

Abstract

Controlled medicine is an aspect of medical sciences that is very fundamental to the practice of medicine. It is also very important for students and researchers in the medical profession to understand the legal and policy basis for controlled medicine. The aim of this paper is to discuss the legal and policy framework for controlled medicine. The paper finds that there is no uniformity in the laws on controlled medicines in Nigeria and recommends the enactment of the Controlled Medicines Act. The paper concludes that there is need for adequate sensitization of Medical Practitioners and students on the regulations on controlled medicines particularly the penalties for contravention.

Key Words: Medicine, Controlled, Drug, Substance

1. Introduction

What is Medicine?

According to the Oxford Advanced Learner's Dictionary,¹ the word 'medicine' means 'a substance that you can drink or swallow in order to cure an illness.' The Black's Law Dictionary² defines the word 'medicine' as 'a substance possessing or thought by Professionals to possess curative or remedial properties; a preparation used in treating disease or other illness.'

A medicine is therefore seen as a substance whether liquid or solid used for the purpose of curing a disease or ailment.

What is Controlled Medicine?

A controlled substance or medicine is 'a drug that is illegal to possess or use without a Doctor's prescription, specifically any type of drug whose manufacture, possession, and use is regulated by Law, including a narcotic, a stimulant, or a hallucinogen.'³ They also include opioids, depressants and anabolic steroids.

What are Narcotics?

A 'narcotic drug' refers to 'any of the substances, natural or synthetic in the First Schedule of the Single Convention of Narcotic Drugs, 1961 and the Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, as amended in the Second Schedule to this Act including the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1989.'⁴

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¹ AS Hornby, *Oxford Advanced Learner's Dictionary*, 8th Edition (United Kingdom, Oxford Press p.923).

² B A Garner, *Black's Law Dictionary*, 10th Edition,(USA, Thomson Reuteur, 2014) p. 1131

³ *Ibid*, p.403.

⁴ See section 52 of the National Drug Law Enforcement Agency Act CAP. N.30 Laws of the Federation of Nigeria, 2004.

What are Psychotropic Substances?

Psychotropic substances refer to ‘any substances, natural or synthetic, or any natural materials specified in Schedules 1, 11, 111, and IV of the Convention on Drugs or Psychotropic Substances Act, 1971.’⁵

2. Legal Framework for Regulation of Controlled Medicine in Nigeria

In Nigeria, the control, availability and access to Narcotics, Psychotropic substances and other controlled medicines are guided strictly the following legislations and policy:

- The National Agency for Food and Drug Administration and Control Act Cap N1, Laws of the Federation of Nigeria (LFN), 2004;
- National Drug Law Enforcement Agency Act Cap N 30 LFN, 2004;
- National Drug Policy;
- Dangerous Drug Act Cap D1, LFN, 2004;
- Poison and Pharmacy Act Cap 535 LFN, 1990;
- Food and Drugs Act Cap F32 LFN, 2004;
- National Drug Formulary and Essential Drugs List Act Cap 252 LFN 1990; and
- Indian Hemp Decree 19 of 1966 (and Amended Act of 1975)¹².

The Federal Ministry of Health has the responsibility to ensure adequate availability and accessibility to essential medicines including Schedule I Narcotics for medical and scientific purposes.

National Drug Law Enforcement Agency

The National Drug Law Enforcement Agency was established⁶ by the Federal Government of Nigeria to enforce laws against the cultivation, processing, sale, trafficking and use of hard drugs. The Agency is also empowered to investigate persons suspected to have dealings in drugs, and other related matters. The functions of the Agency are as set out in section 3 of the Act.⁷ It includes the enforcement of the provisions of the Act and the coordination of all drug laws and enforcement functions conferred on any person or authority, including Ministers in the Government of the Federation, by any such laws.. The Agency also ensures that Nigeria fulfills its obligation under the relevant United Nations Conventions Section 11 of the Act,⁸ deals with the importation, manufacture, production, processing, planting or growing the drugs popularly known as Cocaine, LSD, heroine or any similar drugs. Conviction for this offence attracts a life imprisonment sentence.

Section 19 of the Act⁹ deals with unlawful possession of cocaine, etc. it provides as follows:

‘Any person who without lawful authority, knowingly possesses the drugs popularly known as cocaine, LSD, heroine or any other similar drugs shall be guilty of an offence under this Act and liable on conviction to be sentenced to imprisonment for a term not less than fifteen years and not exceeding twenty-five years.’

National Agency for Food and Drug Administration and Control

The National Agency for Food and Drug Administration and Control was established¹⁰ by the Federal Government of Nigeria with the functions among others, to regulate and control the importation,

⁵ *Ibid.*

⁶ See section 1 of the National Drug Law Enforcement Agency Act, CAP N.30 LFN, 2004.

⁷ See section 3, *ibid.*

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰See National Agency for Food and Drug Administration and Control Act CAP. N.1 L.F.N, 2004.

exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.

The Agency is also empowered to grant authorization for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances.¹¹the Agency has powers to undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes.¹²

The Agency operates in collaboration¹³ with the National Drug Law Enforcement Agency in eradicating drug abuses in Nigeria.

National Drug Formulary and Essential Drugs List Act¹⁴

This Act was enacted by the Federal Government of Nigeria to prescribe a National Drug Formulary and Essential Drugs List and to prohibit importation into and manufacture in Nigeria of any drug not in the list. The list is however subject to review from time to time.

Section 2 of the Act¹⁵makes it an offence for any person to import into, advertise, display for sale, sell or manufacture in Nigeria any drug which is not contained in the list.

Section 8 of the Act¹⁶prescribes a fine of N 100,000 or imprisonment for a term not exceeding five years on conviction based on section 2 of the Act. It also prescribes punishment in the case of a corporate body for every Director or person in authority of such corporate body.¹⁷

Food and Drugs Act¹⁸

This Act was enacted by the Federal Government of Nigeria to make provision for the regulation of the manufacture, sale and advertisement of food, drugs, cosmetics and devices and repeal the existing State laws on those matters.

Section 3 of the Act¹⁹provides;

“except as authorized by regulation, no person shall import into Nigeria or export therefrom, manufacture, sell, distribute or cause to be distributed (whether as samples or otherwise) any of the drugs specified in the Second Schedule to this Act”

Contravention of the provisions of the Act²⁰attracts upon conviction, a fine of not less than fifty thousand naira or imprisonment for a term not exceeding two years or both. Where a body corporate is involved, the Director, Manager, Secretary or other similar officer or any person purporting to act in such capacity as well as the body corporate shall be punished²¹ accordingly.

¹¹ See section 5(k) , *ibid.*

¹² See section 5(j) , *ibid.*

¹³ See section 5(l) , *ibid.*

¹⁴ National Drug Formulary and Essential Drugs List Act CAP. N.29, L.F.N. 2004.

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ See section 8(2) , *ibid.*

¹⁸ Food and Drugs Act CAP F32 L.F.N, 2004.

¹⁹ *Ibid.*

²⁰ See section 17(1) , *ibid.*

²¹ See section 17(2) , *ibid.*

Dangerous Drugs Act²²

This Act was enacted by the Federal Government of Nigeria to regulate the importation, exportation, manufacture, sale and use of opium and other dangerous drugs.

The provisions of the Act²³ applies to the following drugs:

- a) Opium
- b) Cocoa leaves
- c) Indian hemp

Conviction for contravention of any of the provisions of the Act²⁴ attracts a fine of two thousand naira or imprisonment for a term or ten years or both. The punishment also includes forfeiture of all articles in respect of which the offence was committed. In the case of a corporate body, the Chairman and every official concerned in the management of the company shall be punished accordingly unless such an officer is able to prove that the violation was done without his knowledge or consent.

Pharmacists Council of Nigeria Act²⁵

This Act was enacted by the Federal Government of Nigeria to establish the Pharmacists Council of Nigeria to regulate members of the profession and for matters connected therewith.

Section 2 of the Act²⁶ provides for members and associate members. Section 10 of the Act²⁷ makes registration of all Pharmacists in Nigeria mandatory to be able to practice.

Contravention of any of the provisions of the Act²⁸ attracts a fine of an amount not exceeding N 1,000 on summary conviction.²⁹ Conviction on indictment attracts a fine not exceeding N 1, 000 or imprisonment for a term not exceeding two years or both.³⁰ Where a body corporate is involved, any Director, Manager, Secretary, or other similar Officer of the body corporate or any person purporting to act in any such capacity as well as the body corporate shall be guilty and punished accordingly.

National Policy for Controlled Medicines, 2017**Goals and Objectives**

The National Policy for Controlled Medicines is organized around one primary goal, five objectives and thirty-eight targets. They are considered a guiding framework when developing strategies and action plans for implementing interventions to increase access to controlled medicines for medical and scientific purposes.

Goal

Ensure sustainable availability and accessibility to affordable controlled medicines for medical and scientific purposes, while preventing diversion.

²² Dangerous Drugs Act CAP D1, L.F.N, 2004.

²³ See section 4, *ibid*.

²⁴ See section 19(2), *ibid*.

²⁵ Pharmacists Council of Nigeria Act CAP. P.7 L.F.N, 2004.

²⁶ *ibid*

²⁷ *ibid*

²⁸ *Ibid*, s. 23(5)

²⁹ *Ibid*, s.23(5) (i)

³⁰ *Ibid*, s. 23(5) (i)

Objectives

Each of the objectives i.e. viewed through a cross-cutting lens that includes the need to maintain a balance between access and control that protects the patients and the healthcare staff, the need to maintain vigorous documentation of data and reporting, and the need to ensure continuous monitoring of patients' progress and medical condition.

1. Ensure adequate importation, manufacture or supply of controlled medicines in Nigeria.
2. Ensure availability of the controlled medicines for use in healthcare delivery, across the full spectrum of health services in rural and urban areas, for private and public health services, and at all levels of the healthcare system in Nigeria.
3. Improve the capacity, knowledge and skills of healthcare workers to properly assess, diagnose and prescribe controlled medicines for patients with medical necessity in Nigeria.
4. Promote rational prescribing, dispensing and use of controlled medicines in Nigeria.
5. Strengthen legislative and policy administration in support of a comprehensive, synergistic approach to ensuring access to controlled medicines in Nigeria.

3. International Legal Framework for Regulation of Controlled Medicines

The regulation of controlled medicines globally, is guided by three main International Conventions.³¹ Nigeria is a signatory to these conventions. The Conventions are as follows:

1. The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol;
2. The Convention on Psychotropic Substances of 1971 which was adopted in 1988; and
3. The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

List of Banned Drugs in Nigeria³²



³¹ See National Policy for Controlled Medicines, 2017.

³² Obtained from NAFDAC Website.

List of Banned, Restricted or Controlled Food, Drugs, Cosmetics and Chemicals in Nigeria Issued by National Agency for Food and Drug Administration and Controlled (NAFDAC)

The following are a list of banned, restricted or controlled drugs as obtained from the NAFDAC Website:

1. Controlled drugs that are prohibited from being imported into the country are as follows:

Amphetamine
 Dexamphetamine
 Methamphetamine
 Chlormezanone
 Methaqualone
 Methylphenidate
 Pemoline
 Phenmetrazine
 Phencyclidine
 Secorbarbital

All drugs prohibited by ministerial Administrative Regulation eg. Phenylbutazone

2. Drugs and chemicals which will require authorization and permits to import and to clear from NAFDAC before importation.

i. Bulk Narcotics (for end user manufacturers e.g. codeine pholocodenine only) finished Narcotics can only be imported by Federal Ministry of Health.

ii. All benzodiazepines e.g.

– Diazepam
 – Bromazepam
 – Clonazepam
 – Nitrazepam
 – Flunitrazepam
 – Lorazepam
 – Chlordiazepoxide
 – Clobazam
 – Midazolam etc

iii. Barbiturates

e.g.

– Phenobarbital
 – Thiopentone sodium e.t.c

IV. Tricyclic antidepressants

e.g. imipramine, clomipramine, Amytryptillinee.t.c

v. Other controlled drugs

♣ Pentazocine

♣ Ephedrine pseudoephedrine

♣ Ergometrine, Ergotamine

♣ chloramphenicol

♣ Dipyrone

♣ Saccharin (for toothpaste manufacturers only)

♣ Caffeine

- ♣ Lysergide/LSD-25
- ♣ Mescaline Parheyl
- ♣ Psiloein, Psilotsin Psiliocybine
- ♣ Terrahydrocannabinols
- ♣ Amobarbital
- ♣ Cyclobarbital
- ♣ Glutethimide
- ♣ Pentobarbital
- ♣ Secobarbital
- ♣ Amfepramone
- ♣ Barbital
- ♣ Ethylorvynol
- ♣ Ethinamate
- ♣ Meprobamate
- ♣ Methylphenobarbital
- ♣ Methyprylon
- ♣ Phenobarbital
- ♣ Pipradrol
- ♣ SPA
- ♣ Cobalt preparation
- ♣ Cyclizine
- ♣ Sulphamethoxydiazine
- ♣ Sulphadimethoxine
- ♣ Aminopyrine and Dipyrone
- ♣ Acecarbromal
- ♣ Carbromal
- ♣ Bromosoval
- ♣ Metallic and Its compounds
- ♣ Hexachlorophene
- ♣ Elipten
- ♣ Meclozine
- ♣ Bithionol
- ♣ Imipramine
- ♣ Efocaine
- ♣ Neonovum
- ♣ Xenazoic acid or Xenalamine
- ♣ Dithlzanine iodide
- ♣ Chlorophentermine
- ♣ Cyclamates, Cyclohexylemine and their derivatives
- ♣ Chloramphenicol and its preparations
- ♣ Caffeine
- ♣ Ephedrine and its salt

<i>S. No.</i>	<i>Narcotic Medicines</i>	<i>Psychotropic Substances</i>	<i>Precursors</i>
1	Buprenorphine	Amitriptyline	Ephedrine
2	Codeine	Bromazepam	Ergometrine
3	Dextromethorphan	Clomipramine	Ergotamine
4	Fentanyl Citrate	Clonazepam	Pseudoephedrine
5	Methadone	Diazepam	
6	Morphine Sulphate	Flunitrazepam	
7	Pethidine	Ketamine	
8	Tramadol	Lorazepam	
9		Methylphenidate	
10		Midazolam	
11		Nitrazepam	
12		Pentazocine	
13		Pentobarbitone	
14		Thiopentone	

List of controlled medicines in the Nigeria Essential Medicine List (NEML)³³

Above contains the list of controlled medicines in Nigeria. Controlled medicines or drugs are merely listed in the Nigeria Essential Medicine List as opposed to what obtains in other climes. For instance, in the United States of America,³⁴ controlled drugs are not only listed but they are scheduled from I–V based on drugs that have a high potential for abuse and the potential to create psychological and physical dependence. Also in the United States of America, the Drug Enforcement Agency is responsible for the regulation of controlled medicines and enforcement of the Controlled Substance Act.

4. Justification for Controlled Medicines

As earlier observed, controlled medicines are medicines or substances that are strictly regulated by Government. The reason for this is to avoid drug abuse, trafficking or addiction. Furthermore, drug abuse, trafficking and addiction are proscribed as crimes, offences against the society, both under domestic and international Law, because they are considered as socially harmful.³⁵

The regulation of controlled medicines applies to the manner the medicine or substance is made, used, handled, stored, and distributed. Controlled medicines or substances include opioids, stimulants, depressants, hallucinogens, and anabolic steroids. Controlled substances with known medical use, such as morphine, Valium, and Ritalin, are available only by prescription from a licensed medical

³³ See Annexure III of the National Policy for Controlled Medicines and Its Implementation Strategies, 2017

³⁴ <https://www.dea.gov/drug-information>.

³⁵ Osita C Eze, "The political Economy of Drug Trafficking and Narcotic Abuse," *Narcotics Law and Policy in Nigeria*, Editors; Awa Kalu and Yemi Osinbajo, Federal Ministry of Justice Law Series, vol 8, ISBN 978-2439-08-8, P.188.

professional. Other controlled substances, such as heroin and LSD, have no known medical use and are illegal in the United States.³⁶

The prescription medicines which a medical practitioner can undertake can be further sub-divided into two categories viz:

1. Controlled prescriptions
2. Non-controlled prescriptions

Controlled prescriptions are medications that can cause physical and mental dependence, and the manufacturing, possession and use of these medications is regulated by law. They possess the propensity for abuse or addiction. On the other hand, most prescriptions for chronic conditions or infections are non-controlled. For example, most blood pressure and cholesterol medications, diabetes medications, asthma inhalers, and antibiotics are all non-controlled medications.³⁷

Findings

1. There is no uniformity in the laws on controlled medicine in Nigeria
2. The penalties contained in the various laws are inadequate

Recommendations

1. There is need for uniformity in the laws on controlled medicines in Nigeria.
2. The National Assembly should enact the Controlled Medicines Act.

5. Conclusion

Controlled medicines are medicines or substances that are strictly regulated by Government. To that extent, there is the need for strict monitoring of controlled medicines. Medical practitioners must acquaint themselves with the laws on controlled medicines which have been discussed in this paper. This is because adequate knowledge of the laws or regulations on controlled medicines will help a great deal to reduce incidences of drug abuse, drug trafficking and drug addictions which are very common vices in Nigeria today. Medical Practitioners must know that there are penalties for failure to comply with these regulations.

Furthermore, there is need for Nigeria to have a uniform law on Controlled medicines just like what obtains in the United States of America which have enacted the Controlled Substance Act. This is because the laws on controlled medicine in Nigeria are scattered. There is the need to harmonize these laws for purposes of efficiency.

³⁶<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/controlled-substance>.

³⁷ Ibid.