Law Journals

Indian Journal of
Health and Medical Law

Volume 5, Issue 1, 2022
DOI (Journal): 10.37591/IJHML
(January-June)

http://lawjournals.celnet.in/index.php/ijhml/index

Case Study IJHML

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

Enow Godwill Baiye[1,*], Glory Chidimma Obasi[2]

Abstract

This paper examines the extent at which the laws in the pharmaceutical industry addresses 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, objectives of the study and statement of the research problems are what makes up the introductory aspects of this paper.

Background and Rationale to the Study

There is the rise in new legislative exigency due to the express innovation of modern technology. This is in a bid to protect human health and the environment, nevertheless also taking advantage of the opportunities or merits 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 [1]. Biosafety is an interrelated concept that is tied-up to the quest to safeguard human health and the environment against possible adverse effects of the products of modern biotechnology [2]. 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 [3].

Some of the ascendant actors engage in pharmaceutical activities in Cameroon are the public sector, private sector as well as traditional pharmacopoeia. Centrale National d'Approvisionnement en Médicaments Essentiels (CENAME) is the main public actor involved in the pharmaceutical industry in Cameroon after the Ministry of Health (MoH). Private firms who focus on profit consist of the private pharmaceutical sector which 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 [4].

***Author for Correspondence**
Enow Godwill Baiye
E-mail: enowgodwillbaiyebaiye@gmail.com

[1]Ph.D. in English Private Law, University of Dschang, Cameroon
[2]Masters in International Law, University of Yaounde II, Cameroon

Received Date: August 05, 2022
Accepted Date: August 19, 2022
Published Date: August 30, 2022

Citation: Enow Godwill Baiye, Glory Chidimma Obasi. Biosafety in the Pharmaceutical Industry in Cameroon: A Holistic-legal Approach. Indian Journal of Health and Medical Law. 2022; 5(1): 26–34p.

Statement of the Research Problem

Pharmaceutical medicines generally speaking is devoted to the discovery, development and ethical promotion of safe use of pharmaceuticals, vaccines, medical devices and diagnostics [5]. One can define a Pharmaceutical product as a medication or combination of substances used to diagnose, cure, treat or prevent disease either in animals or human beings through diagnosis, adjusting or modifying physiological functions in animals or humans [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. To access the right quality of these pharmaceutical products has become a major difficulty in the pharmaceutical industry. The pharmaceutical industry has been infiltrated by hawkers who sell counterfeit drugs of unknown origin in underground markets through illegal means. Exerting strict control for pharmaceutical products have become a persistent problem as a result to the limited capacity of the institutions mandated for such purposes in Cameroon as well as the laxity of the institutions. 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 laws 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.

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.

The Organization and Practice of Medicine in Cameroon is regulated by Law No. 90-036 of 10th August 1990. 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 perspective, engaging in the practice of medicine in Cameroon it is not a visa free for all. That is to say no one has the right to escape being registered with the Medical Association [7].

The practice of medicine in Cameroon is not only limited to nationals. The law also gives the prerogatives of physicians from foreign nations to also take part in the practice of medicine in Cameroon prior to the fulfillment of the conditions provided for by the law [8]. The law clearly incorporates the principle of Professional secrecy by those involved in the practice of medicines [9]. The law exempts certain nationals from practicing medicine in Cameroon amongst which includes government contract employees and civil servants who are in active service to the nation with precise and concise duties [10].

Though the law does not address biosafety *stricto 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. The Cameroon law punishes those who infringe the practice of medicine in Cameroon with an imprisonment term from 6 days to 6 months or with fine of from 200 000 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 Law N° 2003/006 of 21 April 2003 to lay down safety regulations governing modern biotechnology in Cameroon, covers are the safety, prevention, development, use, including contained use, manipulation as well as cross border movement, including the transit of any genetically modified organism that may negatively affect animal and human health, biodiversity and the environment as such as [12]. This law is followed by its applicable Decree No 2007/0737/PM of 31ST May 2007. There are mechanisms put in place by the law for managing, assessing communicating as well as controlling the risks innate in the use, release and cross border movement of genetically modified organisms or those having new features due to modern biotechnological activity that may have adverse effect the environment, and by augmentation the conservation and sustainable use of biological resources in Cameroon [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 authorisation 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 pending the minister of public health's authorization. The Decree holds that any new pharmaceutical product will have a marketing authorisation valid for 18months. However before the expiration of such authorisation, 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 about the sad drugs.

INSTITUTIONAL MECHANISMS IN REDRESSING BIOSAFETY ISSUES IN THE PHARMACEUTICAL INDUSTRY IN CAMEROON

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

Cameroon National Central Supply of Essential Medicines and Medical Consumables

The Cameroon National Central Supply also called in French as National d'Approvisionnement en Médicaments Essentiels was created in 1996 as a result to the performance below the demand of the *Office National* de *la Pharmacie* (ONAPHARM) as well as 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].

Centrale Interimaire d'approvisionement en Medicaments Essentiels has as public services missions, the implementation of the national pharmaceutical policy in terms of supply of vital drugs as well as 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. CENAME under the technical supervision of the Ministry of Health and the financial supervision of Ministry of Finance submits to the authority of the Prime Minister [17].

CENAME has as principal mission the following [18]:

- Make sure essential medical devices and medicines are available and accessible.
- It also ensures that the standard quality of its products and medical devices are stable and sustained.
- 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.

National Quality Control Program of Cameroon

Also known as LANACOME. LANACOME is the national drug quality control and expertise laboratory. The National Quality Control Program of Cameroon, a public scientific and technical establishment having a legal personality and financial autonomy, [19] Yaoundé is its headquarter. Its Laboratory is submitting under the technical supervision of the Ministry in charge of public health. The minister in charge of public health ensures that the activities carried out by the Laboratory is in compliance with the Government's public policies made available to the sector through orientation [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, agri-food and dietary products, drinking water hygienic drinks, and industrial water treatment systems in compliance with international standards.
- Also Issues opinions in accordance, by pharmaceutical establishments vis a vis manufacturing, packaging, control, distribution, storage, and standards of laboratory in compliance with 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 different countries, prior to the request of public or private international organizations administrations.
- 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 as well as the fight to stop fraud.
- It equally contributes to the improvement students, of executives, and technicians through trainings in different fields of evaluation and, health products and on quality control of drugs products.

The Department of Pharmacy, Drugs, and Laboratory (DPML)

This is the main technical department of the Ministry of Public health. It has as function to organizing and coordinating legal or regulatory matters of the pharmaceutical industry in Cameroon. The Decree No 2013/093 of 3rd April 2013 relating to the organization of the Ministry of Public Health outlines the mission of the aforementioned department [23].

- The development of national policy for the supply of biomedical reagents, drugs and medical devices as well ensuring the implementation of the same policy nationwide.
- Structuring, revising and implementing policy standards, regulations and legislations in the pharmaceutical sector.
- Censuring biomedical reagents and medical devices or apparatus as well as drugs for animal and human use, both locally manufactured and imported.
- 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, agri-food and dietary products, drinking water, hygienic drinks, and industrial water treatment systems in incompliance with standards internationally recognized.
- Also Issues opinions in accordance, by pharmaceutical establishments vis a vis manufacturing, packaging, control, distribution, storage, and standards of laboratory in compliance with 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 different countries, prior to the request of public or private international organizations administrations.
- 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 and the fight to stop 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 product
- It equally contributes to the improvement students, of executives, and technicians through trainings in different fields of evaluation and, health products and on quality control of drugs products [24].

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 Implementaton 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].

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:

Risks Assesement

Risks assesement remains a basic feature in ensuring biosafety in the pharmaceutical industry in Cameroon. Risk involves the exposure of danger or amalgamation of the consequences of danger. The livelihood of its occurrence may results to the fact that consequences will arise [28]. The assessment of risk in the activities of pharmaceutical industry must take into cognizance the precautionary principle; that is taking due care and diligence to avoid undesired or unanticipated outcomes. It should be carried in a careful manner, to ensure that plants, animals and more importantly humans are safeguarded [29].

The reason for risks assessment include assessment of the possibility of occurrence of a particular risk, the analyzation of risk's cost-benefit ratio, the identification of potential risk and the examination of the efficiency of introducing new and better ways of carrying out such activities [30].

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

1. *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 law on biosafety considers it as biotechnological projects that present zero risks to the general environment [31].
2. *Group 2 or Class 2: Average risk for individuals, low for the community:* Such projects basically showcase minor peril to the environment or community.
3. *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.
4. *Group 4: Remarkable risk for individuals and the community:* Some serious diseases can be easily transmitted from one person to another or from an animal to a person either directly or indirectly. Some of this is as a result of biotechnological projects. At times to treat such disease or prevent them becomes so difficult [32].

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 process of informing the public, creating a level of consciousness concerning risks and the safety measures relating to the dangers regarding certain activities [33]. The creation of awareness cut across pharmaceutical industry as well. The citizens have the prerogative to access information on the environment, especially information on dangerous [34].

Labeling, Packaging and Marketing of Pharmaceutical Products

Labeling and packaging are prerequites 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. Most often, the content, marks, characteristics, logo and other indicators of the products are necessary aspect of labeling pharmaceutical products. No marketing of pharmaceutical product should go operational without prior authorization.

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, 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. The competent authority are also responsible for issuing the copy of operating licenses 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 authorisation.
- Other aspects like: the expiry date, method of administration, the labeling, the number of the manufacturing batch, special precautions to eliminate unused products or wastes derived from it must accompanied the documents [38].

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:

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.

Also, the enforcement measures to ensure the effectiveness of pharmaceuticals is weak making the legislations suffer inadequate enforcement measures that regulate the practice of pharmaceutical medicine in Cameroon. This is as a result of weak or inappropriate economic sanctions to deter such acts. Most often the economic sanctions are left out.

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.

The coordination programs between the stakeholders in charge of regulating the sector is very poor. In this light, we noticed a poor link between the regional pharmacy system and the DPM. Added to it is the none respect for the standard of inventory control forms being utilized at several levels by different stakeholders. In addition, we noticed, a loophole in the information management system. Access to data on the reliable consumption of medicine in time is difficult and almost impossible.

Financial Setbacks

Many raise serious problems like product selection and CENAME governance on finance. Its financial state is devastating, with long-ranging government receivables contributing to cash flow problems and wild spread increase 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. Added to it, the Inspection of pharmaceutical services has insufficient resources that slows down the attainment of its mission.

Increase of Clandestine Institutions

The rate at which unlawful pharmaceutical and informal market is increasingly spreading is a call for redress aside the aforementioned issues. The continuity of such acts without prompt actions to stop this illicit pharmaceutical market only opens the way for floodgates to counterfeit 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. Fraudulent practices often confront the registration process of medicines in Cameroon turning some of these institutions to clandestine institutions.

Prevalence of Expired/Counterfeit Drugs

Modern pharmaceutical products are flooding the Cameroonian markets from various organisation 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. Inadditon, 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. Nonetheless, there is much more that 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 organised 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.

Digitised registration process of pharmacies should be strengthened. This will help to easily identify clandestine operators.

REFERENCES

1. Section 5 (6) of Law No. 2003/006 of 21st April, 2003 to lay down Safety Regulations governing Biotechnology in Cameroon.
2. The preamble of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.
3. MBOPI., K., (2015), "The Laboratory Biosafety and Biosecurity Guidance in Cameroon", P. 3.
4. Kwesi, E., (2011), "Assessment of the Pharmaceutical Management System in Cameroon", PP.1-29.
5. Edward, D., et al, (2007), Principles and Practice of Pharmaceutical Medicines, 2nd Ed., Wiley, West Sussex, P.10.
6. Section 15(1) of Law No. 90/035 of 10th August 1990 on the Exercise of the Profession of Pharmacists in Cameroon; Section 2(3) of Decree No.98/405/PM of 22nd October 1998 to lay down Conditions for Approving and Marketing Pharmaceutical Products.
7. Section 2 (1) of Law No. 90-036 of 10th August ,1990 relating to the Organization and Practice of Medicine
8. *Ibid,* Section 2 (2).
9. *Ibid,* Section 4.
10. *Ibid,* Section 13.
11. *Ibid,* Section 17.
12. Section 1(1) of Law N° 2003/006 of 21 April 2003 to lay down Safety Regulations governing Modern Biotechnology in Cameroon.
13. *Ibid,* Section 4.
14. Section 26 of the Decree No 2007/0737/PM of 31ST May 2007 on Modern Biotechnology in Cameroon.
15. Section 30 of Decree No.98/405/PM of 22nd October 1998 lays down Conditions for Approving and Marketing Pharmaceutical Products
16. htpps:// www.osidimbea.cm/enterprises/a-capitaux-publics/cename/ (Lastly Accessed on August 4, 2022).
17. Kwesi, E., (2011), *Op. Cit,* n4, P.6.
18. htpps://www.cename.org/index.php/fr/ (Lastly Accessed on August 4, 2022).

19. Article 2 of Decree No. 2018/764 of December 11, 2018 on the Reorganization of the National Drug Quality Control and Expertise Laboratory.
20. *Ibid,* Article 4.
21. *Ibid* Article 5.
22. *Ibid* Article 3.
23. https://dpml.cm/index.php/en/presentation/our-missions (Lastly Accessed on August 4, 2022).
24. Galega, S., et al, (2018), *The Law on Pharmaceutical Product Liability in Context*, 1st Ed., University Printery, Ibadan PP.66-67.
25. Galega, S., et al, (2018), *Op. Cit*, n.24, P.79.
26. Article 6 of the Law no 96/11/of 5th August 1996 on standardization.
27. MINFI: On an information and sensitization meeting with stakeholders: Cameroon Tribune of 22nd February 2011.
28. Section 5 (43) of Law N° 2003/006 of 21 April 2003 to lay down Safety Regulations governing Modern Biotechnology in Cameroon.
29. *Ibid,* Section 18 (1).
30. *Ibid,* Section 19(1)
31. *Ibid,* Section.
32. *Ibid.*
33. Section 5(44) of Law N° 2003/006 of 21 April 2003 to lay down Safety Regulations governing Modern Biotechnology in Cameroon
34. Section 9 (e) of Law No. 96/12 /05 August 1996 Relating to Environmental Management in Cameroon.
35. *Ibid,* Section 4(1).
36. *Ibid,* Section 4(2).
37. *Ibid,* Section 5(1) (a-d).
38. Annex I to Decree No.98/405/PM of 22nd October 1998 lays down Conditions for Approving and Marketing Pharmaceutical Products

