NATIONAL POLICY FOR CONTROLLED MEDICINES AND ITS IMPLEMENTATION STRATEGIES

Federal Ministry of Health, Nigeria

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RESPONSE TO DRUGS AND RELATED ORGANISED CRIME IN NIGERIA
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FOREWORD

The National Policy for Controlled Medicines (NPCM) and its Implementation Strategies represents the collective will of the government and people of Nigeria to provide and maintain a healthcare system that allows for increased availability and accessibility to affordable controlled medicines to meet the medical needs of patients.

For a long time, this class of medicines has remained largely unavailable and inaccessible for many patients in Nigeria. Apart from the problems of funding availability and accessibility, the training of health care personnel is crucial to filling the gaps in knowledge, skills and attitude towards therapeutic uses of controlled medicines, which is necessary to ensure their rational, safe and effective use.

With the technical support of the United Nations Office on Drugs and Crime (UNODC) and funding by the European Union (EU), Nigeria has developed a comprehensive NPCM as part of efforts to address the basic issues associated with the use of controlled drugs for medical and scientific purposes, as well as ensuring rational prescription and dispensing by qualified health personnel, while preventing diversion and abuse.

The Policy elaborates practical approaches to ensure availability and accessibility to controlled medicines, and articulates a comprehensive policy framework that clearly describes the supply chain with embedded quality assurance mechanisms. It also makes funding recommendations to ensure sustained availability of the medicines and a strategic plan of actions to implement the Policy.

The document also seeks to address the issues of stigma and fear associated with the use of some controlled medicines, as well as promote a collaborative approach and support the rational use of medicines for the patients in need.

While assuring Nigerians of government's commitment and political will to implement this Policy, I wish to express my profound gratitude to the group of experts from the government, private sector, development partners and civil society organizations who generously provided their expertise and precious time in developing this policy.

Finally, I wish to enlist the support and commitment of all stakeholders in ensuring improved availability of, and accessibility to controlled medicines for medical purposes at all levels of the healthcare system while assuring their rational use.

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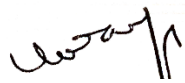
In addition, we recognize and appreciate the contributions of the National Agency for Food and Drug Administration and Control (NAFDAC), Pharmacists Council of Nigeria (PCN), State Ministries of Health (SMOH), Hospice and Palliative Care Association of Nigeria (HPCAN), Society for the Study of Pain Nigeria (SSPN), Committee of Heads of Pharmacy in Federal Health Institutions (COMHPFHI), Association of Community Pharmacists of Nigeria (ACPN), American Cancer Society's (ACS) Treat the Pain Programme, Milestones Rehabilitation Foundation (MRF), Federal Neuropsychiatric Hospitals (FNPH), World Health Organization (WHO) and the Technical Departments of the Federal Ministry of Health for providing expertise to the process of developing and writing of the Policy.

The contribution of the stakeholders in the successful development of the Policy is also appreciated.



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ACRONYMS/ABBREVIATIONS

The following is a compilation of acronyms for use as it pertains to this document. It should be considered a guide and may not constitute an exhaustive list.

ACPN	Association of Community Pharmacists of Nigeria
ADR	Adverse Drug Reaction
APCA	African Palliative Care Association
COMHPFHI	Committee of Heads of Pharmacy in Federal Health Institutions
CSO	Civil Society Organization
DFDS	Department of Food and Drug Services
DRF	Drug Revolving Fund
EU	European Union
EML	Essential Medicines List
FMOH	Federal Ministry of Health
FNPH	Federal Neuropsychiatric Hospital
GMP	Good Manufacturing Practice
HF	Health Facility
HMIS	Health Management Information System
HIV/AIDS	Human Immuno-Deficiency Virus/Acquired Immune Deficiency Syndrome
HPCAN	Hospice and Palliative Care Association of Nigeria
INCB	International Narcotics Control Board
LFN	Law of Federation of Nigeria
LMIS	Logistics Management Information System
LMCU	Logistics Management Coordination Unit
M&E	Monitoring and Evaluation
MDAs	Ministries, Departments and Agencies
MRF	Milestones Rehabilitation Foundation
NAFDAC	National Agency for Food and Drug Administration and Control
NCH	National Council on Health

NDLEA	National Drug Law Enforcement Agency
NHIS	National Health Insurance Scheme
NMA	Nigeria Medical Association
NMDC	Nigeria Medical and Dental Council
NMCN	Nursing and Midwifery Council of Nigeria
NPSCMP	National Product Supply Chain Management Programme
PCN	Pharmacists Council of Nigeria
PHC	Primary Health Care
PPP	Public Private Partnerships
PSN	Pharmaceutical Society of Nigeria
QA	Quality Assurance
STGs	Standard Treatment Guidelines
SDGs	Sustainable Development Goals
SMOH	State Ministry of Health
SSPN	Society for the Study of Pain in Nigeria
TWG	Technical Working Group
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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1.0 INTRODUCTION

1.1 RATIONALE FOR THE NATIONAL POLICY FOR CONTROLLED MEDICINES

The world has made many advances in science and technology, that allow for better and more effective medical interventions for patients. Most recently, the international policy discussion on drugs has shifted to include a focus on ensuring the use of controlled medicines for patients with medical conditions requiring these essential medicines. Unfortunately, despite the international attention, controlled medicines have remained largely unavailable and inaccessible for many patients around the globe, including in Nigeria.

Article 25 of the United Nations' Universal Declaration of Human Rights1948 states that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services." Also in the 1999 Constitution of the Federal Republic of Nigeria it is affirmed that, the principles of societal justice, equity, security, welfare and the fundamental human right to quality healthcare delivery is a primary responsibility of the Government. Therefore, there are clear mandates to support the development of a National Policy for Controlled Medicines in Nigeria and to empower its implementation to ensure the best medical care and health outcomes for Nigerians.

The Global Access to Pain Relief Initiative (GAPRI) in 2012 reported that Nigeria consumed only 0.1% of Narcotic medicines required to manage pain in patients who died of HIV/AIDS and cancer in 2009. Consequently, patients with terminal cancer, those suffering from injuries caused by accident and violence, some chronic illnesses and those recovering from surgery undergo untold suffering due to lack of opioid analgesics which can easily control pain. This was largely attributed to limited or poor quantification of annual estimates, inadequate and irregular release of funds for procurement, limited knowledge and poor attitude, or issues of fear and stigma among many healthcare workers and the general populace.

Various laws and policies related to controlled medicines in the country, focus solely on control without any definitive statement on the necessity for availability and accessibility of these medicines for medical and scientific use. In addition, there is neither specific national policy for controlled medicines nor official statement of the intent of government to enable equitable access and availability of these medicines. The Nigerian laws also include stigmatizing words such as “dangerous drugs” and “addiction” which tend to confuse / dissuade prescribers and contribute to limiting their use for medical conditions. This situation may be due to the fact that most of the legislation governing controlled medicines is out dated and does not conform to modern trends.

Additionally, there is also inadequate capacity among the healthcare personnel on the standard procedures and use of controlled medicines, as evidenced[1]by a myriad of practices which do not conform to the intentions of the treaties and principle of rational drug use[2]. These inadequacies may impact on the right to health of individuals who have condition(s) requiring the use of controlled medicines.

Increasing availability of and accessibility to controlled medicines requires the active participation of key stakeholders, working in cooperation and coordinating systems to promote the rational use of

controlled medicines and protect patients in Nigeria. Government must be actively involved in implementing a structured control system that is balanced by policies that allow physicians to prescribe medications to best manage medical conditions in an ethical and humane manner. Notwithstanding this situation, there is also a strong role for civil society to play in ensuring that patients are cared for and a network of support created for caregivers and family members. This complex issue can only be fully addressed when all aspects of the healthcare system are actively participating; including both public and private healthcare facilities, urban and rural areas, males and females, elderly and new-borns, and healthcare providers working in concert to provide the best medical care available for patients.

It is therefore imperative that Nigeria has an overarching policy framework with explicit objectives to enable and facilitate adequate availability and accessibility to affordable controlled medicines for medical and scientific purposes, as well as to promote necessary controls.

This policy therefore lays the foundation for expanding therapeutic interventions for the care of persons with disease conditions for which controlled medicines and substances may be useful, irrespective of gender, geographic location or financial means. It addresses the challenges of increasing the use of controlled medicines, including training of healthcare workers to meet the health needs of patients. In doing so, Nigeria is addressing the mandate of the International Drug Control Conventions to ensure access to controlled medicines for medical and scientific purposes. Similarly, the development and implementation of this policy is fully in line with the 2030 Agenda for Sustainable Development[3], in particular, SDG 3.8 focusing on increasing access to essential medicines. This further demonstrates the commitment of government to implement the operational recommendations on ensuring the availability and access to controlled substances exclusively for medical and scientific purposes included in the Outcome Document of the 2016 United Nations General Assembly Special Session on the World Drug Problem.[4]

2.0 BACKGROUND

In order to implement a National Policy for Controlled Medicines, it is essential to further define what controlled medicines are, how they are classified and what makes these medicines unique. Controlled medicines are classified as Narcotics, Psychotropic substances and Precursor chemicals.

The issues regarding affordability of controlled medicines are complex and must be analysed very carefully. The government will encourage local manufacturing of controlled medicines which will improve affordability, increase availability, promote self-reliance and control. Additionally, efforts will be made to examine insurance schemes, essential medicine lists and other means to fiscally support the affordability of controlled medicines.

2.1 DEFINITIONS

Narcotics are derived from the opium and its derivatives which include morphine and codeine. They are also derived from cannabis and coca leaf plants. Also included are synthetic Narcotics, such as Pethidine, Fentanyl, and Methadone. Legally they are substances contained in Schedule I, II, III and IV of the UN Single Convention on Narcotics as amended. The differences in the scheduling relate only to the control measures to be applied. The medicines are indispensable for the relief of pain and the convention seeks to make them adequately available for medical and scientific purposes only.

Psychotropic Substances are drugs that alter the central nervous system such as sedatives, hypnotics, hallucinogens and stimulants. Under the UN Convention on Psychotropic Substances of 1971, these substances are listed under Schedules I, II, III, and IV. Some of these medicines are employed in anaesthesia for surgical procedures (such as thipopentone and midazolam), essential in emergency obstetrics (ergometrine) or used as anxiolytics and hypnotics (benzodiazepines) or as anti-epileptics (phenobarbital and benzodiazepines).[5]

Precursors are raw materials which when used in the production of a drug become part of a finished product. Reagent and Solvents are also listed as precursors but usually not a part of the finished product. They are however used in the manufacture and processing of some Narcotic drugs and psychotropic substances. Examples are ephedrine used in the manufacture of methamphetamine; sulphuric acid is a reagent and acetone is a solvent.

2.2 MANDATES

At the international level, the regulation and control of scheduled medicines is guided by the three (3) main conventions to which Nigeria is a signatory. These conventions are:

1. The Single Convention on Narcotic Drugs of 1961[6] as amended by the 1972 protocol[7];
2. The Convention on Psychotropic Substances of 1971[8] and adopted in 1988;

3. The United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances of 1988[9].

Additionally, the International Narcotics Control Board (INCB)[10], an independent, quasi-judicial expert body established by the Single Convention on Narcotic drugs of 1961 by merging two bodies: the Permanent Central Narcotics Board, created by the 1925 International Opium Convention; and the Drug Supervisory Body, created by the 1931 Convention for limiting the manufacture and regulating thedistribution of Narcotic drugs, has the following mandates to work with Member States such as Nigeria:

- As regards the licit manufacture of, trade in and use of drugs, INCB endeavours, in cooperation with Governments, to ensure that adequate supplies of controlled medicines are available for medical and scientific uses and that the diversion of drugs from licit sources to illicit channels does not occur. INCB also monitors Governments' control over chemicals used in the illicit manufacture of drugs and assists them in preventing the diversion of those chemicals into the illicit traffic; and
- As regards the illicit manufacture of, trafficking in and use of drugs, INCB identifies weaknesses in national and international control systems and contributes to correcting such situations. INCB is also responsible for assessing chemicals used in the illicit manufacture of drugs, in order to determine whether they should be placed under international control.

In the discharge of its responsibilities, INCB:

- Administers a system of estimates for Narcotic drugs and a voluntary assessment system for psychotropic substances and monitors licit activities involving drugs through a statistical returns system, with a view to assisting Governments in achieving, inter alia, a balance between supply and demand;
- Monitors and promotes measures taken by Governments to prevent the diversion of substances frequently used in the illicit manufacture of Narcotic drugs and psychotropic substances and assesses such substances to determine whether there is a need for changes in the scope of control of Tables I and II of the 1988 Convention;
- Analyses information provided by Governments, United Nations bodies, specialized agencies or other competent international organizations, with a view to ensuring that the provisions of the international drug control treaties are adequately carried out by Governments, and recommends remedial measures; and
- Maintains a permanent dialogue with Governments to assist them in complying with their obligations under the international drug control treaties and, to that end, recommends, where appropriate, technical or financial assistance to be provided.

In Nigeria, the control, availability and access to Narcotics, Psychotropic substances and other controlled medicines are guided strictly by aforementioned Conventions and 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 2005[11];
- 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 National Agency for Food and Drug Administration and Control (NAFDAC) enforces the provisions of the conventions and legislations that promote access to controlled medicines for medical and scientific purposes only. This includes regulation of importation, manufacture, distribution, warehousing, sales and use of controlled medicines. The Agency also ensures that Nigeria fulfils its obligation under the relevant United Nations Conventions.

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

2.3 CLASSIFICATION

CLASSIFICATION OF NARCOTICS, PSYCHOTROPIC SUBSTANCES AND PRECURSOR CHEMICALS CURRENTLY APPROVED BY INCB FOR USED IN NIGERIA

S/N	LIST OF NARCOTIC DRUGS UNDER THE 1961 CONVENTION				LIST OF PSYCHOTROPIC SUBSTANCES UNDER THE 1971 CONVENTION				LIST OF PRECURSORS UNDER THE 1988 CONVENTION	
	SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV	SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV	TABLE 1	TABLE 2
1	Cocaine	Codeine	None	None	None	Methylphenidate	Flunitrazepam	Alprazolam	Acetic anhydride	Acetone
2	Diphenoxylate	Dihydrocodeine					Pentazocine	Bromazepam	N-Acetylanthranilic acid	Anthranilic acid
3	Etorphine							Buprenorphine	Ephedrine	Ethyl ether
4	Fentanyl							Clonazepam	Ergometrine	Hydrochloric acid
5	Hydromorphone							Diazepam	Ergotamine	Methyl ethyl ketone
6	Methadone							Lorazepam	Isosafrole	Piperidine
7	Morphine							Meprobamate	Lysergic acid	Sulphuric acid
8	Oxycodone							Midazolam	3,4-Metilendioxifenil-propanone	Toluene
9	Oxymorphone							Nitrazepam	Norephedrine	
10	Pethidine							Phenobarbital	Phenylacetic acid	
11	Pholcodine							Temazepam	1-Phenyl-2-propanone	
12								Zolpidem	Piperonal	
13									Potassium permanganate	
14									Potassiumde potassium	
15									Pseudoephedrine	

LIST OF DRUGS NATIONALLY CONTROLLED

Amitryptyline, Caffeine, Chloramphenicol, Dextromethophan, Imipramine, Ketamine, Phenylepherine, Thiopental, Clomipramine and Tramadol HCl

2.4 GOALS AND OBJECTIVES

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

2.2.1 Goal

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

2.2.2 Objectives

Each of the objectives below must be 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.

2.5 THEMATIC AREAS AND TARGETS

Thematic Areas	Specific Target
Coordination & Governance	1. Sensitize regulatory bodies and stakeholders on the need for improved availability of controlled medicines for medical and scientific purposes. 2. Promote coordination among key stakeholders to include but not be limited to government, international and national organizations, associations and civil society. 3. Establish a coordinating mechanism or coordinating platform in the Department of Food and Drug Services of the Federal Ministry of Health to coordinate implementation of NPCM. 4. Identify existing structures such as Technical Working Groups, task forces and working committees with vested interest in controlled medicines. 5. Strengthen the Technical Working Group (TWG) on Access to Narcotics and Psychotropic substances and Precursors as a vehicle to identify and address gaps in the supply chain of controlled medicines. 6. Integrate supply of Scheduled I Narcotics and other controlled medicines with the operations of the Logistics Management Coordination Units (LMCUs) of states to improve ownership, drive and ensure accountability for these medicines[13]. 7. Department of Food & Drugs Service of FMOH shall coordinate PPP arrangements for procurement of Schedule I Narcotic medicines for medical use in the country.
Legislation, Policy, Regulations and Guidelines	8. Review national laws, legislation and existing policies to identify and promote opportunities to increase access to controlled medicines within a framework that recognizes the importance of gender and human rights. 9. Update existing or develop new regulations and guidelines to address emerging issues on availability, accessibility and affordability as well as, rational prescribing, dispensing and use of controlled medicines. 10. Develop policy guidelines for quantification of controlled medicines, pain treatment, palliative care and drug demand reduction.
Healthcare Service Delivery	11. Review and revise the Nigerian Essential Medicines List, including a focus on controlled medicines. The most current version (the 6th edition) was updated in 2016. 12. Review Standard Treatment Guidelines with a focus on including pain management and all conditions requiring the use of controlled medicines.

	13. Review and revise guidelines and standard operating procedures for healthcare personnel to ensure that consideration is taken regarding the safe and ethical use of controlled medicines across all levels of care including tertiary, secondary and primary sites. 14. Incorporate clear and consistent medical assessment of pain levels in all patients, as the 5th vital sign. 15. Ensure all healthcare staff are trained to recognize signs of distress in patients using controlled medicines, and diligently monitor patients under their care that have been prescribed a controlled medicine. 16. Review prescription practices including but not limited to who can prescribe, who can dispense and dispensing practices.
Supply Chain Management	17. Establish a robust and efficient supply chain system for controlled medicines with a strong focus on storage, distribution, pharmacovigilance, import and export, local production and manufacturing and quality assurance including inspections and risk management. 18. Enhance the rational selection of controlled medicines and the process of quantification using consumption and morbidity data as available. 19. Ensure routine procurement of Scheduled I Narcotic medicines to sustain availability and prequalify local pharmaceutical manufacturing industries for the purposes of manufacturing Schedule I Narcotic medicines for the Federal Ministry of Health. 20. Review and enhance the process of supply planning, to include a regular review of quantities before shipment, realignment of inventory, transportation, consumption, manufacturing and purchasing plans. 21. Institute effective pipeline monitoring procedures for controlled medicines including Scheduled I Narcotics to routinely detect and resolve issues that affect the supply system and prevent availability of controlled medicines. 22. Operationalize the decentralization of the central warehousing and distribution of Scheduled I Narcotic medicines in alignment with the integrated warehousing and distribution design of the FMOH. 23. Promote regular inspection of manufacturing outfits and facilities (public and private) where controlled medicines are manufactured, stored and dispensed in line with NAFDAC Good Manufacturing & Good Distribution Practices Guidelines including but not limited to ensuring good storage conditions and quality tests within the distribution channels. 24. Ensure safe and simple recall, with proper disposal of expired or damaged medicines, and of any controlled medicine found to be defective or that no longer meets the required quality standards by NAFDAC to protect individual or public health.

	25. Create a link between pharmacy and prescriber on what controlled medicines are available and ensure documentation of quantity consumed. 26. Support pharmacovigilance practices such as adverse drug reporting across all health facilities, and the proper reporting and documentation of medication error.
Funding	27. Ensure adequate funding of the existing Drug Revolving Fund (DRF) Account for procurement of schedule I Narcotic medicines. 28. Explore the possibility of public private partnership (PPP) funding for procurement of Schedule I Narcotic medicines based on Memorandum of Understanding (MOU) with FMOH. 29. Review existing health insurance schemes and propose that controlled medicines, including those appearing in the Essential Medicines List are covered by the insurance schemes. 30. Ensure funding annually for activities that will improve availability of controlled medicines to include implementation, monitoring and evaluation of the national policy.
Capacity Building	31. Ensure development of standard training modules on rational use of controlled medicines and incorporate into the pre-service and continuing education/training curricula of relevant healthcare workers in accordance with their roles and responsibilities. 32. Mandate regular training for all healthcare workers and professionals in the rational use of controlled medicines, including Narcotics. 33. Identify geographic areas where additional persons must be trained to prescribe controlled medicines and make training available. 34. Provide mandatory training for all healthcare professionals in pharmacovigilance and medication error reporting of controlled medicines, including Narcotics. 35. Ensure availability of fund annually for training and re-training of healthcare workers involved in the prescription and dispensing of controlled medicines.
Monitoring & Evaluation	36. Develop and implement monitoring and evaluation framework for this policy. 37. Implement mentoring and supportive supervision for healthcare workers already working in the field. 38. Support and promote research directed towards major public health issues and challenges that continue to limit the availability of and accessibility to controlled medicines.

2.6 SCOPE OF THE POLICY

The scope of this National Policy for Controlled Medicines is extensive, reflecting thirty-eight targets across seven thematic areas. These include issues of health, supply chain management, building capacity and a focus on monitoring and evaluation. While the approach is broad, the level of detail includes such things as safe transport of controlled medicines to ensure availability, adequate medical training and certification for licensing to prescribe medicines, rational prescribing and dispensing and the means to prevent fake and counterfeit medicines from entering the market.

As earlier mentioned under the introduction, increasing availability of, and accessibility to controlled medicines requires the active participation of a number of key stakeholders, working in cooperation and coordinating systems to promote the rational use of controlled medicines and protect patients in Nigeria. It is crucial to involve all stakeholders in the process, to include but not be limited to government leaders, civil society, private healthcare providers, community leaders and patients themselves.

2.7 POLICY DEVELOPMENT PROCESS

The National Policy for Controlled Medicines was developed in a step-by-step process. The process was inclusive, comprehensive, multi-faceted and based on technical expertise. The experts met in October and November 2016. During that time, the experts drew on professional experience, scientific literature, existing legislation and national policies as well as standard operating procedures in healthcare settings.

A draft was developed and presented to an extensive group of key stakeholders in May 2017.The feedback provided by the key stakeholders was then incorporated into the National Policy in line with the spirit of the document as developed by the group of experts.

The National Policy development followed the established protocol and received the approval of the National Council on Health (NCH) at its 60thmeeting in November 2017 prior to launching and dissemination.

3.0 POLICY FRAMEWORK ELEMENTS

The policy framework, detailed below, is divided into 7 thematic areas that are critical to ensure sustainable availability of, and access to affordable controlled medicines for medical and scientific purposes, while preventing diversion.

While each element is presented separately, they are overlapping and inter-twined and should be integrated in a balanced and coordinated approach, engaging all key stakeholders in Nigeria. In each section, detailed information will be provided to describe the context in which a *Policy Statement* is made, and *Strategic actions* will be implemented.

3.1 COORDINATION AND GOVERNANCE

3.1.1 Policy Statement

Coordination and inclusion are keys to the successful implementation of National Policy for Controlled Medicine (NPCM).

3.1.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Sensitize regulatory bodies and stakeholders on the need for improved availability and accessibility of controlled medicines for medical and scientific purposes;
2. Promote coordination among key stakeholders to include government, international and national organizations, associations and civil society;
3. Strengthen the existing coordinating mechanism in the Department of Food and Drug Services (DFDS) to coordinate the implementation of NPCM;
4. Establish and strengthen existing coordinating mechanism at the state and local government levels to coordinate implementation of NPCM;
5. Identify additional establishments within Nigeria that can be involved in the successful implementation of strategies within the NPCM;
6. Integrate supply of Scheduled I Narcotics and other controlled medicines within the operations of the LMCUs of states, under the supervision of the focal pharmacist, to improve ownership, drive and ensure accountability for these medicines[14];
7. Explore PPP arrangements with FMOH for procurement of controlled medicines, especially Schedule I Narcotic medicines for medical and scientific purposes in the country; and

8. Engender cooperation and collaboration of all health professionals and other stakeholders in the successful implementation of this policy to the benefit of the health care seeking patients and clients including animals.

3.2 LEGISLATION, POLICY, REGULATIONS AND GUIDELINES

3.2.1 Policy Statement

The main regulations guiding Narcotic medicines for medical use in Nigeria are the Poison and Pharmacy Act Cap 535 LFN, 1990, the Dangerous Drug Act (DDA) Cap D1, LFN, 2004 and the NAFDAC Act Cap N1 LFN 2004. Some of these laws are not only outdated but also have the potential to confuse the medical use of controlled medicines with substance abuse.

3.2.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure the review of National laws, legislation and existing policies to identify and promote opportunities to increase access to controlled medicines taking into consideration gender, human rights and administrative bottlenecks that may hinder access;

2. Develop regulations and guidelines to address emerging issues on availability, accessibility and rational prescribing, dispensing and use of controlled medicines;

3. Implement the strategic plan for the National Policy for Controlled Medicine (NPCM), supported by existing or revised legislative and policy frameworks that support increasing access, availability and affordability; and

4. Develop guidelines for quantification of controlled medicines and pain treatment; and policy for palliative care and drug demand reduction.

3.3 HEALTHCARE SERVICE DELIVERY

As indicated earlier in this National Policy, the use of controlled medicines is applicable in the care and treatment of many medical conditions[15].In fact, the use of controlled medicines in specific medical situations is not only recommended but is beneficial to the overall health of the patient. This section will address specific areas of health care that frequently rely on the use of controlled medicines, within a framework of human rights, ethics and gender.

It should be noted that section 3.3 supports a spectrum of healthcare services that meet the needs of patients across the healthcare system. For example, it includes interventions such as specialized units and patient beds dedicated to chronic pain as well as mental health services for patients, care givers and family. It is a comprehensive approach that relies on strong assessment skills, flexible options to

meet patient needs and frequent communication between levels of the healthcare system to accommodate referrals, back referrals and prevent misuse.

As a result of the overlapping and integrated complexity of the components of the healthcare service delivery system, policy statements and Strategic actions have been indicated in a more comprehensive manner and will be followed by more specific areas of focus related to health.

3.3.1 Policy Statement

The Government recognizes and supports the use of controlled medicines as applicable in the care and treatment of many medical conditions[16]. The use of controlled medicines in specific medical situations is beneficial to the overall health of the patient.

3.3.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Mandate a high level of knowledge and skill-based training for all healthcare personnel at each level of the healthcare system on the rational use of controlled medicines;
2. Integrate training and guidance related to the medical use of controlled medicines into established health and disease control programmes. For example, allow refill of prescription medicines including controlled medicines at the Community and Satellite Pharmacies for patients who have been established on a particular medicine therapy;
3. Ensure a consistent and medically supervised continuum of care for patients prescribed controlled medicines;
4. Explore accommodating all medicines identified as essential on the Essential Medicine List for Nigeria, including controlled medicines, in the National Health Insurance scheme;
5. Mandate a minimum level of training for all healthcare staff involved in substance abuse treatment interventions, including the use of controlled medicines as part of the integrated drug use disorder treatment strategy;
6. Expand palliative care services nationwide and include palliative care in the curricula of all relevant undergraduate health care professional courses;
7. Explore means of implementing task shifting/sharing among relevant healthcare professionals and health workers, including medical doctors, dental surgeons, veterinary doctors, pharmacists, nurses, midwives, community health officers, community health extension workers, junior community health workers, and pharmacy technicians. Such as:
    a. Training of relevant cadres of health professional to acquire requisite skills and competence that correspond with the task in line with the National Task Shifting/Sharing Policy for Essential Services[17]; and
    b. Ensure that responsible officers to whom new task are added comply with the existing Standard Operational Procedures on Task Shifting.[18]

3.3.3 Pain Management

Pain is a common complaint in persons seeking medical attention, but it is often overlooked, poorly assessed and poorly relieved in many parts of the world, including Nigeria. Pain is multidimensional and is associated with physical, psychosocial and spiritual experiences. Untreated acute pain conditions may lead to chronic pain thus the need for effective pain treatment.

In Nigeria, more than 80% of cancer patients present with pain in the late stages of the disease, and moderate to severe pain is reported by more than 70% of these terminally ill patients[19]. Further, Nigeria has a high burden of HIV/AIDS, currently about 3.1 million people are living with HIV and in 2016 the estimated annual AIDS death for all ages was 158,925[20]. Pain is a major concern in HIV/AIDS as only 32% of the affected adult population are on antiretroviral therapy (ART) medications, with patients in need of ART doubling from 1.5 million to 3.2 million between 2013 and 2016.[21] The pain prevalence is 25%, a low estimate, and is grossly undertreated[22].

Opioids are essential medicines for the pharmacologic control of moderate to severe pain. The fear of patients experiencing drug use disorders from the rational use of controlled medicines is not supported by evidence. Opioids are the recommended agents for the control of moderate and severe pain using the WHO Analgesic Ladder[23]. For effective pain management, a thorough assessment is required to enhance rational choice and dispensing of opioid analgesics based on the WHO Analgesic Ladder.

Most times however, the opioids, including morphine, are not available for use by patients in need of these medicines.

The barriers to effective pain management may include one or all the three areas, policy factors, clinician factors or patient factors. Policy factors have already been discussed in other parts of the document. Clinician factors include inadequate knowledge of pain management, fear of addiction, and lack of pain assessment skills[24]. The INCB has also identified concerns about addiction and insufficient training for professionals as major impediments to opioid availability[25]. Patient factors can include reluctance to report pain, fear of opioids, lack of funds to purchase the medication and poor adherence to prescription requirements.

Pain assessment should be routine during the medical consultation or treatment and it has been declared the 5thVital sign[26].

Pain management should be dictated by the severity of the condition and the WHO Analgesic Ladder has been adapted for the management of other pain conditions and not just cancer pain.

3.3.4 Palliative Care

In some specific medical cases, it is necessary to go beyond pain management and to engage in palliative care. The World Health Organization defines palliative care as an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

The life-threatening or limiting illnesses addressed by palliative care predominantly include the cancers, HIV/AIDS, chronic cardiovascular, pulmonary and renal diseases, and sickle cell disease. The statistics for these diseases are not comprehensive in Nigeria but for cancers, a study of two cancer registries suggests an incidence rate of about 60 per 100,000 population for men and 130 per 100,000 population for women[27]. World-wide cancer burden is expected to increase from 12 million new cases to 26 million per year by 2030. The WHO also states that "a palliative care program cannot exist unless it is based on a rational national drug policy, including regulations that allow ready access of suffering patients to opioids".

An estimated 150,000 children are born each year with sickle cell anaemia[28]. The trait prevalence is about 25% and the prevalence of the severe form of the disease is about 2%. This disease is well known to be associated with both acute and chronic pain with deleterious consequences on the growth potential of the affected. The opioids are commonly recommended in the control of such pains[29].

Palliative Care as a speciality / subspecialty is just emerging in Nigeria. This model of care was included in the Nigeria Cancer Control Plan 2008-2013 of the Federal Ministry of Health. Article 10 emphasises the need for more Palliative care services in the country, the need to improve and increase the manpower for pain and palliative care, and the need to ensure opioid availability[30]. The National Guidelines for HIV and AIDS Treatment and Care in Adolescents and Adults (FMOH 2010) also includes elements of palliative care[31].

3.3.5 Treatment of Substance Use Disorders

Narcotics are used in the medical management of drug use disorders, specifically, opioid dependence. The components of integrated drug use disorder treatment using controlled medicines include during withdrawal management and as a part of a maintenance therapy. However, the regular non-medical use of opioids can lead to opioid dependence, which is a complex medical condition that often requires long-term treatment and care which is associated with increased disability, mortality and high risk of HIV infection when opioids are injected using contaminated injection equipment.

Controlled medicines, particularly narcotics, play a role in the withdrawal management of opioids to alleviate distress of withdrawal symptoms, prevent severe withdrawal sequelae and provide continuing engagement in ongoing treatment. The two narcotics with strong scientific evidence for opioids withdrawal management are Methadone and Buprenorphine. Incorporating the use of controlled medicines into a treatment care plan for people with drug use disorders, specifically dependence on opioids, is an evidence based strategy to retain clients in services and reduce risky behaviours associated with opioid use, thus enabling an opportunity to improve quality of life. This intervention also reduces mortality and morbidity, improves psychological, emotional, and physical wellbeing of the patients and contributes to reduced social costs associated with problematic drug use and crime.

Maintenance therapy for opioid dependence must be subject to principles of good medical practice. Evidence-based guidelines should be put in place, which includes criteria to define who are considered eligible for the therapy as well as contraindications, and outlines best practices in clinical management, and relevant government regulations. A platform for the registration or accreditation of

treatment providers and registration of those receiving treatment should be created to ensure quality of service and to minimize the risk of prescribed medications being diverted.

3.3.6 Other Uses

Some of the controlled medicines are employed in anaesthesia for surgical procedures (such as Thiopentone and Midazolam), essential in emergency obstetrics (Ergometrine) or used as anxiolytics and hypnotics (Benzodiazepines) or as anti-epileptics (Phenobarbital and Benzodiazepines).

3.3.7 Roles and Responsibilities of Healthcare Personnel in Prescribing and Dispensing of Controlled Medicines

For purpose of clarity, the roles and responsibilities of healthcare workers that are, or may be, involved in the use of controlled medicines for medical purposes are outlined below:

- The Federal Ministry of Health through the Department of Food and Drug of Services in collaboration with NAFDAC imports and procures Schedule I Narcotic medicines for use by the health, training and research facilities (both public and private) in Nigeria. These medicines are first stored at the Federal Medical Stores from where the health, training and research facilities (both public and private) source their narcotics needs after due clearance from Director of Pharmaceutical Services of the State Ministry of Health and NAFDAC. Other controlled medicines apart from Schedule I Narcotic medicines are imported and manufactured by corporate bodies after obtaining relevant approval from NAFDAC.

- The Physicians shall be responsible for proper filling in, signing and stamping of the controlled medicines prescription form. It shall be the duty and responsibility of the registered Pharmacists to import, manufacture, procure, store, distribute, sell, compound, and dispense controlled medicines and substances in accordance with extant rules and laws in Nigeria. The pharmacists shall ensure rational dispensing and use of controlled medicines.

- It shall be the duties and responsibility of registered pharmacist to ensure proper handling of controlled medicines to ensure that quality and potency are maintained throughout the shelf life of controlled medicines. They will take all appropriate steps to prevent diversion of controlled medicines and substances in his or her custody.

- At the facility level, the pharmacist in-charge shall be responsible for stocking narcotics and psychotropic medicines, dispensing to the ward and patient in accordance with prescriptions. They will check the prescription order and make sure that all the information is complete. Additionally they will ensure that the consumed amount in the ampoule is indicated, and the remaining balance is properly discarded, documented, signed and stamped. Pharmacist in-charge inspect stock periodically (weekly and monthly) and monthly check the expiration date of the narcotic and controlled medicines in the pharmacy. Finally, they prepare a monthly statistic of the consumed medicines.

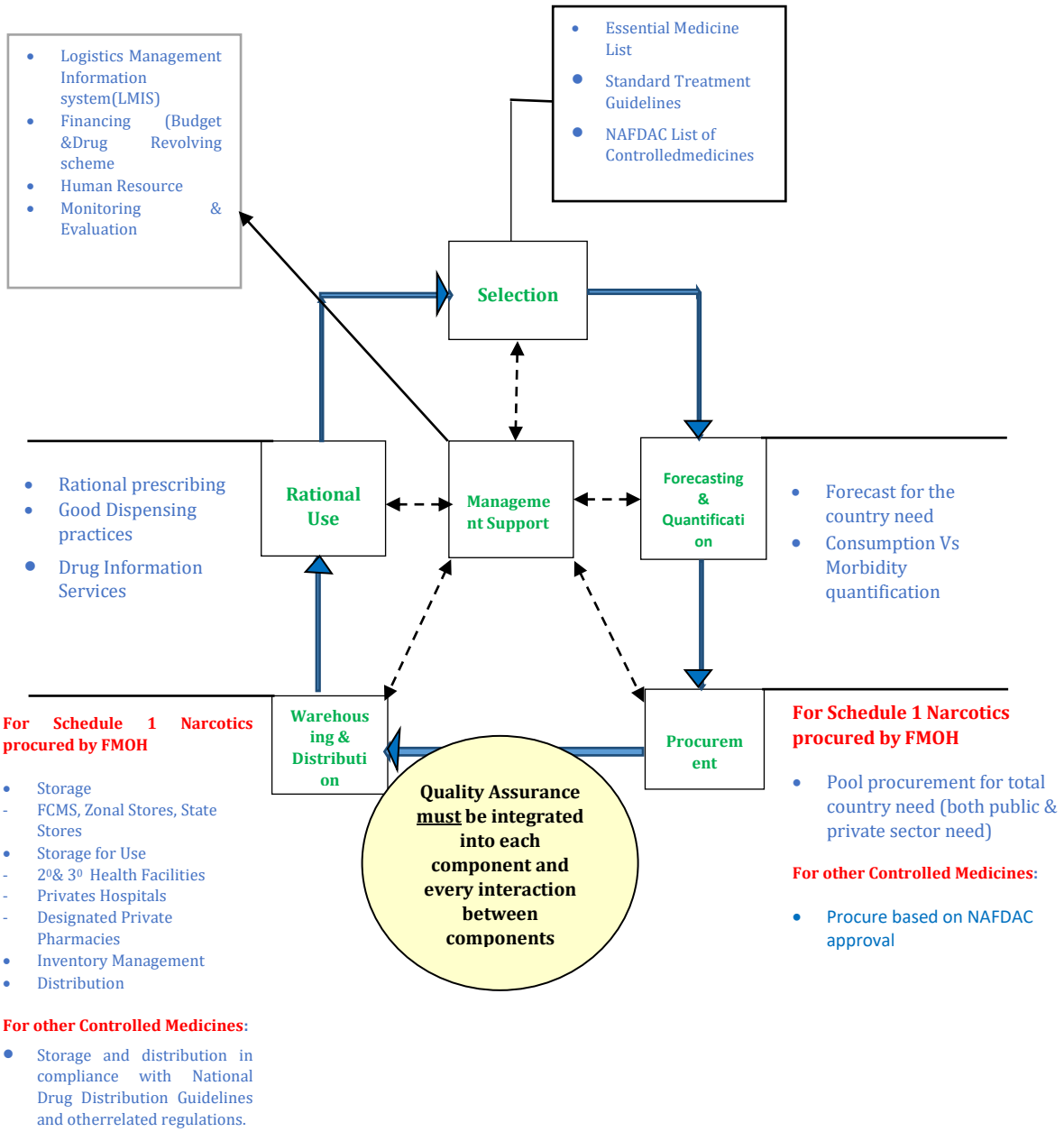
- At the facility level, it shall be the duty of a duly licensed medical practitioner, dental surgeon and veterinary surgeon to prescribe the controlled medicines to patients, clients and animals for the treatment and management of diagnosed ailments.

- The head nurse shall be responsible for keeping custody of scheduled I narcotic medicines for emergency ward supply under lock and key in a designated cup-board or box for emergency or routine use within 24 hours.
- Nursing officer in charge shall be responsible for direct administration of any controlled medicines to the patient during every shift in respective nursing unit and shall also maintain proper documentation of the medicines and their use.
- Where a medical doctor is absent, licensed Community Health Officer (CHO), Community Health Extension Worker (CHEW) or Junior Community Health Extension Worker (JCHEW) shall be responsible for prescription of controlled medicines at the Primary Health Centres, Primary Health Clinics and Health Posts respectively, in line with existing protocols.
- The prescription by this category of health workers shall be in adherence to the Standing Order for primary healthcare and the provisions in the Essential Medicines List in Nigeria, and therefore the standing order should be reviewed and workers trained to ensure consistent application of the policy as it pertains to controlled medicines.
- It shall be the duty of the pharmacist or licensed pharmacy technician under the supervision of a registered pharmacist to dispense controlled medicines at any Primary Health Centres, Primary Health Clinics and Health Posts.

3.4 SUPPLY CHAIN MANAGEMENT

Supply Chain Management is the coordination and integration of all the planning and management of activities in sourcing and procurement, storage, distribution and all logistics management activities involved in moving a product from the manufacturer or source to the end user or client to guarantee optimal inventory in a cost-effective manner[32]. Supply Chain Management of controlled medicines will therefore be the coordination of the flow of the medicines which is connected by transportation and storage activities and integrated through the use of information and planning to ensure that they are available for therapeutic use at all times in a cost-effective manner. Below is a sequential description of the supply chain with *Strategic actions* included in each section.

Supply Chain for Controlled Medicines



Please note, as a result of the complexity of the components of section 3.4 Supply chain management, policy statements and strategic actions have been indicated as part of each component.

3.4.1 Selection

The objective of the medicine selection process is to have a national list of medicines rationally chosen to satisfy the health care needs of the majority of the population. In carrying out the selection, priorities are given to medicines on the National Essential Medicines List[33].

Nigeria has developed the Essential Medicines List (EML) patterned in line with the World Health Organization (WHO) Model List. Also, considered in product selection are Standard Treatment Guidelines (STGs)[34]and National Agency for Food and Drug Administration and Control (NAFDAC) list for controlled medicines.

3.4.1.1 Policy Statement

The Government recognizes and supports the selection of medicines from a national list of rationally chosen medicines that satisfy the health needs of the majority of the population.

3.4.1.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, Government shall ensure rational selection of controlled medicines for medical needs of Nigerians.

FMOH shall:

1. Ensure selection of Schedule I Narcotic medicines is from the extant EML and STGs for the purpose of procurement for use in public health facilities in Nigeria. Inclusion of new medicines in the list shall follow the process for the review of EML and STGs. This action shall be carried out by the Federal Ministry of Health;

NAFDAC shall:

2. Ensure selection of other Controlled Medicines is from EML, STGs and any other list approved by the Agency.

3.4.2 Quantification

It is the process of estimating the quantity and cost of the products required to ensure uninterrupted supply of the products for medical and scientific purposes.

3.4.2.1 Policy Statement

The Government recognizes and supports a process for estimating the quantity and cost of products, including controlled medicines, to ensure the uninterrupted supply for medical and scientific purposes.

3.4.2.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society **the Government shall**:

1. Carry out quantification of controlled medicines using consumption and/or morbidity methods on an annual basis in line with the National Guidelines for the Quantification of Narcotics and estimation of Psychotropic Substances and Precursors;

2. Ensure that health facilities and community pharmacies that stock controlled medicines use standardized tools in the National Guidelines for the Quantification of Narcotics and Psychotropic Substances and Precursors to report logistics data (Stock on Hand, Consumption and Losses/adjustment) on quarterly basis through the State Logistic Management Coordination Unit (SLMCU) for onward transmission to FMOH and NAFDAC for quantification, pipeline monitoring and reporting to INCB.

3.4.3 Procurement

Procurement process is a major determinant of availability and affordability of controlled medicines.

3.4.3.1 Policy Statement

The Government recognizes and supports the procurement of appropriate, adequate and quality medicines that ensure affordability and satisfy the health needs of the majority of the population.

3.4.3.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society,

FMOH shall:

1. Ensure uninterrupted supply of Schedule I Narcotics for medical and scientific purposes, including enough advanced notice to ensure timely re-stocking and availability;
2. Operationalize the Narcotic Drug Revolving Fund (DRF) Account to facilitate uninterrupted supply of controlled medicines, including Schedule I Narcotic medicines;
3. Ensure commitment to good procurement practices for the procurement of Schedule I Narcotics in line with the Public Procurement Act of 2007and other extant policy documents and circulars of Government, including Presidential fiat;
4. Ensure that emergency procurement of Schedule I Narcotic medicines by FMOH conform to provisions of the Public Procurement Act 2007 and the prevailing policy direction of Government;

NAFDAC shall:

1. Ensure that approval is granted promptly, following due process, to importers/ manufacturers of controlled medicines;
2. Ensure quality assessment of procured controlled medicines before distribution and use.

3.4.4 Importation of controlled medicines

3.4.4.1 Policy Statement

The Government recognizes and supports an efficient and appropriate process by which controlled medicines are imported into Nigeria to satisfy the health needs of most of the population.

3.4.4.2 Strategic Actions

Working in collaboration with other partners, **the Government shall**:

1. Recognize and empower FMOH as the only legitimate source through which Schedule 1 Narcotic medicines is imported into the country for medical and scientific purposes;
2. Recognize and support importation of other controlled medicines only in accordance with the extant Guidelines and Regulations by NAFDAC.

3.4.5 Production/manufacturing of controlled medicines

A number of controlled medicines are manufactured locally with the exception of Scheduled I Narcotic medicines.

3.4.5.1 Policy Statement

The Government recognizes and supports the potential expansion of the production and manufacturing of controlled medicines to satisfy the health needs of the majority of the population.

3.4.5.2 Strategic Actions

Working with all key stakeholders,

FMOH shall:

1. Resuscitate and strengthen the Federal Pharmaceutical Manufacturing Laboratory, Yaba, Lagos or any other approved local pharmaceutical manufacturing company for the production of controlled medicines, Schedule I Narcotics, beyond oral morphine solutions.

NAFDAC shall:

1. Prequalify local pharmaceutical manufacturing industries for the purposes of manufacturing Schedule I Narcotic medicines for the Federal Ministry of Health.
2. Ensure that local production of all controlled medicines shall be in accordance with the extant regulation and guidelines by NAFDAC.

3.4.6 Warehousing

Controlled medicines are warehoused to ensure security and maintenance of quality throughout their shelf life and accessibility.

3.4.6.1 Policy Statement

The Government recognizes and supports the proper and appropriate warehousing of controlled medicines that ensures the security and quality of the product while taking measures to enhance geographical access and satisfy the health needs of most of the population.

3.4.6.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Decentralize the central warehousing and distribution of Scheduled I Narcotic medicines in alignment with the integrated warehousing and distribution design of the FMOH;

2. Ensure the warehouses and storage areas are equipped with adequate security measures to ensure safety of narcotic medicines;
3. Ensure that its staff in these warehouses take responsibility for the storage and accountability of these controlled medicines;
4. Ensure the warehouses conform to standard procedures to ensure safety and efficacy of the narcotic medicines;
5. Ensure adequate documentation system for all the warehousing activities, including providing support for inventory management software that ensures visibility to all stakeholders;
6. Ensure that all health facilities dealing in controlled medicines provide adequate security for these medicines held in stock.

3.4.7 Distribution

Effective distribution through the pipeline to the end users is key to improving access to controlled medicines for medical and scientific purposes.

3.4.7.1 Policy Statement

The Government recognizes and shall support the distribution of medicines that satisfy the health needs of the majority of the population.

3.4.7.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Effectively distribute Schedule I Narcotic medicines from Federal Central Medical Stores (FCMS) to the Zonal Medical Stores or designated tertiary health institution in the zone and ultimately to service delivery points. The Federal and States Ministries of Health shall communicate availability of these medicines to health care facilities and designated private pharmacies;
2. Ensure the distribution of other controlled medicines is in accordance with the provisions of the National Drug Distribution Guidelines and the NAFDAC Good Distribution Practices Guidelines (2016);[35]
3. Mainstream the service providers in the private sector into the distribution system for all controlled medicines. For example, community and satellite pharmacies should be encouraged and so designated to stock and sell Schedule I Narcotic medicines.

3.4.8 Inspection

Effective inspection of premises and persons involved in production, warehousing and sales of controlled medicines is critical to ensure the quality, safety, efficacy and adequate documentation of these medicines.

3.4.8.1 Policy Statement

The Government recognizes and supports the ongoing inspection of all aspects of the supply chain related to controlled medicines to ensure quality and safety of the products.

3.4.8.2 Strategic Actions

Working in cooperation with all key stakeholders, the Government shall:

1. Regularly inspect manufacturing outfits and facilities (public and private) where controlled medicines are manufactured, stored and dispensed in line with NAFDAC Good Manufacturing & Good Distribution Practices Guidelines[36].
2. Conduct inspection and supportive supervision of all premises where pharmaceutical activities are carried out, including handling of controlled medicines through the Pharmacists Council of Nigeria (PCN).
3. Ensure collaboration of regulatory bodies for efficient and joint coordination of inspections through the creation of a committee or by identifying a lead agency to coordinate inspection process.
4. Ensure all inspectors are well trained and experienced.

3.4.9 Rational Drug Use (RDU) and Pharmacovigilance

RDU of controlled medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community. This implies rational prescribing, good dispensing practices and concordance.

3.4.9A Pharmacovigilance

Pharmacovigilance, also known as Drug Safety, is the pharmacological science relating to collection, detection, assessment, monitoring and prevention of adverse effects with pharmaceutical products including controlled medicines[37]. Effective use of pharmacovigilance will ensure the rational safe use of controlled medicines and the assessment and communication of the risks of controlled medicines and substances in the country.

3.4.9A.1 Policy Statement

The Government recognizes and supports the effective use of pharmacovigilance to ensure rational and safe use of controlled medicines to satisfy the health needs of the majority of the population.

3.4.9A.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure availability and use of Adverse Drug Reactions (ADRs) reporting forms in the healthcare facilities;
2. Promote reporting of ADRs by patients and healthcare providers to NAFDAC;

3. Strengthen pharmacovigilance units of NAFDAC nationwide to collect, evaluate and disseminate relevant information on ADRs and poisoning arising from use of controlled medicines;
4. Evaluate ADRs from the use of controlled medicines on a periodic basis and result of such evaluation shall be as evidences to modify or the discontinuous of use of such controlled medicines on a case-by-case basis;
5. Prioritize data collection, feedback and monitoring, including standardizing the issue of reporting in local languages for more accurate data that can then be included on a universal form preferably in electronic format.

3.4.9[B] Rational Prescribing

3.4.9[B].1 Policy Statement

The Government recognizes and supports the rational prescribing of medicines from a national list of rationally chosen medicines that satisfy the health needs of the majority of the population.

3.4.9[B].2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure prescribers follow a standard process of prescribing which includes diagnosis, therapeutic goals and treatment options;
2. Review facility based policies regarding prescription practices that may contribute to reducing access, such as the requirement of "special" prescription forms different from the standard;
3. Provide guidance and support to prescribers to decide which treatment (drug and non-drug) is required, based on up-to-date information on medicines and therapeutics, to achieve the desired goal for an individual patient based on efficacy, safety, suitability, and cost;
4. Provide standard operating procedures and guidelines to support prescribers as they determine the dose, route of administration, and duration, taking into account the condition of the patient;
5. Mandate prescribers to provide information to the patient about both the medicine and patient's condition;
6. Guide prescribers in the standard protocol and decisions on how to monitor the patient's treatment, after considering the probable therapeutic and adverse effects of treatment.

3.4.9.[C] Good Dispensing Practices

This is to ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, with clear instruction, and in a package, that maintains the potency of the medicine[38].

3.4.9C.1 Policy Statement

The Government recognizes and supports the good dispensing practice for medicines from a national list of rationally chosen medicines that satisfy the health needs of the majority of the population.

3.4.9C.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure the dispensing of controlled medicine is carried out only in duly licensed premises and by authorised persons;
2. Ensure compliance with the minimum information requirement on the label of a dispensed medicine;
3. Ensure patient education/counselling on the use of dispensed medicines is carried out in a conducive environment suitable for effective communication;
4. Ensure that medicines are dispensed in a suitable container that will ensure the stability of the medicine dispensed;
5. Ensure the response to medication is monitored to ensure patients optimal benefits from therapy;
6. Ensure that controlled medicines dispensed are documented in designated registers and required format;
7. Ensure the retention of prescription for controlled medicines on the premises for 3 years.

3.4.9.D Concordance

This is the practice of involving patients in decision-making to improve patient adherence with medication plan.

3.4.9D.1 Policy Statement

The Government recognizes and supports a rigorous practice of involving patients in the decision-making regarding medications to improve adherence and reduce unsafe or unhealthy patient practices in regard to use of medication.

3.4.9D.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure that health facilities where controlled medicines are prescribed and dispensed createa conducive environment for privacy of the patient to discuss medication plan with a view to achieving adherence.

3.4.9[E] Drug Information Services

Drug information is intended to provide unbiased, scientifically validated drug information to promote rational prescribing, dispensing and use.

3.4.9[E].1 Policy Statement

The Government recognizes and supports the dissemination of information to a variety of key stakeholders to assist in providing unbiased and scientifically valid information to support rational prescribing, dispensing and use of controlled medicines.

3.4.9[E].2 Strategic actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall***:*

1. Establish Drug Information Units in all the public tertiary and secondary health facilities;
2. Suitably equip and provide the drug information units/centres with up-to-date reference materials and equipment, including computers, and internet access, to guarantee the acquisition and dissemination of current and accurate drug information.

3.4.10 Logistics Management Information System (LMIS)

Logistics Management Information System (LMIS) is a system of records and reports, whether paper-based or electronic, used to aggregate, analyse, validate and display data (from all levels of the logistics system) that can be used to make logistics decisions and manage the supply chain. It provides data for informed decision-making with respect to commodity procurement, inventory management and distribution.

LMIS data elements include stock on hand (SOH), consumption, losses and adjustments, demand, issues, shipment status, and information about the cost of commodities managed in the system.

3.4.10.1 Policy Statement

The Government recognizes and supports the comprehensive use of LMIS system to support a more effective and efficient system of supply and supply management.

3.4.10.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Design and disseminate standardized LMIS tools to capture essential logistics data in all facilities to ensure uniformity of data capturing and reporting, strongly supporting the use of electronic data systems;
2. Ensure that each health facility focal person sends logistics data on controlled medicines on quarterly basis to the States Logistics Management Coordinating Unit (LMCU) for collation on a format agreed and validated by the Technical Working Group on Access to Controlled Medicines;

3. Ensure that the essential logistics data (Stock on Hand, consumption, losses and adjustments) shall be sent at the end of the reporting period (quarterly) to the Ministry for quantification and to NAFDAC for reporting to the International Narcotics Control Board (INCB) with the intent to ensure supplies and stocks are sufficiently available to meet demand in a timely manner.

3.4.11 Quality Assurance

The Quality Assurance of Controlled Medicines and substances is intended to ensure the availability of safe, efficacious and quality medicines to all patients at all times. The process of quality assurance shall comprise all activities, processes, persons, places, conditions from manufacture to the point of administration to patients. These shall comply with all set standards as contained in the compendia in relation to current Good Manufacturing Practices (cGMP), Good Pharmacovigilance Practices (GPP), Good Distribution Practices (GDP), and Good Clinical Practices guidelines of 2016 as provided for on the National Drug Policy (NDP) 2005 and National Quality Assurance Policy (NQAP) 2015.

3.4.11.1 Policy Statement

The Government recognizes and supports the importance of assuring high standards and quality of controlled medicines.

3.4.11.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure only controlled medicines registered by NAFDAC are handled by licensed healthcare workers in approved or licensed healthcare facilities;
2. Ensure full implementation of the National Quality Assurance Programme (NQAP) in the management of controlled medicines is in accordance with NQAP 2015 & NAFDAC's Good Practices Guidelines 2016[39];
3. Ensure adequate amounts of controlled medicines are made available for legitimate non-medical use such as teaching, research and quality controls;
4. Ensure that NAFDAC maintain and publish periodically, the list of approved manufacturers and importers of controlled medicines.

3.4.12 Risk Management and Disposal of Controlled Medicines

Risk management of controlled medicines and substances refers to the effort to minimize harms associated with controlled medicines and substances while maintaining appropriate access to therapeutic use.

3.4.12.1 Policy Statement

The Government recognizes and supports the importance of managing risk to minimize harms to patients and professional healthcare workers.

3.4.12.1 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure administrative and regulatory procedure concerning use and safe disposal of controlled medicines, in line with national drug and administrative legislations, are adopted and implemented.
2. Ensure proper disposal of expired, not fully used by the patient or damaged controlled medicines, in a prompt manner, by identifying, documenting, and holding separately and securely, transporting, and disposing of in accordance with relevant guidelines.
3. Ensure recall of any controlled medicines found to be defective or no longer meet the required quality standards to protect individual or public health. In addition to NAFDAC, this shall be done by the manufacturer, distributor or importer, health facility in accordance with set standards, extant rules and protocols.

3.5 FUNDING

Funding is critical to ensuring sustained availability and the successful implementation of the NPCM.

3.5.1 Policy Statement

*T*he Government recognizes and supports the provision of funding to support this critical work to ensure availability and affordability of critical controlled medication.

3.5.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Ensure adequate funding of the existing Drug Revolving Fund (DRF) Account for the procurement of Schedule I Narcotic medicines;
2. Ensure the fund in DRF Account for Narcotic medicines is maintained and not diverted for other purposes;
3. Ensure inclusion of controlled medicines under the national and state health insurance schemes;
4. Explore all avenues to engage public private partnerships (PPP) where fund could be sourced from relevant partners or stakeholders for procurement of schedule I Narcotics based on Memorandum of Understanding (MOU) with FMOH;
5. Ensure funds are made available regularly (annually) for activities that will improve availability of controlled medicines including monitoring and evaluation of the policy;
6. Ensure funds are made available annually for training and re-training of healthcare personnel involved in the prescription and dispensing of controlled medicines.

3.6 CAPACITY BUILDING

Capacity building is a planned development of or increase in knowledge, output rate, management, skills, and other capabilities of an individual or organization through acquisition, incentives, technology, and/or training. It is expedient that healthcare delivery systems strive to increase its capacity building to be prepared to take on evolving challenges in the health sector as well as to allow it to evolve and adapt to the new contextual requirements and fulfil its role within a governance structure[40]. Training, retraining of, and continuing education for healthcare workers should be given priority.

Inadequate training, lack of awareness as well as poor attitude of health workers are major barriers to improving access to, and rational use of controlled medicines in Nigeria[41]. The curricula for health workers in most of our training institutions do not provide sufficiently for specific education on pain management. It is essential to incorporate the most recent scientific literature and standard procedures regarding rational use of controlled medicines for healthcare workers at all level to include but not be limited to prescribers, pharmacists, nurses, peri-care nurses and any care provider who comes into contact with patients.

The need for continuing education programme (CEP) for all health professionals was acknowledged by the World Health Assembly (WHA) resolution 27.31[42] and the maiden national health summit of 1995 in Nigeria[43]. The need was also reinforced and recognized in 1996 by the directive of the Honourable Minister of Health to all health regulatory bodies to develop the modalities for CEP for their members. The healthcare professions are at various stages of administration of Continuing Professional Development (CPD)[44]Programme or CEP but a lot more needs to be done to incorporate the use of controlled medicines for medical purposes into relevant CPD curricula. In addition, the 2016 Revised HRH Policy on in-service training and continuing education states that "Governments shall ensure that all health staff irrespective of their gender, cadre, work locations, are regularly provided with in-service training and continuing education to enhance their knowledge, skills and attitudes in the performance of their assigned roles and responsibilities"[45].

The need for continuing education programme (CEP) for all health professionals was acknowledged by the World Health Assembly (WHA) resolution 27.31[46] and the maiden national health summit of 1995 in Nigeria[47]. The need was also reinforced and recognized in 1996 by the directive of the Honourable Minister of Health to all health regulatory bodies to develop the modalities for CEP for their members. The use of controlled medicines for medical purposes should be incorporated into relevant Continuing Professional Development (CPD) curricula.

3.6.1 Policy Statement

The Government recognizes and shall support the capacity building of healthcare professionals to increase the likelihood of patients receiving the highest level of medical care, including access to controlled medicines when appropriate.

3.6.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Develop training modules on rational use of controlled medicines and incorporate into the school curriculum, pre-service orientation and continuing education/training of relevant healthcare workers in accordance with their roles and responsibilities;
2. Include doctors, dentists, veterinary doctors, pharmacists, nurses, midwives, community health extension workers, community health officers, and pharmacy technicians and scientific researchers in the target group for capacity building;
3. Sensitize and educate the general public, especially the service providers, patients themselves and caregivers, on the appropriate use of controlled medicines for medical and scientific purposes.

3.7 MONITORING, EVALUATION AND RESEARCH

3.7.1 Monitoring and Evaluation

Monitoring and evaluation are critical components necessary to ensure quality and consistent implementation of policies and practices. Routine monitoring and periodic evaluation of activities, processes, places, systems, and inventory of controlled medicines and outcome are necessary to determine the level of compliance with the NPCM and will ensure tracking of progress in the implementation of the policy, identify possible challenges and evolving effective strategies to fix them.

It is crucial that data is collected and maintained, in an electronic format whenever possible, at each point in the healthcare system where controlled medicines are stocked and used.

3.7.1.1 Policy Statement

The Government recognizes and shall support the monitoring and evaluation of each aspect of the complex components related to access to controlled medicines.

3.7.1.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society,

FMOH shall:

1. Develop and make available appropriate tools (indicators) that conform to international standards for each thematic area in the policy;
2. Conduct routine monitoring of the policy on a quarterly basis based on the developed indicators, to measure the progress in the implementation;
3. Ensure full evaluation of the Policy implementation every 2 years;
4. It is expected that activities related to the implementation of the National Policy will be monitored regularly, at least annually. The reports from the monitoring and evaluation processes will inform the policy review which is to be done at the five-year cycle of implementation.

NAFDAC shall:

1. Ensure that all stakeholders charged with the responsibility of handling controlled medicines report all documented activities and processes (HFs, DPSs, FCMS, FMOH, etc.).

3.7.2 Operational Research

Operational research is an analytical method of problem–solving and decision-making and will be necessary for the successful implementation of the National Policy for Controlled Medicines. Deliberate efforts will be made to undertake systematic collection, analysis and interpretation of data to answer emerging questions and/or solve problems arising from implementation of the Policy.

3.7.2.1 Policy Statement

The Government recognizes and shall support the implementation of the National Policy for Controlled Medicines while promoting operational research.

3.7.2.2 Strategic Actions

Working in collaboration with international and national organizations, associations and civil society, **the Government shall**:

1. Support and promote research directed towards major public health issues and problems facing availability of, and accessibility to controlled medicines.
2. Ensure that research is geared towards behavioural change interventions, availability, accessibility and rational use of controlled medicines for medical and scientific purposes.
3. Support and promote research on rational use of controlled medicines.

4.0 POLICY DISSEMINATION AND REVIEW PROCESS

The Nigerian National Policy for Controlled Medicines shall be disseminated locally and internationally. The following methods will be utilized to disseminate and support the implementation of the National Policy in Nigeria:

- Experts contributing to the National Policy will voluntarily disseminate through existing professional networks;
- Civil Society and other organizations will disseminate at all levels utilizing existing advocacy networks;
- Zonal presentations to key stakeholders will be made to clarify any questions and support a consistent understanding of the key elements of the policy.

5.0 ANNEX I–DEFINITION OF TERMS

The following is a compilation of terms and definitions for their use as it pertains to this document. It should be considered a guide and may not constitute an exhaustive list.

Abuse is defined by the WHO Expert Committee on Drug Dependence as "persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice". The term "abuse" is sometimes used disapprovingly to refer to any drug use at all, particularly of illicit drugs.

Accessibility is the degree to which a medicine is obtainable for those who need it at the moment of need with the least possible regulatory, social or psychological barriers.

Adverse Drug Reaction is defined by WHO as response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases, of for modification of physiological function

Affordability is the degree to which a medicine is obtainable for those who need it at the moment of need at a cost that does not expose them to the risk of serious negative consequences such as not being able to satisfy other basic human needs.

Analgesic is a medicine that reduces pain.

Availability is the degree to which a medicine is present at distribution points in a defined area for the population living in that area at the moment of need.

Consumption statistics have to be reported by governments (National Drug Regulatory Agencies) to the International Narcotics Control Board (INCB) annually and represent the amounts of narcotic drugs that were distributed in the country to the retail level, i.e. to hospitals, pharmacies and practitioners.

Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. They may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging'**.**

Controlled medicines are medicines containing controlled substances.

Convention is a formal agreement between States. The generic term "convention" is thus synonymous with the generic term "treaty". Conventions are normally open for participation by the international community as a whole, or by a large number of states.

Drug includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any diseases or disorder, abnormal physical state or symptoms thereof, in man or in animals; restoring, correcting or modifying organic functions in man or animal's disinfection or the control of vermin, insects, pests or contraception[48].

Dependence is defined by the WHO Expert Committee on Drug Dependence as "A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour.

Diversion refers to the movement of controlled drugs from licit to illicit distribution channels or to illicit use, non-medical use or use unrelated to scientific purposes.

Essential medicines are defined, as medicines or drugs that satisfy the health needs of the majority of the population. An Essential Medicine List is developed at the national level based on the needs of the majority of the population making them available in adequate amounts and in appropriate dosage forms at all levels of health care delivery system of the country.

Estimates of the requirements for controlled substances for legitimate purposes have to be submitted to INCB by the national competent authority. For Narcotic medicines and certain precursor chemicals, estimates have to be submitted to INCB annually and for psychotropic substances, simplified estimates (known as assessments) have to be submitted at least every three years.

Law refers to a set of rules on a specific topic enacted by the legislative body at the national, state or local level and having binding legal force.

Legislation refers to all rules having binding legal force at the national, state or local level.

Medicine: Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.

Misuse (of a controlled substance) for the purposes of these guidelines, is defined as the non-medical and non-scientific use of substances controlled under the international drug control treaties or under national law.

Narcotic drug is a term that refers to all those substances defined in the 1961 Single Convention as such.

National authority, in these guidelines, refers to any government institution involved with the issues discussed in this document. The term applies not just to national government institutions but may equally apply to other relevant institutions in the national territory involved with these issues, such as federal, state or provincial institutions.

National competent authority, in these guidelines, refers to any government agency responsible under its national law for the control or regulation of a particular aspect of the country's controlled substances legislation, in particular to issue certificates and authorizations for the import and export of narcotic drugs and psychotropic substances.

Opioid means literally "opium-like substance". It can be used in different contexts with different but overlapping meanings:

Opioid Substitution Therapy refers to treatment of opioid dependence with relatively stable doses of the long acting agonists (usually **methadone** or **buprenorphine**) prescribed over prolonged

periods of time (usually more than six months), which allows stabilization of brain functions and prevention of craving and withdrawal.

Palliative Care: The World Health Organization defines Palliative "as an approach that improves the quality of life of patients and their families facing the problem associated life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual……."

Policy: A set of policies are principles, rules, and guidelines formulated or adopted by an organization to reach its long-term goals and typically published in a booklet or other form that is widely accessible[49].

Psychotropic substances is a legal term that refers to all those substances listed in the Convention on Psychotropic Substances.

Rational drug use requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community. This implies rational prescribing, good dispensing practices and concordance[50].

Regulation refers to a set of rules on a specific topic with binding legal force at the national, state or local level and enacted by an administrative body to which the authority to issue such rules has been delegated by the national, state or local legislative body.

Single Convention refers in this publication to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961.

6.0 ANNEX II – STRATEGIC PLAN OF ACTION TO IMPLEMENT THE NATIONAL POLICY FOR CONTROLLED MEDICINES

6.1 THEMATIC AREA: COORDINATION & GOVERNANCE

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Sensitize regulatory bodies and stakeholders on the need for improved availability of controlled medicines for medical and scientific purposes.	Print and disseminate the National Policy with press release, talking points and summary notes.	FMOH	NAFDAC, PCN, SMOH, NMDC, 3⁰ Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Programme & Other Development	Government staff, regulatory bodies and other stakeholders receive printed copies. Soft copies posted online	* Hard copies of National Policy are disseminated to 1000 government staff and 1000 other stakeholders. *Electronic copy of National Policy is posted on 5 websites. *5 articles are published in newspaper.	**X**				

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			Partners	Press coverage.	*Every 6 months an expert is interviewed on TV.					
	Organize local town hall meetings to share information regarding the National Policy and implications for communities.	FMOH	NAFDAC, PCN, NMDC, SMOH, 3^0 Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Stakeholders in the 6 Geo-Political Zones sensitized.	*2 meetings held per Geo-political Zone. *500 persons or more in attendance total. *Minimum of 10 civil society partners participating.	**X**	**X**			
Promote coordination among key stakeholders to include but not limited to government, international and national organizations, associations and civil society.	Identify key stakeholders and the areas they intersect with increasing access and availability.	FMOH	NAFDAC, PCN,NMDC, SMOH, 3^0 Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Map of resources available to assist in increasing access to controlled medicines.	*List of stakeholders complete. *Map of resources available complete.	**X**	**X**			
	Assign roles to stakeholders regarding the collection of baseline data to demonstrate engagement with the National Policy.	FMOH	NAFDAC, PCN, SMOH, 3^0 Health Institutions, ACPN, NAHAP, WHO, UNODC,	Data available for key indicators or targets as a baseline.	*Stakeholders identify 5-10 key indicators or targets. *Baseline data is collected at all levels.	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			ACS'sTreat the Pain Prog., Development Partners and CSOs							
Establish a coordinating mechanism or coordinating platform in the Department of Food and Drug Services of the Federal Ministry of Health to coordinate implementation of NPCM.	Develop an Advisory Board at the National Level as a model for development at the local level through local health system delivery.	FMOH	NAFDAC, PCN, NMDC, SMOH, 3⁰ Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Advisory Board meets 2 times per year at National Level and 4 times per year at local level.	*Advisory Board meets and identifies 3 key areas of focus for annual implementation. *Local advisory boards are established in more than 75% of the country. *Local advisory boards submit reports to the National Advisory Board each quarter.	**X**	**X**	**X**	**X**	**X**
Identify existing structures such as Technical Working Groups, task forces and working committees with vested interest in controlled medicines.	Map existing structures and working groups that may contribute to work on controlled medicines.	FMOH	NAFDAC, PCN, NMDC, SMOH, 3⁰ Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Create a wider range of intersecting support for National Policy.	*Map created with a minimum of 5 identified groups. *Minimum of 3 non-traditional partners are incorporated into the map.	**X**	**X**			
	Identify key areas of focus for each working group as they contribute to the implementation of the National Policy.	FMOH	NAFDAC, PCN, NMDC, SMOH, 3⁰ Health Institutions, ACPN, NAHAP, WHO,	Working groups will be assigned key areas of focus to cover all	*Key areas of focus are identified. *Working groups are assigned a key area of focus. *Working group submits	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	aspects of access, availability and affordability.	an action plan to account for their key area of focus.					
Strengthen the Technical Working Group (TWG) on Access to Narcotics and Psychotropic substances and Precursors as a vehicle to identify and address gaps in the supply chain of controlled medicines.	Assign the TWG quarterly activities designed to support the implementation of the National Policy.	FMOH	NAFDAC, PCN, NMDC, SMOH, 3^0 Health Institutions, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	A committee is established as part of the TWG with a focus on increasing access.	List of gaps in supply chain. List of actions that can be taken to address the gaps.	**X**	**X**	**X**	**X**	**X**
Integrate supply of Scheduled I Narcotics and other controlled medicines with the operations of the Logistics Management Coordination Units (LMCUs) of States in order to improve ownership, drive and ensure	Organize meeting for leaders in the LMCUs to familiarize them with the National Policy.	FMOH	NAFDAC, PCN, State DPSs, 3^0 Health Institutions, NPSMP, ACPN, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog, Development Partners and CSOs	A minimum of one meeting per state is held with the LMCUs.	*Meeting is held and materials are distributed. *A list of potential strategies for implementation of the National Policy and monitoring are developed by LMCUs. Proportion of LMCU in the states that held minimum of one meeting.	**X**				

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
accountability for these medicines.	Establish a system linking the LMCUs from each State to each other in a forum.	FMOH	NAFDAC, PCN, State DPSs, 3^0 Health Institutions, ACPN, NPSMP, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	An interactive forum is created and LMCUs interact regularly regarding implementation of the National Policy.	*Interactive forum is established. *Biannual regional interactive sessions are scheduled and held across the country. *Data is shared via the interactive forum allowing for accountability and healthy competition.		**X**	**X**	**X**	**X**
Coordinate PPP arrangement for procurement of Schedule I Narcotic medicines for medical use in the country.	Establish a coordinating	FMOH	NAFDAC, PCN, SMOH, 3^0 Health Institutions, State DPSs, ACPN, NPSMP, NAHAP, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs				**X**	**X**	**X**	**X**

6.2 THEMATIC AREA: LEGISLATION, POLICY, REGULATIONS AND GUIDELINES

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Review National laws, legislation and existing policies to identify and promote opportunities to increase access to controlled medicines within a framework	Identify existing laws and legislation to be reviewed and mapped against the National Policy.	FMOH	NAFDAC, PCN, NMDC, State DPSs, ACPN, NAHAP, NDLEA, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Document detailing the laws and legislation with areas for improvement identified per the National Policy.	* Laws are identified. * Map of Laws and legislation clearly identify gaps and cross-cutting areas such as gender and human rights. Proportion of relevant existing law and legislation reviewed and mapped against National Policy	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
that recognizes the importance of gender and human rights.	Identify policies at the national and local level that contribute to decreasing access to controlled medicines.	FMOH	NAFDAC, PCN, State DPSs, NMDC, ACPN, NAHAP, NDLEA, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Document detailing the policies and rating if they increase access on a scale of 1 to 10 with 10 being the best score.	*Identify existing local or health practices that are not in line with the National Policy. *Explore means to change or update these policies to reflect the National Policy.	**X**	**X**			
Update existing, or develop new regulations and guidelines to address emerging issues on availability, accessibility and affordability as well as, rational prescribing, dispensing and use of controlled medicines.	Identify any documents, regulations or guidelines that need to be edited related to the National Policy.	NAFDAC	FMOH, PCN, State DPSs, ACPN, NMDC, NAHAP, NDLEA, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Mechanism to identify and edit all pertinent information related to access and availability of controlled medicine.	*List of documents, websites, regulations, guidelines and any other government based dissemination of health information that must be updated. *Design a mechanism that allows for these to be reviewed and updated quarterly.	**X**				
	Develop regulations in support of the National Policy.	NAFDAC	FMOH, PCN, State DPSs, ACPN, NMDC, NAHAP, NDLEA, WHO, UNODC, ACS's Treat the Pain	Regulations developed for management of pain, and other areas related to National Policy.	*Review the National Policy and identify areas where regulations would make the implementation smoother. *Create the regulations. *Avoid making regulations that	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			Prog., Development Partners and CSOs		inadvertently increase the barriers to access and availability.					
Develop policy guidelines for quantification of controlled medicines, pain management, palliative care and drug demand reduction.	Develop guidelines in support of the National Policy.	FMOH	NAFDAC, PCN, State DPSs, NMDC, ACPN, NAHAP, NDLEA, WHO, UNODC, ACS's Treat the Pain Prog., Development Partners and CSOs	Guidelines developed for management of pain, and other areas related to National Policy, without inadvertently increasing the barriers to access and availability.	* Review of the National Policy and list of areas where guidelines would make the implementation smoother. *The guidelines are approved, printed and disseminated.	**X**	**X**	**X**		

6.3 THEMATIC AREA: HEALTHCARE SERVICE DELIVERY

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Review and revise the Nigerian Essential Medicine List, including a focus on controlled medicines. The most current version was updated in 2016.	Create an advisory committee or use an existing NDF/EDL Committee to review the current Nigerian Essential Medicine List.	FMOH	NAFDAC, WHO, PCN, PSN, NMA, SMOH, 3º Health Institutions, ACS's Treat the Pain Programme and WHO	Review the existing list through the lens of the National Policy.	* Committee is created. *List of issues created with justification for inclusion or exclusion provided based on scientific studies.	**X**				
	Revise the existing Nigerian Essential Medicine List and Guidelines for use the list.	FMOH (NDF/EDL Committee)	FMOH, NAFDAC, WHO, ACS's Treat the Pain Programme,	Revised document completed.	*Committee revises Nigerian Essential Medicine List and Guidelines with input from key stakeholders.	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			WHO and other Development Partners		*Support is provided by international organizations, in particular WHO. *Civil society partners are included in the process.					
Review Standard Treatment Guidelines with a focus on including pain management and all conditions requiring the use of controlled medicines.	Create an advisory committee or use an existing group to review the current Nigerian Essential Medicine List.	FMOH	NAFDAC, SMOH, 3º Health Institutions, WHO, ACS's Treat the Pain Programme and WHO	Review the guidelines through the lens of the National Policy.	* Committee is created. *List of issues created with justification for inclusion or exclusion provided based on scientific studies.		**X**			
	Revise the existing Nigerian Standard Treatment Guidelines, in particular as it needs to be in line with the above revised Essential medicine list.	FMOH (NDF/EDL Committee)	FMOH, NAFDAC, SMOH, 3º Health Institutions WHO, ACS's Treat the Pain Programme, WHO and other Development Partners	Revised document completed.	* Committee revises Guidelines with input from key stakeholders. *Support is provided by international organizations, in particular WHO. *Civil society partners are included in the process.		**X**	**X**		
Review and revise guidelines and standard operating procedures for healthcare, to ensure that consideration	Identify guidelines and standard operating procedures across the healthcare system that can be reviewed and include a focus on controlled medicines.	FMOH	NAFDAC, SMOH, 3º Health Institutions PCN, NMA, NNMC, WHO, ACS's Treat the Pain Programme and WHO	Review of existing healthcare standard operating procedures compiled into one document.	*Map the existing standard operating procedures and identify gaps. * Document the breadth of standard operating procedures and clearly highlight the areas of overlap in focus on controlled medicines.		**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
is taken regarding the safe and ethical use of controlled medicines across all levels of care including tertiary, secondary and primary sites.	Revise existing standard operating procedures to ensure the safe and ethical use of controlled medicines at all levels of healthcare.	FMOH	NAFDAC, PCN, NMA, SMOH, 3o Health Institutions NNMC, WHO, ACS's Treat the Pain Programme, WHO and other Development Partners	Revise operating procedures to be consistent with implementation of the National Policy.	* Committee revises Guidelines with input from key stakeholders. *Support is provided by international organizations, in particular WHO. *Civil society partners are included in the process.			**X**	**X**	
Incorporate clear and consistent medical assessment of pain levels in all patients, as the 5th vital sign.	Ensure all patients are screened and assessed for pain levels at each interaction with the healthcare system.	FMOH	NMDC, NAFDAC, NNMC, SMOH, 3o Health Institutions PCN, WHO, ACS's Treat the Pain Programme, WHO and other Development Partners	Patients and Caregivers will anticipate being asked to describe a level of pain on a scale, with results documented.	*Prepare normative guidance to ensure consistent and clear screening and assessment of pain levels in all patients interacting with all levels of the healthcare system. *Document responses to perceived levels of pain.	**X**	**X**	**X**	**X**	**X**
Ensure all healthcare staff are able to recognize signs of distress in patients using controlled medicines, and closely	Provide existing healthcare workers, at all levels, with information and opportunities for skill development related to monitoring patients under the care of controlled medicines.	FMOH	NAFDAC, NMDC, NNMC, PCN, PSN, NMA, WHO, ACS's Treat the Pain Programme, WHO, CSOs and other Development Partners	Current workforce will be knowledgeable about patient safety and monitoring patients, even those	*Quarterly review of staff indicate that between 75 and 85% of staff are skilled and can monitor patients effectively. *Staff monitor and document patient status regularly.		**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
monitor patients under their care that have been prescribed a controlled medicine.				using controlled medicines.						
	Incorporate information related to the importance of monitoring patients who are prescribed controlled medicines.	FMOH	NMDC, NFDAC, NNMC, PCN, WHO, ACS's Treat the Pain Programme, WHO and other Development Partners	All future healthcare workers receive knowledge and skills during their education to prepare them to monitor patients prescribed controlled drugs.	*Skills-based modules are incorporated into all levels of the higher education system for healthcare providers. *Civil society is engaged in discussions related to monitoring patients and actions to take in an emergency situation such as overdose or allergic reaction.		**X**	**X**	**X**	**X**
Review prescription practices including but not limited to who can prescribe, who can dispense and dispensing practices.	Review current prescription practices to determine if they are in line with the National Policy and with current laws, regulations and legislation.	FMOH	NMDC, PCN, NAFDAC, PSN, WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	Identify existing practices that limit access and availability when used safely for medical purposes.	*Review practices and identify barriers. *Revise practices to be in line with the National Policy and to address the barriers. *Ensure prescribers are well trained and have staff able to monitor patients who are prescribed controlled medicines.		**X**	**X**	**X**	**X**

6.4 THEMATIC AREA: SUPPLY CHAIN MANAGEMENT

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Establish a robust and efficient supply chain system for controlled medicines with a strong focus on pharmacovigilance, import and export, local production and manufacturing and quality assurance	Map the existing supply management system from manufacturing or import to the end user.	FMOH	NAFDAC, 3^0 Health Institution, NPSCMP, ACPN, State LMCUs, 3^0 Health Institutions, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN,	Document detailing all aspects of the supply chain management in one graphic.	* Committee is formed with diverse stakeholders. *Map existing system. *Create graphic.	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
including inspections and risk management.			ACS's Treat the Pain, UNODC, WHO and other Development Partners							
	Identify gaps in the supply chain management system and work to address these gaps.	FMOH	NAFDAC, 3⁰ Health Institution, NPSCMP, ACPN, State LMCUs, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	Gaps are identified and highlighted in a different color on the graphic.	*Committee identifies gaps. * Committee lists actions that can be taken to address the gaps.	**X**				
Enhance the rational selection of controlled medicines and the process of quantification using consumption and morbidity data as available.	Identify a more extensive process to assess consumption and morbidity data.	FMOH	NAFDAC, 3⁰ Health Institution, NPSCMP, ACPN, State LMCUs, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN,	Create a systemic approach to collect consumption and morbidity data.	*Enlist diverse stakeholders in methods to collect data. *Build the capacity of key leaders to ensure data is collected accurately.	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			ACS's Treat the Pain, UNODC, WHO and other Development Partners							
	Refine the process of quantification of controlled medicines using the more detailed data.	FMOH	NAFDAC, 3⁰ Health Institution, NPSCMP, ACPN, State LMCUs, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	A more clearly refined and systemic approach that takes into account all data related to controlled medicines.	*Identify current process and gaps in process. *Refine the mandates to ensure higher quality of data to determine quantification.	**X**	**X**			
Ensure routine procurement of Scheduled I Narcotic medicines to sustain availability and prequalify local pharmaceutical manufacturing industries for the purposes of	Identify and take measures to increase the options available to procure controlled medicines, including support for local manufacturing.	FMOH	NAFDAC, 3⁰ Health Institution, NPSCMP, ACPN, State LMCUs, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, PCN, ACS's	Increased venues available for procurement purposes to ensure stock is available.	*Identify current procurement process. * Note and address gaps in process, particularly as it relates to procurement in a timely manner. * Encourage local production and consider incentives such as tax reductions for businesses invested in	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
manufacturing Schedule I Narcotic medicines for the Federal Ministry of Health.			Treat the Pain, UNODC, WHO and other Development Partners		production.					
Review and enhance the process of supply planning, to include a regular review of quantities before shipment, realignment of inventory, transportation, consumption, manufacturing and purchasing plans.	Systematize the process for supply planning to include more regular review of quantities.	FMOH	NAFDAC, ACPN, 3^{0} Health Institution, NPSCMP, NPSCMP, State LMCUs, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	Create a quarterly review plan that is consistently implemented to inform quantification data and alert to any new trends.	*Create a small group of stakeholders to design a more refined supply planning process. * Inform all stakeholders in the process that the new system and forms will be in place by end of 2018.	**X**				
	Ensure enhanced communication between all components of the supply chain to inform the establishment of a more receptive process.	FMOH	NAFDAC, NPSMP, ACPN, State LMCU, 3^{0} Health Institution, TWG on Access to Narcotics	Create an electronic communication platform to manage all aspects of supply planning.	*Once new process is designed, create a password protected database that stakeholders complete. * Analyze data frequently, minimum of once per month.	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			&Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners							
Institute effective pipeline monitoring procedures for controlled medicines including Scheduled I Narcotics in order to routinely detect and resolve issues that affect the supply system.	Using the electronic platform referenced above, analyze the data on a monthly basis to identify inconsistencies and possible trends.	FMOH	NAFDAC, NPSCMP, ACPN, State LMCU, 3^{0} Health Institution, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	A more streamlined and seamless system will allow for the faster resolution of challenges in the system, thus averting a crisis.	*Monitor the input of the data to the electronic platform. * Ensure all stakeholders are regularly updating data. * Run monthly reports and compare the output to previous months. * Regularly analyze the results and work to account for any reasons for discrepancies. * Monitor trends and report to Minister.	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Operationalize the decentralization of the central warehousing and distribution of Scheduled I Narcotic medicines in alignment with the integrated warehousing and Distribution design of the FMOH.	Identify and highlight the mandates of FMOH directly in line with the decentralization of the central warehousing and the National Policy for Controlled Medicines.	FMOH	NAFDAC,NPSCMP, ACPN, State LMCU, 3^0 Health Institution, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	Create a list of mandates that support decentralization.	*Small working committee creates a list of mandates reflecting decentralization. * Highlight the mandates and the cross-over with the National Policy. * Suggest targets to be met regarding decentralization.	**X**	**X**			
	Create and implement a plan to support the existing mandates of FMOH related to decentralization.	FMOH	NAFDAC, NPSCMP, ACPN, State LMCU, TWG on Access to Narcotics & Psychotropic Substances, PMGMAN, APIN, PCN, ACS's Treat the Pain, UNODC, WHO and other Development Partners	Use data and the electronic platform to support the decentralization plan.	*Create a plan to meet targets for decentralization while protecting the health of all patients. * Take steps to ensure wider distribution of controlled medicines. * Ensure well trained and knowledgeable leadership at all levels to support decentralization.	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Promote regular inspection of manufacturing outfits and facilities (public and private) where controlled medicines are manufactured, stored and dispensed in line with NAFDAC Good Manufacturing & Good Distribution Practices Guidelines including but not limited to ensuring good storage conditions and quality tests within the distribution channels.	Support regular inspections by NAFDAC that are well planned, coordinated with other inspections and done by a knowledgeable inspection team.	NAFDAC	FMOH, PCN, NMDC, NMCN, WHO and other Development Partners	Ensure proper and safe handling of controlled medicines to ultimately protect patients.	* Identify and map all the inspectors and persons who come to inspect manufacturing outfits. * Coordinate inspections to bring a united team approach that consolidates time and allows for less down time in manufacturing. * Provide inspection forms to manufacturers prior to the inspection, use the forms during the inspection and leave a signed copy with the manufacturer. All parties involved in the inspection should sign including the manufacturer.	**X**	**X**	**X**	**X**	**X**
Ensure safe and simple recall, with proper disposal of expired or damaged medicines, of	Create and implement a consistent policy related to recall and proper disposal of controlled medicines in line with quality standards at the international and national	NAFDAC	FMOH, PCN, ACS's Treat the Pain Programme, WHO, PMGMAN, APIN and	Protect individual and public health as it relates to expired medication,	* Review the current policy and update any gaps in the recall and proper disposal methods. * Disseminate a revised policy with support and	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
any controlled medicine found to be defective or that no longer meets the required quality standards by NAFDAC to protect individual or public health.	level.		other Development Partners	fraudulent medication or medication that is defective and not able to work.	approval of all involved stakeholders.					
Create a link between pharmacy and prescriber on what controlled medicines are available and ensure documentation of quantity consumed.	Establish a communication system between pharmacists and prescribers, preferable electronic, that allow for a "real time" knowledge of the availability of each controlled medication.	FMOH	FMOH, PCN, NMDC, NMCN, ACS's Treat the Pain Programme, WHO, PMGMAN, APIN and other Development Partners	Support enhanced communication between the pharmacist and the prescriber to ensure the safety of all patients.	* Identify reasonable means of communication between pharmacists and prescribers. * Ensure that this communication is intent to increase access and does not serve as a barrier. * Keep both informed of any changes such as new training or other components that may increase demand.	**X**	**X**	**X**	**X**	**X**
Support pharmacovigilance practices such as adverse drug reporting across all health facilities, and the proper	Define pharmacovigilance across vectors. For example, clearly define what is expected of the patients, what is expected of the physician, what is expected of the pharmacist, et.	NAFDAC	FMOH, NMDC, NMCN, ACS's Treat the Pain Programme, WHO, PMGMAN, APIN and	A stronger sense of responsibility to protect and monitor the patient, within a framework of ensuring the	* Identify vectors with a stake in pharmacovigilance. * Create a summary of standard operating procedures to support pharmacovigilance without being a barrier to accessing controlled	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
reporting and documentation of medication error.			other Development Partners	best medical care including access to controlled medicine.	medications. * Disseminate the expectations of each vector of the supply chain management system.					

6.5 THEMATIC AREA: FUNDING

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Ensure adequate funding of the existing Drug Revolving Fund (DRF) Account for procurement of schedule I Narcotic medicines.	Brainstorm and identify sustainable means by which the DRF Account can ensure adequate funding.	FMOH	Ministry of Budget & National Planning, NAFDAC, 3^{o} Health Institution, SMOH, and ACS's Treat the Pain, CSOs, UNODC, WHO and other Development Partners	Listing of all potential funding mechanisms that can support the funding of controlled medicines.	* Convene a small working committee with expertise in government budgeting. * List all creative and feasible means to ascertain funding.	**X**	**X**			

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
	Work with a financial expert to strategize a fiscal approach to support the ongoing procurement of controlled medicines for use in Nigeria.	FMOH	Ministry of Budget & National Planning, NAFDAC, 3º Health Institution, SMOH, and ACS's Treat the Pain, WHO, UNODC, CSOs, WHO and other Development Partners	Detailed strategic fiscal approach that demonstrates sustainability over the next ten years to institutionalize the ongoing procurement of controlled medicines.	*Identify or hire a fiscal expert to lead the strategic approach. * Engage civil society and insurance providers in the discussion. * Present the plan for sustainability for approval.		**X**	**X**		
Explore the possibility of public private partnerships (PPP) funding for procurement of Schedule I Narcotic medicines based on MOU with FMOH.	Identify all public and private funding that may be available to support procurement of controlled medicines.	FMOH	WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	Full list of public and private funding that can contribute to the funding challenges.	*Work with the working committee identified above to note the public and private funding. * Think of non-traditional partners that might be supportive.		**X**	**X**	**X**	
	Create a competitive environment to help in defraying the costs of the medications.	FMOH	PMGMAN, WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	Widen the field of competitors to win a procurement bid to include both in-country and out-of-country companies.	*Inform all manufacturers and importers of the incentives to make economical controlled medicines available to patients. * identify incentives that are in compliance with current import/export regulations.				**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Review existing health insurance schemes and propose controlled medicines, including those appearing in the Essential Medicine List are covered by the insurance schemes.	Ensure patients have a minimum of one insurance scheme that covers the costs of controlled medicines for patients with a qualifying medical diagnosis.	FMOH	NHIS,WHO, 3⁰ Health Institutions ACS's Treat the Pain Programme, WHO and other Development Programme	Make controlled medicines, particularly those on the Essential Medicine List one of the areas covered under the government insurance scheme.	*Work with a small committee of experts, including civil society, to explore various insurance schemes and coverage for controlled medicines. * Include at least one insurance scheme in the overall financial plan as presented by the expert above.		**X**	**X**	**X**	**X**
Ensure availability of funding annually for activities that will improve availability of controlled medicines to include implementation, monitoring and evaluation of the National Policy.	Identify funding that can support the sustainable implementation of the National Policy for Controlled Medicines to include but not be limited to capacity building, monitoring and evaluation and dissemination.	FMOH	NAFDAC, Ministry of Budget & National Planning, 3⁰ Health Institutions, WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	Ongoing support for activities related to implementation of the National Policy.	*Work with the working committee identified above to note the public and private funding that might be available to support implementation of the National Policy. * Think of non-traditional partners and strategies that more effectively use resources and staff time.	**X**	**X**	**X**	**X**	**X**

6.6 THEMATIC AREA: CAPACITY BUILDING

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Ensure development of standard training modules on rational use of controlled medicines and incorporate into the pre-service and continuing education/tra	Develop and design standard training modules on rational use of controlled medicines for each sector.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	A multi-component set of training modules is developed and tailored for each sector.	* With the assistance of existing training materials and research, develop standard training modules. * Tailor the training modules for each sector to include but not be limited to prescribers, pharmacists, nurses, community staff. * Include assessment measures to ensure development of					

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
ining curricula of relevant healthcare workers in accordance with their roles and responsibilities.					knowledge and skills.					
	Use standard training modules on rational use of controlled medicines for each sector.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Cascading training package to be implemented in higher education programs for health workers.	*Identify and train skilled leaders to be the first phase of the cascading training package. * Build in incentives for volunteer trainers. * Identify structured system and implement though higher education programs. * Assess the trainers, the materials and the learning of each participant.		**X**	**X**	**X**	**X**
Mandate regular training for all healthcare workers and professionals in the rational use of controlled medicines, including narcotics.	Mandate that each healthcare workers complete the standard training modules on rational use of controlled medicines for each sector.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Use multi-component set of training modules is developed and tailored for each sector to work with existing health workers.	* Use developed standard training modules. * Tailor the training modules for each sector to include but not be limited to prescribers, pharmacists, nurses, community staff. * Include assessment measures to ensure development of knowledge and skills.	**X**	**X**			
	Use standard training modules on rational use of controlled medicines for each sector.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog,	Cascading training package to be implemented in continuing education programs for	*Identify and train skilled leaders to be the first phase of the cascading training package. * Build in incentives for volunteer trainers.		**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			WHO and other Development Programme	health workers.	* Identify structured system and implement though continuing education programs. * Assess the trainers, the materials and the learning of each participant. Proportion of trainees who rate the training as useful					
Identify geographic areas where additional persons must be trained to prescribe controlled medicines and make training available. Provide mandatory training for all healthcare professionals in pharmacovigilance and medication error reporting of controlled	Map the existing healthcare workers in each State and conduct a gap analysis for where no prescribers are available.	FMOH	NUC, NMDC, PCN, NMCC, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Create a database of healthcare workers, their expertise, training and ability to prescribe medication.	*Develop a database of healthcare workers. * Register their work experience, training and responsibilities. * Identify gaps and make training available in geographic areas without full coverage.	**X**	**X**	**X**	**X**	**X**
	Incorporate a stand-alone module on pharmacovigilance that is mandatory for every healthcare worker in Nigeria.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Implement a mandatory training session on pharmacovigilance for healthcare workers at all levels.	* Build a targeted module on pharmacovigilance with a particular focus on protecting patients. * Stress the issue of safety and the measures in place to protect patients. * Focus on the human right to health and the high standards needed to ensure that right.	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
medicines, including narcotics.					Availability of stand-alone module on pharmacovigilance for healthcare worker in Nigeria.					
Ensure availability of fund annually for training and re-training of healthcare workers involved in the prescription and dispensing of controlled medicines.	Explore funding options for capacity building as a core component of the fiscal plan developed above.	FMOH	NUC, NMDC, PCN, NMCN, PSN, NMA, NAFDAC, Ministry of Budget and National Planning, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Ensure sustained funding is part of the fiscal plan developed above to sustain a change in the use of controlled medicines.	* Ensure that members of civil society, training leaders, and higher education providers are represented on the working committee looking at sustainable funding.	**X**	**X**	**X**	**X**	**X**

6.7 THEMATIC AREA: MONITORING AND EVALUATION

Overall Goal:

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

Overall Objectives:

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, scientific 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.

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
Develop and implement monitoring and evaluation framework for the National Policy.	Develop a monitoring and evaluation framework for the National Policy.	FMOH	NAFDAC, PCN, NMDC, NMCN, WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	A detailed monitoring and evaluation framework is developed with timelines and responsibilities.	* Experts review the implementation plan and incorporate strategies into the monitoring and evaluation framework.	X				
	Implement a monitoring and evaluation framework for the National Policy that mirrors the strategies and	FMOH	NAFDAC, PCN, NMDC, NMCN, WHO, ACS's Treat	Implement the monitoring and	*Identify experts and leaders that will volunteer to monitor the implementation.	X	X	X	X	X

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
	activities put forth in the Policy itself.		the Pain Programme, WHO and other Development Partners	evaluation plan as a support to increasing access and availability not an additional barrier.	* Provide the experts the tools and training to implement standard monitoring activities. * Incorporate monitoring and evaluation tools and data into the electronic platform.					
Implement mentoring and supportive supervision for healthcare workers already working in the field.	Establish a national interactive website to provide support and collect data related to the implementation of the National Policy.	FMOH	NAFDAC, PCN, NMDC, NMCN, WHO, ACS's Treat the Pain Programme, WHO and other Development Programme	Development of a multi-faceted electronic platform, website that can be used to provide support knowledge and to collect data.	*Create a mentoring or "buddy" link on the website to provide real time answers to questions and support. * Host webinars and blogs by experts to continue to provide supportive supervision for healthcare workers. * Utilize trainers and leaders as mentors in the larger healthcare settings.	**X**	**X**	**X**	**X**	**X**
	Identify and train supportive supervision for healthcare workers working in the field as they implement the National Policy.	FMOH	NMDC, PCN, NMCN, PSN, NMA, NAFDAC, Ministry of Budget and National Planning, WHO, ACS's Treat the Pain Prog, WHO and other	Build a cadre of trainers, experts and leaders that can be called upon as supportive supervisors when needed in the field.	*Identify trainers, experts and leaders willing to volunteer time to support this effort. * Map the supportive supervisors to "cover" geographic areas. * Utilize supportive supervisors for anecdotal data related to monitoring and evaluation of the implementation of the	**X**	**X**	**X**	**X**	**X**

Strategies	Activities	Responsible	Partnering Agencies	Expected Outcome	Performance Indicators	Time Frame				
						2018	2019	2020	2021	2022
			Development Programme		National Policy.					
Support and promote research directed towards major public health issues and challenges that continue to limit the availability of and accessibility to controlled medicines.	Create and empower a scientific network of experts focused on studying controlled medicines, policy and outcomes of implementation.	FMOH	NMDC, PCN, NMCN, PSN, NMA, NAFDAC, Ministry of Budget and National Planning, WHO, ACS's Treat the Pain Prog, WHO and other Development Programme	Journal articles written and published in peer reviewed journals highlighting the work being done in Nigeria around controlled medicines.	*Identify participants from higher education and other areas that may be willing to participate in a scientific network. * Network with international organizations regarding the scientific nature of the work being done in Nigeria related to controlled medicines. * Support ongoing meetings of the scientific network.	**X**	**X**	**X**	**X**	**X**

7.0 ANNEX III – NIGERIA ESSENTIAL MEDICINE LIST (NEML)

List of controlled medicines in NEML

S. No.	*Narcotic Medicines*	*Psychotropic Substances*	*Precursors*
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	

8.0 ANNEX IV – REFERENCES

[1]Universal Declaration of Human Rights, United Nations, (1948)

[2] Report of Assessment of Barriers to Access to Narcotics and Controlled Medicines in Nigeria, (FMOH & WHO, 2013).

[3] Resolution 70/1

[4] General Assembly Resolution S-30-1, annex. Adopted on 19 April 2016.

[5] Ensuring balance in national policies on controlled substances. Guidance for Availability and Accessibility of Controlled Medicines. (WHO 2011).

[6] United Nations, Treaty Series, vol. 520, No. 7515.

[7] United Nations, Treaty Series, vol. 976, No. 14152.

[8] United Nations, Treaty Series, vol. 976, No. 14152.

[9] United Nations, Treaty Series, vol. 1019, No. 14956.

[10]http://www.incb.org/incb/en/about/mandate-functions.html

[11] National Drug Policy, (2005).

[12] National Drug Control Master Plan, (2015 – 2019).

[13] National Supply Chain Policy for Pharmaceuticals and Other Healthcare Products, FMOH, (2016).

[14] National Supply Chain Policy for Pharmaceuticals and Other Healthcare Products, FMOH, (2016).

[15] Ensuring balance in national policies on controlled substances. Guidance for Availability And Accessibility Of Controlled Medicines. (WHO 2011).

[16] Ensuring balance in national policies on controlled substances. Guidance for Availability And Accessibility Of Controlled Medicines. (WHO 2011).

[17] National Task Shifting/Sharing Policy for Essential Services

[18]Standard Operating Procedures for Task Shifting

[19] O'Brien M, Mwangi-Powell F, Adewole I F, Soyannwo OA, Amandua J, Ogaja E, Okpeseyi M, Ali Z Kiwanuka R, Merriman A. Improving access to analgesic drugs for patients with cancer in sub-Saharan Africa. The Lancet Oncology. (2013; 14: 176-182).

[20]National Agency for the Control of AIDS (NACA). (2017). National HIV/AIDS Epidemiology and Impact Analysis (NHEIA) Report

[21]National Agency for the Control of AIDS (NACA). (2017).

[22] Beshel-Akpeke RA, Eshiet AI, Ilori IU, Oku AO, Onwuadika PU. Pain management in patients with HIV/AIDS in a tertiary health facility in South-South Nigeria Afr J AnaesInt Care (2015; 15: 20)

[23] World Health Organization Cancer Pain Relief (WHO 1986)

[24] Amanor-Boadu SD, Adebamowo CA, Olubowale A, Soyannwo OA. Evaluation of Surgical Resident Staff Knowledge of Cancer pain assessment and treatment. Nigerian Journal of Clinical Practice (2002; 5: 10-13).

[25] Impediments to availability of opioid analgesia. 2010 Report of the International Narcotics Control Board (INCB). Availability of internationally Controlled Drugs: Ensuring adequate access for medical and scientific purposes. Page 44.

[26] Campbell J. Presidential Address, American Pain Society (1996). www1.va.gov/PAINMANAGEMENT/docs/TOOLKIT.pdf

[27] Jedi-Agba SE, Curado MP, Ogunbiyi O, Oga E, Fabowale T, Igbinoba F, Osubor G, Out T, Kumai H, Koechin A, Osinubi P, Dakum P, Blattner W, Adebamowo CA. Cancer incidence in Nigeria: a report from population based cancer registries. Cancer Epidemiology (2012; 36: 1-8).

[28] Abubakar S, Lawan U., Mijinyawa M., Adeleke S., Sabiu H. Perceptions about Sickle Cell Disease and its Prevention among Undergraduates of Tertiary Institutions in Kano State, Nigeria. Niger J Clin Med. (2010 Jul 15;3(1). [WHO reference yes – keep both]

[29] Sickle cell disease prevention and control www.afro.who.int (2015).

[30] Federal Ministry of Health. Nigeria Cancer Control Plan (2008-2013).

[31] National Guidelines for HIV and AIDS Treatment and Care in Adolescents and Adults (FMoH 2010).

[32] The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities (2011).

[33] National Essential Medicines List, FMOH (2016).

[34] Nigeria Standard Treatment Guidelines (2016).

[35] NAFDAC Good Distribution Practices Guidelines (2016).

[36]NAFDAC Good Manufacturing & Good Distribution Practices Guidelines.

[37] Nigeria National Pharmacovigilance Policy and Implementation Framework, (FMOH, 2012).

[38]Managing Access to Medicines and Health Technologies (2011).

[39] Good Practices Guidelines (2016).

[40]http://www.businessdictionary.com/definition/capacity-building.html, 10:36am

[41] Soyannwo OA. Pain management in Nigeria – Challenges, gains and future prospects. Pain News A publication of the British pain Society, Winter. 2010;23–6).

[42] WHA 27.31 Resolution.

[43] Communique of the Maiden National Health Summit, (1995).

[44] Pharmacists Council of Nigeria (PCN) Mandatory Continuing Professional Development (MCPD) Programme Manual, (1998).

[45] Revised Nigeria Human Resources for Health (2016-2020).

[46] WHA 27.31 Resolution.

[47] Communique of the Maiden National Health Summit, (1995).

[48]National Drug Policy, (2005).

[49] Read more: http://www.businessdictionary.com/definition/policies-and-procedures.html.

[50] WHO definition.

Full list of these controlled substances can be obtained on the INCB websites

- https://www.incb.org/incb/en/narcotic-drugs/Yellowlist_Forms/yellow-list.htm;
- https://www.incb.org/incb/en/precursors/Red_Forms/red-list.htm;
- https://www.incb.org/incb/en/psychotropic-substances/green-lists.html