing authorization valid for 18months. However before the expiration of such authorization, the holder may requests that it be renewed for a period of 5years [15]. This will depend on the report also given by the National Drug Quality and Assessment Laboratory (NDQAL) about the sad drugs.

2. Institutional mechanisms in redressing biosafety issues in the pharmaceutical industry in Cameroon

The major Institutions concerned in regulating biosafety in the pharmaceutical industry are:

2.1 National central supply of essential medicines and medical consumables: National Central Supply of Essential Medicines as called in French was created in 1996 due to the under performance of the Office National de la Pharmacie (ONAPHARM) and the Centrale Interimaire d'approvisionement en Medicaments Essentiels (CIAME). CENAME as it is abbreviated initially functioned as a project emanating from the corporation between the Government of Cameroon, Belgium and the European Union. In 2005 CENAME became a public establishment orchestrated by the presidential Decree No 2009/252 of June 30, 2005 [16].

CENAME is invested with a public services missions, it is the primary body in the implementation of the national pharmaceutical policy in terms of supply of essential drugs and medical devices. By virtue of decree No 2009/386 of November 30th 2009, it became a Public Administrative Establishment endowed with legal personality and financial autonomy. It is subject to the immediate authority of the Prime Minister, under the technical supervision of the Ministry of Health and the financial supervision of Ministry of Finance [17].

CENAME has as principal mission the following [18]:

- Make sure essential medical devices and medicines are available and accessible.
- Ensure that the quality of these medical devices and medicines which it distributes is of quality standard.
- Supply medical devices and drugs at best quality prices.
- Managing the products of public health programs
- Carries out purchasing at the local and international level.

2.2 National quality control program of Cameroon: Also known as LANACOME. LANACOME is the national drug quality control and expertise laboratory. It is a public scientific and

technical establishment endowed with legal personality and financial autonomy [19], with headquarters located in Yaoundé. The Laboratory is placed under the technical supervision of the Ministry in charge of public health. She ensures that the activities carried out by the Laboratory comply with the orientations of the Government's public policies in the sector concerned [20]. Also the Laboratory is placed under the financial supervision of the Ministry of finance which ensures, the compliance of management operations with a financial impact on the Laboratory together with public finance regulations on the one hand, and the a prior regularity of the accounts on the other hand [21].

The laboratories mission is to ensure the quality control of drugs and various health products, intended for consumptions and exportation, as well as those imported and locally manufactured as defined by regulations in force. In this light it is has the responsibility to [22];

- Undertake studies, analysis and test on a bid to promote medicines and products for therapeutic use, biomaterials, improved indigenous medicines and any other assimilated products of human or veterinary medicine.
- Identify and analyze drugs;
- Monitor the formulation of pesticides, biocides and other products for agricultural use;
- Supervise the quality of food products, agro-food and dietary products, hygienic drinks, drinking water and industrial water treatment systems in accordance with international standards;
- Issue an opinion on compliance, by pharmaceutical establishments, manufacturing, control, packaging, storage, distribution and laboratory standards, as provided by international standards, in collaboration with the structures concerned;
- To undertake expert appraisals of medicines and other consumer products placed on the national market or of any other sample from other countries, at the request of administrations, public or private international organizations.
- To carry out any expertise entrusted to it by the public authorities, in particular within the framework of the International Health Regulations, the fight against smuggling and counterfeiting, the fight against fraud; to contribute to the training of executives, students and technicians from various backgrounds, in the fields of evaluation and quality control of drugs, health products and other related products.

2.3 Department of Pharmacy, Drugs and Laboratory (DPML): The DPML is the central technical department of the Ministry of Public health. It is the organ responsible for organizing and coordinating the regulatory activities of the pharmaceutical industry in Cameroon. Its missions are defined by Decree No 2013/093 of 3rd April 2013 relating to the organization of the Ministry of Public Health [23].

- Developing and monitoring the implementation of the national policy for the supply of drugs, biomedical reagents and medical devices.
- Developing and implementing legislations, regulations and policy standards in the clinical and pharmaceutical fields.
- Approving biomedical reagents and medical devices as well as medicines for human use, both imported and locally manufactured.
- Monitoring and evaluating the activities of biomedical analyses in laboratories
- Approval of drug promotion agencies, medical devices and the issuance of advertising visas for these products.
- Quality control of biomedical reagents, medical devices and drugs manufactured and used local, as well as control of the importation and exportation and distribution of pharmaceutical products.
- The implementation of international agreements on pharmacy, drugs, medical biology, narcotic and psychotic substances, in collaboration with the administrations and organizations concerned.
- Undertake studies, analysis and test on a bid to promote medicines and products for therapeutic use, biomaterials, improved indigenous medicines and any other assimilated products of human or veterinary medicine.
- Identify and analyze drugs;
- Monitor the formulation of pesticides, biocides and other products for agricultural use;
- Supervise the quality of food products, agro-food and dietary products, hygienic drinks, drinking water and industrial water treatment systems in accordance with international standards;
- Issue an opinion on compliance, by pharmaceutical establishments, manufacturing, control, packaging, storage, distribution and laboratory standards, as provided by international standards, in collaboration with the structures concerned;

To undertake expert appraisals of medicines and other consumer products placed on the national market or of any other sample from other countries, at the request of administrations, public or private international organizations.

To carry out any expertise entrusted to it by the public authorities, in particular within the framework of the International Health Regulations, the fight against smuggling and counterfeiting, the fight against fraud; -to contribute to the training of executives, students and technicians from various backgrounds, in the fields of evaluation and quality control of drugs, health products and other related products [24].

2.4 Standard and quality agency: The organ known by its acronym, ANOR was created by Law no 96/11/of 5th August 1996 on standardization. Its decree of application came into effect on 17th September, 2009 [25]. Its role is to conceive and ensure proper Implementation of standards and quality in the industrial, commercial, health and environmental sectors. It has to oversee the certification of compliance with standards and quality, the accreditation of experimental laboratories, inspection bodies and inspection of quality as well as agencies and offices of standard organization [26]. The certifying scheme went operational in-mid 2011 [27].

3. Key aspects in ensuring biosafety in the pharmaceutical industry

The use of regulations as discussed above stands as one of the key aspects in ensuing biosafety rules are respected in the pharmaceutical industry. However, other aspects addressed by this paper include:

3.1 Risks Assessments: Risks assessment remains a basic feature in ensuring biosafety in the pharmaceutical industry in Cameroon. Risk is the combination of the consequences of danger. The livelihood of its occurrence may results to the fact that consequences will arise [28]. Risk assessment in any activity related to the pharmaceutical industry must take into account the precautionary principle. It should be carried in a suitable manner, to guarantee the safety of humans, animals and plants [29].

The purpose of risks assessment is as follows: identify potential risks; assess the likelihood of occurrence of the risks; manage risks; analyze the risk's cost-benefit ratio and examine the efficacy of introducing alternative ways of carrying out the activities [30].

Classification of safety levels is very imperative in the risk management process in pharmaceutical activities. Safety levels can be grouped into 4:

• Group 1 or Class 1: No risk for individuals or the community

It constitutes micro-organisms that, in all probability, cannot cause human or animal disease.

The biosafety law considers it as biotechnological projects that present no risks to the community and the environment as a whole [31].

• Group 2 or Class 2: Moderate risk for individuals, low for the community

They are projects known to present minor risks to the community and/or the environment.

• Group 3: High risk for individuals, low for the community

They are pathogenic germ that causes a serious human or animal disease, but is not usually transmitted from one individual to another.

• Group 4: Significant risk for individuals and the community

Biotechnological projects that usually causes a serious human or animal disease and can be easily transmitted from one individual to another, either directly or indirectly. There is usually no treatment or effective preventive measures [32].

3.2 Public Awareness: Given the potential threats that pharmaceutical industry can caused, it is imperative for the actors to inform the community about the environmental and health effects of their activities. Public awareness is the fact of educating and informing the public about risks and the safety measures relating to the hazards about certain activities [33]. The pharmaceutical industry is not an exception to the public awareness principle. It is the right of citizens to have access to information on the environment, including information on dangerous substances and activities [34].

3.3 Labeling, packaging and marketing of pharmaceutical products: Labeling and packaging are pre requites for products to be marketed at pharmaceutical industry. Labeling creates awareness on the type of pharmaceutical products the consumers are buying and at the same gives prescription on how the products are to be used. The logo, content, marks, characteristics and other indicators of the products are important aspect of labeling in pharmaceutical products. Marketing of pharmaceutical products must be authorized.

4. Conditions for the approval of pharmaceutical products in Cameroon

- Application for the approval of pharmaceutical products must be written in English or French and must be duly stamped and addressed to the minister in charge of public health [35].
- The application form must include: The name of the manufacturer, name of applicant, name of pharmacist representing him, place of manufacture and packing, generic name, full composition of product contra-indication, therapeutic category, and side effects amongst others [36].
- In addition, administrative documents showing receipt of payment of fees must be attached to the document. The fees are paid per type and quantity. Copy of operating license issued by the competent authority is also filed. An undertaking where the owner assumes full responsibility of any incident that may arise from the sad product [37].
- Documents showing analyses of the research carried out on the raw materials, the finished product and stability tests, along with a summary report explaining the choice of control methods must be affixed to the authorization.
- Other aspects like: The expiry date, method of administration, the labeling, and the number of the manufacturing batch, special precautions to eliminate unused products or wastes derived from it must accompanied the documents [38].

5. Challenges in enforcing biosafety in the pharmaceutical industry in Cameroon

The pharmaceutical sector in Cameroon faces a number of impediments; these setbacks can be summed up into socio-economic and legal constraints, and shall be discussed as follows:

5.1 Legal loopholes: Cameroon still does not meet regulatory standards required. The legal frameworks on pertaining to biosafety in the pharmaceutical sector are complex with unclear definitions of responsibilities, regulatory gaps and overlaps, some statutes are not fully established and thus, not performing their full range of regulatory functions.

Moreover, even the available legislations in force suffer from weak enforcement mechanisms to regulate the practice of pharmacy and assure safety and effectiveness of pharmaceuticals. This is also influenced by the weakness of sanctions which provide little deterrence as they are rarely applied.

5.2 Institutional challenges: Most of the institutions in charge of control and monitoring of pharmaceutical activities are underfunded and understaffed; in this light we find the lack of

suitably qualified pharmaceutical personnel at lower levels, there are inadequate operational resources, lack of quality management system and poor staff development programs.

There are equally poor coordination programs between different stakeholders in charge of regulating the sector. In this regard we observe a poor link between the DPML and the regional pharmacy system coupled with nonstandard inventory control forms being used at various levels and by different stakeholders. We also observe, a lacuna in the information management system, that cannot provide timely and reliable medicine consumption data, for example lack of stock cards, incomplete records, poor reporting.

5.3 Financial constraints: The governance of the CENAME (The public central medical store) and in particular supplies and product selection raises serious problems. Its financial situation is cataclysmic, with long-standing government receivables contributing to cash flow issues and rampant growing debt to suppliers. Poor organization and control capabilities, together with these financial constraints, it makes it burdensome to effectively monitor the pharmacy activities and compliance to biosafety levels. Moreover, the general inspection of pharmaceutical services equally has inadequate resources that hinder its mission.

5.4 Growth of clandestine institutions: Besides these issues, the informal and illicit pharmaceutical market is growing raptly, opening the floodgate to counterfeit and substandard medicines. These clandestine institutions careless of complying to biosafety measures and more interested in profit making at the detriment of the harm it causes to human health and the environment. The registration process of medicines is vulnerable to fraudulent practices, and this has given rise to more and more clandestine institutions.

5.5 Prevalence of expired/counterfeit drugs: Modern pharmaceutical products are flooding the Cameroonian markets from various organization with various appellations. Injections, capsules and tablets are examples of such products. Medicines that are expired are relabeled and puts in the market again for sale. In addition, these medicines are exposed to temperatures and conditions making them to become defective, hence no longer suitable for consumption. This is common with the roadside retailers and hawkers of drugs. Also, most of the drugs have been cloned and fails to meet the requirements for their manufacturing. All this further aggravates the poor health situations existing in Cameroon.

Conclusion

Summarily, the purpose of this study was to examine how biosafety concerns are addressed in the laws relating to the pharmaceutical industry in Cameroon. In order to attain this objective, the different legal and institutional frameworks were examined. The work further examined specific aspects of the biosafety concerns in the pharmaceutical sector. The conditions for the approval of pharmaceutical products was also examined. The result of the findings shows that the government, private individuals and NGOs involved in this sector have taken considerably steps to in ensuring that pharmaceutical products respect biosafety norms. That notwithstanding, more needs to be done in this sector.

We therefore recommend that the regulatory authority and medicines registration processes be strengthened. This will help to enhance better inspection of the pharmaceutical products puts out for sale in the market. Also, capacity building programs should be regularly organized for the personnel who worked at the different regulatory institutions. Punitive Measures should be instituted against/roadside retailers and hawkers of pharmaceutical products. Border control should be intensified to verify the quality of pharmaceutical products entering the country. Digitized registration process of pharmacies should be strengthened. This will help to easily identify clandestine operators.

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