



NATIONAL DRUG POLICY

3rd EDITION 2021

Published by
**FEDERAL MINISTRY
OF HEALTH**
NIGERIA

In Collaboration with



World Health
Organization
Nigeria



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FOREWORD

It is my pleasure to write the foreword to the third edition of the National Drug Policy (NDP) 2021, coming sixteen years after the first revision in 2005. This is a long interval for the review of a policy document especially in the face of rapid and epic developments in the pharmaceutical sector.

As expected, the review was an opportunity to assess the performance of the second edition in terms of realization of its goals, objectives, and targets. It emerged that substantial progress was made in some aspects, while not much was attained in others. Factors responsible for the low performance included changes in the economic fortune of the nation, lack of proper performance indicators and very ambitious targets.

The delay however gave the opportunity to reflect in the revised edition on some key areas and align the NDP with the vision and aspiration of the National Health Act (NHA) 2014, the National Health Policy (NHP) 2016, the National Strategic Health Development Plan II (NSHDP II) 2018 to 2022, and other relevant policies and guidelines.

An implementation framework is as important as the NDP itself and to ensure proper implementation, strategies for development of SMART indicators, data collection, monitoring and evaluation plan as well as dissemination of the policy document were provided for.

In addition, this third edition of the NDP recognizes many key factors that must be coordinated for the Nigerian populace to be assured of access to high quality, affordable medicines.

These key factors include Medicine Legislation and Regulation, Quality Assurance of Pharmaceuticals and Related Products, Financing, Procurement, Storage and Distribution, Local Production of Pharmaceuticals, Rational Drug Use, Medicine Selection, Human Resource Development, Research and Development, Traditional Medicines and International Cooperation. Adequate attention was given to them in this edition.

Our NDP will ensure that medicines play the rightful role in the health care ecosystem as the essence of the National Drug Policy.

The journey to successful implementation of the revised 2021 edition of the NDP is promising.



Dr. Osagie Ehanire, MD, FWACS
Honourable Minister of Health

ACKNOWLEDGEMENT

The Federal Ministry of Health recognises and appreciates the contributions of the following stakeholders and staff of the Federal Ministry of Health towards the successful revision of the 2nd edition of the National Drug Policy. It is also worthy of note, the technical and financial support provided by the World Health Organization (WHO).

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PREFACE

The History of the National Drug Policy started with the adoption and launch of the first edition in a well-attended event in 1990. In 2005, the Policy was reviewed because it did not achieve its intended objectives of improving drug availability, distribution and rational use in the country. The reviewed 2nd edition of 2005 suffered a similar fate to the 1st edition. This was due to the fact that there were no inbuilt implementation and monitoring plans to ensure the effectiveness of the Policy.

Following the poor outcomes of the first two editions, the government constituted a committee to review the 2nd edition in 2019. The Committee was supported by three Consultants led by Professor Fola Tayo. The 3rd edition took into cognisance lessons learnt, challenges in the implementation of the 2nd edition and shortcomings of the previous editions. Additionally, more realistic targets were set in the development of the implementation and monitoring plans. It is therefore expected that this 3rd edition of the National Drug Policy should witness visible improvements in all facets of drug management in the country particularly concerning local drug production, patronage of locally produced drugs, effective drug procurement and availability as well as rational use.

This Policy also provides strategic direction to consolidate the efforts of Government in curbing the growing menace of Antimicrobial Resistance in the country.

This Policy is a dynamic and living document that will continue to benefit from periodic review in line with global best practices.



Pharm. (Mrs.) Olubukola Ajayi
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LIST OF ABBREVIATIONS

AMR	Antimicrobial Resistance
APIs	Active Pharmaceutical Ingredients
DELSUTH	Delta State University Teaching Hospital
DFDS	Department of Food and Drug Services
DMIS	Drug Management Information System
DRF	Drug Revolving Fund
DTCs	Drug and Therapeutics Committees
EDLRC	Essential Drugs List Review Committee
FMC	Federal Medical Centre
FMOH	Federal Ministry of Health
cGMP	current Good Manufacturing Practices
IPL	Import Prohibition List
INCB	International Narcotics Control Board
INN	International Non-Proprietary Names
IPC	Infection Prevention and Control
KPIs	Key Performance Indicators
LGAs	Local Government Areas
M&E	Monitoring and Evaluation
MDAs	Ministries, Departments and Agencies
NAFDAC	National Agency for Food and Drug Administration and Control
NCDC	Nigeria Centre for Disease Control
NDDG	National Drug Distribution Guidelines
NDP	National Drug Policy
NEML	Nigeria Essential Medicines List
NIMR	Nigerian Institute for Medical Research
NIPRD	National Institute for Pharmaceutical Research and Development
NHIS	National Health Insurance Scheme
NNMDA	Nigeria Natural Medicine Development Agency
NPHCDA	National Primary Health Care Development Agency
NPSCMP	National Product Supply Chain Management Programme
NSHDP II	National Strategic Health Development Plan II
NSTG	Nigeria Standard Treatment Guidelines
OTC	Over-the-Counter
PCN	Pharmacists Council of Nigeria
PMG-MAN	Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria
PPMVs	Patent and Proprietary Medicine Vendors
PSN-PACFAH	Pharmaceutical Society of Nigeria-Partnership for Advocacy in Child and Family Health
PSD	Pharmaceutical Services Division
SMOH	State Ministry of Health
TSA	Treasury Single Account

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1.0 INTRODUCTION

The maiden National Drug Policy (NDP) for Nigeria was adopted and launched in 1990; this was reviewed in 2005 against the background of inadequacies in drug availability, supply, distribution and manpower resulting from various factors, such as:

- i. An ineffective system of drug administration, regulation, control and enforcement;
- ii. Inadequate funding of drug supply;
- iii. High dependence on foreign sources for finished drug products, pharmaceutical raw materials, reagents and equipment;
- iv. Inadequate facilities for storage, transportation and distribution of drugs;
- v. Poor selection and procurement practices;
- vi. The involvement of unqualified persons in procurement, distribution and sale of drugs;
- vii. Poor performance of drug suppliers to public health care institutions;
- viii. Non-adherence to extant rules and regulations;
- ix. Lack of political will to provide safe, efficacious and good quality drugs to meet the health needs of Nigerians.

The policy was formulated with a laudable goal and objectives intended to address the unsatisfactory situation at that time. Its adoption was seen as a positive development by observers.

1.1 ACHIEVEMENTS

After many years of its implementation and review, some modest progress has been recorded, these include:

- i. The establishment of a statutory regulatory agency with responsibility for drug administration and control, the National Agency for Food and Drug Administration and Control (NAFDAC);
- ii. The introduction of drug registration procedures;
- iii. The publication of 7th edition of Nigeria Essential Medicines List (NEML);
- iv. The publication of maiden edition of Nigeria Essential Medicines List for Children (NEMLc);
- v. The publication of two editions of the Nigeria Standard Treatment Guidelines (NSTG) by the National Drug Formulary and Essential Drugs List Review Committee (NDF/EDL RC) established by Decree 43 of 1989 now CAP 252 N29 LFN 2004;
- vi. The publication of National Guidelines for the management of pain in Nigeria;
- vii. The publication of National Guidelines for Quantification of Narcotic Medicines;

- viii. The publication of the National Policy for Controlled Medicines and its Implementation Strategies;
- ix. The establishment of the Traditional, Complementary and Alternative Medicines (T-CAM) Department;
- x. The construction of two pharma-grade National Warehouses in Lagos and Abuja;
- xi. The establishment of the National Product Supply Chain Management Programme (NPSCMP);

However, much more remains to be done in all the areas, especially in the realisation of self-sufficiency in the local production of essential medicines; the establishment of an effective drug procurement system; evolving a well-ordered drug distribution system; the harmonisation and updating of drug legislations; the effective control of drug advertisement and promotion; the entrenchment of and commitment to rational drug use and antimicrobial stewardship; regulation of traditional, complementary and alternative medicines at all levels of health care; drug research and development; and the menace of drug and substance abuse.

Thus, the revision of this Policy presents an excellent opportunity for formulating new strategies for consolidating achievements in areas where progress have been recorded and addressing those areas that call for more positive action. More importantly, it offers an opportunity to align the National Drug Policy with the vision and aspiration of the National Health Act 2014, the National Health Policy 2016 and the National Strategic Health Development Plan II (NSHDP II) 2018 - 2022.

The NSHDP II Strategic Pillar 3 and Priority Area 11 seeks to strengthen the Health System for Delivery of Essential Health Care Package including Medicines, Vaccines, and Other Health Technologies and Supplies.

It is hoped that with the judicious implementation of the revised policy alongside the NSHDP II, as laid out in the accompanying Implementation Plan, the Nigerian people will have sustainable access to safe, efficacious and good quality medicines.

2.0 GOAL AND OBJECTIVES OF THE NATIONAL DRUG POLICY

2.1 GOAL

The goal of the policy shall be to make available at all times, to the Nigerian populace, adequate supplies of drugs that are efficacious, affordable, safe and of good quality.

2.2 OBJECTIVES

The objectives of the policy shall be:

- i. To ensure efficient and effective drug management in the public and private sectors;
- ii. To ensure equitable access to safe, efficacious, good quality and affordable drugs at all levels of health care delivery;
- iii. To promote rational drug use by prescribers, dispensers, and consumers;
- iv. To promote local production of drugs and pharmaceutical raw materials through favourable policies and advocacy for local manufacturing;
- v. To promote the export of locally produced drugs;
- vi. To establish a well-ordered drug distribution system for Nigeria;
- vii. To strengthen institutions responsible for the administration, legislation and regulation of the National Drug Policy;
- viii. To promote pharmaceutical research and development in support of the National Drug Policy;
- ix. To strengthen Post Marketing Surveillance and Pharmacovigilance for all drugs including traditional, complementary and alternative medicines;
 - x. To reduce the burden of Antimicrobial Resistance (AMR);
 - xi. To reduce and prevent the menace of Drug and Substance Abuse;
 - xii. To strengthen the use of data for evidence-based decision making in the implementation of National Drug Policy;
 - xiii. To enlist government commitment at all levels in the implementation of the National Drug Policy;
 - xiv. To harmonise and optimise international collaborations and support to achieve the objectives of the National Drug Policy.

3.0 TARGETS OF THE NATIONAL DRUG POLICY

The implementation of the NDP shall be directed at achieving the following targets:

- i. Strengthen the National Drug Policy/Essential Medicines List Branch in the Pharmaceutical Services Division of Food & Drug Services Department with the creation of a desk for Monitoring and Evaluation of the implementation of NDP by 31st December 2021;
- ii. 80% adherence to the Essential Medicines List in the selection, procurement, prescription and dispensing at all levels of healthcare by 31st December 2025;
- iii. 80% adherence to the use of National Standard Treatment Guidelines (NSTGs) at all levels of healthcare by 31st December 2025;
- iv. 80% adherence to due process in drug procurement practices in the public health sector by 31st August 2022;
- v. 50% implementation of the National Drug Distribution Guidelines by 31st December 2022;
- vi. Publish prices of 90% of medicines in the Nigeria Essential Medicines List biennially by 31st December 2025;
- vii. Availability of adequate drug storage conditions in 80% of the healthcare sector (public and private) by 31st December 2025;
- viii. Proper disposal of expired, deteriorated and sub-standard drugs in 60% of healthcare facilities (public and private) by 31st December 2022;
- ix. Establish appropriate drug quality control laboratories at designated storage facilities at ports of entry/exit by 31st December 2023;
- x. Strengthen at least one fully equipped and adequately staffed laboratory in each of the six geo-political zones of the country for effective quality assurance of drugs and pharmaceutical products in Nigeria by 31st December 2024;
- xi. 80% adherence to Drug Revolving Fund (DRF) scheme with transparent drug procurement procedures, distinct bank accounts and mechanisms to check diversion of funds for other purposes at all levels of healthcare delivery by 31st December 2025;
- xii. 100% compliance with National Guidelines on Drug Donations by 30th June 2022;
- xiii. 70% increase for local production capacity and utilisation of essential medicines by 31st December 2025;
- xiv. 80% awareness of the concept of rational drug use to prescribers, dispensers and consumers by 31st August 2022, and 60% adherence to rational drug prescription, dispensing and use by 30th June 2023;
- xv. Strengthen Rational Drug Use concept and National Drug Policy strategies in the curricula for training of all health professionals and Continuing Education Programmes by 31st December 2025;

- xvi. 80% adherence to the laid down procedures for rational prescribing, dispensing and use of antimicrobials in the country by 31st December 2025;
- xvii. Institutionalise functional Drug and Therapeutics Committees and Drug Information Centres in all secondary and tertiary health facilities by 31st December 2025;
- xviii. Publish a National Drug Formulary and categorisation of the medicines into prescription-only, pharmacist-only and Over-The-Counter (OTC) medicines by 31st December 2022;
- xix. Create awareness on the risks of self-medication in 40% of the population by 31st December 2024;
- xx. Strengthen National and Zonal Pharmacovigilance Centres and achieve 40% reporting of adverse drug reactions as well as feedback concerning reported cases by 31st December 2022;
- xxi. Federal Government shall allocate and release a minimum of 1% annual health sector budget for pharmaceutical research and development by 31st December 2023;
- xxii. 60% compliance with the use of Essential Veterinary Drug List (EVDL), Veterinary Drug Formulary (VDF), Standard Veterinary Treatment Guidelines (SVTG) in veterinary practice by 31st December 2025.

4.0 STRATEGIES FOR IMPLEMENTING THE NATIONAL DRUG POLICY

The strategies that shall be used to implement the National Drug Policy will focus on effective drug management processes, such as rational drug selection, proper quantification of drug needs at all levels of health care delivery and effective procurement practices. Others shall include assurance of the quality of drugs at all levels, appropriate storage, pricing and effective distribution of drugs, creating enabling environment to enhance local drug manufacturing, appropriate legislation, product registration, research and development, human resources development, monitoring and evaluation.

Furthermore, the strategies shall emphasise proper accountability and rational drug use by health workers and consumers.

In view of the fact that these activities are purely technical, the government at all levels shall be required to employ pharmacists and other relevant personnel to ensure effective implementation of the Policy.

4.1 SELECTION OF MEDICINES

The objective of the medicines' selection process is to have a list of essential medicines rationally chosen to satisfy the priority healthcare needs of the population¹.

Such a list shall be revised regularly and shall be the basis for medicine selection at all levels of health care. In this regard, the Federal Ministry of Health shall take the following steps:

- i. Publish and make available a revised Essential Medicines List to health professionals at all levels of health care. Medicines included on the list shall:
 - a. be based on the healthcare needs of the majority of the population;
 - b. be listed using generic or International Non-Proprietary Names (INN);
 - c. have a substantial safety and risk/benefit ratio with sufficient accumulated scientific data;
 - d. be registered by the National Drug Regulatory Authority (NAFDAC);
 - e. as much as possible, avoid inclusion of formulations containing more than one active ingredient, unless one or more of the following criteria are met:
 - the clinical condition justifies the use of more than one drug in a fixed combination;

¹ WHO, 2021: Essential Medicines and health products: Essential medicines; https://who.int/medicines/services/essmedicines_def/en/

- two or more pharmacologically active ingredients are synergistically active in a product; or
 - patient compliance is enhanced by the combination.
- f. when two or more drugs are therapeutically equivalent or several medicines are available for the same indication, preference shall be given to products with the:
- most scientific research and clinical data;
 - most favourable pharmacokinetic properties;
 - best cost advantage;
 - best patient compliance;
 - most stable pharmaceutical dosage form for which appropriate storage facilities exist;
 - locally produced evidence
- ii. Ensure periodic review of Essential Medicines List by the Essential Drugs List Review Committee and advise the Minister on any addition to or deletion from the List, as may be necessary. Suggestions for amendment shall be made in writing on a prescribed form to the Federal Ministry of Health, justifying such amendment. New medicines shall only be added to the list if sufficient scientific and clinical data are available to show that they offer distinct advantage(s) over existing ones. Medicines that no longer have a favourable risk/benefit ratio shall be withdrawn and replaced with safer alternatives. The Essential Medicines List shall be used for:
- a. the procurement of medicines and their use in the public sector;
 - b. prescribing medicines in the public and private sectors;
 - c. drug information to health care providers;
 - d. the production of Standard Treatment Guidelines and a National and or Hospital Drug Formulary;
 - e. reimbursements on medicines in the National Health Insurance Scheme and others.

4.2 PROCUREMENT OF MEDICINES

The procurement process is a major determinant of the safety, efficacy, quality, affordability, and availability of drugs. Its objective is to provide medicines based on relevant information, need and available resources. To address the situation, the following criteria shall be adhered to:

- i. The government shall be committed to good pharmaceutical procurement practices in the public sector;
- ii. Procurement of medicines shall be restricted to medicines registered in Nigeria and on the Essential Medicines List;

- iii. Procurement in the public sector shall be by International Non-Proprietary Names (INN) or generic names only;
- iv. Procurement at all levels shall be by open competitive tender and in line with the Public Procurement Act 2007 and other extant rules, regulations and circulars, as amended, and shall be conducted transparently with the advice of the Department of Food and Drug Services of FMOH and/or Pharmacy Departments of health facilities;
- v. Preference shall be given to locally manufactured medicines;
- vi. Procurement shall be based on accurate quantification of drug requirements by the Department of Food and Drug Services of FMOH and/or Pharmacy Departments of health facilities;
- vii. Procurement and receipt procedures shall ensure that medicines supplied are of good quality;
- viii. Medicines shall, as much as possible, be purchased in bulk from local manufacturers or importers to keep prices low;
- ix. Medicines procured at all levels shall be subjected to quality assessment before distribution and use.
- x. All medicines procured shall have at least 75% shelf life at the time of receipt.

4.3 MEDICINE STORAGE

The objectives of the storage of medicines shall be to ensure stock security and maintenance of the quality of medicines throughout their shelf life.

Government shall ensure that suitably located, constructed and equipped storage facilities are maintained at every level of the medicine distribution system, in both public and private sectors under the supervision of a pharmacist.

The efficient and successful operation of medicine storage and distribution system requires the professional skills of pharmacists. In addition, the following measures shall be implemented:

- i. All public and private medical stores shall be properly managed to avoid medicine expiration and deterioration. The stock of expired or deteriorated medicines shall be officially destroyed using appropriate guidelines within six months;
- ii. Medical stores shall have quality control laboratories where basic periodic checks are undertaken to determine the quality of medicines received or supplied;
- iii. Medicines shall be maintained within the appropriate temperature stipulated by the manufacturer;
- iv. Provision shall be made for appropriate cold chain storage of vaccines and biological products; and

- v. Government shall ensure the establishment of a central computerised inventory control system for effective medicine management.

4.4 DRUG DISTRIBUTION

The Government shall ensure effective and efficient medicine distribution in both the public and private sectors. In this regard the following measures will be enforced in line with National Drug Distribution Guidelines (NDDG) 2012 (as amended):

- i. Medicine manufacturing, wholesaling and retailing activities shall be registered as distinct enterprises;
- ii. Medicine supplies to public health facilities shall be sourced from government medical stores;
- iii. A central computerised inventory control system shall be established for effective medicine management;
- iv. Medicines purchased or donated to governments at all levels shall be channelled through the medical stores;
- v. All inventory control systems shall be linked to a central computerised inventory control system in the Department of Food & Drug Services, FMOH;
- vi. Adequate security shall be provided in all areas where medicines are stored;
- vii. Medicines distributed in the country shall be labelled in English language;
- viii. Enabling environment in the health sector shall be provided to establish professional practices in rural areas to complement government efforts in promoting greater access to medicines;
- ix. Transportation of medicines shall be covered by goods-in-transit insurance; and
- x. The channel for private sector medicines distribution shall flow from manufacturers/importers to wholesalers and retailers.
- xi. Implementation of national pharmaceutical traceability strategy which shall among others, provide visibility of drug status and movement; improve quality of data to support pharmacovigilance and decision-making; decrease the presence of substandard and falsified medicines; and facilitate efficiency within the value chain.

4.5 DRUG FINANCING AND AFFORDABILITY

Financing the various provisions of the National Drug Policy shall be the primary responsibility of the government at all levels. Participation in the National Health Insurance Scheme (NHIS) by individuals, organisations and communities shall, however, be encouraged; and if necessary, enforced under the provisions of extant laws. The three tiers of Government shall ensure that:

- i. Adequate budgetary allocation and release shall be made for medicines, in line with the provision of the National Health Act 2014 and other regional and International Declarations that the country is a signatory to;
- ii. Priority is given to the provision of adequate funds for medicines and other pharmaceutical products including consumables, used at all levels of health care delivery especially in the public health facilities and for health programmes;
- iii. The cost of medicines to the patient is, affordable, but sufficient to recover total costs with a mark-up for administrative expenses and adequate maintenance of the Drug Revolving Fund (DRF);
- iv. DRF and other health financing mechanisms are strengthened;
- v. Financial provisions are made within the total health budget for sustainable implementation and monitoring of the policy;
- vi. The costs of the promotion and preventive aspects of the National Drug Policy like health information and education; human resources development and research are fully borne by the government.

4.6 DRUG REVOLVING FUND SCHEME

The Drug Revolving Fund Scheme is a very effective strategy for ensuring uninterrupted drug supply in the health care delivery system. Experience from several health institutions in the country has, however, shown that its advantages have not been apparent due to a variety of reasons, including the following:

- i. Poor management of the scheme;
- ii. Misapplication of the fund;
- iii. Purchasing of medicines at exorbitant prices;
- iv. Lumping of the proceeds of the fund into a general account;
- v. Non-reimbursement of the cost of medicines for exempted patients;
- vi. Executive interference;
- vii. Lack of sanctions for non-adherence to laid down procedure and rules;
- viii. Lack of training and retraining of DRF operators;
- ix. Abuse of deferral and exemption privileges;
- x. Lack of proper understanding/misapplication of the Treasury Single Account (TSA) Policy

Consequently, the Drug Revolving Fund Scheme shall be strengthened at all levels of healthcare delivery system and government through:

- i. Establishment of a DRF Committee in every health institution for effective and transparent fund management;

- ii. Provision of adequate capital for the procurement of required medicines;
- iii. Ensuring that the funds in the DRF account do not go below the seed capital;
- iv. Maintenance of a separate account for the DRF scheme, which shall be used exclusively for the purchase of medicines;
- v. Ensuring strict accountability for the medicines provided in the system by supplying them on a “cash-and-carry” basis;
- vi. Inclusion of the head of the pharmacy department as a mandatory signatory to the DRF account;
- vii. Regular capacity building for the DRF personnel;
- viii. Five (5) year periodic review of DRF Guidelines;
- ix. Generation and maintenance of quality data on medicines utilisation and inventory control to stem expiries and wastages;
- x. Usage of data for strategic planning for guideline development, quantification and procurement;
- xi. Establishment and strengthening of independent DRF Monitoring & Evaluation Committee and Medicines Pricing Committee; and
- xii. Appropriate legislation to support the DRF guidelines.

4.7 PRICING POLICY

Experience over the years has shown that the cost of procurement of medicines has been consistently high in both public and private health institutions. It has also been observed that there are wide variations in the prices of the same medicines from one health institution to another. Therefore, to ensure the affordability of medicines in public as well as private health institutions, the government shall:

- i. Establish necessary mechanisms to guarantee that medicine supply to patients cost less by strengthening the Drug Revolving Fund (DRF) Scheme in the public sector while ensuring price control mechanism; and
- ii. Ensure the procurement of medicines by the government and all health Institutions will only be directly from local manufacturers or importers (where there are no local manufacturers).

4.8 LOCAL MEDICINE PRODUCTION

The need for increased capacity in local drug production has been well recognised. Such capacity should cover the production of pharmaceutical raw materials and finished products. Medicine production facilities in the country are presently operating under severe constraints such as:

- i. Poor infrastructural facilities (i.e. water and electricity supply);

- ii. Poor transportation and communication;
- iii. Poor waste disposal management;
- iv. Inadequate incentives such as tax relief, capital allowance, and government patronage;
 - v. Limited access to long term single-digit funding for capital development;
 - vi. Unfair competition from imported medicines;
- vii. Total reliance on imported pharmaceutical raw materials especially APIs, machinery and spare parts;
- viii. Low patronage by the government coupled with delayed payment for medicines supplied.

To achieve the target of self-sufficiency in local medicine production, the government shall:

- i. Encourage the development of a stable economic and political environment;
- ii. Intensify efforts to improve basic infrastructure and facilities;
- iii. Provide an efficient regulatory environment;
- iv. Provide favourable interest rates, tax and duty structures for locally manufactured products and imported pharmaceutical raw materials, as well as packaging materials;
- v. Strengthen the petrochemical and other essential industries for the development of pharmaceutical raw materials;
- vi. Promote the development of associated industries for the production of materials, such as plastics, glass, paper, aluminium foil, etc., which are essential for drug packaging;
- vii. Encourage research and development of pharmaceutical raw materials;
- viii. Patronise locally manufactured medicines;
 - ix. Conduct regular review of Import Prohibition List (IPL) of medicines based on available local capacity to manufacture.

4.9 IMPORTATION AND EXPORTATION OF MEDICINES

Approximately 70% of medicines consumed in Nigeria are imported², while the export of medicines is insignificant. The National Drug Policy shall seek to promote an increase in local medicines production to achieve self-sufficiency and export. Government shall also establish suitable mechanisms for inspecting the import and export of drug products, in line with the various regulations, and apply appropriate sanctions where violations are committed.

² Pharmaceutical Sector Profile: Nigeria. Vienna: United Nations Industrial Development Organisation; 2011. Available from: http://www.unido.org/sites/default/files/2011-04/Nigeria-Pharma%20Sector%20Profile_032011_Ebook_0.p

The overall objective shall be to ensure that the import and export activities with regards to medicines are effectively regulated so that the products meet the required standards of quality, safety and efficacy. Therefore, the following measures shall be implemented:

- i. Medicines imports and exports shall be restricted to designated ports which shall be equipped with adequate storage and on-the-spot test facilities to monitor quality;
- ii. Inter-sectorial collaboration amongst relevant drug regulatory authorities and other government agencies at the ports, shall be encouraged; and deliberate antagonism to this shall be adequately sanctioned;
- iii. Pharmaceutical manufacturers shall be encouraged to maximise the use of their installed production capacity for export purposes;
- iv. Government shall provide support to promote the export of locally manufactured medicines through tax review, grants, trust funds, etc.

4.10 DONATED MEDICINES

Experience has shown that donated medicines have often not been relevant to the health needs of the nation. In light of this, the following measures shall be taken:

- i. All medicine donations for use in the country shall be processed through the Federal Ministry of Health as a clearing house to ensure compliance with the Guidelines for Donations of Medicines and Healthcare Equipment in Nigeria;
- ii. Donated medicines shall among other things:
 - a. be registered for use, both by the Drug Regulatory Authority of the donor country and in Nigeria;
 - b. have at least 50% shelf life at the point of delivery to the Federal Ministry of Health;
 - c. be labelled in the English language to include its international non-proprietary or generic name.
- iii. The Federal Ministry of Health shall put in place adequate machinery for monitoring the distribution of donated medicines;
- iv. Medicines that can be produced locally in adequate quantity should not be accepted as donated items from foreign countries;
- v. Medicine donation shall be at the request of the receiving country/community;
- vi. In an emergency, the Federal Ministry of Health, in collaboration with the National Emergency Management Agency (NEMA), shall immediately establish a coordinating body to:
 - a. assess and inform donors about national needs;
 - b. approve donations; and

- c. co-ordinate receipt, inventory management, distribution and use of the donated medicines.

4.11 LEGISLATION

Legislation is the instrument by which the implementation of a drug policy is given a legal basis by statutorily defining the various strategies for achieving the objectives of the policy. For effective implementation of legislation, there is a need to regularly review and update the relevant laws in collaboration with relevant stakeholders. Accordingly, the government shall:

- i. Strengthen and enforce legislation relating to all existing policies and guidelines on matters relating to essential medicines including controlled medicines;
- ii. Provide the necessary material and financial resources to strengthen enforcement of the provisions of the laws and regulations; and
- iii. Designate special courts for drug-related offences in each of the geo-political zones of Nigeria for the speedy trial of persons or corporate bodies apprehended for such offences.

4.12 QUALITY ASSURANCE

Quality assurance of medicine aims to ensure that the medicine provided to the patient is safe, efficacious and of good quality. The process of quality assurance begins from the manufacturer and continues to the point of administration of the medicine to the patient. Compliance with cGMP is an important component of quality assurance. Therefore, the government shall take appropriate actions to ensure that:

- i. Regulatory authorities are strengthened and empowered to monitor and enforce effective compliance with quality assurance provisions by manufacturers of imported and locally produced medicines to ensure that patients and consumers receive only safe, efficacious and good quality medicines;
- ii. Medicine imports and purchases at all levels in public and private health facilities meet the standards of good quality and safety before such medicines are distributed to the end-users;
- iii. Current Good Manufacturing Practices continue to be monitored and enforced in all medicine manufacturing facilities in the country;
- iv. Duly qualified individuals, University departments and organisations with appropriate personnel and equipment are licensed to set up quality control laboratories for assessing the quality of medicines in the national drug distribution system;

- v. Adequately staffed and equipped medicines quality control laboratories are established in strategic locations within the various geo-political zones of the country;
- vi. Manufacturers package their products in appropriate containers to ensure the quality and stability of such products.

4.13 INSPECTION OF MANUFACTURING FACILITIES

Effective inspection of manufacturing facilities is critical to ensuring the quality, safety and efficacy of medicines. The inspection process ensures compliance with current Good Manufacturing Practices (cGMP) and other storage, supply and distribution requirements. Therefore, national regulatory authorities shall establish effective mechanisms for inspection in all drug manufacturing establishments and all locally produced medicines.

4.14 REGISTRATION OF MEDICINES

Medicine registration is the process of ensuring that the government has control over medicines that are offered for sale and use in the country. It ensures that medicines distributed in the country have been produced under cGMP and have passed the tests for safety, efficacy and good quality. It is an essential element in limiting the number and types of medicines imported or manufactured in the country. It is also the instrument by which new medicines can be added or removed from the list of approved medicines. In light of this, the government shall:

- i. Continue to strengthen the medicines registration mechanism within the National Agency for Food and Drug Administration and Control (NAFDAC);
- ii. Ensure that all medicines (human and veterinary), herbal remedies, homoeopathic preparations, as well as vitamins and mineral supplements are registered;
- iii. Ensure annual publication and wide dissemination of the list of registered medicines;
- iv. Enforce appropriate sanctions on any violation of the laws, regulations and guidelines on medicines registration.

4.15 PATENTS

Patent protection has been an incentive for promoting research and the development of new medicines. While patent protection is desirable, it should not constitute a hindrance to access to essential medicines by Nigerians. The government shall, therefore, put in place strategies to ensure that public health interests are protected when trade matters conflict with health issues, especially in:

- i. Securing coordination between health, justice and trade ministries to ensure that public health issues are taken into consideration in international negotiations;
- ii. Ensuring effective monitoring of international trade agreements on Nigerians' access to medicines;
- iii. Exploring existing international trade agreements to protect public health, especially those that affect access to essential medicines.

4.16 RATIONAL DRUG USE

The requirements for rational drug use are that patients shall receive the right medicines appropriate for their clinical needs in the right dose and dosage form for the right duration and at the lowest cost.

Rational drug use as an essential element of a National Drug Policy seeks to avoid the all-too-frequent problems of under- and over-prescription, inappropriate prescription, and the use of new, expensive drugs when equally effective, time tested, safe and cost-effective alternatives are available. Concerted efforts shall be made by government and relevant stakeholders at all levels to promote rational drug use through:

4.16.1 Education and Training

The objective is to ensure that all health personnel involved in the diagnosis, prescription and dispensing of medicines, as well as consumers, receive adequate training in rational drug use. It will, therefore, be necessary to take the following initiatives:

- i. Promote the teaching of the concepts of rational drug use in pharmacy, medical, nursing, veterinary schools, etc;
- ii. Teach communication skills in pharmacy, medical, nursing and veterinary schools to promote rational prescribing and dispensing;
- iii. Develop educational strategies and programmes directed at the public on the appropriate use of medicines; and
- iv. Capacity building on rational drug use shall be always part of Mandatory Continuing Professional Development for all health professionals.

4.16.2 Rational Prescribing

The objective is to ensure that medicines are prescribed rationally. Consequently,

- i. Copies of Standard Treatment Guidelines, Essential Medicines List, National Drug Formulary and other relevant documents shall be made available to all prescribers at all levels of care;
- ii. Prescribing shall be by International Non-Proprietary Names (INN) or generic names.

4.16.3. Rational Dispensing

The objective of rational dispensing shall be to ensure that patients receive adequate information on the use of dispensed medicines to derive the desired benefits. In this regard, the following shall be put in place:

- i. Dispensing shall only be carried out under a conducive environment in duly licensed premises;
- ii. The minimum information required on the label of a dispensed medicine shall be the following:
 - a. Name of the patient;
 - b. Generic name of the dispensed drug;
 - c. Strength of the medicines;
 - d. Dosage instruction in symbols or words as may be appropriate;
 - e. Duration of treatment;
 - f. Date of dispensing;
 - g. Identity of the dispensing pharmacist;
 - h. The name of the institution where the drug was dispensed.
- iii. The patient shall be counselled on the use of dispensed medicines, in a conducive environment suitable for effective communication; and
- iv. Medicines shall be dispensed in a suitable container that is tamper-proof and will ensure stability.

4.16.4 Drug Information Services

Drug information is intended to provide unbiased, scientifically validated medicine information to promote rational prescribing, dispensing and use. In this respect, therefore, Drug information units shall:

- i. Be established in all public tertiary and secondary health facilities;
- ii. As much as possible be established in private health facilities;
- iii. Be suitably equipped and provided with up-to-date reference materials, computers, internet access, etc, to guarantee the acquisition and dissemination of current and accurate drug information to health care practitioners and the general public.

4.16.5 Drug and Therapeutics Committees

Drug and Therapeutics Committees are an institutionalised mechanism for promoting, implementing and monitoring the concept of rational drug use in healthcare institutions. Thus, the following measures shall be taken:

- i. Drug and Therapeutics Committees (DTCs) shall be established in all tertiary and secondary health facilities;

- ii. Membership of such committees shall comprise representatives of the pharmaceutical, nursing, medical, laboratory and administrative services of the facility.
- iii. A DTC shall, among other functions, be responsible for:
 - a. the selection of medicines for use in the institution, based on the Nigeria Essential Medicines List;
 - b. proper quantification of the pharmaceutical requirements for the facility;
 - c. monitoring the use of therapeutic guidelines and overall medicines utilisation;
 - d. monitoring rational drug use in the facility.

4.16.6 Informed Self-Medication

Self-medication is useful in any situation where access to health care facilities is limited or not immediately available. It can offer the advantage of providing quick and effective relief that does not require medical attention. However, it could lead to inappropriate use of medicines, delay and failure of proper diagnosis and the delivery of effective treatment. It could also lead to medicines misuse and abuse. To obtain the benefits of self-medication while avoiding its risks, the following steps shall be taken:

- i. A list of over-the-counter medications shall be published by the government. These are medicines that can be sold without a prescription and used for the short-term relief of symptoms, without prior medical consultation and precise diagnosis;
- ii. Such medicines shall satisfy the criteria for the selection of essential medicines, be effective for their condition of use, and have a wide margin of safety;
- iii. The list shall be reviewed from time to time in the light of experience and available new information;
- iv. Information on, and the labelling and promotion of medicines, meant for self-medication, shall conform to laws and regulations set out for such categories of medicines;
- v. Health education to the public on appropriate self-medication shall be vetted by appropriate authorities and provided using print, electronic media and other communication methods.

4.16.7 Antimicrobial Stewardship

The emergence and spread of Antimicrobial Resistance (AMR) are complicating the management of many infectious diseases with consequences on the Global Health Security Agenda. AMR is decreasing the usefulness of modern medical technologies and jeopardising both common and complex surgical procedures while endangering human and animal health. Therefore, Antimicrobial Stewardship is critical to mitigating issues surrounding AMR.

The strategic directions of Antimicrobial Stewardship aim to preserve the effectiveness of safe and affordable antimicrobials. The strategies include:

- i. Development of a national policy on antimicrobial stewardship;
- ii. Creating awareness on the use of antimicrobials;
- iii. Strengthening of the surveillance system;
- iv. Strengthening of laboratory services;
- v. Strengthening infection prevention and control;
- vi. Promoting rational use of antimicrobials; and
- vii. Research and development.

There should be One-Health coordination across the human, animal and environmental health sectors in line with the National Action Plan on AMR. The Government shall be committed to the research and development of vaccines, new antimicrobial agents and diagnostic tools while strengthening appropriate use of the existing ones.

The following measures shall be taken:

- i. The State Government shall establish One Health AMR committee that shall consist of members from Ministries of Health, Agriculture, Environment and other stakeholders to monitor the use of antimicrobials in human and animals and its impact on the environment;
- ii. Each health facility shall institutionalise a Drug and Therapeutics Committee (DTC) and Infection Prevention and Control (IPC) Committee which shall be responsible for rational use of antimicrobials in the health facility;
- iii. These two committees (DTC & IPC) shall also be responsible for the development of annual state-specific AMR action plans;
- iv. Every facility shall sensitise and raise awareness on AMR by observing annual national antimicrobial awareness week;
- v. Health facilities shall institutionalise antimicrobial stewardship programmes;
- vi. There should be national and regional/state-level surveillance of AMR and Antimicrobial Use (AMU) and data should be shared locally, nationally and internationally.

4.16.8. Drug and Substance Abuse Prevention, Treatment and Care

The menace of drug abuse is on the increase globally and in Nigeria in particular. According to the 2018 National Drug Use Survey, the 2017 prevalence of any drug use was estimated at 14.4 per cent, corresponding to 14.3 million people aged 15-64 years who had used a psychoactive substance such as opioids, amphetamines, cannabis and cocaine for non-medical purposes. This is comparatively higher than the 2016 global annual prevalence of any drug use of 5.6 per cent among the adult population.

Bearing in mind the significant threat of drug abuse to the health, security, and socio-economic wellbeing of Nigerians, the government shall ensure that:

- i. Narcotics, psychotropic substances and precursors are made available for medical and scientific purposes only while preventing their diversion to non-medical use in line with the National Policy for Controlled Medicines and Its implementation Strategies;
- ii. Rational use of controlled medicines is incorporated into the curriculum of medical, pharmacy and nursing schools as well as mandatory continuing professional development programmes;
- iii. Relevant stakeholders at Federal, State and Local Government Areas (LGAs) carry out evidence-based drug and substance abuse prevention activities;
- iv. Access to standard rehabilitation and drug treatment centres is increased.

4.17 REGULATIONS FOR PRESCRIBING AND DISPENSING MEDICINES

A prerequisite for effective medicines control is that prescribing, dispensing and the sale of medicines shall be undertaken by duly authorised persons. Regulations for prescribing, dispensing and sale of medicines shall take into consideration the policy goal of rational drug use and the supply of safe and efficacious essential medicines at affordable cost.

In view of the fact that medicines are prescribed and dispensed at all levels of health care, including the most peripheral health stations manned by village health workers, regulations for prescribing and dispensing of medicines shall be sufficiently flexible to cover the activities of such health workers under the supervision of relevant professionals. Research in many countries has shown that dispensing doctors or prescribing pharmacists use more medicines than others; it has become necessary to separate prescribing and dispensing functions. Therefore, the laws and regulations regarding those who are allowed to prescribe, supply, sell and dispense medicines to the public at different levels of the health care system shall be periodically updated, with the following minimum provisions:

4.17.1 Prescribing

- i. In tertiary and secondary health care institutions, only duly qualified and licensed medical practitioners shall have the authority to prescribe medicines. At the primary healthcare level, the government shall designate appropriate health care personnel to prescribe medicines.
- ii. Only qualified and licensed medical professionals shall have the authority to prescribe medicines in private healthcare facilities.
- iii. Medicines shall be prescribed using the International Non-Proprietary Names or generic names.

- iv. Prescription records shall be kept at the pharmacy departments of both private and public healthcare facilities for at least five years.
- v. Government shall expedite action on the development of a prescription policy in line with emerging global developments and national needs.

4.17.2 Dispensing

- i. Only duly licensed pharmacists shall have the authority to supply, sell and dispense medicines to the public. Such sales shall take place in premises licensed for the purpose by the Pharmacists Council of Nigeria (PCN), which shall be subject to regular inspection.
- ii. Given the need for every Nigerian to have access to appropriate medicines, it shall be permissible for certain OTC medicines to be sold in patent medicine shops operated by licensed pharmacy technicians, Registered Patent and Proprietary Medicine Vendors (PPMVs), in areas where there are no licensed pharmacists. The premises for the sale of such medicines shall be approved and licensed by the Pharmacists Council of Nigeria (PCN) and subject to periodic inspection by pharmaceutical inspectors of the Council. The list of medicines to be sold in such premises shall be those approved by the government.
- iii. In every healthcare facility where there is a qualified and licensed medical practitioner, there shall be a qualified and licensed pharmacist to manage medicines.
- iv. To enhance total patient care, the government shall promote clinical pharmacy in healthcare facilities.

4.17.3 Online Pharmacy

With the penetration of the internet and increasing acceptance of e-commerce, there is the need to protect the quality, safety and efficacy of medicines irrespective of the channel of distribution of the medicines and other pharmaceutical products and services. Therefore:

- i. The operation of an online pharmacy shall be through a registered community pharmacy and be in line with the regulations and guidelines of the Pharmacists Council of Nigeria (PCN);
- ii. Request for Over-the-Counter (OTC) medicines shall be by consultation with the community pharmacist;
- iii. There shall be evidence of a valid prescription for the ordering or purchasing of Prescription-Only Medicines (POM);
- iv. The Community Pharmacy shall be responsible for proper documentation of all online transactions including the evidence of a valid prescription;
- v. Advertisement of pharmaceutical products shall be as prescribed by relevant laws.

4.18 PHARMACOVIGILANCE

Since no active medicine is entirely free from adverse reactions, the introduction of an adverse drug reaction (ADR) reporting system is an essential component of a national healthcare delivery system. In addition to the Directorate of Pharmacovigilance and Post Marketing Surveillance of the National Agency for Food and Drug Administration and Control (NAFDAC); the government shall:

- i. Encourage the establishment of adequately equipped pharmacovigilance units nation-wide to collect, collate, evaluate and disseminate relevant information on adverse drug reactions;
- ii. Regularly monitor the efficacy, safety, quality of medicines as well as adverse drug reactions to evaluate the need to change the conditions of their continuing registration or withdrawal from the market;
- iii. Encourage all healthcare practitioners and the general public to report adverse drug reactions to NAFDAC via all media of reporting including *MedSafety App*.

Any medicine found to have unacceptable health risk in Nigeria or reported to have been withdrawn or banned in other countries shall be withdrawn from distribution in Nigeria.

4.19 DRUG INFORMATION AND PROMOTION

Information about medicines is usually provided by manufacturers in the form of package inserts and labels, as well as promotional literature and advertisements.

These shall be in keeping with the National Health Policy, 2016 and compliance with national regulations. The information on the medicines shall be reliable, accurate, valid and up to date. In this regard government shall continue to:

- i. Sustain ethical, professional and scientific standards regarding the content of package inserts, labels, advertisements and other medicines promotional materials to ensure that healthcare providers, practitioners, and patients have accurate and relevant information about the medicines;
- ii. Prevent all forms of direct advertisement of prescription and controlled medicines to consumers;
- iii. Prevent media advertisements of orthodox or traditional medicines, used in the treatment of ailments and diseases, as contained in the drug laws of the country;
- iv. Vet and approve advertisement scripts and formats concerning the advertisement of OTC medicines;
- v. Undertake post-marketing surveillance of medicines to make appropriate changes in approved information in light of new relevant data.

4.20 RESEARCH AND DEVELOPMENT

The aim of Research and Development (R&D) is to promote, encourage and support ethical, scientific and operational research in the pharmaceutical sector and facilitate the effective implementation of the National Drug Policy to meet the healthcare needs of the country. Considering the enormous cost of research and development, the government shall provide support and an enabling environment to encourage such activities, specifically as described below:

4.20.1 Drug Research and Development

This aims at developing new medicines and improving existing ones, with the ultimate goal of producing safer, more efficacious and better-quality medicines. Medicine research and development are essential components of health research that enhance the attainment of the goals and objectives of the National Health Policy. There shall be a percentage of the annual Health budget to fund research on medicines. Medicine research and development shall be encouraged, especially in the following areas:

- i. Active Pharmaceutical Ingredients (APIs), excipients, pharmaceutical raw materials from natural sources and petrochemicals;
- ii. Development of new drug molecules, repurposing of existing medicines and formulation for the treatment of ailment/diseases;
- iii. Traditional medicines for the promotion of health and the treatment of diseases;
- iv. Enhancing the quality and stability of pharmaceutical products;
- v. Coordination of a multi-disciplinary approach to documentation, analysis and/or reduction of adverse drug reactions.

4.20.2 Operational Research

Operational research is necessary for the successful implementation of the National Drug Policy. It aims to identify the best methods of selecting, procuring, distributing and using medicines rationally. Its application shall lead to practical and cost-effective measures which would inform managerial, educational and regulatory interventions to improve access to and the use of medicines. Drug discovery efforts and targets should focus on priority areas of common ailments and diseases. The research will focus particularly on the following areas:

- i. Identifying and evaluating the impact of the National Drug Policy and its components on the national health system and health service delivery using health indicators every 2 - 4 years;
- ii. Medicine utilisation at different levels of health care facilities;
- iii. The economics of medicines supplies;

- iv. Social and cultural aspects of medicine use, such as self-medication, drug and substance abuse, acceptability and attitudes of medicine consumers, etc.

4.20.3 Health Research and Development Financing

At least 5% of the 1% Basic Healthcare Provision Fund shall be allocated to NIPRD, NIMR, Nigeria Natural Medicine Development Agency (NNMDA), academia and other relevant research institutions for healthcare research and development. This will also involve the promotion of implementation research towards the operationalisation of this policy.

4.21 TRADITIONAL, COMPLEMENTARY & ALTERNATIVE MEDICINES (T-CAM)

The traditional, complementary and alternative medicines are used globally, including in Nigeria where they are utilised by the majority of the populace. Therefore, there is a need for further research and interventions, which shall be supported by the government, donors, private sector, etc, in the following areas:

- i. Promotion of rational use of phytomedicines;
- ii. Review of the National Policy on Traditional Medicine (2007), and formulation of a National Policy on Complementary and Alternative Medicines by the Federal Ministry of Health;
- iii. Co-ordinated promotion, support, and sponsorship of research on medicinal plants;
- iv. Investigation of claims on traditional, complementary and alternative medicine treatment of some priority diseases for safety, efficacy and quality with a view to integrating them into the national health care system;
- v. Integration of scientifically verified herbal remedies/formulations in the healthcare system;
- vi. Cultivation and management of herbaria to ensure the conservation of medicinal herbs and sustainability of supplies;
- vii. Standardisation of products to ensure efficacy;
- viii. Review of national compendium of medicinal plants and traditional, complementary and alternative therapies.
- ix. Collaboration between the Federal Ministry of Health and other relevant MDAs, research institutes, international partners, regional and local organisations; and practitioners to promote multidisciplinary inputs necessary for discovery, development, promotion, commercialisation, and application of drugs from plants and other natural sources;
- x. Development of a “Code of Ethics & Practice” for traditional complementary and alternative medicine practitioners;

- xi. Legislation and enforcement of policy guiding the practice of traditional, complementary and alternative medicines;
- xii. Encouragement and support for practitioners to patent their discoveries;
- xiii. Promotion and exportation of traditional, complementary and alternative medicines;
- xiv. Documentation of adverse drug reactions due to traditional, complementary and alternative medicines.

4.22 CONTROL OF VETERINARY MEDICINES

The objective of controlling veterinary medicines is to ensure the quality, safety and rational distribution, storage, prescribing, dispensing and use of veterinary medicines. The uncontrolled administration of veterinary medicines, particularly the use of antibiotics and hormones in animals used for food leads to the presence of residues of these medicines in meat and meat products. This is one of the factors responsible for the development of Anti-Microbial Resistance (AMR). Consequently, the government shall enforce the following measures:

- i. The National Drug Policy shall apply to veterinary medicines;
- ii. The essential drug concept shall equally apply to the procurement, distribution, supply and utilisation of veterinary medicines;
- iii. Set up a Committee comprising of competent persons in the field of veterinary medicine, agriculture, pharmacy and other relevant stakeholders to compile a list of Essential Veterinary Medicines, Standard Veterinary Treatment Guidelines and a Veterinary Medicines Formulary to be adopted for use throughout the country;
- iv. The utilisation of veterinary medicines shall comply with ethical veterinary practices and government shall ensure the effective monitoring of medicines utilisation in this area of practice;
- v. NAFDAC and PCN shall be responsible for the registration of veterinary medicines and premises respectively;
- vi. Generic prescribing shall as much as possible be adopted by registered Veterinary Practitioners and other authorised prescribers of veterinary medicines;
- vii. The sale of veterinary medicines shall be undertaken by pharmacists and any other persons authorised or licensed by the PCN.

4.23 EMERGENCY DRUG PREPAREDNESS

Government shall ensure a healthier and safer Nigeria through evidence-based prevention and control of diseases of public health importance, integrated disease surveillance and response activities using a one-health approach, guided by research and led by a skilled workforce.

Therefore, the government at all levels with other relevant agencies are to always ensure adequate stockpiling of Medical Counter Measures (MCM) and medicines in preparedness for emergencies. This shall be under the policy framework of the Nigeria Centre for Disease Control (NCDC) which defines “Medical Counter Measures, or MCMs, as life-saving medicines and medical supplies that can be used to diagnose, prevent, protect from, or treat conditions associated with Chemical, Biological, Radiological, or Nuclear (CBRN) threats, emerging infectious diseases or natural disaster”. The MCMs include:

- i. Biological products, such as vaccines, blood products and antibodies;
- ii. Medicines, such as antimicrobial drugs;
- iii. Medical devices including diagnostic tests to identify threat agents; personal protective equipment (PPE) such as protective gowns, gloves and respirators (face masks) and ventilators.

4.24 INTERNATIONAL COOPERATION

Cooperation between countries, particularly importing and exporting countries can be advantageous in combating the influx of falsified, substandard and controlled medicines, and thereby help to reduce substantially illicit drug trafficking. Such cooperation shall be achieved through:

- i. The establishment and maintenance of appropriate channels of communication and exchange of information between drug regulatory and law enforcement authorities;
- ii. Promoting the training of personnel and human resource development;
- iii. Using diplomatic channels for the exchange of information on substandard and falsified drugs in international commerce;
- iv. Using the WHO Certification Scheme to enhance international trade of pharmaceutical products;
- v. Liaising with the International Narcotics Control Board (INCB) and governments of other countries to limit the influx of illicit narcotics and psychotropic substances.

4.25 HUMAN RESOURCE DEVELOPMENT

Well-trained and experienced professional, managerial, technical and other personnel are necessary for planning, organising, implementing and monitoring the National Drug Policy. Government shall, therefore, take the following actions:

- i. Develop capacity-building programmes for implementers of the National Drug Policy;
- ii. Leverage on statutory Councils and Boards of health professions for further capacity building on the implementation of relevant aspects of the National Drug Policy in their continuing education programmes;

- iii. Promote cooperation with academia, research institutes such as NIPRD, NIMR and other relevant stakeholders to enhance human resource development for efficient implementation of the National Drug Policy;
- iv. Engage relevant experts to support the implementation of the National Drug Policy.

5.0 NATIONAL DRUG POLICY IMPLEMENTATION: MONITORING AND EVALUATION

5.1 BACKGROUND

The revised drug policy recognises the important role Monitoring and Evaluation (M&E) plays in assessing the implementation of the various strategies as spelt out in this document. An effective M&E system will require the collaboration of all relevant MDAs. M&E will provide data to document progress, gaps and opportunities for improvement. It will support the tracking of the implementation of this policy. Generally, the M&E of a policy play a crucial role in the realisation of the intended goals and objectives. A veritable monitoring mechanism for the drug policy will therefore provide a platform for the following:

- i. **Accountability:** To help FGN decision-makers and donors to track implementation and progress towards set targets. It will also serve as a cost-benefit tool to make decisions regarding financing and thus, galvanise stakeholders to commit to the implementation of the policy.
- ii. **Operational management support:** Provide feedback that will serve as the basis to improve the implementation of NDP. The elements that are not producing the desired effect can be detected early while new opportunities can be discovered and incorporated.
- iii. **Strategic and knowledge management support:** Provide information about opportunities that work under different contexts to strategize implementation and future revision towards promoting, sharing and use of data.
- iv. **Fidelity:** Provide data on the level or degree to which the policy was implemented as intended.

The success of the National Drug Policy would depend on how well its provisions are implemented. Mechanisms shall, therefore, be put in place for monitoring and evaluating the Policy's performance and impact, and for identifying possible gaps and evolving effective strategies to address them. In this regard, the government shall ensure:

- i. The setting up of a desk for Monitoring and Evaluation of the implementation of NDP in the National Drug Policy/Essential Medicines List Branch of the Pharmaceutical Services Division (PSD), Department of Food & Drug Services (DFDS);
- ii. Periodic review of the Key Performance Indicators (KPIs);
- iii. The outcomes of M&E including all observations on the performance of the implementation process are properly documented and transmitted to the authorities as appropriate feedback.

- iv. This policy supports the institutionalisation of Drug Management Information System (DMIS);
- v. Close monitoring of the effects of international trade agreements on Nigerians' access to essential drugs;
- vi. The execution of the monitoring and evaluation framework for the implementation of NDP;
- vii. Undertaking mid-term and end-term assessments of NDP.

5.2 STRATEGIES FOR IMPLEMENTATION

Policy statements in this document will serve as the main thrusts for the achievement of NDP objectives. The strategies that drive NDP shall continue to focus on effective drug management processes as listed in section 4.1 to 4.25. These strategies can be grouped under the following thematic areas as shown in the table below:

Table 1: Thematic Areas for Implementation strategies

S/N	Thematic Areas	Implementation Strategies	Remarks
1	Access	Selection of Medicines	Direct link
		Procurement of Medicines	Direct link
		Medicines Storage	Direct link
		Drug Distribution	Direct link
		Drug Financing and Affordability	Direct link
		Drug Revolving Fund Scheme	Direct link
		Pricing Policy	Direct link
		Local production of medicines	Direct link
		Importation and Exportation of medicines	Direct link
		Donated Medicines	Direct link
		Monitoring & Evaluation	Direct link
		Drug and Therapeutics Committees	Indirect link
		Drug and Substance Abuse Prevention, Treatment and Care	Indirect link
		Legislation	Indirect link
		Drug research and development	Indirect link
		Patent	Indirect link
Emergency Preparedness	Indirect link		
Human resource development	Indirect link		
International Cooperation	Indirect link		
2	Quality	Legislation	Direct link
		Quality Assurance	Direct link
		Inspection of manufacturing facilities	Direct link

		Registration of medicines	Direct link
		Procurement of Medicines	Direct link
		Medicines Storage	Direct link
		Drug Distribution	Direct link
		Pharmacovigilance	Direct link
		Patent	Direct link
		Monitoring & Evaluation	Direct link
		Selection of Medicines	Indirect link
		Local production of medicines	Indirect link
		Drug research and development	Indirect link
		Human resource development	Indirect link
		International Cooperation	Indirect link
3	Rational Use	Legislation	Direct link
		Education and Training	Direct link
		Rational Prescribing, Dispensing and Use	Direct link
		Pharmacovigilance	Direct link
		Drug Information Services	Direct link
		Drug and Therapeutics Committees	Direct link
		Informed Self-Medication	Direct link
		Antimicrobial Stewardship	Direct link
		Drug and Substance Abuse Prevention, Treatment and Care	Direct link
		Monitoring & Evaluation	Direct link
		Selection of Medicines	Indirect link
		Procurement of Medicines	Indirect link
		Drug research and development	Indirect link
		Emergency Preparedness	Indirect link
		Human Resource Development	Indirect link
		International Cooperation	Indirect link

5.3 DEVELOPMENT OF NDP INDICATORS

The NDP covers a lot of areas to provide an environment suitable for sustainable, effective and efficient drug management and to contribute to the economic growth of the nation while ensuring the health of the populace. As such, there is an opportunity to develop several indicators for monitoring and evaluation. However, a Results-based Management (RBM) strategy was employed to streamline efforts and resources for an optimal system. Therefore, more attention was placed on output and outcome indicators and to a lesser extent on input and process indicators.

Essentially, for monitoring and evaluation, indicators will be developed. Also, some indicators which are already being tracked by public health programmes and MDAs will be adapted. This approach will strengthen and encourage data collection and usage.

5.4 DATA COLLECTION TOWARDS IMPLEMENTATION OF NDP

Data collection tools will be developed by the M&E Desk at PSD/DFDS in collaboration with other stakeholders to serve as means of collecting data for indicators already being tracked by public health programmes, MDAs and other stakeholders. This will entail reviewing already existing data collection system and tools including electronic platforms. As much as resources and time permit, the collaboration between Federal and State governments on the implementation and monitoring of NDP will be strengthened. Thus, States can own a lot of the initiatives and be principal stakeholder in identifying and addressing gaps. Data quality must be maintained in the course of the implementation of NDP.

5.5 MONITORING PLAN

Monitoring involves the continuous collection, tracking and analysis of data to assess progress, the trend over time and gaps. The collection of relevant data for the implementation of the policy will be based on the agreed timeline/frequency of reporting established.

The priority is to ensure high-quality data are collected for decision making and to improve the implementation of the policy. Data quality issues will be promoted in terms of availability, completeness, consistency and timeliness.

Despite the flexibility in reporting, overall performance will be reviewed every quarter to guide implementation and provide insight into necessary changes needed for improvement.

5.6 EVALUATION PLAN

Evaluation leverages on monitoring data and involves collecting additional data based on the goal and context to assess the contribution or changes attributable to the policy. The implementation of NDP needs to be evaluated to document learning for immediate and future purposes. This will help in understanding how the policy was implemented while identifying critical differences or barriers between planned and actual implementation. Furthermore, understanding success and limiting factors help to determine what needs to be reinforced and removed.

A starting point will be a baseline assessment, and there will also be mid-term and end-term assessments to review the level of implementation of the policy. For a robust result, evaluation may entail the use of both quantitative and qualitative data collection methods.

5.7 DISSEMINATION:

One important aspect of this policy is ability to communicate the level of implementation and achievement at different stages. Thus, the level of policy implementation can be showcased at local and international fora using the following means:

- i. Developed factsheet at national and state levels;
- ii. Reports of assessments;
- iii. Stakeholders meeting or workshop;
- iv. Abstracts; and
- v. Publications.

6.0 NATIONAL DRUG POLICY MONITORING AND EVALUATION FRAMEWORK

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
To ensure efficient and effective drug management in the Public and Private Sectors.	Number of health facilities with functional DRF Scheme	Output	Number of health facilities with functional DRF Scheme	Assessment /Survey		M&E of PSD/DFDS, FMOH	
To ensure equitable access to safe, efficacious good quality and affordable drugs at all levels of health care delivery.	Number of health facilities using EML for procurement	Output	Number of health facilities using EML for procurement	Health Facility Assessment/Survey	80% adherence to the Essential Medicines List in the selection, procurement, prescription and dispensing at all levels of healthcare by 31st December 2025	M&E of PSD/DFDS, FMOH	Data collection will be undertaken annually to assess the level of compliance
	Number of health facilities using EML for prescribing	Outcome	Number of health facilities using EML for prescribing	Health Facility Assessment/Survey	80% adherence to the Essential Medicines List in the selection, procurement, prescription and dispensing at all levels of healthcare by 31st December 2025	M&E of PSD/DFDS, FMOH	
To promote the rational use of drugs by prescribers,	% of health facilities (secondary and tertiary only) with a	Output	Numerator: Number of health facilities with a	Survey/assessment	80% adherence to the National Standard	M&E of PSD/DFDS, FMOH	

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
dispensers and consumers	functional Drugs and therapeutics committee (Hospital drug formulary exists and evidence of meeting at least once in last 6 months)		functional Drugs and Therapeutics Committee Denominator: Total number of health facilities assessed		Treatment Guideline/Essential Medicines List in the selection, procurement, prescription and dispensing at all levels of healthcare by 31st December 2025		
	Number of health facilities using the National Standard Treatment Guideline/Essential Medicines List	Outcome	Number of health facilities using the National Standard Treatment Guideline/Essential Medicines List	Survey/assessment	80% adherence to the National Standard Treatment Guideline/Essential Medicines List in the selection, procurement, prescription and dispensing at all levels of healthcare by 31st December 2025	M&E of PSD/DFDS, FMOH	Strengthening of the Rational Use of Drugs Concept and the National Drug Policy Issues in the curricula of all health professional schools and Continuing Education Programmes by 2025
	% of health facilities prescribing medicines with generic names in line with NDP	Output	Numerator: Number of health facilities that are prescribing medicines with generic name	Survey/assessment		M&E of PSD/DFDS, FMOH	Compliance with the criteria for EML in order to ensure affordability

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
			Denominator: Total number of health facilities assessed				and access to medicines
	% of health professional school curriculum that includes rational drug use and NDP.	Input	Numerator: Number of professional schools with curriculum that includes rational drug use Denominator: Total number of professional schools assessed	Survey/assessment	Strengthen the Rational Drug Use Concept and the National Drug Policy issues in the curricula of all Health Professional Schools and Continuing Education Programmes by 31st December 2025	FD&S FMOH, Fed Ministry of Education	
To promote local production of drugs and pharmaceutical raw materials through favourable policies and advocacy for local manufacturers;	% of medicines in the essential medicines list that are produced by at least one local manufacturer in the country	Output	Numerator: Number of medicines on the Essential medicines list manufactured locally Denominator: Total number of medicines on the Essential drug list	NAFDAC list of manufacturers	70% increase for local production capacity and utilisation of essential medicines by 31st December 2025	FD&S, NAFDAC	
To promote export of locally produced drugs	% of local medicine manufacturers that are prequalified by WHO	Process	Numerator: Number of local medicine manufacturers who	List of WHO prequalified manufacturers from WHO & NAFDAC		FD&S, NAFDAC, PMGMAN	

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
			are prequalified by WHO Denominator: Total number of registered local medicine manufacturers				
To establish a well-ordered distribution system for Nigeria;	% of Government owned warehouses with pharma grade standard		Numerator: Number of government owned warehouses with pharma grade standard Denominator: Total number of government owned warehouses.	PCN, DFDS (PSD and NPSCMP)		M&E of PSD/DFDS, FMOH	
	Number of functional coordinated drug distribution centres		Number of coordinated drug distribution centres	PCN, DFDS (PSD and NPSCMP)		M&E of PSD/DFDS, FMOH	
To promote pharmaceutical research and development in support of the National Drug Policy;	% of annual health sector budget approved and released for pharmaceutical research and development	Input	Numerator: Amount of money approved and released for pharmaceutical research and development Denominator: Total amount of	Research Institutes		M&E of PSD/DFDS, FMOH	

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
			annual health budget				
	Number of pharmaceutical research publications in the preceding year	Output	Number of documented pharmaceutical research conducted by relevant organisation in the last full fiscal year	NIPRD, NIMR, Universities		M&E of PSD/DFDS, FMOH	
To strengthen Post Marketing Surveillance and Pharmacovigilance for all drugs including traditional, complementary and alternative medicines;	% of regulatory enforcement actions taken in the preceding year as a consequence of post marketing surveillance activities	Impact	Numerator: Number of regulatory enforcement actions taken in the preceding year as a consequence of post marketing surveillance activities Denominator: Total number of post marketing surveillance activities undertaken in the preceding year	NAFDAC Database		M&E of PSD/DFDS, FMOH	
	% of health facilities with functional Pharmacovigilance committee (documented)	Output	Numerator: number of health facilities that have a functional Pharmacovigilance	NAFDAC		M&E of PSD/DFDS, FMOH	

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
	meeting in last 3 months and reported adverse event to NAFDAC in last 12 months)		committee Denominator: Total number of health facilities assessed				
To reduce the burden of Antimicrobial Resistance (AMR);	1. % of Federal tertiary health institutions with a functional AMR Stewardship committee instituted	Input	Numerator: Number of federal tertiary health institutions with a functional AMR stewardship committee Denominator: Total Number of federal tertiary health institutions	Survey/assessment, NCDC Database	80% of Federal Tertiary health institutions have a functional AMR Stewardship committee institutionalised by December 31, 2025	M&E of PSD/DFDS, FMOH	
	2. Percentage of federal tertiary health institutions documenting antimicrobial consumption for facilities	2.Outcome	Numerator: Number of federal tertiary health institutions providing evidence of the antimicrobial consumption Denominator: Total Number of federal tertiary health institutions	Survey/assessment, NCDC Database	80% of Federal Tertiary health institutions document Antimicrobial consumption by December 31, 2025		

OBJECTIVES	INDICATORS	TYPE OF INDICATOR	INDICATOR DEFINITION	DATA SOURCE	TARGET	RESPONSIBLE BODY OR ORGANISATION	COMMENTS
To reduce and prevent the menace of Drug and Substance Abuse;	Prevalence of drug and substance abuse in Nigeria	Impact	Numerator: number of people using drugs and substance in Nigeria Denominator: Total number of people surveyed	Survey	10%	Narcotics & Drug Abuse Branch, DFDS	Current evidence shows that prevalence of drug use is 14.4% as at 2018. This policy seeks to achieve 10% by 2025.
	Number of drug treatment centres in Nigeria	Output	Number of drug treatment centres in Nigeria	Nigeria Epidemiological Network on Drug Use (NENDU Database)		Narcotics & Drug Abuse Branch, DFDS	
To enlist government commitment at all levels for the achievement of the goals and objectives of the National Drug Policy.	% of states that have a designated desk officer for national drug policy implementation	Input	Numerator: Number of states with a designated officer for implementation of NDP Denominator: Total number of states	Assessment and survey		DFDS	M&E desk officer designated in DFDS

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