

National Drug Policy



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FOREWORD

I am indeed very delighted to write the foreword to this second edition of the National Drug Policy. The maiden edition of the Policy was launched in 1990. However many of the expectations of that edition were unrealized due mainly to lack of political will by past governments and the absence of a well-structured monitoring system. This revised edition has taken care of those identified lapses. It was developed with adequate consultation with relevant stakeholders in the Pharmaceutical sector in order to ensure a coherent and multisectoral platform for achieving the main goals of the National Drug Policy.

The launching of this edition is against the backdrop of the overall Health Sector Reform (HSR) Programme of my Ministry. One of the major outputs of the ongoing HSR is the adoption of a revised National Health Policy by the Federal Government. While the chronological synchronization of the revised National Drug Policy with the updated National Health Policy may appear coincidental, it is nonetheless providential and fortuitous.

No matter how vibrant a health policy, without availability of good quality and affordable medicines, that policy will be sterile. Fortunately, the Government of President Obasanjo has been paying special attention to the pharmaceutical sub-sector. The Presidential Forum on the Pharmaceutical Sector held in November 2003 underscored this special focus. Since that event, the Government has taken a number of pragmatic steps towards boosting the local capacity for the manufacture of essential medicines. This is to ensure that the local pharmaceutical industry becomes a major actor in providing good quality essential medicines for our health care programmes.

The recently released 2005 Fiscal Policy is the most favourable ever, as far as the pharmaceutical sector is concerned. It provides very attractive incentives both to the existing players and prospective investors in the production of life-saving essential medicines. It is my earnest hope that the launching of the second edition of the National Drug Policy will further increase the vibrancy of the pharmaceutical sector for the overall improvement of people's health.

In concluding this foreword, I would like to express my sincere appreciation to the National Drug Policy Review Committee headed by Dr. Philip Emafo, a

renowned pharmacist and a World Health Organisation consultant. The diligence of the committee is warmly and heartily acknowledged. Without the financial and technical support of the Nigerian Country office of the World Health Organisation, the review exercise would not have succeeded. I feel greatly indebted to them. Government shall do its utmost to ensure that this revised edition is faithfully and successfully implemented.



Professor Eyitayo Lambo
Honourable Minister of Health,

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National Drug Formulary and EDL Review Committee

Nigerian Medical Association

Pharmaceutical Society of Nigeria

Pharmacists' Council of Nigeria

Planned Parenthood Federation of Nigeria (PPFN)

Sokoto State Ministry of Health

University of Uyo

Veterinary Council of Nigeria

ACRONYMS

CIDA	Canadian International Development Agency
DFID	Department for International Development
DIC	Drug Information Centre
DRA	Drug Regulatory Authority
DRF	Drug Revolving Fund
DTC	Drugs and Therapeutic Committee
ECOWAS	Economic Community of West African States
EDL	Essential Drugs List
EVDL	Essential Veterinary Drugs List
FMOH	Federal Ministry of Health
GMP	Good Manufacturing Practices
INN	International Non-Proprietary Names
LGA	Local Government Area
MDCN	Medical and Dental Council of Nigeria
NAFDAC	National Agency for Food and Drug Administration and Control
NCN	Nursing Council of Nigeria
NDF	National Drug Formulary
NDLEA	National Drug Law Enforcement Agency
NDP	National Drug Policy
NEMA	National Emergency Management Agency

NIMR	National Institute for Medical Research
NIPRD	National Institute for Pharmaceutical Research and Development
NPI	National Programme on Immunisation
NUC	National Universities Commission
OTC	Over the Counter
PCN	Pharmacists' Council of Nigeria
PMG-MAN	Pharmaceutical Manufacturing Group of the Manufacturing Association of Nigeria
PPMVL	Patent and Proprietary Medicine Vendors Licence
QC	Quality Control
RMRDC	Raw Materials Research and Development Council
SMOH	State Ministry of Health
STG	Standard Treatment Guidelines
SVTG	Standard Veterinary Treatment Guidelines
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organisation
UNODCCP	United Nations Office for Drug Control and Crime Prevention
USAID	United States Agency for International Development

VCN	Veterinary Council of Nigeria
VDF	Veterinary Drug Formulary
VRI	Veterinary Research Institute
WHO	World Health Organisation

TABLE OF CONTENTS

FOREWORD	1
ACKNOWLEDGEMENTS	2
ACRONYMS	3
TABLE OF CONTENTS	5
1.0 INTRODUCTION	7
2.0 DEFINITION	7
3.0 GOALS OF THE NATIONAL DRUG POLICY	7
4.0 OBJECTIVES OF THE NATIONAL DRUG POLICY	8
5.0 TARGETS OF THE NATIONAL DRUG POLICY	8
6.0 STRATEGIES FOR IMPLEMENTING THE NATIONAL DRUG POLICY	9
6.1 SELECTION OF DRUGS	10
6.2 PROCUREMENT OF DRUGS	11
6.3 DRUG REVOLVING FUND SCHEME	11
6.4 PRICING POLICY	12
6.5 DRUG STORAGE	12
6.6 DRUG DISTRIBUTION	13
6.7 RATIONAL DRUG USE	13
<i>6.7.1 Education and Training:</i>	<i>13</i>
<i>6.7.2 Rational Prescribing:</i>	<i>14</i>
<i>6.7.3. Rational Dispensing</i>	<i>14</i>
<i>6.7.4 Drug Information Services</i>	<i>14</i>
<i>6.7.5 Drugs and Therapeutics Committees</i>	<i>15</i>
<i>6.7.6 Self Medication</i>	<i>15</i>
6.8 DONATED DRUGS	15
6.9 LOCAL DRUG PRODUCTION	16
6.10 LEGISLATION	17
6.11 INSPECTION OF DRUGS	18
6.12 IMPORTATION AND EXPORTATION OF DRUGS	18
6.13 REGISTRATION OF DRUGS	19

6.14 PATENTS	1	19
6.15 QUALITY ASSURANCE		19
6.16 REGULATIONS FOR PRESCRIBING AND DISPENSING DRUGS		20
<i>6.16.1 PRESCRIBING</i>		20
<i>6.16.2 Dispensing</i>		21
6.17 PHARMACOVIGILANCE		21
6.18 DRUG INFORMATION AND PROMOTION		21
6.19 DRUG FINANCING AND AFFORDABILITY		22
6.20 RESEARCH AND DEVELOPMENT		22
<i>6.20.1 Drug Research and Development</i>		22
<i>6.20.2 Operational Research</i>		23
6.21 HERBAL AND OTHER TRADITIONAL REMEDIES		23
6.22 HUMAN RESOURCES DEVELOPMENT		24
6.23 CONTROL OF VETERINARY DRUGS		24
6.24 INTERNATIONAL COOPERATION		25
6.25 MONITORING AND EVALUATION		25

1.0 INTRODUCTION

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

- An ineffective system of drug administration and control;
- Inadequate funding of drug supply and drug control activities;
- High dependence on foreign sources for finished drug products, pharmaceutical raw materials, reagents and equipment;
- Inadequate facilities for storage, transportation and distribution of drugs;
- Poor selection and procurement practices;
- The involvement of unqualified persons in procurement, distribution and sale of drugs;
- Poor performance of drug suppliers to public health care institutions; and
- Lack of political will to provide safe, efficacious and good quality drugs to meet the health needs of Nigerians.

The policy was formulated with laudable goals and objectives intended to address the unsatisfactory situation at that time. Its adoption was seen as a positive development by observers. After over a decade of its adoption and implementation, some modest progress has been recorded. These include the publication of an Essential Drugs List (EDL), and a National Drug Formulary (NDF), the establishment of a statutory agency with responsibility for drug administration and control, and the introduction of drug registration procedures. However, much more still remains to be done in many areas, such as the realisation of self-sufficiency in local production of essential drugs, the establishment of an effective drug procurement system, evolving a well-ordered drug distribution system, the harmonisation and updating of drug legislation, the effective control of drug advertisement and promotion, the entrenchment of and commitment to rational use of drugs at all levels of health care, and drug research and development etc. The revision of the Policy presents an excellent opportunity for formulating new strategies, for consolidating achievements in areas where progress has been recorded, and addressing those areas that call for more positive action. It is hoped that with judicious implementation of the revised policy, as laid out in the accompanying implementation plan, the Nigerian people will have sustainable access to safe, efficacious and good quality drugs.

2.0 DEFINITION

Drug includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state, or the symptoms thereof, in man or in

animals; restoring, correcting or modifying organic functions in man or in animals; disinfection, or the control of vermin, insects or pests; or contraception;

3.0 GOALS OF THE NATIONAL DRUG POLICY

The goals of the policy shall be to make available at all times to the Nigerian populace adequate supplies of drugs that are effective, affordable, safe and of good quality; to ensure the rational use of such drugs; and to stimulate increased local production of essential drugs.

4.0 OBJECTIVES OF THE NATIONAL DRUG POLICY

The objectives of the policy are:

- i. To ensure efficient and effective drug management in the public and private sectors;
- ii. To ensure access to safe, effective, affordable and good quality drugs at all levels of health care on the basis of health needs;
- iii. To promote the rational use of drugs by prescribers, dispensers and consumers;
- iv. To increase local drug manufacture/production and promote export;
- v. To ensure that all drugs in the national drug distribution system are safe, efficacious, effective and of good quality;
- vi. To strengthen administrative, legislative, and regulatory controls of the importation, manufacture, procurement, storage, distribution, supply, sale and use of drugs;
- vii. To promote research on herbal remedies and integrate those found to be safe and efficacious into the health care system;
- viii. To promote pharmaceutical research and development of raw materials for the production, compounding and formulation of pharmaceutical products, as well as operational research for the effective implementation of the National Drug Policy; and
- ix. To enlist government commitment at all levels for the achievement of the goals and objectives of the National Drug Policy.

5.0 TARGETS OF THE NATIONAL DRUG POLICY

The implementation of the NDP shall be directed towards accomplishing the following targets:

- i. Establishment of a National Drug Policy Monitoring and Evaluation Division in the Food and Drugs Services Department of the Federal Ministry of Health by the year 2005;
- ii. Total adherence to the use of the Essential Drugs List in public health institutions by 2008;

- iii. Production of National Standard Treatment Guidelines (STGs) for all levels of the health care system by 2006 and 80% adherence by 2008;
- iv. 80% adherence to good drug procurement practices in the public sector by 2008;
- v. Entrenchment of a rational and properly structured drug distribution system in the private sector by 2008;
- vi. 90% of targeted publication of prices of essential drugs by 2005;
- vii. Availability of adequate drug storage conditions in 80% of the public and private health care sectors by 2008;
- viii. Proper disposal of expired, deteriorated and sub-standard drugs in 60% of public and private care health facilities by 2008;
- ix. Establishment of appropriate storage and quality control laboratories at designated ports of entry and export of drugs by 2005;
- x. Establishment of three new, fully equipped and adequately staffed laboratories in strategic locations of the country for more effective quality assurance of drugs and pharmaceutical products in Nigeria by 2005;
- xi. Establishment in every public health care delivery institution at the federal, state, and local government levels by the end of 2005, properly operated drug revolving fund schemes with distinct bank accounts, transparent drug procurement procedures and mechanisms to check diversion of the fund for other purposes;
- xii. Total compliance with national guidelines on drug donations by 2008;
- xiii. Increase in local production capacity to a level where 70% of total output satisfies at least 60% of national drug requirements of essential drugs while the balance is exported by 2008;
- xiv. 80% awareness of the concept of rational use of drugs by prescribers, dispensers and consumers by 2006; and 60% adherence by prescribers and dispensers by 2008;
- xv. Inclusion 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 2006;
- xvi. 80% adherence to the rational use of narcotics and antimicrobials in the country by 2008;
- xvii. Institutionalization of functional Drugs and Therapeutics Committees and drug information centres in 60% of secondary and tertiary health facilities by 2007;
- xviii. Publication of a list of all medicines in the Nigerian market in three categories, namely prescriptions only, pharmacy only, and general sale by 2005;
- xix. Awareness of appropriate self-medication practices by 40% of the population by 2008.

- xx. Establishment, by 2006, of well-equipped national and zonal pharmacovigilance centres and achievement of 40% reporting of adverse drug reactions by 2008;
- xxi. Total compliance of all drug promotion and information with national regulations by 2005;
- xxii. Annual publication of registered drugs by 2004 and thereafter;
- xxiii. Provision of funds to satisfy a minimum of 70% of research needs by 2006;
- xxiv. Publication of a Nigerian Pharmacopoeia, incorporating a list of effective herbal medicines by 2005;
- xxv. Enactment of a reviewed and harmonised drug legislation in Nigeria by 2006;
- xxvi. Commencement of harmonisation of drug laws in the ECOWAS sub-region by 2006;
- xxvii. Full integration of the drug management aspects of all Ministry of Health programmes by 2005; and
- xxviii. 60% compliance with the use of EVDL, VDF, SVTG in veterinary practice by 2008.

6.0 STRATEGIES FOR IMPLEMENTING THE NATIONAL DRUG POLICY

The strategies that shall be used to implement the National Drug Policy shall 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 quality of drugs at all levels, appropriate storage, proper costing and effective distribution of drugs, promotion of local drug manufacture, appropriate legislation, product registration, research and development, human resources development, monitoring and evaluation. Furthermore, the strategies shall emphasise proper accountability and rational use of drugs by health workers and consumers.

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

6.1 Selection of Drugs

The objective of the drug selection process is to have a national list of drugs rationally chosen to satisfy the health care needs of the majority of the population. Such a list shall be revised regularly and shall form the basis of drug selection by

primary, secondary and tertiary public health-care institutions. In this regard, the Federal Government shall take the following steps:

- i A revised Essential Drugs List shall be published by the Federal Ministry of Health and made available to health professionals, state and local governments, primary, secondary and tertiary health institutions.
- ii Drugs included on the list shall:
 - be listed using generic or International Non-Proprietary Names (INN)
 - be based on the health needs of the majority of the population
 - have substantial safety and risk/benefit ratio with sufficient accumulated scientific data
 - be registered by the national drug regulatory authority
- iii As much as possible, formulations containing more than one active ingredient shall be avoided, 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, or
 - two or more pharmacologically active ingredients are synergistically active in a product, or
 - patient compliance is enhanced by the combination.
- iv When two or more drugs are therapeutically equivalent or several drugs 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.
- v The Essential Drugs List Review Committee shall update the list every four years.
- vi Suggestions for amendment shall be made in writing on a prescribed form to the Federal Ministry of Health, justifying each suggested amendment. New drugs shall only be added to the list if sufficient scientific and clinical data are available to show that they offer distinct advantages over existing ones. Drugs on the list for which information becomes available that they

no longer have a favourable risk/benefit ratio shall be withdrawn and replaced with safer alternatives.

- vii The Essential Drugs List shall be used for:
 - the procurement of drugs and their use in the public sector;
 - prescribing drugs in the public sector;
 - drug information to health care providers;
 - the production of Standard Treatment Guidelines and a National Formulary;
 - reimbursements on drugs in the National Health Insurance Scheme.

6.2 Procurement of Drugs

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

- i Government shall be committed to good pharmaceutical procurement practices in the public sector;
- ii Procurement of drugs shall be restricted to drugs registered in Nigeria and on the Essential Drugs 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 shall be conducted in a transparent manner with the advice of the Pharmacy Department. To encourage local drug manufacture, preference shall be given to the purchase of locally manufactured drugs;
- v Procurement shall be based on accurate quantification of drug requirements by the Pharmacy Department;
- vi Procurement and receipt procedures shall ensure that drugs supplied are of good quality;
- vii In order to keep prices low and undertake adequate quality assessment, drugs, shall as much as possible, be purchased in bulk;
- viii Drugs procured at all levels shall be subjected to quality assessment before distribution to dispensing units.

6.3 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, however, has shown that its advantages have not been apparent due to a variety of reasons, including the following:

- poor management,
- misapplication of the Fund,
- purchasing of drugs at exorbitant prices,
- lumping of the proceeds of the Fund into a general account, and
- non-reimbursement of the cost of drugs for exempted patients.

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

- i. Establishment of a DRF committee in every health institution for an effective and transparent fund management;
- ii. Provision of adequate capital for the procurement of required drugs;
- iii. Maintenance of a separate account for the DRF scheme, which shall be used exclusively for drug purchasing;
- iv. Ensuring strict accountability for the drugs provided in the system by supplying them on a “cash-and-carry” basis;
- v. Empowering the head of the pharmacy department of the health institution as the custodian of drugs to the institution and making him a required signatory to the DRF account; and
- vi. Provision of appropriate training for the DRF personnel.

6.4 Pricing Policy

Experience in recent years has shown that drugs have been procured at much higher prices in public health institutions than in private retail pharmacies. Even within the public sector, there are wide variations in the prices of the same drugs from one institution to another. Therefore, to ensure affordability of drugs in public health institutions, government shall establish necessary mechanisms to guarantee that drug supply to patients shall cost less than in the private sector.

6.5 Drug Storage

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

Government shall ensure that suitably located, constructed and equipped storage facilities will be available at every level of the drug distribution system, in both public and private sectors.

The efficient and successful operation of a drug storage and distribution system requires the professional skills of pharmacists. Therefore, pharmacists shall be in charge of the drug stores operated by federal, state and local governments as well as in the private sector.

In addition, the following measures shall be implemented:

- i Central Medical Stores and stores in both public and private health care facilities shall be properly managed to ensure that drugs do not expire or deteriorate on the shelf. However, any stock of expired or deteriorated drugs shall be officially destroyed within six months;
- ii Central Medical Stores shall have Quality Control Laboratories where basic tests shall be undertaken to determine the quality of drugs received or supplied.
- iii Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions;
- iv Public and private sector establishments shall put adequate mechanisms in place to ensure that the temperature in all drug storage facilities is maintained at not more than 20°C for the sustenance of the shelf life of drugs. In respect of vaccines and biological products they shall provide appropriate cold storage for the maintenance of the shelf life of such vaccines and products.
- v Government at all levels shall ensure the establishment of central computerised inventory control systems in the central stores for effective drug management; and
- vi Government shall encourage the computerisation of private drug stores for effective inventory control.

6.6 Drug Distribution

Rational drug distribution channels shall be promoted in both public and private sectors. In this regard the following measures shall be enforced by the Federal Government:

- i Drug distribution, supply, sale and dispensing shall be under the control and supervision of pharmacists at all levels;
- ii Government shall ensure that drug manufacturing, wholesaling and retailing activities are registered as distinct enterprises;
- iii The channel for private sector drug distribution shall flow from manufacturers or importers to wholesalers and retailers;
- iv Government shall ensure that drug supplies to public health facilities will be based on expressed need and, in the main, shall be from the Central Medical Stores;
- v Government shall ensure that all drugs purchased or donated to governments at all levels are channelled through the Central Medical Stores;
- vi Government shall establish inventory control systems, including computerisation, in all hospital pharmacies and clinics for effective inventory

- control. These shall be linked to a central computerised inventory control system in the Central Medical Stores;
- vii Adequate security shall be provided for storage areas, and, in particular, for narcotic drugs;
 - viii Drugs distributed in the country shall, at least, be labelled in English;
 - ix Government shall create incentives for pharmacists to establish practices in rural areas in order to promote rational drug distribution and use. Professional associations and regulatory bodies involved in health care shall encourage their members to establish professional practices in rural areas to complement government efforts in promoting greater access to and rational use of drugs.

6.7 Rational Drug Use

The requirements for rational drug use are that the right drugs shall be used for the right indications in the right dose and dosage form for the right duration. 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, well-tried, safe and cheaper alternatives are available. Concerted efforts shall be made by government at all levels to promote rational drug use through:

6.7.1 Education and Training:

The objective is to ensure that all health personnel involved in the diagnosis, prescription and dispensing of drugs, as well as consumers, receive adequate theoretical and practical 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 and veterinary schools;
- ii Teach communication skills in pharmacy, medical, nursing and veterinary schools to promote rational prescribing and dispensing; and
- iii Develop educational strategies and programmes directed at the public on appropriate use of drugs.

6.7.2 Rational Prescribing:

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

- i Up-to-date Standard Treatment Guidelines and a National Formulary shall be made available to all prescribers according to the level of care;
- ii Prescribing shall be by International Non-Proprietary Names (INN) or generic names; and

- iii At health care facilities, diagnostic services appropriate to the level of health provided so as to improve the accuracy of diagnosis.

6.7.3. Rational Dispensing

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

- i Dispensing shall only be carried out on duly licensed premises;
- ii The minimum information requirement on the label of a dispensed medicine shall be the following:
 - Name of patient,
 - Generic name of dispensed drug,
 - Strength of the drug,
 - Dosage instruction in symbols or words as may be appropriate,
 - Duration of treatment
 - Date of dispensing, and
 - The name of the institution where the drug was dispensed;
- iii The patient shall be counselled on the use of dispensed drugs, in a conducive environment suitable for effective communication; and
- iv Dispensing shall be carried out in a suitable container that will be child-proof and ensure the stability of the drug dispensed.

6.7.4 Drug Information Services

Drug information is intended to provide unbiased, scientifically validated drug information to promote rational prescribing, dispensing and use. In this respect, therefore, the following measures shall be taken:

- i Drug information units shall be established in all public health institutions.
- ii The drug information units/centres shall, at all times, be suitably equipped and provided 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.

6.7.5 Drugs and Therapeutics Committees

Drugs and Therapeutics Committees are institutionalised mechanisms for promoting, implementing and monitoring the concept of rational drug use in health care institutions. Therefore, the following measures shall be taken:

- i Drugs and Therapeutics Committees (DTCs) shall be established in all tertiary and secondary health care institutions;

- ii Membership of such committees shall comprise representatives of the pharmaceutical, nursing, medical, and administrative services of the institution; and
- iii A DTC shall, among other duties, be responsible for:
 - the selection of drugs for use in the institution, based on the National Essential Drug List,
 - the accurate estimation of pharmaceutical requirements for the hospital,
 - monitoring of the use of therapeutic guidelines and overall drug utilisation, and
 - monitoring of the rational use of drugs in the institution.

6.7.6 Self Medication

Self-medication is especially useful in any situation where access to health care facilities is limited. It can offer the advantage of providing quick and effective relief that does not require medical attention, thereby relieving pressure on medical personnel and freeing them to devote more time to serious problems. However, it could lead to inappropriate use of drugs, delay of proper diagnosis and the delivery of effective treatment. It could also lead to drug misuse and abuse. In order to obtain the benefits of self-medication while avoiding its risks, the following steps shall be taken:

- i A list of drugs that can be sold without prescription and used for the short-term relief of symptoms, without prior medical consultation and precise diagnosis, shall be drawn up and published by government;
- ii Such listed drugs shall satisfy the criteria for the selection of essential drugs, 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 drugs, meant for self-medication, shall conform to laws and regulations set out for such categories of drugs;
- v Health education to the public on appropriate self-medication shall be provided through the use of print and electronic media, and other communication methods.

6.8 Donated Drugs

Experience has shown that some donated drugs have often not been relevant to the emergency situation for which they were donated or for the disease pattern, or for the level of care that was available. They may sometimes be unknown to

local health professionals and patients and may not comply with locally agreed policies and standard treatment guidelines; they may even be harmful. In the light of this experience, the following measures shall be taken;

- i All drug 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 drug donations.
- ii Donated drugs shall among other things be required to:
 - be registered for use, both by the Drug Regulatory Authority of the donor country and in Nigeria,
 - have at least twelve months remaining shelf life after arrival in the country, and
 - be labelled in English to include its international non proprietary or generic name; and
- iii. The Federal Ministry of Health shall put in place an adequate machinery for monitoring the distribution of donated drugs. In an emergency, the Federal Ministry of Health, in collaboration with National Emergency Management Agency (NEMA), shall immediately establish a co-ordinating body to assess and inform donors about national needs, approve donations, and co-ordinate their receipt and distribution.

6.9 Local Drug Production

The need for increased capacity in local drug production has been well recognised. Such capacity should cover the production of raw materials and intermediate products, not just formulation and packaging. Drug production facilities in the country are presently operating under severe constraints, including the following:

- poor infrastructural facilities such as water and electricity supply,
- poor transportation and communication,
- poor waste disposal management,
- inadequate incentives such as tax relief, capital allowance, and government patronage
- limited access to funds for capital development,
- unfair competition by imported drugs, and
- reliance on imported raw materials, machinery and spare parts.

In order to achieve the target of greater reliance on local drug production, steps shall be taken by government to:

- 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 tax, interest rate regime and duty structures for locally manufactured products and imported raw materials, as well as for drug packaging materials;
- v. Intensify efforts to ensure that the petrochemical and other essential industries for the proper development of the pharmaceutical manufacturing industry come on stream;
- vi. Encourage research on pharmaceutical raw materials;
- vii. 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;
- viii. Encourage patronage of local drug manufacturers by public and private health care institutions;
- ix. Provide grants for the establishment of plants for the production of basic raw materials.
- x. Encourage small-scale pharmaceutical production.

6.10 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. It also defines the qualifications, duties, privileges, and obligations of individuals, organisations, institutions, and other bodies concerned with the implementation of the various strategies of the policy, and provides for sanctions in the event of violations.

For the effective implementation of legislation, there is need to review and update the relevant laws regularly, in consultation with relevant stakeholders, in order to achieve the desired objectives. Some of the existing drug laws are in dire need of review and harmonisation.

Accordingly the following measures shall be taken:

- i. Government shall strengthen legislation relating to:
 - The essential drugs policy,
 - Definition of drugs,
 - Registration of drugs,
 - Control of the supply, importation, exportation, production, manufacture, storage, distribution, and sale of drugs;
 - Prescribing and dispensing of drugs;
 - Quality control of drugs and pharmaceutical substances;
 - Licensing of manufacturing, wholesale and retail premises and their inspections;

- Regulation of the labelling and promotion of medicines (including traditional medicines);
 - Establishment of different control regimens for drugs and especially scheduling of controlled substances;
 - Imposition of fees for services;
 - Administration and control of drugs including the procedure for appealing against regulatory decisions;
 - Licensing of qualified persons;
 - Types of packaging materials of medicines and other pharmaceutical products;
 - National Health Insurance as it relates to drug supply to patients
 - Disposal of unwanted or expired drugs;
 - Delineation of prescribing/dispensing functions;
 - Clinical trials;
 - Offences and sanctions;
- ii. Government shall also enact appropriate legislation in respect of the following:
 - generic prescription and substitution,
 - removal of import taxes on pharmaceutical raw materials,;
 - parallel importation in accordance with Trade-Related Intellectual Property Rights (TRIPS),
 - compulsory licensing in accordance with Trade-Related Intellectual Property Rights (TRIPS),
 - drug donations,
 - Good Manufacturing Practice,
 - traditional and herbal medicines (advertisement and sales), and
 - use of antibiotics and hormones in agriculture and livestock products;
 - iii. Government shall provide the necessary material and financial resources to strengthen enforcement of the provisions of the laws and regulations.
 - iv. Government shall 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.

6.11 Inspection of Drugs

Effective inspection of drug products and manufacturing facilities is critical to ensuring the quality, safety and efficacy of drugs. It is also necessary in order to ensure compliance with the statutory requirements relating to the storage, supply, distribution and sale of drugs, etc. Therefore, national regulatory authorities shall

establish effective mechanisms for inspection in all drug manufacturing establishments, public and private health institutions, as well as, in drug sales and distribution outlets.

Government shall also establish suitable mechanisms for inspecting the import/export of drug products, in line with the various regulations, and apply appropriate sanctions where violations are committed.

6.12 Importation and Exportation of Drugs

A substantial proportion of drugs consumed in Nigeria is imported, while the export of drugs from the country is insignificant. Ideally, there should be a balance between importation and exportation of drugs. The National Drug Policy shall seek to promote self-reliance in national drug consumption, as well as, the contribution of the local pharmaceutical industry to the national economy through exportation. The overall objective shall be to ensure that the import and export activities in regard to drugs are effectively regulated so that all products, whether imported or exported, meet the required standards of quality, safety and efficacy. Therefore, the following measures shall be implemented:

- i. Drug imports and exports shall be restricted to designated ports which shall be equipped with adequate storage facilities and on-the-spot test facilities to ensure quality;
- ii. Personnel of regulatory authorities shall be regularly trained to effectively carry out inspectorate activities;
- iii. Inter-sectoral collaboration between the drug regulatory authorities and other government agencies at the ports such as the Customs, Police, NDLEA, etc., shall be encouraged;
- iv. Pharmaceutical manufacturers shall be encouraged to maximise the use of their installed production capacity for export purposes; and
- v. A strong advocacy machinery shall be established to promote the export of drugs manufactured in Nigeria.

6.13 Registration of Drugs

Drug registration is the vehicle for ensuring that government has control over drugs that are offered for sale and use in the country. It ensures that drugs distributed in the country have been produced under Good Manufacturing Practices and have passed the tests of need, efficacy, safety and good quality. It is an essential element in limiting the number and types of drugs and drug products brought into or manufactured in the country. It is also the instrument by which new drugs can be added to, and old drugs found unsuitable removed from, the list of approved drugs.

In light of this, government shall:

- i. Continue to strengthen the drug registration mechanism that is presently in place within the National Agency for Food and Drug Administration and Control [NAFDAC];
- ii. Ensure that all drugs (human and veterinary), traditional, homeopathic preparations, as well as vitamin and mineral supplements are registered.;
- iii. Ensure periodic and regular publication and wide dissemination of the list of registered drugs; and.
- iv. Prescribe the imposition of appropriate sanctions on any violation of the laws, regulations and guidelines on drug registration.

6.14 Patents

Patent protection has been an incentive for promoting research and development of new drugs. While patent protection is desirable, it should not constitute a hindrance to access to essential drugs by Nigerians. Government shall, therefore, put in place strategies to ensure that public health interests are protected when trade matters conflict with health, 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. Developing mechanisms to monitor the effect of international trade agreements on Nigerians' access to medicines; and
- iii. Exploring existing mechanisms provided by international agreements to protect public health, especially those that affect access to affordable, good quality and essential drugs.

6.15 Quality Assurance

The aim of quality assurance of a drug product is to ensure that the drug 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 drug to the patient. Compliance with Good Manufacturing Practices (GMP) is an important component of quality assurance.

Therefore, government shall take appropriate action 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 drugs to ensure that patients and consumers receive only safe, efficacious and good quality drugs;

- ii. Drug imports and purchases at all levels in public and private health facilities shall meet the standards of good quality and safety before such drugs are distributed to dispensing units;
- iii. Good Manufacturing Practices [GMP] shall continue to be monitored and enforced in all drug manufacturing outfits in the country;
- iv. Duly qualified individuals and organisations shall be licensed to set up quality control laboratories for assessing the quality of drugs in the national drug distribution system;
- v. University departments with appropriate personnel and equipment will be encouraged to assess drug quality to complement the functions of the laboratories of the regulatory authorities;
- vi. Adequately equipped and staffed drug quality control laboratories will be established in strategic locations within the various geo-political zones of the country; and
- vii. Manufacturers will be required to package their products in appropriate containers in order to ensure the quality and stability of such products.

6.16 Regulations for Prescribing and Dispensing Drugs

A prerequisite for effective drug control is that prescribing, dispensing and the sale of drugs be undertaken by duly authorised persons. Regulations for prescribing, dispensing and sale of drugs shall take into consideration the policy goal of rational drug use and the supply of safe and efficacious essential drugs at affordable cost. In view of the fact that drugs will be 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 drugs shall be sufficiently flexible to cover the activities of such health workers.

In view of the fact that research in many countries has shown that dispensing doctors or prescribing pharmacists use more drugs 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 drugs to the public at the different levels of the health care system shall be periodically updated, with the following minimum provisions:

6.16.1 Prescribing

- i. In tertiary and secondary health care institutions, only duly qualified and licensed medical practitioners shall have the authority to prescribe drugs. At the primary health care level, government shall designate appropriate health care personnel to prescribe drugs;
- ii. Only qualified and licensed medical practitioners shall have the authority to prescribe drugs in the private sector; and

- iii. Prescriptions shall be made, using the International Non-Proprietary or Generic Names. It shall be made in a manner to ensure that proper records are kept at the records and pharmacy departments of health care institutions in both private and public sectors.

6.16.2 Dispensing

- i. Only duly licensed pharmacists shall have the authority to supply, sell and dispense drugs to the public. Such sales shall take place in premises licensed for the purpose, which shall be subject to regular inspection. Continuing registration of a licensed premise shall depend on a satisfactory report by inspectors of the Pharmacists' Council of Nigeria (PCN) and the payment of prescribed fees;
- ii. In view of the need for every Nigerian to have access to appropriate drugs, it shall be permissible for certain OTC drugs to be sold in patent medicine stores operated by Patent and Proprietary Medicine Vendor's Licensees (PPMVL), particularly in areas where there are no licensed pharmacists in practice. The premises for the sale of such drugs shall be approved and licensed and shall be subject to periodic inspection by pharmaceutical inspectors of the PCN. The list of drugs to be sold in such premises shall be those approved by government;
- iii. In every health care facility where there is a qualified and licensed medical practitioner, there shall be a qualified and licensed pharmacist to manage drugs; and
- iv. In order to enhance total patient care, particularly as regards in-patients, government shall promote the practice of clinical pharmacy in secondary and tertiary health care institutions.

6.17 Pharmacovigilance

Since no active drug is entirely free from adverse reactions, the introduction of an adverse drug reaction reporting system is an essential component of a national healthcare delivery system, government shall, therefore, encourage the establishment of adequately equipped pharmacovigilance units nation-wide, to collect, evaluate and disseminate relevant information on adverse drug reactions and poisoning. All drugs shall be regularly monitored with respect to their efficacy, safety, quality as well as adverse reactions to evaluate the need to change the conditions of their continuing registration or withdrawal from the market.

Any drug withdrawn or banned in many countries, due to unacceptable health risks, shall be automatically withdrawn from distribution in Nigeria.

6.18 Drug Information and Promotion

Information about drugs 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 and in compliance with national regulations. They shall be reliable, accurate, informative, balanced, up-to-date, capable of substantiation, not misleading and in good taste. In this regard government shall continue to:

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

6.19 Drug Financing and Affordability

Financing the various provisions of the National Drug Policy shall be the primary responsibility of government at all levels. Participation in the National Health Insurance Scheme by individuals, organisations and communities shall, however, be encouraged. In order to realise the objectives of the NDP, the Federal Government shall ensure that:

- i. Suitable financial provisions are made within the total health budget for sustainable implementation and monitoring of the policy;
- ii. Adequate budgetary allocations are made for drugs, in line with internationally recommended norms;
- iii. Priority is given to the provision of adequate funds for drugs used in primary health care and the control of endemic diseases;
- iv. The cost of drugs to the patient is low, but sufficient to recover total costs with a little mark-up for administrative expenses and adequate maintenance of the drug revolving fund;
- v. The costs of the promotive and preventive aspects of the National Drug Policy like health information and education; human resources development and research are fully borne by government;

- vi. Government at all levels makes specific budgetary provisions to cover the cost of exemptions which shall apply to such categories of patients as accident victims, TB patients, the destitute, the mentally retarded, children, and the elderly, etc.

6.20 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 health care needs of the country. Considering the enormous cost of research and development, government shall provide support and an enabling environment to encourage such activities, specifically as described below:

6.20.1 Drug Research and Development

This aims at developing new drugs and improving existing ones, with the ultimate goal of producing safer, more effective and better quality drugs. Drug research and development are essential components of health research that enhance the attainment of the goals and objectives of the National Health Policy.

Drug research and development shall be encouraged, especially in the following areas:

- i. Local raw materials with particular emphasis on petrochemicals as sources for new drugs and excipients.;
- ii. Traditional medicines for the promotion of health and the treatment of diseases;
- iii. Enhancing the quality and stability of pharmaceutical products. and
- iv. Documenting and reducing adverse drug reactions.

6.20.2 Operational Research

Operational research is necessary for the successful implementation of the National Drug Policy. Its aim is to identify the best methods of selecting, procuring, distributing and using drugs 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 drugs.

Research will focus particularly on the following areas:

- i. Identifying the impact of the National Drug Policy and its components on the national health system and health service delivery;
- ii. Drug utilisation at different levels of health care facilities;
- iii. The economics of drug supplies; and

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

6.21 Herbal and Other Traditional Remedies

Herbal and traditional medicines are widely used in the country. Many of the drugs used in modern medicine today originate from plants and there is no doubt that new drugs can still be discovered from plants, including those indigenous to Nigeria. There is, therefore, a need for the government to provide adequate funds in institutions and universities to promote research in drug development, especially herbal medicine. Such research shall have demonstrable relevance to the needs of the society, with a high potential for immediate application.

The following list, of possible areas of research and interventions, which is by no means exhaustive should be supported with the provision of grants for their attainment by government and local and international development partners:

- i. Rational use of herbal medicines;
- ii. Formulation of a national policy on herbal medicinal plants and traditional medicines by the Federal Ministry of Health;
- iii. Co-ordinated promotion, support and sponsorship of research on medicinal plants;
- iv. Investigation of traditional medicines, particularly herbal medicines for efficacy, safety, and quality with a view to integrating them into the health care system;
- v. Cultivation and management of herbaria to ensure conservation of medicinal herbs and sustainability of supplies
- vi. Standardisation of products to ensure efficacy;
- vii. Compilation of a compendium of herbal medicines;
- viii. Collaboration between the Federal Ministry of Health, and other relevant ministries and agencies (Universities, Ministries of Agriculture, Science and Technology, Raw Materials Research and Development Council, National Institute for Pharmaceutical Research and Development, National Institute for Medical Research and State Ministries of Health) to promote multidisciplinary inputs necessary for discovery, development and application of drugs from plants and other natural sources, in the search for useful medicines;
- ix. Encouragement of the development of a “Code of Practice” by herbal medicine practitioners;
- x. Regulation and control of advertisements of traditional medicine and practices by the government; and
- xi. The protection of patents for efficacious and safe herbal medicines.

6.22 Human Resources Development

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

- i. Expand the facilities in the universities and award scholarships for the training of pharmacists and other relevant professionals required for the successful implementation of the National Drug Policy;
- ii. Ensure constant review of pharmacy, medical, and veterinary surgeon curricula, in cooperation with the relevant professional regulatory bodies and the National University Commission (NUC), to reflect the needs of drug policy implementation;
- iii. Strengthen the capacity of trainers to appropriately train undergraduates and postgraduates on the relevance and challenges of implementing the National Drug Policy;
- iv. Develop in-service training programmes to address on-the-job requirements in the implementation of the policy;
- v. Encourage statutory councils and boards of health professions to give prominence to the implementation of relevant aspects of the National Drug Policy in their continuing education programmes as a basis for periodic renewal of licenses; and
- vi. Promote cooperation with foreign governments, research institutes and relevant international agencies such as the World Health Organisation and the United Nations Office for Drug Control & Crime Prevention [UNODCCP] for the purpose of enhancing human resources development for the efficient implementation of the National Drug Policy.

6.23 Control of Veterinary Drugs

The objective of controlling veterinary drugs is to ensure the safe and rational distribution, storage, prescribing, dispensing and use of veterinary drug products. The uncontrolled administration of veterinary drugs, particularly the use of antibiotics and hormones in animals used for food leads to the presence of residues of these drugs in meat and meat products. It also leads to the development of resistant strains of micro-organisms.

Consequently, government shall enforce the following measures:

- i. The National Drug Policy shall apply in equal force to veterinary pharmaceuticals;
- ii. The essential drugs concept shall equally apply to the procurement, distribution, supply and utilisation of veterinary drugs. Government shall set

- up a committee comprising competent persons in the field of veterinary medicine, agriculture and pharmacy to compile a list of Essential Veterinary Drugs, Standard Treatment Guidelines and a Veterinary Drug Formulary to be adopted for use throughout the country;
- iii. The utilisation of veterinary drugs shall comply with ethical veterinary practices, and government shall ensure the effective monitoring of drug utilisation in this sector;
- iv. Generic prescribing shall be adopted by appropriately authorised and registered prescribers;
- v. Dispensing of veterinary drugs shall be on the basis of prescriptions given by authorised and registered veterinary practitioners; and
- vi. The sale of veterinary drugs shall be undertaken by pharmacists and any other persons authorised or licensed by the PCN.

6.24 International Cooperation

Cooperation between countries, particularly between importing and exporting countries can be advantageous in combating the influx of sub-standard and counterfeit drugs into importing countries, 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. The use of diplomatic channels for the exchange of information on substandard and counterfeit drugs in international commerce;
- iv. Using the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce or any similar scheme for all drug imports and exports; and
- v. Liaising with the International Narcotics Control Board and governments of other countries to limit the importation and use of narcotic drugs and psychotropic substances to medical and scientific purposes only.

6.25 Monitoring and Evaluation

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, measuring and evaluating the Policy's performance and impact, and for identifying possible problems and evolving effective strategies to address them.

In this regard government shall ensure:

- i. The setting up of a National Drug Policy Monitoring and Evaluation Unit in the Federal Ministry of Health, to measure progress in the implementation of the policy and to run a national evaluation scheme;
- ii. Compilation of indicators for monitoring the National Drug Policy as an integral part of the National Health Information System, and evaluating these indicators at all levels of health care at the local, state and federal governments;
- iii. Institutionalising of drug management information systems as a basis for deriving drug management and other relevant information for taking decisions on the National Drug Policy;
- iv. Close monitoring of the effects of international trade agreements on Nigerians' access to essential drugs; and
- v. Undertaking of a full evaluation of the National Drug Policy every three