

FEDERAL MINISTRY OF HEALTH

NATIONAL DRUG DISTRIBUTION GUIDELINES

2ND EDITION 2012

INTRODUCTION

One of the major challenges of the Pharmaceutical Sector and the Health care delivery system of Nigeria is the uncoordinated drug distribution system which is not in line with the good drug supply management that the National drug Policy stipulates. Consequently Government established the Presidential Committee on the Pharmaceutical Sector Reform (PCPSR) and charged it among others to develop strategy towards the institutionalization of a well ordered drug distribution system in Nigeria. The strategies adopted by the Committee to achieve this include the development of the National Drug Distribution Guidelines which will provide guidance to drug distribution in Nigeria. This proposal was approved by Mr. President and also endorsed by the National Council on Health (NCH) in 2009. In 2010 the Federal Ministry of Health In collaboration with the PCPSR developed the National Drug Distribution Guidelines.

However the Ministry saw the need for a review of the Guidelines and in 2011 the Honourable Minister of Health, Professor C.O. Onyebuchi Chukwu set up the Ministerial Committee on the National Drug Distribution Guidelines and charged it with the responsibility of reviewing the Guidelines and consequently we presently have the First Revised Edition of the National Drug Distribution Guidelines 2012

According to the Guidelines the States are to establish the State Drug Distribution Centers (SDDCs) which will be supervised by a Standing Committee while the private sector is to establish the Mega Drug Distribution Centers (MDDCs) which will be represented in the six geopolitical zones before they can be registered as MDDC.

Direction is provided in respect of source of drugs to every level of pharmaceutical practice including primary health care facilities, Private Health care facilities and the Patent and Proprietary Medicine Vendor. (PPMV).

In the course of developing this document there were wide consultations with the various stakeholders, the Drug Distribution Guidelines of other countries were consulted and the provisions of the National Drug Policy were taken into cognizance.

The development and implementation of the Guidelines are empowered by the constitution of the Federal Republic of Nigeria; Drugs are on the exclusive legislative list and therefore drug matters are under the jurisdiction of the Federal Government.

- i. The NAFDAC Act CAP N.I. LFN 2004 stipulates one of the primary functions of the Agency as regulation and control of importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- ii. The Pharmacist's Council of Nigeria Cap P 17 LFN 2004 Section B 148 on inspection, location and structure of pharmaceutical premises regulations 2005.
- iii. The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous provisions) Cap C 34 LFN 2004 prohibits the sale of drugs in premises not duly licensed by appropriate authority

There is no gainsaying that these Guidelines when effectively implemented will to a large extent address the present challenges of the drug distribution system of Nigeria

FOREWORD

It gives me pleasure to write the foreword of this 2nd edition of the National Guidelines on Drug Distribution which is mainly based on the provisions of the National Drug Policy (NDP).

The drug distribution system of the country has remained uncoordinated, a situation which has posed a very big challenge to the pharmaceutical sector in particular and to government in general because of the negative impact the situation has had on the entire health care delivery system of the country over the years up to date

It has been established that the uncoordinated drug distribution is the major reason why we still have some level of fake, adulterated and sub standard drugs in circulation in the country which is not in the interest of the health care delivery system

In order to address this ugly situation a Presidential Committee on Pharmaceutical Sector Reform (PCPSR) was constituted in 2003 to among others develop strategies towards the sanitization of the drug distribution system. The development of this National Guidelines is one of the strategies adopted by the PCPSR to coordinate the drug distribution sub-sector.

The process of developing the National Guidelines on Drug Distribution began in 2009 as a collaborative effort of the Federal Ministry of Health, the PCPSR with other relevant stake holders. The Guidelines have now been developed and it serves as a reference to all those involved in drug distribution

It is believed that the Guidelines will ensure the availability of good quality, safe efficacious and affordable drugs in the Health care delivery system of the country considering the centrality of good quality drugs and vaccines in the achievement of MDGs 4,5 and 6 and attainment of vision 20-20-20

According to the Guidelines, states are to establish State Drug Distribution Centers (SDDCs) while the Private sector is to establish Mega Drug Distribution Centers (MDDCs).

The Guidelines also provide a distribution channel which is in consonance with the National Drug Policy. It identifies source of drugs for every level of health care delivery as well as mode of distribution thereby introducing orderliness in the drug distribution system if all concerned comply with the guidelines.

The main attraction of the Guidelines is that drugs will no longer be sold in the open market because in line with the Guidelines the manufacturers and the importers will channel drugs to only the SDDCs and MDDCs. In this way government would have overcome a major challenge of uncoordinated drug distribution.

Health care facilities at all levels including Private are guided by the Guidelines in their drug procurement activities in order to avoid the current practice that is lacking in professionalism and which is not in line with the provisions of the National Drug Policy.

While the implementation of the Guidelines is with immediate effect from the day of launching, the Federal Government encourages States and the Private Sector to effectively establish the operational structures e.g. the SDDCs and the MDDCs as well as other necessary requirements with effect from December 31st 2013 after which sanctions will commence for non compliance.

The present States' Central Medical Stores (CMSs) can be used as the take off hubs for the State Drug Distribution Centers.

Drug manufacturers and importers are expected to strictly adhere to the provisions of the Guidelines and should note that defaulters face varying degrees of sanctions

The populace is expected to support this action of Government which is aimed at further protecting the citizens.

Government will put in place a monitoring system that will address implementation gaps and subsequently lead to achievement of the objectives of the Guidelines.

Finally, I wish to seize this opportunity to appreciate all those who have contributed in one way or the other to the production of these guidelines.

Prof. C. O. Onyebuchi Chukwu
Honourable Minister of Health
2012

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Niger State Ministry of Health
Rivers State Ministry of Health
FCDA Dept. of Health Services
Ogun State Ministry of Health
Oyo State Ministry of Health
Osun State Ministry of Health
Lagos State Ministry of Health
Edo State Ministry of Health
Anambra State Ministry of health

Abbreviations/ Acronyms

PCPSR Presidential Committee on Pharmaceutical Sector Reform

SDDCs State Drug Distribution Centers

MDDCs Mega Drug Distribution Centers

NAFDAC National Agency for Food and Drugs Administration and Control

NIPRD National Institute for Pharmaceutical Research and Development

PSN Pharmaceutical Society of Nigeria

PCN Pharmacists' Council of Nigeria

PMG-MAN Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria

ACPN Association of Community Pharmacists of Nigeria

FCDA Federal Capital Development Authority

RMRDC Raw Material Research and Development Council

NIPC Nigeria Investment Promotion Commission

FMS&Tech Federal Ministry of Science and technology

FMC&I Federal Ministry of Commerce and Industry

CMS Central Medical Store

PHC Primary Healthcare

DG Director General

GM General Manager

DGM Deputy General Manager

AGM Assistant General Manager

PPMVL Patent and Proprietary Medicines Vendors License

Nat Prog. National Programme

FCDA Federal Capital Development Authority

FMOH Federal Ministry of Health

SMOH State Ministry of Health

PRS Planning Research and Statistics

CPC Consumer Protection Council

ADR Adverse Drug Reactions

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GOAL:

- i. To establish a well ordered drug distribution system for Nigeria

OBJECTIVES:

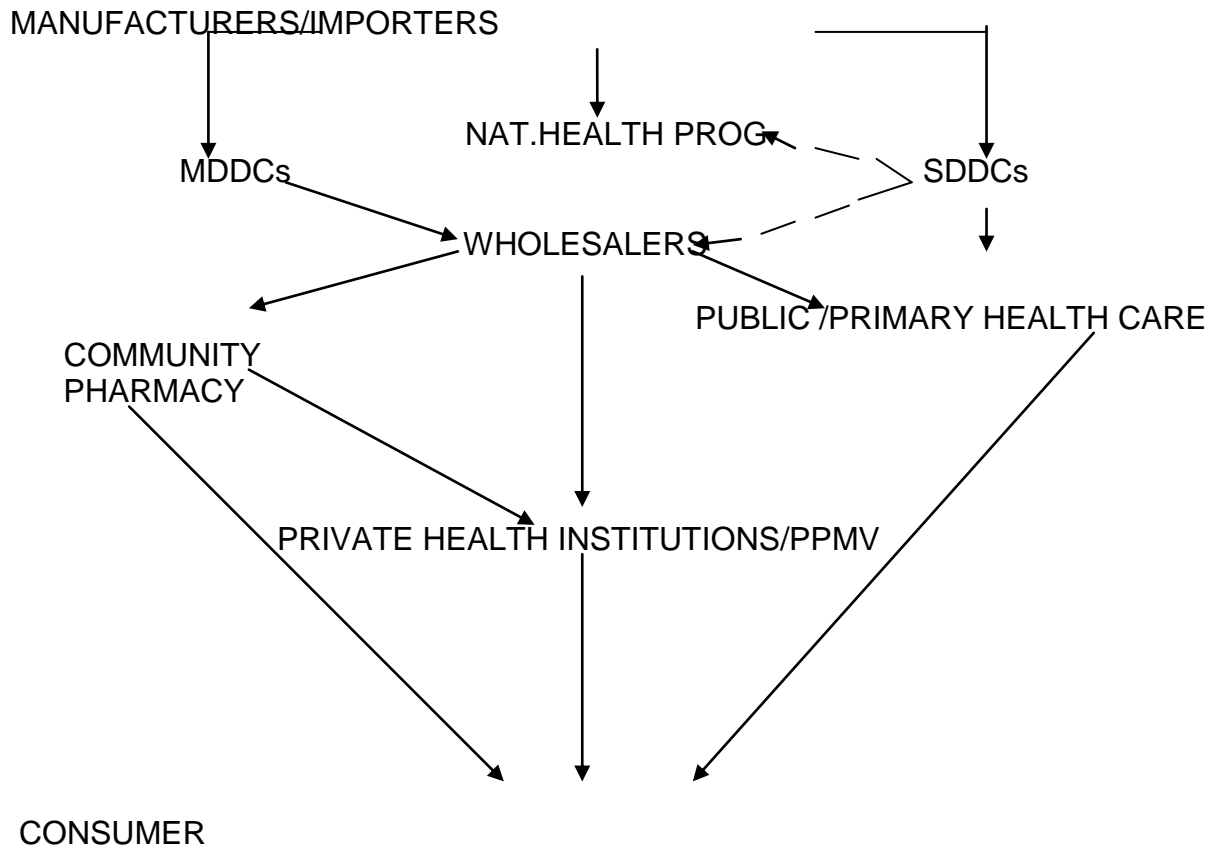
- i. To ensure efficient and effective drug supply management in the Public and Private Sectors
- ii. To ensure that all drugs in the National Drug Distribution system are safe, efficacious, effective, affordable and of good quality
- iii. To ensure access to good quality and affordable drugs at all levels.

TARGETS:

- i. Establishment of State Drug Distribution Centers (SDDCs) by the State Government by 31st December 2013
 - ii. Establishment of the Mega Drug Distribution Centers (MDDCs) by the Private Sector by December 31st 2013
 - iii. Establishment of Wholesale and Retail outfits by the Private Sector
- Registration of all Pharmaceutical Premises by the Pharmacists' Council of Nigeria (PCN) i.e. both Public and Private Sector including Hospital Pharmacies

Fig 1.

THE CHANNEL FOR DRUG DISTRIBUTION SHALL BE:



Note: States shall establish the State Drug Distribution Centers (SDDCs)
States can upgrade existing CMSs to meet required standard.

Private Sector shall establish MEGA Drug Distribution Centers (MDDCs).

Private health institutions include corporate organizations e.g. Shell, NNPC, CBN, etc.

Public health facility include Tertiary, Secondary and Primary Health Care Facilities

1. MANUFACTURERS/IMPORTERS

- i. Shall be registered with the Pharmacists Council of Nigeria (PCN)
- ii. All pharmaceutical products sold by manufacturers and importers shall be registered by NAFDAC. In case of orphan drugs, approval shall be sought from NAFDAC for their importation.
- iii. Shall sell to only the SDDCs and MDDCs
- iv. Shall abide by good storage practices as stipulated by NAFDAC and PCN
- v. Shall ensure that all transactions are properly documented for easy monitoring and tracking of the products.

NOTE: Provision is made for the manufacturers/importers to sell to wholesalers till December 31st 2013 to allow for full establishment of SDDCs and MDDCs after which they shall cease selling to wholesalers.

2. STATE DRUG DISTRIBUTION CENTRES SDDCs

- i. Shall be owned by the State Government and under direct supervision of the Pharmaceutical Services Department of the State Ministry of Health.
- ii. Shall be self accounting.
- iii. Shall be registered by PCN
- iv. Shall be headed by a General Manager (GM) appointed by the State government, who is a registered pharmacist with a minimum of 15 years post qualification experience.
- v. The GM tenure shall be 4 years, and renewable once.
- vi. There shall be adequate number of registered pharmacists in the SDDC
- vii. There shall be adequate number of distribution vans for delivery services.
- viii. Shall follow the drug supply chain as stipulated by the National Drug Policy i.e. selection, procurement, storage, distribution, transportation, documentation, tracking and recall.
- ix. Shall sell to public health facilities and wholesalers
- x. The following Committees shall be established:

2A. THE STANDING COMMITTEE:

A 5- member Standing Committee comprising:

- i. A pharmacist of not less than 20 years experience as chairman to be appointed by the State.
- ii. Director of Pharmaceutical Services.
- iii. Director Medical Services
- iv. General Manager as secretary
- v. A representative of public interest.

2B. THE MANAGEMENT/ TECHNICAL COMMITTEE:

A 5- member Technical Committee comprising

- i. The GM as the chairman
- ii. A Pharmacist of 5 years cognate experience on the programme as secretary
- iii. A programme accountant and 2 other heads of units

2C. DUTIES OF THE STANDING COMMITTEE

- i. Ratify decisions made by the Technical Committee
- ii. Receive and ratify periodic reports of the Technical Committee which shall be made biannually.
- iii. Advocacy for the SDDC with Community, Government, NGOs etc
- iv. Give approval for annual work plan of the SDDC and provide enabling environment for officers to function.
- v. Ensure that appropriate and adequate staff is employed for the centre.
- vi. Oversee the accounts of the centre.
- vii. Ensure biannual internal auditing of the Accounts of the SDDCs, receive and approve the report.
- viii. Ensure yearly auditing of the Accounts of the SDDCs by external auditor, receive and approve report.
- ix. Approve sanctions and/or legal action against any erring supplier when necessary.
- x. Make recommendations to Government on issues of appointment and discipline of staff.

2D. DUTIES OF THE MANAGEMENT/ TECHNICAL COMMITTEE

- i. Plan and oversee the day to day running of the organization.
- ii. Ensure good drug supply management.
- iv. Approve the release of funds for drug procurement and day to day running of the SDDC.
- v. Recommend disciplinary measures or otherwise of erring staff to the Management Committee

2E. Selection of Drugs

- i. Medicines should be selected based on the EDL.
- ii. Medicines selected should be registered by NAFDAC

2F. Procurement of Drugs

- i. Shall follow the drug supply chain as stipulated by the National Drug Policy i.e. selection, procurement, storage, distribution, transportation, documentation, tracking and recall.
- ii. Shall be directly from registered drug manufacturers/importers

- iii. Quantification shall be based on consumption patterns
- iv. Shall be by bulk purchase
- v. They shall own or have access to facilities for quality assessment.
- vi. Drug purchase/order shall be by pull / push system
- vii. Payment shall be made directly to the manufacturer/importer that made the supplies within 30 days.
- viii. All supplies shall be properly receipted and documented.

2G. Pricing: Mark-up shall be determined by market forces.

2H.Storage

- i. The objectives of drug storage shall be to ensure stock security and the maintenance of the quality of drugs throughout their shelf life.
Requirements are:
- ii. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- iii. Overall storage area shall not be less than 300sq. meters.
- iv. There shall be clearly demarcated areas for storing damaged and expired products, including returned or recalled products.
- v. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.
- vi. The store shall be kept clean and dry always at acceptable temperature limits using air-conditioners of appropriate capacities and temperature and humidity log recording equipment.
- vii. The storage areas shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- viii. Products shall be stored off the floor and wall on pallets or shelves and suitably spaced to permit cleaning and inspection.
- ix. Appropriate storage facilities shall include sufficient refrigerators and a cold room (for vaccines and biologicals) and evidence of uninterrupted supply of electricity.
- x. The stores shall be properly illuminated and fire-fighting equipment provided
- xi. The store shall have quality control laboratories where basic tests shall be undertaken to determine the quality of drugs received or supplied
- xii. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions.
- xiii. Dangerous Drug Cupboards shall be in place for narcotics
- xiv. Storage shall comply with other provisions of PCN and NAFDAC

2. I. Distribution

- i. The SDDC shall sell to only public health care facilities including primary health care facilities.
- ii. Can sell to wholesalers in certain special situations
- iii. The Wholesalers/public health care facilities shall be registered and currently licensed by the Pharmacists Council of Nigeria (PCN)

2J. Transportation

- i. Vehicles and equipment used in the transportation of pharmaceutical products shall be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.
- ii. Cold chain facilities must be in place for all thermo-labile products, including vaccines and biologicals.

2K. Documentation

- i. The SDDCs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution of all pharmaceutical products.

2L. Tracking and Recall

There should be Standard Operating Procedures (SOPs) for product tracking and recall.

2M. FUNDING

- i. State Governments shall provide adequate take off grant for the scheme.
- ii. Money provided shall be strictly used for drug procurement.
- iii. Adhere to strict accountability for the drugs provided to ensure sustainability

2N. In a Public-Private Partnership (PPP) arrangement:

- i. The two parties involved should adopt the Federal Government Guidelines on PPP and develop an MOU for the partnership

2.1. MANAGEMENT STRUCTURE OF THE SDDC

- i. The State Government is to appoint the General Manager (GM) of the SDDC, who shall be a registered pharmacist with at least 15 years post qualification experience.

2.1A. DUTIES OF THE GENERAL MANAGER

- i. The General Manager shall be the head of the Technical Committee and accounting officer of the SDDC
- ii. The tenure of the GM shall be 4 years, renewable once.

2.1B. THERE SHALL BE THREE DEPARTMENTS AND TWO UNITS. I.E

- i. The Drugs and Health Commodities Department
- ii. Accounts Department
- iii. Administrative Department
- iv. Procurement Unit and
- v. Internal Audit Unit

2.1C. Drugs and Health Commodities Department

The head of the Drug and Health Commodities Department shall be a registered pharmacist of not less than 10yrs experience.

2.1D. DUTIES OF THE HEAD OF DRUGS AND HEALTH COMMODITY DEPARTMENT.

- i. Shall be directly responsible for drug and health commodity supply management

2.1E. Head of Drug Store

- i. Shall have not less than 8 years cognate experience.

2.1F. DUTIES OF HEAD OF DRUG STORE:

- i. Shall ensure efficient management of drug stock and updating the Management / Technical Committee on stock levels.
- ii. Shall Ensure that drugs are sold on cash and carry basis
- iii. Shall initiate procurement as appropriate.

2.1G. Head of Health Commodities store

- i. The head of the Health Commodities store shall have not less than 8 years experience.
- ii. Shall be a pharmacist or scientific officer

2.1H. DUTIES OF HEAD OF HEALTH COMMODITIES STORE

- i. Shall ensure the effective and efficient operations of the store.
- ii. Ensure availability of store items by regularly updating the technical committee on stock levels.
- iii. Initiate request for procurement as appropriate

2.1I. ADMINISTRATION DEPARTMENT

- i. The head of the Administration Department shall have a degree in health related discipline or administration.
- ii. Shall have not less than 10 years cognate experience.
- iii. Shall be directly responsible for overseeing the administrative functions of the Centre.

2.1J. ACCOUNTS DEPARTMENT

The head of the Accounts Department:

- i. Shall be a professional accountant.
- ii. Shall have not less than 10 years cognate experience
- iii. He shall prepare quarterly and annual financial report and present to the Management

2.1k. DUTIES OF THE HEAD OF ACCOUNTS DEPARTMENT

- i. Shall be directly responsible for overseeing the accounting functions of the Centre.

2.2.k. PROCUREMENT UNIT

- i. Head of procurement shall be a professional procurement officer of not less than 8 years cognate experience.
- ii. All heads of departments shall be members of the procurement unit.
- iii. The General Manager shall be the chairman of procurement
- iv. The procurement unit shall report directly to the General Manager

2.3.k.DUTIES OF HEAD OF PROCUREMENT UNIT

- i. Shall carry out procurement activities of the SDDC in line with the provisions of the Public Procurement Act (PPA) 2007
- ii. shall prepare quarterly report and submit to Management.

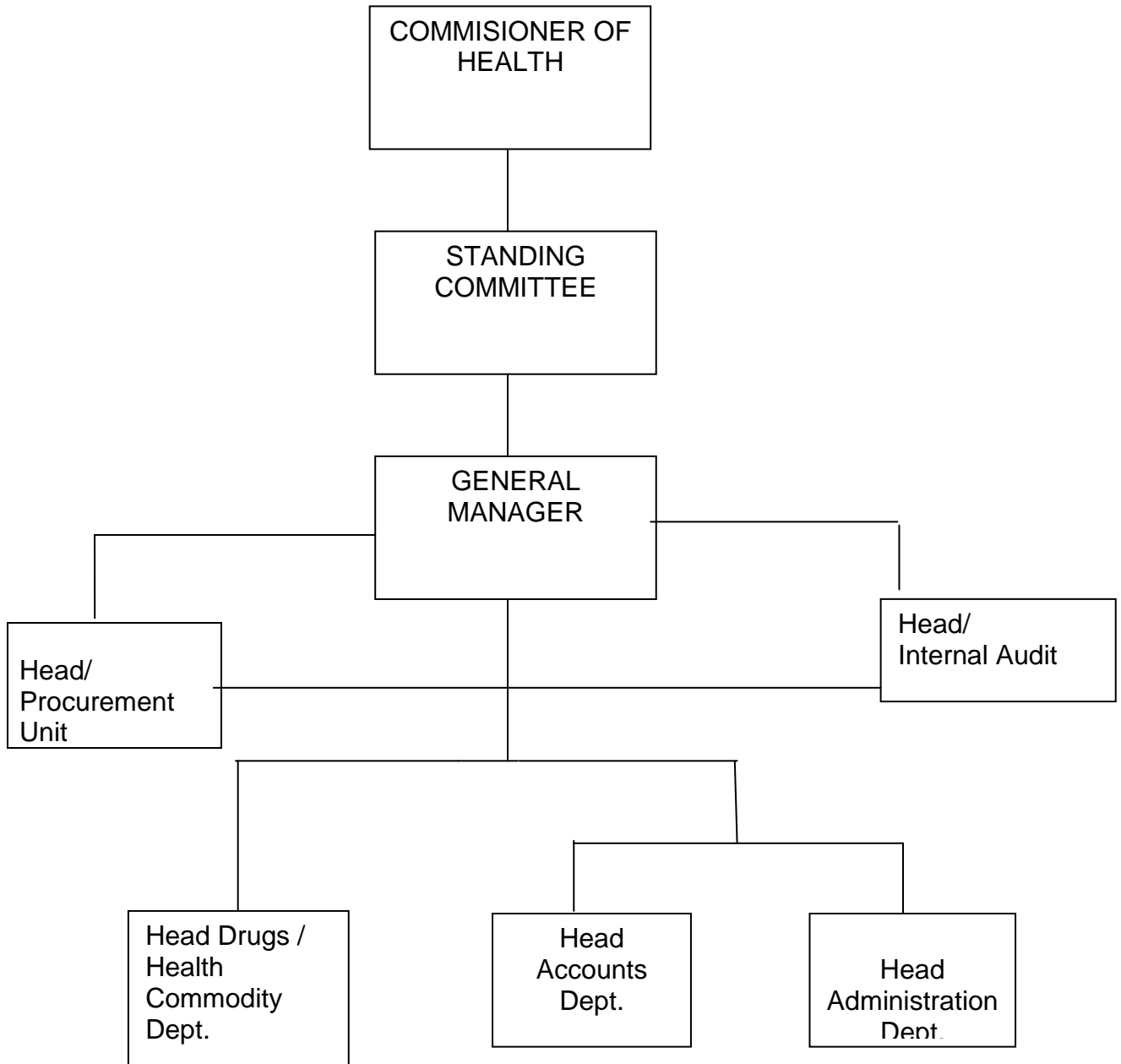
2.1l. Internal Audit Unit

The head of the internal audit shall be a professional accountant of not less than 8yrs cognate experience

2.1M. DUTIES OF HEAD OF INTERNAL AUDIT

- i.
- ii. Shall report directly to the General Manager
- iii. Ensure Biannual auditing of SDDC activities
- iv. Ensure monthly stock taking,
- v. Shall report and keep all records.
- vi. Shall audit the SDDC quarterly and present report to the Management and the Standing Committee.

Fig 2. **THE MANAGEMENT ORGANOGRAM**



3. MEGA DRUG DISTRIBUTION CENTRES MDDCs

- i. Shall be Private Sector Initiative
- ii. To be registered as an MDDC, such a centre shall be established in all the States or at least in each geo-political zone.
- iii. States or at least in each geo-political zone.
- iv. Each MDDC premises shall be manned by a superintendent pharmacist who shall have 10yrs cognate experience.
- v. All drugs shall be received and issued by registered pharmacists.
- vi. Distribution and Quality Assurance Managers must be pharmacists.
- vii. All MDDC premises must be registered by PCN
- viii. All MDDCs must consistently comply with all regulations on Good Distribution Practices as stipulated by PCN & NAFDAC
- ix. A registered pharmacist must be on the board of Directors of the company
- x. He shall have at least 10 years cognate experience.
- xi. The pharmacist on the board shall have oversight function on all superintendent pharmacists of the SDDC

3.1. SPECIFIC REQUIREMENTS

3.1A. Personnel

- i. Every premise shall be registered by a superintendent pharmacist
- ii. There shall be a Drug Distribution Manager who shall be a registered pharmacist
- iii. There shall be personnel for quality assessment in each MDDC

3.1B. Selection of Drugs

- i. Shall be based on the prevalent disease pattern in the state
- ii. Medicines selected shall be registered by NAFDAC

3.1C. Procurement of Drugs

- i. Shall be directly from registered drug manufacturers/importers
- ii. Quantification shall be based on consumption patterns
- iii. Shall be by bulk purchase
- iv. There shall be facilities for quality assessment
- v. Drug purchase/order shall be by pull or push system
- vi. Payment shall be made directly to the manufacturer/importer that made the supplies within a stipulated period of 14days
- vii. All supplies shall be properly receipted and documented.

3.1D. Storage facilities

- i. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- ii. There shall be a minimum of 3 storage areas and each storage area should have a minimum of 100sq meters.
- iii. There shall be clearly demarcated areas for storing damaged and expired products, including returned or recalled products.
- iv. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.
- v. The store shall be kept clean and dry always at acceptable temperature limits using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- vi. The storage areas shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- vii. Products shall be stored off the floor and wall on pallets and suitably spaced to permit cleaning and inspection.
- viii. Appropriate storage facilities shall include sufficient refrigerators and a cold room (for vaccines and biological products) and evidence of uninterrupted supply of electricity.
- ix. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions.
- x. There shall be Dangerous Drugs cupboard for the storage of narcotics and special storage areas for scheduled drugs.
- xi. Shall observe all other storage conditions as prescribed by PCN ad NAFDAC

3.1E Distribution and Logistics

- i. MDDCs shall sell to Wholesalers only.
- ii. The Wholesalers/public health care facilities should be registered and currently licensed by the Pharmacists Council of Nigeria (PCN)
- iii. The MDDCs shall have a register of the wholesalers/public health institutions that they supply to.
- iv. Vehicles and equipment used in the transportation of pharmaceutical products shall be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.
- v. A cold chain must be in place for all thermo-labile products, including vaccines and biological.

3.1F. Documentation, Tracking and Reporting.

- i. The MDDCs shall establish and maintain inventories and records of all transactions regarding the receipt, distribution of pharmaceutical products.
- ii. There shall be Standard Operating Procedures (SOPs) for product tracking reporting and recall.
- iii. There shall be Standard Operating Procedures for disposal of defective, expired, pharmaceutical products

4. WHOLESALERS

- i. Shall be a corporate body duly registered by PCN.
- ii. Shall procure their medicines from MDDCs and SDDCs in some peculiar conditions.
- iii. Shall be involved in the distribution of pharmaceutical products to community pharmacies, public health care facilities including PHCs, private health care facilities as well as the distribution of limited products (i.e. PPMVL approved drug list) to licensed PPMVL holders.
- iv. Products shall not be displayed openly
- v. Wholesalers shall not retail to consumers.

4A. MANAGEMENT

- i. There should be a registered pharmacist on the board of directors with not less than 10 years cognate experience
- ii. The premises shall be registered by PCN and be under the direct supervision and management of a superintendent pharmacist. with not less than 10 years cognate experience

4B. STORAGE

- i. The premises shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- ii. There should be a separate and well secured area for poisons and controlled drugs.
- iii. The premises shall be a minimum of 70 square meters.
- iv. There should be clearly demarcated areas for storing damaged and expired products.
- v. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.

- vi. The premises shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- vii. The premises shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- viii. Products should be stored off the floor on shelves/pallets and suitably spaced to permit cleaning and inspection.
- ix. Appropriate storage facilities should include sufficient and functional refrigerators and evidence of uninterrupted supply of electricity.
- x. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions
- xi. Shall observe all other storage conditions as prescribed by PCN and NAFDAC

4C. DOCUMENTATION

- i. Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of pharmaceutical products.
- ii. Shall have the required record books.
- iii. There shall be a Standard Operating Procedure (SOP) for product tracking and recall.
- iv. A register of detailed addresses of retailers / community pharmacies, private health facilities which the wholesaler supplies shall be maintained. Post Office Box addresses are not acceptable.
- v. Wholesaler to ensure that both public and private health facilities are registered by PCN before it can supply drugs to such facilities.

5. RETAILING OUTFITS/ COMMUNITY PHARMACIES

- i. The premises shall be registered by PCN and be owned by a registered pharmacist.
- ii. Shall be involved in selling drugs to consumers.
- iii. A superintendent pharmacist shall have not less than 5 years experience and shall be in direct supervision and management of the outfit.
- iv. The premises licence and annual licence of the superintendent pharmacist must be clearly displayed.
- v. Shall not be located in the market place, motor park, petrol station or in clustered area. If in a supermarket,
- vi. There shall be a patient counseling area.
- vii. There shall be a well secured cupboard for poisons and controlled drugs
- viii. There shall also be a poisons and drug sales register.
- ix. Current pharmaceutical and medical reference books should be available.
- x. There shall be a box for consumer suggestions and complaints

5A. STORAGE:

i. Drugs shall be stored in retail shops in accordance with PCN and NAFDAC regulatory provisions.

5B. DOCUMENTATION

- i. Sales receipts and invoices shall be well kept
- ii. There shall be SOP for product tracking and recall.
- iii. Inventories, records and logs shall be kept for a period of 5 years.
- iv. Report adverse drug reactions (ADR) and submit yellow forms to national pharmacovigilance office

6. NATIONAL HEALTH PROGRAMMES:

i. Include Hiv/AIDs, National Malaria Control Programme , TB/Leprosy and others.

6A. Selection of Drugs

- i. Medicines shall be selected based on the EDL.
- ii. Medicines selected shall be registered by NAFDAC

6B. Procurement of Drugs

- i. Shall be based on needs as recommended by the Public Health Department.
- ii. Shall procure directly from Manufacturer/ Importer/ SDDCs
- iii. Shall be under the direct supervision and management of the Food and Drugs Services Department of the Federal Ministry of Health (National Products Supply Chain Management Programme)
- iv. Shall follow the drug supply chain as stipulated by the National Drug Policy i.e. selection, procurement, storage, distribution, transportation, documentation, tracking and recall.
- v. Quantification shall be based on consumption patterns
- vi. Shall be by bulk purchase
- vii. There shall be facilities for quality assessment.
- viii. Drug purchase/order shall be by pull system
- ix. Payment shall be made directly to the manufacturer/importer that made the supplies within 30 days.
- x. All supplies shall be properly receipted and documented.

6C. STORAGE:

i. Drugs procured shall be received and stored at the Federal Central Medical Stores (by the pharmacist) under storage conditions as provided in the National drug Policy.

6D . Drug Distribution

- i. Shall be by pull or push system
- ii. Vehicles and equipment used in the transportation of pharmaceutical products shall be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind.
- iii. A cold chain must be in place for all thermo-labile products, including vaccines and biologicals.

6E. Documentation, Tracking and Reporting.

- i. The Programmes shall maintain inventories and records of all transactions regarding the receipt and distribution of pharmaceutical products.
- ii. There shall be Standard Operating Procedures (SOPs) for product tracking and recall.

7. PUBLIC HEALTH CARE FACILITIES TERTIARY/SECONDARY

- i. Shall have Pharmacy Departments that are registered by the PCN
- ii. Shall be manned by a pharmacist.

7A. Selection of Drugs

- i. Shall be based on the EDL and
- ii. Drugs selected must have been registered by NAFDAC

7B. Procurement of Drugs

- i. Shall procure from wholesalers,
- ii. Shall be under the supervision and advice of the pharmacy department
- iii. Shall follow the drug supply chain as stipulated by the National Drug Policy i.e. selection, procurement, storage, distribution, transportation, documentation, tracking and recall.
- iv. Quantification shall be based on consumption patterns

- v. Shall be by bulk purchase
- vi. They shall have access or own facility for quality assessment
- vii. Drug purchase/order shall be by pull or push system
- vii Payment shall be made within 30 days.
- viii. All supplies shall be properly receipted and documented.

7C. STORAGE

- i. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- ii. There shall be a separate and well secured area for poisons and controlled drugs.
- iii. There shall be clearly demarcated areas for storing damaged and expired products.
- iv. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.
- v. The store shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- vi. The store shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- vii. Products shall be stored off the floor on shelves/pallets and suitably spaced to permit cleaning and inspection.
- viii. Appropriate storage facilities shall include sufficient and functional refrigerators and evidence of uninterrupted supply of electricity.
- ix. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions
- x. Shall comply with provisions of NAFDAC and PCN on storage.

7D. Documentation, Tracking and Reporting.

- i. The public health facilities shall maintain inventories and records of all transactions regarding the receipt and distribution of pharmaceutical products.
- ii. There shall be efficient record of patients' prescriptions.
- iii. There shall be Standard Operating Procedures (SOPs) for product tracking and recall.
- iv. There shall be reporting of ADR

8. PRIMARY HEALTH CARE CENTERS

- i. Shall have a pharmacy department which shall be registered by the PCN
- ii. Shall be manned/ supervised by a pharmacist

- iii. Pharmacists shall be employed at this tier for the supervision of the pharmaceutical activities. Due to inadequate availability of pharmacists at this level of care, a pharmacist is allowed to supervise up to four primary health care center pharmacies.

8A. Selection of Drugs

- i. Medicines shall be selected based on the EDL.
- ii. Medicines selected shall be registered by NAFDAC

8B. Procurement of Drugs

- i. Shall procure from SDDCs / wholesalers.
- ii. Shall be under the supervision and advice of the Pharmaceutical Services Department of the State Ministry of Health.
- iii. Shall follow the drug supply chain as stipulated by the National Drug Policy i.e. selection, procurement, storage, distribution, transportation, documentation, tracking and recall.
- iv. Quantification shall be based on consumption patterns
- v. Shall be by bulk purchase
- vi. There shall be facilities for quality assessment.
- vii. Drug purchase/order shall be by push/pull system
- viii. Payment shall be made directly to the / wholesalers that made the supplies within 30 days.
- ix. All supplies shall be properly receipted and documented.

8C. STORAGE:

- i. There shall be a defined drug store supervised by a registered pharmacist.
- ii. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- iii. There shall be a separate and well secured area for poisons and controlled drugs.
- iv. There should be clearly demarcated areas for storing damaged and expired products.
- v. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.
- vi. The store shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- vii. The store shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.

- viii. Products shall be stored off the floor on shelves/pallets and suitably spaced to permit cleaning and inspection.
- ix. Appropriate storage facilities should include sufficient and functional refrigerators for storage of thermo labile products and evidence of uninterrupted supply of electricity.
- x. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions
- xi. Shall comply with other PCN and NAFDAC stipulations

8D. DOCUMENTATION

i. Primary health care facilities shall establish and maintain inventories and records of all transactions regarding the receipt and sale of drugs and other health commodities to patients.

9.PRIVATE HEALTH FACILITIES:

- i. **Shall** meet the PCN requirements in areas of personnel and infrastructure.
- ii. Shall have pharmacy departments that are registered with PCN and manned by pharmacists.

9A.Selection of Drugs

- i. Shall be in line with the provisions of the National Drug Policy
- ii. Medicines selected must have been registered by NAFDAC

9B PROCUREMENT OF DRUGS

i. Shall procure from wholesalers/ community pharmacies and sell to only consumers/ patients

9C STORAGE:

- i. There shall be a defined drug store manned by a pharmacist.
- ii. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- iii. There shall be a separate and well secured area for poisons and controlled drugs.
- iv. There should be clearly demarcated areas for storing damaged and expired products.
- v. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.

- vi. The store shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- vii. The store shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- viii. Products shall be stored off the floor on shelves/pallets and suitably spaced to permit cleaning and inspection.
- ix. Appropriate storage facilities should include sufficient and functional refrigerators for storage of thermo labile and evidence of uninterrupted supply of electricity.
- x. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions
- xi. Shall comply with all other storage conditions stipulated by NAFDAC and PCN

9D. DOCUMENTATION

- i. Private health facilities shall establish and maintain inventories and records of all transactions regarding the receipt and sale of drugs and other health commodities to patients.
- ii. There shall be ADR reporting

10. PATENT AND PROPRIETARY MEDICINES VENDORS' (PPMV) SHOPS

- i. All PPMV shops shall be registered with the PCN

10A. PROCUREMENT OF DRUGS

- i. Shall procure from wholesaler / retail pharmacies
- ii. Shall sell only drugs on the approved list of Federal Ministry of Health for the PPMVs
- iii. Shall sell to only consumers / end users / patients

10B. STORAGE:

- i. The store shall be of sufficient capacity to allow for the orderly storage of various categories of materials and products.
- ii. There should be clearly demarcated areas for storing damaged and expired products.
- iii. Any stock of expired or deteriorated drugs shall be officially destroyed within six months.

- iv. The store shall be kept clean and dry always at acceptable temperature limits, using air-conditioners of appropriate capacities, temperature and humidity log recording equipment.
- v. The store shall be furnished with adequate number of shelves and pallets which must be in a good state of cleanliness and repair.
- vi. Products shall be stored off the floor on shelves/pallets and suitably spaced to permit cleaning and inspection.
- vii. Appropriate storage facilities should include sufficient and functional refrigerators for storage of thermo labile and evidence of uninterrupted supply of electricity.
- viii. Regular checks on the quality of stored drugs shall be undertaken to ensure that they do not deteriorate under storage conditions
- ix Shall comply with all other NAFDAC and PCN conditions

10C. DOCUMENTATION

- i. PPMVLs shall establish and maintain inventories and records of all transactions regarding the receipt and sale of drugs and other health commodities to consumers.

11. MONITORING AND EVALUATION

- ii. For sustainability, this programme should be periodically monitored by the Department of Food and Drug Services Federal Ministry of Health in collaboration with other relevant stakeholders.
- iii. For the avoidance of doubt this National Drug Distribution Guidelines do not allow the operations of hawkers in the motor parks, markets, bus stops, kiosks etc.

12. SANCTIONS

Non-compliance shall attract professional disciplinary measures as provided by PCN and NAFDAC laws.

