



Nigeria Supply Chain Policy for Pharmaceuticals and Other Healthcare Products

**Department of Food and Drug Services
Federal Ministry of Health, Abuja-Nigeria**

**National Products Supply Chain Management Programme
(NPSCMP)**

FEBRUARY 2016



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Foreword

The development of Nigeria Supply Chain Policy for Pharmaceutical and other Health Products is an important step in the process of leveraging available resources to achieve positive and sustained health outcomes. This Policy comes at a crucial time, as competing needs and emergencies continue to exert downward pressures on resources available for health interventions.

The Policy aims at providing a direction as to how Nigeria can harness the strengths and address the weaknesses of the existing supply chain system through coordination and collaboration of all Supply Chain systems. It also aims at putting into place appropriate institutional, regulatory and legal frameworks that should effectively support efficient planning and utilization of Procurement and Supply Chain Management (PSM) resources at all levels of the supply chain network.

To achieve its objectives, the Policy examines the key components of the supply chain cycle and articulates key policy thrusts and actions to be taken by the stakeholders within Nigeria's supply chain environment. The policy will be applicable to all public health programmes within the country and in consonance with the government's overarching strategy; the policy will be implemented in partnership with the private sector. Implementation will also be driven by the vision of the policy, which embodies inclusiveness, collaboration and coordination.

I wish to thank everyone who has been involved in putting this Policy together. Kindly continue to work together to ensure its implementation at the various levels of the supply chain network in Nigeria.



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Preface

The Nigeria Supply Chain Policy for Pharmaceuticals and other Healthcare Products provides a succinct guide for how supply chain activities should be managed in country and coordinated across various programmes, development partners and donors. Whilst ensuring some flexibility is maintained, it provides a platform for closer collaborations in planning and implementation between the Government, its partners and all stakeholders. The policy is directed at all actors within the supply chain system, this includes governments at various levels, development partners, procurement entities, regulators, agencies and private sector participants who are involved in the supply chain of pharmaceutical and other healthcare products.

This policy provides the overarching principles, which will govern the coordination expected between the Government and other stakeholders. The principles espoused in the Policy will also underlie the planning, implementation, reporting and monitoring & evaluation of supply chains across different government tiers, programmes, development partners and other stakeholders. The Policy also outlines the governance structures for supply chain management of pharmaceuticals and other products along the tiers of governments and clarifies the roles and responsibilities of each of the stakeholders within these structures.

Broadly, the policy examines the key human resource management, financial management, monitoring & evaluation and risk management considerations for achieving the overall vision of a harmonised, responsive, and supportive supply chain system. It also defines key actions for coordinating the supply management of pharmaceuticals and other healthcare products from selection, forecasting/quantifications, supply planning through to procurement, warehousing, distribution and waste management.

Particularly, the development and Implementation of this Policy in addition to other needs will reinforce the commitment of the Federal Government of Nigeria to achieving a vibrant and effective supply chain system for pharmaceuticals and other healthcare products. To achieve inclusiveness and embrace the spirit of coordination from the onset, the development of the Policy takes into account all the systematic issues affecting the effective procurement and distribution of pharmaceuticals and other healthcare products to the end-user but ensured that a carefully planned and consultative process involving all stakeholders was adopted.

The successful implementation of the Nigeria Supply Chain Policy for Pharmaceuticals

and other Healthcare Products will require the sustained stewardship of the Government and the involvement of development partners and other stakeholders. We look forward to working together with all stakeholders to achieve measurable and sustained improvements in the supply chain of pharmaceuticals and other healthcare products.

Acknowledgements

We wish to appreciate the enthusiastic and robust support demonstrated by the Honourable Minister of Health, Professor Isaac Folorunsho Adewole, to the vision of this Policy.

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We appreciate the commitment of the Global Fund in fighting AIDS, Tuberculosis and Malaria (GFATM) and its partnership with the Federal Ministry of Health in achieving its vision of improving the efficiency and effectiveness of Nigeria's supply chain for pharmaceutical and other healthcare products. Specifically, we wish to thank the GFATM team, Patrick Githendu, Bhushan Shrestha, Shimelis Endailalu and Steve Hornsby for their input and contributions.

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Our gratitude also goes to all the other organisations for their contributions.



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- 8) National Malaria Elimination Programme (NMEP)
- 9) National AIDS/STD Control Programme (NASCP)
- 10) National Tuberculosis and Leprosy Control Programme (NTBLCP)
- 11) National Agency for the Control of AIDS (NACA)
- 12) National Primary Health Care Development Agency (NPHCDA)
- 13) Country Coordinating Mechanism (CCM)
- 14) The Nigeria Army
- 15) Howard University
- 16) Development Partners/Donor Organizations-
 - The Global Fund(TGF)
 - United Nations Children's Fund (UNICEF)
- 17) Implementing Partners:
 - Crown Agent
 - Partnership for Transforming Health Systems 2 (PATHS2)
 - Clinton Health Access Initiative (CHAI)
 - Institute of Human Virology, Nigeria (IHVN)
 - Association for Reproductive and Family Health (ARFH)
 - Society for Family Health (SFH)
 - AIDS Prevention Initiative in Nigeria (APIN)
 - Family Health International (FHI)
 - PROHEALTH
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 - Management Sciences for Health (MSH)
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 - Medical Laboratory Science Council of Nigeria
 - National Agency for Food and Drug Administration and Control(NAFDAC)
- 19) Capacity Building Services Providers
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 - Mckinsey Consortium
 - I+ Consult

Acronyms/Abbreviations

| | |
|---------|--|
| ADR | Adverse Drug Reaction |
| ARFH | Association for Reproductive and Family Health |
| BMGF | Bill and Melinda Gates Foundation |
| CCM | Country Coordinating Mechanism |
| CDC | Centre for Disease Control and Prevention |
| CMS | Central Medical Stores |
| DFDS | Department of Food and Drug Services |
| DFID | Department for International Development |
| CHAI | Clinton Health Access Initiative |
| DPS | Director of Pharmaceutical Services |
| ELMIS | Electronic Logistics Management Information System |
| EML | Essential Medicines List |
| FCMS | Federal Central Medical Stores |
| FHI 360 | Family Health International |
| FMOH | Federal Ministry of Health |
| GFATM | Global Fund to fight AIDS, Tuberculosis and Malaria |
| HMIS | Health Management Information System |
| HSCL | Health Systems Consult Limited |
| IHVN | Institute of Human Virology, Nigeria |
| JSI | John Snow, Incorporated |
| LGA | Local Government Area |
| LMCU | Logistics Management Coordinating Unit |
| MDCN | Medical and Dental Council of Nigeria |
| M and E | Monitoring and Evaluation |
| MLSCN | Medical Laboratory Science Council of Nigeria |
| NACA | National Agency for the Control of AIDS |
| NAFDAC | National Agency for Food and Drug Administration and Control |
| NANM | National Association of Nurses and Midwives |
| NASCP | National AIDS/STD Control Programme |
| NCH | National Council on Health |
| NDP | National Drug Policy |
| NMA | Nigerian Medical Association |
| NMCN | Nursing and Midwifery Council of Nigeria |
| NMEP | National Malaria Elimination Programme |
| NPHCDA | National Primary Health Care Development Agency |
| NPSCMP | National Products Supply Chain Management Programme |
| PATHS2 | Partnership for Transforming Health Systems 2 |
| PCN | Pharmacists Council of Nigeria |
| PSM | Procurement and Supply Management |
| PSM/TWG | Procurement and Supply Management Technical Working Group |
| PSN | Pharmaceutical Society of Nigeria |
| SCMS | Supply Chain Management System |
| SFH | Society for Family Health |
| SMOH | State Ministry of Health |
| STGs | Standard Treatment Guidelines |

UN United Nations
UNAID United Nations Joint Programmes on HIV/AIDS
UNFPA United Nations Population Fund
UNICEF United Nations Children's Fund
USAID United States Agency for International Development
USG United State Government
WHO World Health Organisation

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SECTION ONE: INTRODUCTION:

1.1. RATIONALE FOR THE NIGERIA SUPPLY CHAIN POLICY FOR PHARMACEUTICALS & AND OTHER HEALTHCARE PRODUCTS

The national supply chain for pharmaceuticals and other healthcare products has been plagued over several years with numerous challenges resulting mainly from inadequate funding, infrastructure and coordination. Specific challenges include weak capacity, poor supply and demand management for pharmaceutical and healthcare products, and parallel systems by different programmes and implementers. These have resulted in stock outs, damages, expiries, and other forms of wastages, which ultimately lead to sub-optimal health outcomes¹

In 2014, the National Product Supply Chain Management Programme (NPSCMP) of the Department of Food and Drug Services (DFDS) of the Federal Ministry of Health in collaboration with other stakeholders conducted an integrated assessment of the national supply chain using a common toolkit: The National Supply Chain Assessment (NSCA) Toolkit. The assessment further corroborated the challenges above.

The key issues experienced with the supply chain management of pharmaceuticals and other healthcare products in the country stem primarily from the fact that Nigeria, until now, does not have an overarching policy that provides the framework for procurement and supply chain management activities in the country.

Over time, the overwhelming need for the coordination of Nigeria's public health supply chain system has become even more pressing and it has now become imperative for the country to develop a policy that outlines the governance framework and guidelines for an integrated, effective and efficient supply chain system.

1.2. THE VISION OF THE POLICY

The vision of the policy is a National Supply Chain System that is **harmonised, responsive, and supportive**. This system will foster optimal healthcare service delivery, by making pharmaceuticals and other healthcare products available, accessible and affordable, in a transparent and expeditious manner, while underscoring effective and efficient resource utilisation.

1.3. THE GOALS AND OBJECTIVES OF THE POLICY

1.3.1. POLICY GOAL

The goal of this policy is to provide a framework for streamlining supply chain management within the public health system. The policy seeks to enhance, catalyse and sustain positive healthcare development outcomes critical to Nigeria's vision of improved healthcare and quality of life for its citizens.

¹Nigeria Country Profile Assessment- Supply Review, 2013

1.3.1. POLICY OBJECTIVES

1. Address the realities of operations and challenges in Nigeria's supply chain landscape as they are relevant to pharmaceutical and other healthcare products
2. Provide a mechanism for coordination of linked and related interventions by different parties including Government (across all levels), Partners and other stakeholders along the supply chain network
3. Clarify the roles and responsibilities of different parties in operating a vibrant and efficient supply chain management framework while ensuring clear lines of accountability
4. Promote harmony among the various policies operating on the supply chain in Nigeria, while increasing their individual and joint visibility.

1.1. SCOPE OF THE POLICY

The policy will be applicable to all public health programmes within the country, whether directly funded by government (federal, state, and LGA), or funded by any international organisation (either in part or full) or any other national organisation implementing healthcare projects/interventions within the country.

The policy will be applicable to all pharmaceuticals and other healthcare products to be procured, distributed, dispensed and used for public health programmes, irrespective of whether they are provided free of cost or for a user fee to the end users.

1.2. GUIDING PRINCIPLES, DECLARATIONS AND COMMITMENT

1.2.1. UNDERLYING PRINCIPLES AND VALUES

The underlying Principles and Values of the Nigeria Supply Chain Policy for Pharmaceuticals and other Healthcare Products are premised on clear concepts of what supply chain management entails, especially as it showcases the cumulative efforts of several organisations, in linkage and in alignment. These are:

1. Government Stewardship at all Levels
2. Integration through Alignment and Harmonisation
3. Transparency and Accountability
4. Competitiveness
5. Effectiveness and Efficiency
6. Public Sector Involvement
7. Equity
8. Community Engagement
9. Sustainability

1.2.2. DECLARATIONS AND COMMITMENT

The Federal, State and Local Governments, and all stakeholders in the public and the private sectors of the Nigerian health system hereby commit themselves to all actions

necessary to achieve the goals and objectives of the Nigeria Supply Chain Policy for Pharmaceuticals and other Healthcare Products.

- Governments at all levels and the private sector are committed to the improvement of the supply chain of Pharmaceuticals and other Healthcare Products as a very crucial element in the national vision to achieve improved health, quality of life and well being of individuals and families.
- All stakeholders and, including the Governments of the Federation, National and International Non-Governmental organisations and the organised private sector, therefore agree to work together in partnership, and deploy all necessary resources to achieve the goals of the Nigeria Supply Chain Policy for Pharmaceuticals and other Healthcare Products.
- The Government of Nigeria, its development partners and other stakeholders will develop Action Plans, Strategic Frameworks and Monitoring & Evaluation Plans for operationalising the policy.

The implementation of this policy will be in consonance with other relevant policies, strategies and guidelines, particularly the National Drug Policy.

SECTION TWO: POLICY THRUSTS

2.1. POLICY GOVERNANCE, ADMINISTRATION AND MANAGEMENT SUPPORT

The governance and administration of the Nigeria Supply Chain Policy for Pharmaceuticals and other healthcare products will initially be facilitated for the first three years when the policy should have been sufficiently implemented at all levels.

The NPSCMP shall be accountable for establishing/strengthening the required and sustainable institution capacities, systems and processes across levels, and for building the necessary collaborations with all key stakeholders across all healthcare delivery programmes. State level accountability will be vested with the Directors, Pharmaceutical Services under the State Ministry of Health.

During the said period, necessary steps shall be taken by the FMOH through the Department of Food and Drug Services to develop NPSCMP's institutional structure and capacity to effectively consolidate its roles and responsibilities, ensuring sustainability.

2.1.1. Organisation of the Supply Chain System

To ensure effective management, coordination and supervision of the supply chain of pharmaceuticals and other healthcare products across all levels in Nigeria, the National Products Supply Chain Management Programme (NPSCMP) shall harmonise supply chain of all healthcare programmes in Nigeria. This will be effected by coordinating and facilitating supply chain events with relevant ministries, departments and agencies at the federal level and the Directorates of Pharmaceutical Services (DPS) / Logistics Management Coordinating Units (LMCU) of all states.

- 2.1.1.1. All supply chain components of all health programmes across all states shall be coordinated by the NPSCMP through the state LMCUs, which will provide accountability for procurement and supply management (PSM) resources.
- 2.1.1.2. NPSCMP shall further develop a National Supply Chain Coordination Framework to be applicable to all health programmes (donor funded or otherwise).
- 2.1.1.3. The National LMCU Task Team under the supervision of the NPSCMP shall;
 1. Be made up of staff of NPSCMP, donors, health programmes, Principal Recipient (PRs), Sub-Recipient (SRs) and Implementing partners (IPs).
 2. Facilitate the establishment, strengthening and continuous support of the state LMCUs.
 3. Coordinate the collation, analyses and dissemination of data on the national health supply chain to relevant national stakeholders, to monitor the status of the supply chain system and trends on supply chain performance.
 4. Review periodic reports from state LMCUs; evaluate performance based on LMCU performance indicators; identify gaps/strengths; support LMCUs to design interventions.

1. Provide mentoring/supportive supervision to assigned state LMCU Team members.
2. Perform other tasks as defined in their TOR, which is to be developed as part of the implementation plan.

2.1.1.2. State LMCUs shall;

1. Be an established unit of the Directorate of Pharmaceutical Services of the State Ministry of Health.
2. Be made up of state Ministry of Health staff, health programme staff and representatives of donors and implementing partners and other relevant stakeholders.
3. Facilitate capacity building of service providers on procurement, supply chain management and provide mentoring and supportive supervision to facilities in the state.
4. Collect, collate, validate and disseminate LMIS and ADR reports.
5. Coordinate the development of distribution matrix for pharmaceutical and other healthcare products, its implementation and monitoring at all levels in the state.
6. Monitor the state supply chain (at LGA and facilities) to detect potential risks and recommend appropriate interventions to the States' Procurement and Supply Management Technical Working Group (PSM/TWG).
7. Act as the implementation arm and Secretariat of the state PSM/TWG.

2.1.1.3. The PSM/TWG shall be responsible for reviewing state PSM activities and proffering solutions to challenges encountered in the management of the supply chain. The membership of the PSM/TWG includes the LMCUs, health programmes, development partners and other relevant stakeholders.

2.1.1.4. The Director of Pharmaceutical Services in the State Ministry of Health shall provide oversight function on the State LMCU.

2.1.1.5. All communications relating to pharmaceuticals and healthcare products supply chain in the State shall be routed through the LMCU and the Director of Pharmaceutical Services.

2.1.1.6. The LMCU in each state shall establish sub-committees as necessary, with clear TORs and work plans.

2.1.1. Financial Management

The NPSCMP, in collaboration with health programmes, shall present and justify national needs for pharmaceuticals and other healthcare products, to facilitate budgeting, resource mobilisation and allocation.

2.1.2.1. The NPSCMP and the DPS at the states shall support the development of suitable and sustainable financing mechanisms through:

1. Facilitation of government budgetary allocation, appropriate and timely disbursement and use of funds for the supply chain of pharmaceuticals and other healthcare products.
2. Harmonisation of resources for multiple state or donor funded programmes.
3. Public/private partnerships and outsourcing of appropriate supply chain functions to competent institutions/organisations.
4. Establishment of an effective mechanism at national and state levels for the rapid mobilisation of funds for pharmaceuticals and other healthcare products required in health emergencies (e.g. epidemics and disasters).
5. Liaison with relevant MDAs and development partners to conduct price intelligence activities to guide procurement at each level to ensure that prices of pharmaceuticals and other healthcare products, and services, procured for the public sector reflect best market rates.
6. Collaboration with relevant departments/agencies, development partners and other stakeholders to establish a financial monitoring framework for supply chain for pharmaceuticals and other healthcare products.

2.1.2.1. A separate budget line shall be created to cover the costs for supply chain of pharmaceuticals and other healthcare products by governments at all levels.

2.1.2.2. To ensure uninterrupted supplies to the end-user, all health programmes shall allocate between 7.5% and 15% of the procurement value for in-country supply chain management of pharmaceuticals and other healthcare products across all levels. The NPSCMP shall develop a detailed framework for managing and allocating these funds at the different levels, in collaboration with governments and development partners.

2.1.1. Human Resources Management

To develop and maintain an adequate human resource base, government at all levels shall support the availability/engagement of required healthcare workers for supply chain management, across all levels.

2.1.3.1. The Department of Food and Drug Services (through NPSCMP)/Directorate of Pharmaceutical Services shall develop and facilitate the implementation of a Human Resource Plan for supply chain management at national and state levels.

2.1.3.2. The Federal Ministry of Health shall ensure that the NPSCMP's capacity is adequately developed to execute its mandate and responsibilities. The NPSCMP, in turn, shall facilitate the capacity development of the state LMCUs, in collaboration with development partners and other stakeholders.

2.1.3.3. The state LMCUs shall facilitate capacity development on supply chain management across the state, LGA and facility levels.

2.1.1. Logistics Management Information Systems and Processes

To ensure smooth coordination, accountability, visibility and government ownership of health programmes, all Programme Managers and key stakeholders at all levels shall work closely with and share periodic logistics information with NPSCMP and LMCUs.

- 2.1.4.1. The NPSCMP and relevant stakeholders shall harmonise all existing tools into a unified LMIS, which shall be composed of key data sets for logistics management.
- 2.1.4.2. The NPSCMP shall seek to enhance integrity and comprehensiveness of logistics data management systems, through automation into a national e-LMIS, adoption of new technologies and relevant best practices.
- 2.1.4.3. The e-LMIS shall be linked with the Health Management Information System (HMIS) to enhance decision-making.
- 2.1.4.4. All health programmes and development partners shall use the nationally endorsed paper-based and electronic LMIS platforms: the country shall maintain both paper and electronic based systems.
- 2.1.4.5. A data hub shall be established within the NPSCMP and State LMCUs to consolidate the data on pharmaceuticals and other healthcare products' procurement and supply chain, across all levels and programmes.
- 2.1.4.6. The NPSCMP, in collaboration with the health programmes and development partners, shall develop curricula and train LMCUs and relevant state-level staff on the unified LMIS tools, data analyses, use and feedback.
- 2.1.4.7. The LMCU, in collaboration with the health programmes and development partners, shall step down (to LGAs and facilities) the training on the unified LMIS tools, data analyses, use and feedback.
- 2.1.4.8. The NPSCMP and LMCUs shall ensure establishment of systems for continuous data quality improvement.
- 2.1.4.9. The NPSCMP and LMCUs shall collect, collate, analyse and disseminate logistics information for use in decision-making.

2.1.2. Monitoring and Evaluation

To ensure effective policy implementation, a systematic monitoring and evaluation plan shall be developed and executed at all levels by NPSCMP and LMCUs, in collaboration with health programmes and development partners, to track progress towards achievement of policy objectives.

2.1.5.1. The NPSCMP and LMCUs, in collaboration with health programmes and development partners, shall develop key performance indicators, measurement methodologies and responsibilities for monitoring the policy implementation.

2.1.5.2. The effectiveness of policy implementation shall be evaluated after two years, towards generating evidence for policy review on the third year of implementation.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.1. SELECTION

To ensure that the healthcare delivery system in Nigeria uses highly efficacious and cost-effective pharmaceuticals and other healthcare products that are proven to have low usage risks and efficient therapeutic values, the selection of all public sector healthcare products shall comply with stipulations and requisite procedures outlined in the National Drug Policy and other relevant national policies and guidelines.

2.2.1. NPSCMP, in collaboration with relevant regulatory agencies, shall ensure that all procuring entities comply with the stipulations and procedures for selection thus established.

2.2.2. To procure any pharmaceuticals and other healthcare products that are not in the Essential Medicine Lists and other national guidelines and lists, for any special requirements, the defined processes shall be followed as stipulated in nationally approved guidelines.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.2. QUANTIFICATION AND PROCUREMENT

2.3.1. Quantification: Forecasting and Supply Planning

To ensure that the need for the pharmaceutical and other healthcare products are met accurately and on time, in an efficient, coordinated and integrated manner, all programmes shall conduct annual forecasting exercises involving relevant stakeholders.

2.3.1.1. A five-year broad forecasting plan that reflects the needs at national and state levels shall be developed. This forecast plan shall be reviewed every two years.

There shall be an annual comprehensive and consolidated quantification report derived from individual programmes and states' quantifications. The

- 2.3.1.1. annual quantification exercises for all programmes shall be concluded not later than 3 months before the onset of the national budgeting exercise. The output of all the quantification exercises shall be made available to the LMCUs and NPSCMP for collation into state and national reports.
- 2.3.1.2. Gap analyses generated in the quantification report shall be utilised for sourcing and efficient direction of additional funding.
- 2.3.1.3. This annual quantification shall be subject to review every 6 months to assess performance and to provide an opportunity for adjustments based on consumption pattern and/or exigencies in order to prevent stock outs and/or wastages.
- 2.3.1.4. This annual quantification shall be the basis for the procurement of all pharmaceutical and other healthcare products for all programmes irrespective of source of funding. In emergencies however, procurement can be done outside this quantification after following due approval processes.

2.3.1. Procurement Methods and Processes

To promote efficient procurement of pharmaceuticals and other healthcare products through competitive and coordinated processes that promote value for money and reduce the cost of human and material resources. All pharmaceutical and other healthcare products procured by Federal, State and other government bodies will be carried out in an open, transparent, timely, equitable, and accountable manner, ensuring probity as per the Public Procurement Act 2007.

To avoid duplications and wastages, the Federal and State Ministries of Health, through their relevant technical departments, shall provide guidance and supervision for the adoption and implementation of a coordinated process for procurement of pharmaceuticals and other healthcare products by federal/state governments and donor funded programmes.

- 2.3.2.1. To improve visibility, information on the procurement or donation of pharmaceuticals and other healthcare products by government and development partners shall be made available to the Federal and State Ministries of Health, through the Department of Food and Drug Services and Directorate of Pharmaceutical Services respectively.
- 2.3.2.2. The NPSCMP shall, in collaboration with health programmes and development partners, define Key Performance Indicators (KPIs) which will be utilised in measuring supplier performance in key areas, and ensuring continuous improvement.

2.3.2. Quality Assurance

To ensure that the pharmaceuticals and other healthcare products provided to

the patient/user are safe, efficacious and of good quality, the government shall take various steps as stated in the National Drug Policy and the National Quality Assurance Policy for Medicines and other Health Products:

- 2.3.3.1. NAFDAC and other relevant national regulatory authorities in Nigeria shall monitor manufacturers' compliance with Good Manufacturing Practices (GMP). NPSCMP shall share the required information about the manufacturers and products to be procured under all programmes with the regulatory authorities.
- 2.3.3.2. Institutions recognised by relevant regulatory authorities, with appropriate personnel and equipment, will be engaged in assessing the quality of pharmaceuticals and other healthcare products, to complement the functions of the laboratories of the regulatory authorities.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.1. WAREHOUSING AND DISTRIBUTION

2.4.1. Customs and Regulatory Clearance

To ensure timely custom and regulatory clearance on all imported pharmaceuticals and other healthcare products for health programmes in the country, NPSCMP in collaboration with relevant stakeholders, shall develop a streamlined mechanism for regular clearance from the entry ports.

- 2.4.1.1. The NPSCMP shall work in conjunction with the procuring entities to oversee customs and regulatory clearances. The key responsibility of the NPSCMP is to identify and list all imports expected well in advance, in consultation with the programmes and accordingly plan and facilitate the clearances with respective government agencies.
- 2.4.1.2. NPSCMP shall advocate to the procuring entities for adequate budgetary provisions for customs and regulatory clearance of pharmaceuticals and other healthcare products.

2.4.2. Receiving Stocks and Inventory Management

To enhance efficiency, the NPSCMP shall coordinate the integration of the inventory management systems at all levels of the supply chain.

The NPSCMP, in collaboration with other relevant stakeholders, shall produce and circulate guidelines on recommended good practices for receipts and inventory control procedures for all levels (warehouses and facilities).

2.4.2.1. The NPSCMP/LMCUs shall review and improve relevant record-keeping to ensure that required data are accurate and readily available.

2.4.2.2. The Federal/State Medical Stores and NPSCMP/LMCUs in partnership with the health programmes shall consolidate data on procurement to facilitate redistribution/transfer between programmes/locations to adjust stock situations as necessary.

2.4.2.3. Upon receipt of pharmaceuticals and other healthcare products, all warehouse and facility managers shall inspect the products in line with the defined quality assurance standards and specifications.

2.4.1. Warehouse/Stores Management

To ensure proper warehousing and stores management of pharmaceuticals and other healthcare products in accordance with global standards and national best practices, Federal and State governments shall develop and execute long term plans for warehousing at national, zonal, state and other levels, based on the procurement and inventory forecasts and plans developed by NPSCMP and LMCUs.

2.4.3.1. The NPSCMP/LMCUs, in collaboration with other relevant stakeholders, shall carry out assessments of existing storage facilities in the public sector to determine status, additional requirements and needed improvements.

2.4.3.2. The NPSCMP/LMCUs will lead the advocacy team, which comprises the Federal/State Medical Stores and other relevant stakeholders, for assessing and planning for upgrading/renovation of warehousing and distribution infrastructure at relevant levels.

2.4.3.3. NPSCMP shall also advocate for adequate budgetary provisions for effective warehouse management and quality assurance. This budget shall be incorporated into the annual and five year forecast plans.

2.4.3.4. Governments at all levels shall encourage private sector participation as appropriate to improve efficiency and sustainability.

2.4.3.5. In accordance with best practices, NPSCMP/LMCUs shall develop, publish manuals and guidelines for warehouse management, and track compliance to ensure proper warehousing.

2.4.2. Distribution and Transportation

NPSCMP/LMCUs shall coordinate the processes of establishing and maintaining an

effective and efficient distribution system that ensures the constant availability of all required pharmaceuticals and other healthcare products for all programmes, throughout the country.

2.4.4.1. NPSCMP/LMCUs shall advocate for adequate budgetary provisions for distribution and transportation services. This budget shall be incorporated into the annual and five year forecast plans.

2.4.4.2. In accordance with best practices, NPSCMP/LMCUs shall develop and publish manuals and guidelines for distribution and transportation, and track compliance.

2.4.4.3. Governments at all levels shall encourage private sector participation as appropriate to improve efficiency and sustainability.

2.4.1. Waste Management

To protect the public from potential harm that may result from the unsafe or ineffective disposal of expired or otherwise unusable pharmaceuticals and other healthcare products, Federal and State Ministries of Health, relevant Regulatory Agencies and all stakeholders at every level in the supply chain shall promote proper waste management in line with global and national best practices.

2.4.5.1. NPSCMP/LMCUs shall be involved in the implementation of all available guidelines on waste management.

2.4.5.2. NPSCMP/LMCUs shall collaborate with NAFDAC and other relevant agencies for the development and institution of training programmes for all those who will be involved in the handling and processing wastes from pharmaceuticals and other healthcare products.

2.4.5.3. Department of Food and Drug Services/State Directorates of Pharmaceutical Services and its development partners shall advocate for adequate budgetary provisions for the management of wastes from pharmaceuticals and other healthcare products.

2.5. RISK MANAGEMENT

To ensure effective identification, mitigation and response to potential risks to all stages of supply chain management at all levels, the Department of Food and Drug Services, through the NPSCMP along with relevant stakeholders and technical partners, shall support the development and application of a holistic risk management plan.

- 2.5.1. NPSCMP/LMCUs, along with other relevant stakeholders, will develop a Country Risk Management plan with control and response mechanisms. This shall be derived from a risk analysis of each component of the PSM system, in line with the provisions of this policy.
- 2.5.2. The DFDS and NPSCMP shall identify/engage risk management experts to support risk analysis and development of the Country Risk Management Plan.
- 2.5.3. The risk analysis and control mechanisms shall be reviewed annually to reflect the dynamic nature of the PSM environment.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.1. RATIONAL USE

To ensure rational use of pharmaceuticals and other healthcare products, the Department of Food and Drug will coordinate with all relevant stakeholders for the promotion, implementation and monitoring of the National Drug Policy and extant policies/guidelines.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.2. OPERATIONS RESEARCH AND KNOWLEDGE MANAGEMENT

To ensure the use of evidence for decision-making and continuous improvement of the supply chain system, the Department of Food and Drug Services through NPSCMP shall develop and facilitate implementation of an operations research and knowledge management plan. This will be in collaboration with the Department of Planning, Research and Statistics, FMOH and other relevant stakeholders at all levels.

- 2.6.1. The operations research and knowledge management plan shall include provisions for south-south and north-south exchange, capacity building for research at all levels, and dissemination of research findings.
- 2.6.2. Government, development partners and implementing partners shall make available adequate budgetary provisions for operations research and knowledge management, as prescribed by African Health Ministers at the high-level ministerial meeting on Health Research in Africa, held in 2006 and agreed to by the National Council on Health.

DFDS shall promote cooperation and collaboration between Federal and State Ministries of Health, LGA health authorities and Universities, communities, Civil

2.6.1. Society Organisations (CSOs), Organised Private Sector (OPS), National Institute for Medical Research (NIMR), National Institute for Pharmaceutical Research and Development (NIPRD), development partners and other sectors, for supply chain research and utilisation of findings.

2.6.2. Public and non-public health research organisations shall be contracted to conduct research to ensure quality and wide acceptance of findings.

Government, development partners and other stakeholders shall adhere to the norms and standards prescribed in this policy. Programme reporting and information sharing will be harmonised, irrespective of the specific programmatic monitoring plans.

2.1. POLICY REVISION AND UPDATE

An independent policy analysis exercise shall be carried out after 3 years of implementation of this policy, and based on the findings, the policy shall be reviewed for a further period of 3 years or longer.

ANNEXES

Annex 1: References

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Annex 2: Referenced National Policies/Guidelines-Supply Chain-Related

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Annex 3: Glossary

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| Adverse Drug Reaction | A response to a medicine which is noxious and unwanted, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of diseases or for the modification of physiological functions |
| Commodity Security | Exists when every person is able to choose, obtain, and use appropriate |
| Community-based distribution | Delivery of healthcare products to people in the community through community health workers (CHWs) |
| Consumption, Dispensed, Dispensed-to-user, Usage data | Data on the quantity of goods actually given to or used by customers. |
| Essential Drug (Medicines) List | A defined list of drugs/medicines focused on satisfying the priority healthcare needs of the population. Criteria for selection include evidence of efficacy and safety, and comparative cost-effectiveness. |
| Forecasting | Management function that estimates the quantities of products required by an organisational entity to respond to needs during a specific period of time in the future. |
| Generic name | Approved non-proprietary name of a (pharmaceutical) products. In most cases, this is the International Non-proprietary Name (INN) as published by WHO. |
| Healthcare products | Includes pharmaceutical products, diagnostic technologies and supplies, bed nets, insecticides, aerial sprays against mosquitoes, other products for prevention, laboratory equipment, and supportive products (e.g. microscopes and reagents). |
| Inventory control | Operate manual or automated inventory control system; provide directions for moving supplies to/from storage; provide information to management on receipts, issues, and stock balances; reconcile inventories to book or automated records; coordinate physical inventories. |
| Lead time | Time between when products are ordered and when they are received and available for use. |
| Level | The specific location in the health system hierarchy, central, region, district, or service delivery point |
| Logistics Management Information System (LMIS) | The coordinated recording, organising, and reporting of logistics data (essential data items). The information gathered is used to improve product availability by improving the quality of management decisions about supplies. |
| Monitoring | Checking on a regular basis to ensure that planned programme activities are carried out. |
| National Regulatory Authority | An independent government organisation (or agency authorised by government) responsible for enforcing legislation to ensure that medicines and biological products marketed in the country are safe, effective, and complying with quality standards, and handled appropriately in the distribution chain. |

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| North-South Exchange | A term historically used by policymakers and academics to describe the exchange of resources, technology, and knowledge between developing countries and their more developed counterparts |
| Pharmaceuticals | Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. |
| Pharmacovigilance | This is the detection, assessment, and prevention of adverse reactions to medicines, and includes monitoring and providing early warnings of adverse effects due to medicines. |
| Procuring Entity | An appointed public body engaged and responsible for the purchasing and awarding contracts for goods, services and works. |
| Procurement and Supply Management | Refers to all management activities required for getting sufficient healthcare products of assured quality, procured at the lowest price and in accordance with national and international laws to the end user in a reliable and timely fashion |
| Product | Combining the management of some or all logistics functions for different commodity categories. |
| Public Health Programme | Refers to all organised measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases. (WHO) |
| Quality Assurance | This is the management of activities that are required in order to ensure that pharmaceutical products that the patients are taking are safe, effective and acceptable |
| Quantification | Quantification involves the determination of the number of treatments expected to be needed during a defined period. It is usually undertaken at national level based on information from all geographical areas and all levels of the healthcare system. |
| Rational Use of Medicines | This is when patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. |
| Redistribution | The transfer of commodity from a facility (having excess) to another facility in need using transfer form to ensure proper documentation of the process. |
| South-South Exchange | A term historically used by policymakers and academics to describe the exchange of resources, technology, and knowledge between developing countries, also known as countries of the global South |
| Standard Operating Procedures (SOPs) | A series of guidelines and procedures that are developed to define how tasks and activities are to be performed to ensure the safe, effective, efficient, and consistent operation of an organisation or entity. |
| Standard Treatment Guidelines (STGs) | A series of disease-specific evidence based clinical treatment, drug management, and referral protocols whose primary purpose is to improve the quality and cost effectiveness of medical care services through harmonised knowledge and practices. |

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| Stock | Used interchangeably with commodities, goods, products, supplies, and other terms to refer to all the items that flow through a logistics system. |
| Storage | This is the safekeeping of pharmaceuticals and other healthcare products to avoid damage, expiry, and theft. |
| Supervision | The process of ensuring that personnel have the knowledge and skills required to carry out their responsibilities effectively and to provide immediate on-the-job training and support, as needed. |
| Supply Chain | Refers to the systems and organisations that are involved in all activities that move supplies from the source to the end users. |
| Supply chain integration | A performance-improving approach that develops seamless linkages between the various staff, levels, and functions within a given supply chain in order to optimise customer service. |