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FEDERAL MINISTRY OF HEALTH
DEPARTMENT OF FOOD AND DRUG SERVICES

NIGERIA VACCINE POLICY

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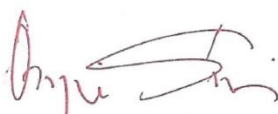
Foreword

The newly developed Nigeria Vaccine Policy is coming at a time when the global community is confronted with the challenge of developing a vaccine to combat the Coronavirus pandemic that has devastated the entire world. The driving force of the Nigeria Vaccine Policy is to encourage local production of vaccines and to ensure self-sufficiency in vaccines availability which will further boost the already existing National Immunisation Policy. The commitment of the Federal Government towards this venture cannot be overemphasised as evident in the steps taken by the government in combating vaccine preventable diseases (VPD) through the National Immunisation Programmes and health surveillance systems for re-emerging epidemic and pandemic diseases. It is imperative for Nigeria to urgently commence the manufacture of vaccines for the use of her citizens.

The Policy was developed by local and international experts in vaccine Research and Development (R and D), Policy and administration under the leadership and guidance of the FMOH and in due deference to the recommendations from WHO. Technocrats and consultants who developed the Nigeria Vaccine Policy made concerted efforts to make the Policy concise and simple with robust targets and implementation strategies to achieve the goal and objectives of this policy. In undertaking this task, they were guided primarily by considerations for the safety and wellbeing of the Nigerian population and the desired efficacy of vaccines.

Government commitment and political will is focused on making our country a hub for the production of good quality, safe, affordable and efficacious vaccines.

I wish to express my profound gratitude to the group of experts from the government, private sector, civil societies and development partners who generously provided their expertise and time in developing this policy. I enlist the support and commitment of all stakeholders in ensuring the successful implementation of this policy.



Dr. Osagie E. Ehanire
Honourable Minister of Health
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Preface

One of the setbacks of the Nigerian immunisation drive has been the absence of a Nigeria Vaccine Policy. As a result of the Coronavirus pandemic, the Federal Government felt the need to develop a vaccine policy to achieve availability and self-sufficiency of vaccines. Hence, the Ministry through its Department of Food and Drug Services mobilised a team of experts to develop the Policy.

Today, Nigeria has a Policy on Vaccines which should drive all efforts that will lead to the availability and self-sufficiency of vaccine requirements. The Policy provides for the setup of governing structures to effectively monitor the implementation of the Policy.

As a leading African Nation, it is in our interest and that of the continent to pursue innovative developments as visibly demonstrated by the speed and manner the new COVID vaccines were developed in other parts of the world. Luckily, the response by Nigerian Scientists towards local development of the COVID vaccines suggests that the country can compete favourably with others if given the necessary support.

The team that worked on the Policy project deserves every accolade for their spirit of commitment. They worked tirelessly with very little motivation. We wish to specifically thank WHO for their support in the development of this Policy.



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We sincerely thank the Technical Team who worked tirelessly to develop the Nigeria Vaccine Policy despite the enormous challenges posed by COVID -19 Pandemic. We are equally grateful to the Department of Food and Drug Services, Drug and Vaccine Development Division who coordinated the process.

Our appreciation also goes to the Honourable Minister of Health, Dr. E. Osagie Ehanire for his leadership. We are indebted to the Honourable Minister of State for Health, Dr. A. Olorunnimbe Mamora, and the former Permanent Secretary of the FMOH, A. M. Abdullahi for their guidance and commitment to the success of this process.

Finally, we wish to express our profound gratitude, to the World Health Organisation (WHO), Development Partners and the Consultants who demonstrated high level commitment and expertise in guiding the process to its successful conclusion.

It is noteworthy to state that the Nigeria Vaccine Policy is a product of an extensive consultative process that involved all stakeholders in the health sector. We are therefore grateful to all.



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Executive Summary

Vaccines are recognised globally for their importance in the reduction of vaccine preventable diseases to improve the quality of life of the entire population. The importance of vaccines has been further demonstrated with the COVID-19 outbreak with countries scrambling to produce vaccines to combat the effect of the pandemic amongst their citizens.

The purpose of this Vaccine Policy is to address the goal and objectives of achieving availability, self-sufficiency and vaccine security in the country. It is hoped that the development of this Policy will complement the already existing Immunisation Policy and provide the platform for the amelioration of vaccine-preventable diseases in Nigeria.

Highlights of the Policy include: its vision, mission, goal, objectives, targets and implementation strategies for achieving local vaccine production and ownership of the vaccine supply chain management processes towards vaccine availability and security in the country.

To achieve these, the Policy needs to be implemented and monitored hence the Policy provides for the establishment of appropriate governing structures to oversee the implementation process. The governing council and its various structures will pursue the achievement of the goal and objectives of the Policy. They will mobilise resources from the governments across all levels, individuals, the international communities, donor agencies.

Other critical areas include the resuscitation of local production of vaccines, intensification of research and development and strengthening of the legislature and regulatory agencies to support the quality and safety of vaccines in Nigeria. It is recommended that all stakeholders responsible for implementing this policy should work collaboratively to ensure the goal and objectives are met.

Acronyms/Abbreviations

ADR	Adverse Drug Reactions
AEFI	Adverse Effects Following Immunisation
ARC	African Resource Centre
BVNL	Bio-Vaccines Nigeria Limited
CSOs	Civil Society Organisations
DHIS	District Health Information System
DPs	Development Partners
DSS	Department of State Services
FCT	Federal Capital Territory
FDI	Foreign Direct Investment
FGoN	Federal Government of Nigeria
FMoH	Federal Ministry of Health
FMoF	Federal Ministry of Finance
FMoTI	Federal Ministry of Trade and Investment
GAVI	Global Alliance on Vaccines and Immunisation
GBT	Global Benchmarking Team
GoN	Government of Nigeria
GVAP	Global Vaccine Action Plan
HMIS	Health Management Information System
HPRS	Health Planning, Research and Statistics
ICT	Information and Communication Technology
IPs	International Partners
IRB	Institutional Review Board
LDC	Least Developed Countries
LGA	Local Government Authority
LGAs	Local Government Areas
LIC	Low Income Country
LSS	Life Saving Skills

M&E	Monitoring and Evaluation
MDAs	Ministries, Departments, and Agencies
MDCN	Medical and Dental Council of Nigeria
MDGs	Millennium Development Goals
MICS	Multiple Indicator Cluster Survey
ML3	Maturity Level 3
MMEIG	Maternal Mortality Estimation Inter-Agency Group
MNCH	Maternal, New-born, and Child Health
MoFA	Ministry of Foreign Affairs
MSS	Midwives Services Scheme
NABDA	National Biotechnology Development Agency
NAFDAC	National Agency for Food and Drug Administration and Control
NARHS	National AIDS and Reproductive Health Survey
NCDs	Non-Communicable Diseases
NCH	National Council on Health
NDHS	National Demographic and Health Survey
NGITAG	Nigeria Immunisation Technical Advisory Group
NHIS	National Health Insurance Scheme
NHLMIS	National Health Logistics Management Information System
NHP	National Health Profiles
NNMDA	Nigeria Natural Medicine Development Agency
NPHCDA	National Primary Health Care Development Agency
NRA	National Regulatory Authority
NVRI	National Veterinary Research Institute
NSHDP	National Strategic Health Development Plan
OOPE	Out-of-Pocket Expenditure
OP	Operational Plan
PATHS2	Partnership for Transforming Health Systems-2
PEBEC	Presidential Enabling Business Environmental Council
PHC	Primary Health Care

PHCUOR	Primary Health Care Under One Roof
PMS	Post Marketing Surveillance
PPP	Public-Private Partnership
SDGs	Sustainable Development Goals
SERVICOM	Service Compact
SHDP	Strategic Health Development Plan
SPHCDA	State Primary Health Care Development Agency
SMoH	State Ministry of Health
SON	Standards Organisation of Nigeria
SRH	Sexual and Reproductive Health
SSHDP	State Strategic Health Development Plan
STIs	Sexually Transmitted Infections
TA	Transformation Agenda
TB	Tuberculosis
TBL	Tuberculosis and Leprosy
TRIPS	Trade Related Intellectual Property Rights
TWG	Technical Working Group
VAD	Vitamin A Deficiency
VCT	Voluntary Counselling and Testing
VGC	Vaccine Governing Council
VPD	Vaccine-Preventable Disease
VVF	Vesico-vaginal Fistula
VVM	Vaccine Vial Monitor
UNFPA	United Nations Population Fund
UNIAEG	United Nations Inter-Agency Expert Group
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHA	World Health Assembly
WHO	World Health Organisation
WTO	World Trade Organisation

SECTION ONE: INTRODUCTION

1.1. BACKGROUND

Vaccines are biological products that can be used to safely induce an immune response to confer protection against infection and/or disease on subsequent exposure to a specific pathogen. It is the most cost-effective intervention in public health and has created a significant impact on the reduction of diseases globally. The advancement made in the eradication of smallpox virus (1966-1980) gave credence to the fact that vaccines have a remarkable effect on disease elimination and eradication.

Nigeria is one of the developing countries that face a "double burden of diseases" with a high prevalence of communicable diseases and non-communicable diseases.

Based on forecasts and estimates from the latest statistics derived from the United Nations; Nigeria's population is expected to have reached 206 million by 2020 and 264 million by 2030-surpassing the estimated 300 million mark for 2036. The increase in population will heighten the need for more vaccines.

The Global Vaccine Action Plan (GVAP) provides WHO member countries with a robust immunisation plan and monitoring framework; in August 2020 the WHA approved the IA2030 as a post GVAP strategic plan for immunisation. The plan needs critical assessment especially in the face of Nigeria's transition out of GAVI support for immunisation programme. This is to ensure that Nigeria continues to have access to safe and affordable vaccines.

The FGoN and GAVI re-negotiated the co-financing arrangement for vaccines with a view to ensuring a smooth transition to full country ownership. This led to the signing of the Nigeria Strategy for Immunisation and PHC System Strengthening (NSIPSS) between the FGoN and GAVI. NSIPSS serves as the basis for the extension of GAVI support to 2028. An Accountability Framework (AF) was developed to guide the implementation of the NSIPSS. The most salient aspect of the AF is that the FGoN must provide incremental funds from budgetary sources every year culminating in 100% funding for vaccine procurement by 2028.

Attempts have been made in Nigeria in the past to ensure the local production of vaccines and also to protect the integrity of vaccines within the country and in the sub-region. Between 1940 and 1991, the vaccine production unit in Yaba, Lagos was active and manufactured vaccines against Smallpox, Rabies and Yellow Fever for both local use and exports to neighbouring countries in the West African sub-region. However, the facility has remained inactive since 1991. Hence, Nigeria has relied on UNICEF Supply division for vaccine procurement through procurement services MoU between the Federal government of Nigeria and UNICEF. Funding for procurement of vaccines has been through a co-financing mechanism between FGoN and GAVI. Nigeria would have transitioned out of GAVI support but a re-negotiation took place to extend the support to 2028.

The way forward for Nigeria in the present circumstances is for the country to chart its path towards its vaccine security. The development of a Nigeria Vaccine Policy is a key step towards realising this objective.

1.2. RATIONALE FOR THE NIGERIA VACCINE POLICY

This is the first attempt by the Nigerian government to produce a Nigeria Vaccine Policy (NVP). Before now the country operated a National Immunisation Policy that ensured Nigeria took appropriate actions in line with Global trends to minimise vaccine preventable deaths and to eliminate vaccine preventable diseases such as Poliomyelitis. It is expected that the Nigeria Vaccine

Policy (NVP) will enable the country to achieve self-sufficiency in local vaccine production and assume ownership of vaccines availability and security.

There is a need to strengthen the development, local production, efficient and rational use of vaccines in Nigeria to achieve vaccine security. The Policy also recognises and builds on the existing National Health Policy, other relevant Policies and Acts of Parliament. It shall provide a clear organisational and managerial structure with the appropriate mandates to effectively offer stewardship, coordination and management of the Policy across all levels of the national healthcare system. It shall also take into consideration all the challenges that tend to impede the implementation of sound Policies by making appropriate suggestions on how to mitigate such challenges.

The Nigeria Vaccine Policy will create and regulate a supportive environment for access and use of vaccines to set the requirements and mandates for protection of citizens from internal and external harm. Additionally, it reduces the barriers and creates opportunities that influence the choices made by stakeholders to impact health.

A Nigeria Vaccine Policy will also reflect new realities and trends, including the provisions enumerated in the Universal Health Coverage (UHC), Sustainable Development Goals (SDGs), National Health Act 2014, National Health Policy 2016, and PHC Under One Roof (PHCUOR). This will further ensure the development of strategies that will respond adequately to global health trends for emerging diseases and pandemic that impact on the Nigerian health system.

Most importantly, the ongoing global efforts to develop COVID-19 vaccines further provide a strong justification for enacting a Nigeria Vaccine Policy in the interest of achieving Vaccine Security in Nigeria.

1.3. VISION STATEMENT

To achieve vaccines availability and self - sufficiency for the mitigation of vaccines preventable diseases as a functional component of the Universal Health Coverage in Nigeria.

1.4. MISSION STATEMENT

To establish governing structures for effective implementation of the vaccine policy to achieve local production of vaccines and assume ownership of vaccines supply chain management employing modern technologies and human resources towards the attainment of vaccines availability and self-sufficiency.

1.5. THE GOAL AND OBJECTIVES OF THE POLICY

1.5.1. POLICY GOAL

To achieve vaccines availability and self-sufficiency in Nigeria through local vaccines production and ownership of vaccines supply chain management in the country.

1.5.2. POLICY OBJECTIVES

- To establish appropriate and sustainable structures for effective implementation of the Nigeria Vaccine Policy towards achieving local vaccines production and ownership
- To achieve local production and uptake of vaccines that meet all global quality standards and ensure vaccines security in line with the requirements of the Sustainable Development Goals and Universal Health Coverage

- To achieve ownership of all vaccines supply chain management processes in order to improve accessibility of vaccines to optimise utilisation
- To support research and development of existing and new vaccines using innovative technologies
- To engender sustainable access to funding for local vaccines production and availability and for research and development using innovative technologies
- To strengthen bilateral/multilateral cooperation and to encourage public/private partnerships for the local production of vaccines and vaccines research and development.

1.6. POLICY GUIDING PRINCIPLES, DECLARATIONS AND COMMITMENT

1.6.1. UNDERLYING PRINCIPLES AND VALUES

Country Ownership - Nigeria has the responsibility for providing affordable vaccines of good quality and efficacy for its citizens.

Shared Responsibility and Partnership – Use of vaccines against preventable diseases is a global responsibility that transcends across different sectors, government and people.

Equity – Equitable access to vaccines is a core component of the ‘Right to Health’ for every Nigerian in line with the provisions of the Universal Health Coverage (UHC).

Integration – To ensure the effectiveness of the NVP, all existing health system structures should work collaboratively to achieve UHC leveraging on the PHC which is the foundation of the national health system.

Sustainability – This shall be achieved through effective monitoring, evaluation and application of lessons learned to address bottlenecks and ensure adherence to the goal and objectives of the NVP.

Innovation – Continuous improvement shall be imbibed across all thematic areas of the vaccine policy.

Ethics- The highest level of ethics shall be applied in every aspect of the NVP leveraging on professional principles through the observance of Human Rights and dignity while assuring confidentiality and respect of different cultural orientations.

1.6.2. DECLARATIONS AND COMMITMENTS

This policy guides key stakeholders regarding their responsibilities relating to vaccines security and conformity with local and international best practices in demonstrating efficiency in the development of vaccines.

1. SECTION TWO: AN OVERVIEW OF VACCINES IN NIGERIA

1.1. SIGNIFICANCE OF VACCINES IN PUBLIC HEALTH

Vaccines are significant in public health and have both economic and social impacts. Vaccines are proven agents for controlling and eliminating life-threatening infectious diseases by reducing morbidity, mortality and disease complications. The use of vaccines could also protect the unvaccinated population through herd protection or source drying. Herd protection provides an indirect effect or protection of the unvaccinated individuals in the community when a sufficient proportion of the group use efficacious vaccines which reduce diseases among the unimmunised. On

the other hand, source drying applies where targeted vaccination of sub-group identified as the reservoir of infection protects the whole population. Vaccines also contribute to the prevention of the development of anti-microbial resistance by reducing the need for antimicrobials.

2. SECTION THREE: POLICY THRUSTS

3.1. POLICY THRUSTS

3.1.1. Establishment of Leadership and Governance Structures in order to guide the implementation of the Nigeria Vaccine Policy by pursuing:

- Endorsements
- Dissemination and Socialisation of policy document
- Implementation plan to guide the roll-out
- Roll-out

Target: March 2022

3.1.2. Enhance Regulatory Capability for Vaccines Handling

Target: December 2022

3.1.3. Access to vaccines (Material sourcing, importation, manufacturing, distribution and use) through:

- Ownership of vaccines supply chain management processes
- Resuscitation of Local Vaccines Manufacture (LVM)

Target: December 2023

3.1.4. Emergency preparedness

- Reserve funds for procurement
- Programmatic readiness for emergency response
- Local vaccines manufacturing capability

Target: December 2021

3.1.5. Cold chain: Investment to harness appropriate technology at all levels

Target: December. 2022

3.1.6. Hesitancy/Resistance: Identify, engage and empower Opinion Leaders (LOL) in the advocacy effort

Target: December 2022

3.1.7. Vaccines Information: This will focus on standardised means of collecting, processing, analysing and sharing information on vaccines by:

- Accessing information on a global scale
- Standardising means of collecting and sharing information e.g.
 - Inventory information
 - Equipment information
 - VVM information

Target- December 2023

3.1.8. Vaccines Financing: Ensuring sustainable vaccines financing through:

- Special budgetary allocation by governments at all levels
- Leveraging on support through Corporate Social Responsibility (CSR)

Target – December 2024

3.1.9. Human Resources for implementing the Nigeria Vaccine Policy: This is critical and therefore efforts shall be made to:

- Identify roles and competencies required
- Cadres of human resources needed to deliver the Policy
- Establish a pipeline of professionals that will operate in the vaccines space

Target – December 2023

3.1.7. Technology Innovation and Intellectual Properties: Shall remain the mainstay of the Policy and therefore government shall:

- Draw on global innovative technologies
- Take advantage of the provisions of the World Trade Organisation (WTO) Trade Related Intellectual Property Rights (TRIPS) flexibilities/waivers to support local manufacture of vaccines

Target – December 2023.

3.2. TARGETS

The following shall be the targets of the Nigeria Vaccine Policy:

1. Establishment of a Vaccine Policy Governing Council or Committee by the Government of Nigeria. This should comprise of eminent Scientists, Immunologists, Vaccinologists, Administrators, Financial Experts and high-level relevant government officials to drive the implementation of the Nigerian Vaccine Policy. This Body should be under the direct supervision of the Honourable Minister for Health with the Department of Food and Drug Services of the Federal Ministry of Health serving as the Secretariat.

The Council shall meet periodically to review the progress of Policy implementation and the reports from its TWGs.

The Council shall advise the Federal Government through the Federal Ministry of Health on the need to review any section of the Policy in order to improve the process of its implementation.

Target: March 2022.

2. Establishment by the Governing Council of Technical Working Groups to handle critical issues such as:
 - i) Resource Mobilisation and advocacy
 - ii) Local Vaccines Production
 - iii) Ownership of Vaccines Procurement and Distribution
 - iv) Public Private Partnerships and Collaborations
 - v) Vaccines Research and Development
 - vi) Technology
 - vii) Intellectual Property Rights

Target: March 2022

3. Establishment of Vaccines Council Secretariat in the Department of Food and Drug Services and appointment of Desk Officer to oversee the running of the Nigeria Vaccine Policy Secretariat
 - a. The Head of the Secretariat shall not be below the rank of a Assistant Director in the Federal Service

Target: March 2022 and December 2021

4. Commencement of Local Vaccines Production at three levels, namely:

- i. Implementation of existing PPP MOU-JVA for the local production of some of the vaccines required in Nigeria through Bio-vVaccines Nigeria Limited and National and International collaboration with Key Players and manufacturers using the appropriate technologies in modern vaccines production and their engagement in local production of vaccines as may be required in Nigeria (technology transfer)

Target: 2026

- ii. Mobilising and engaging Nigerian Experts and Scientists to be part of the Local Vaccines production, Research, Development and Vaccines Security Architecture

Target: 2026

- iii. Ownership of Vaccines Procurement and Distribution in anticipation of the withdrawal of the main suppliers of vaccines in Nigeria, namely: GAVI/UNICEF

Target: 2026

- iv. Government to sponsor Intensified Vaccines Research and Development across board leveraging on local and global collaborations and partnerships

Target: 2026

- v. Government should take advantage of the World Trade Organisation (TRIPS) Flexibilities/Waivers for Low Income Countries (LICs) to manufacture Vaccines that are under Patents including the Covid-19 vaccines in the interest of Nigeria's Public Health.

Target: 2026

3.3. STRATEGIES

1. Inauguration of Vaccine Governing Council and its Technical Working Groups
2. Appointment of Desk Officer and Vaccines Secretariat in the Department of Food and Drug Services
3. Establishment of a dedicated and sustainable Nigeria Vaccines Security Fund by governments at all levels and commencement of aggressive resource mobilisation by the Vaccine Governing Council/TWG
4. GoN shall honour existing agreements for vaccine financing to provide funds for procuring vaccines, until local vaccine production can take care of our needs
5. GoN shall resuscitate vaccine production through joint venture initiatives, such as the existing Bio-Vaccines project and engender bilateral agreements for local production of vaccines and transfer of technology
6. GoN shall continue to explore and support opportunities to increase the number of local vaccine manufacturing companies in the country
7. Mobilisation of local and international experts including Nigerians in Diaspora in support of the implementation of the Nigeria Vaccine Policy
8. Provision of incentives to attract Foreign Direct Investments for local development and production of vaccines
9. Strengthening of existing legislation to support the implementation of the Vaccine Policy to ensure patronage of locally produced vaccines
10. Strengthening of the Drug Regulatory Agencies to effectively support the implementation of the Vaccine Policy
11. Strengthening processes of Supply Chain Management to improve vaccines selection, quantification, procurement, local production, storage, distribution and use
12. Engage in advocacy to whittle vaccines hesitancy/resistance and to improve vaccines uptake in the country
13. Put in place mechanisms to minimise vaccines wastage and improve disposal of vaccines waste
14. Fund and support Vaccines Research and Development.

3. SECTION FOUR: RESUSCITATION OF LOCAL VACCINES PRODUCTION

- 3.1. The goal of the Policy is to achieve vaccines availability and sufficiency and consequently vaccines security in the country
- 3.2. Sustained local production of vaccines shall remain the Cruz of the Nigeria Vaccine Policy.

4. SECTION FIVE: FOREIGN DIRECT INVESTMENTS

- 4.1. Government shall provide the conducive environment to encourage Foreign Direct Investments (FDI) into the vaccines manufacturing space in Nigeria
- 4.2. Special attention shall be given to investments in the area of vaccines research and development and production
- 4.3. Tax incentives and holidays shall be employed as well as other investment friendly approaches and enabling environment.

5. SECTION SIX: LEGISLATION

- 5.1. Current legislation on regulation of vaccines in the country should be strengthened and enforced.

6. SECTION SEVEN: LICENSURE

- 6.1. Licensure of Vaccines: Licensure of vaccines is a fundamental requirement for its use in Nigeria. Licensure of vaccines manufacture, marketing and use in Nigeria is a shared responsibility of NAFDAC and PCN.

7. SECTION EIGHT: VACCINES SUPPLY CHAIN MANAGEMENT

The term supply chain management is used to signify all aspects of raw material sourcing and development, manufacturing/production, procurement, distribution and use. The success of SCM hinges on adequate information flow. In order to achieve vaccines availability and security the organs responsible for Vaccines Supply Chain Management shall undertake the following:

- 7.1. Vaccines Selection, Forecasting, Quantification, Procurement and Use
 - 7.1.1. Vaccines Selection
 - i. Vaccines selection for inclusion in National Health Programme is influenced by several factors
 - ii. Selection shall be based on priority needs of the country and the following considerations as highlighted by the NGITAG shall guide such selection:
 - 7.1.1.1. Consideration of Needs

The following shall be the basis for the consideration of needs:

- Types and prevalence of specific vaccines-preventable diseases within the country, or in countries with very close proximity to Nigeria. Disease burden (incidence/prevalence, the absolute number of morbidity/mortality, epidemic/pandemic potential): The decision to include a vaccine should be guided by the disease burden in Nigeria and supporting information should be derived through strong surveillance system within the country. The data from investigator-initiated researches, modelling studies and relevant data from countries with either geographical proximity or similar demography may also be used for these decision-making processes
- Safety and efficacy of the vaccines - use of vaccines that have proven effective and safe against target diseases should be prioritised except where all vaccines available for such disease conditions are still in clinical trial phases but have been approved for emergency use by relevant local and global authorities in cases of emerging diseases while implementing appropriate Pharmacovigilance and Post Market surveillance protocols with minimal adverse effect
- Dosage formulation and packaging: Vaccines formulations could either be injectable or oral. The composition could be monovalent or combination products. Less complex formulations of vaccine variants are preferred especially with regards to administration and ease of use. However, Combination Vaccines require fewer delivery devices (e.g. syringes) and less cold storage space, but they can be less flexible
- Lyophilized vs. liquid products: Lyophilized products require diluents and reconstitution devices. They also require extra cold storage space at the peripheral level because the diluents need refrigeration before reconstitution. Additionally, some lyophilized vaccines also result in higher wastage rates due to the need to discard the vaccines within six hours after being reconstituted. Lastly, they are associated with the risk of causing adverse events if an incorrect diluent is used. On the other hand, lyophilized vaccines are often more heat stable than comparable liquid vaccines
- Number of required doses: Vaccines with less frequency of administration are preferred for convenience, cost-effectiveness and to improve compliance
- Temperature sensitivity: All vaccines have specific guidelines due to their peculiarities; vaccines that are more stable in tropical regions and can better withstand fluctuations in storage temperature conditions are preferred in Nigeria where applicable.

7.2. Vaccine Financing

Explore Public Private Partnerships in the areas of research and development, procurement and supply management. In addition, the country should consider bilateral and multilateral cooperation in vaccines financing. Internal resources and incentives for local production should be harnessed to create an enabling environment for local vaccines manufacturers.

1.1.1. Public-Private-Partnerships (PPP)

The Federal Government of Nigeria shall engage in various forms of PPP for the purpose of financing vaccines manufacturing and other supply chain activities.

In order to strengthen the PPP mechanisms in vaccines production and research, the following approaches shall be applied:

- i. Evolving a flexible governing and sustainable funding mechanisms to support product development in the PPP mode
- ii. Build flexibility in contracting experts both from the national and global pool for a defined period.

1.2. Vaccines Forecasting and Quantification

Forecasting and Quantification of vaccines requirements are critical as it informs decision making on financing and procurement of vaccines.

In line with the National Health Policy, NPHCDA shall coordinate the forecasting and quantification of vaccines required for the country and mobilise resources for their procurement. Quantification shall be done using existing standard guidelines, procedures and other relevant global best practices.

1.3. Supply Planning for Vaccines

In identifying vaccines of local relevance, the following should be considered for informed decision-making when procuring vaccines for use in-country:

- Affordability and financial sustainability of the vaccination programmes, even if the initial introduction is supported by an external funding agency
- Programme capacity to introduce a new antigen, including the capacity of the cold chain
- Availability of a domestic or external vaccines production capacity
- Cost-effectiveness of the vaccination programmes and also of other alternatives apart from vaccination
- Status of registration of relevant vaccines with the National Agency for Food and Drug Administration and Control (NAFDAC).

1.4. Vaccines Procurement

The following critical steps shall be observed:

1.4.1. Contract/Tender Management for Vaccines

This shall be in line with the provisions of the Public Procurement Act. Preference shall be accorded to locally produced vaccines.

1.4.2. Supplier Performance Monitoring

The NPHCDA shall monitor Vaccines Supplier Performance in line with extant guidelines and global best practices.

1.4.3. Management of Vaccines Shipments

Nigeria shall ensure that:

- i. Global best practices are applied in the management of vaccines shipments
- ii. Personnel charged with managing vaccines shipments possess relevant expertise
- iii. Shipments of vaccines and biologicals are accompanied by functional cold chain monitoring devices at the ports of entry and are maintained according to stipulated conditions at the warehouses.

1.4.4. Ports Clearance of Vaccines

To maintain cold chain and consequently assure quality, safety and efficacy, clearance of vaccines at the ports shall not exceed 24hours. Where this is not feasible, products should be released within 24 hours to the importer and placed on hold at the importer's cold chain warehouse, until the clearance process is completed.

1.5. Vaccines Storage and Distribution

1.5.1. Licensure of Vaccines Warehousing/Storage

The Pharmacists Council of Nigeria shall be responsible for licensure of vaccines warehousing and storage in Nigeria and shall ensure that the conditions of storage/holding in established warehouses and other relevant spaces are verified and confirmed as appropriate.

1.5.2. Inventory Control of Vaccines

Vaccines inventory provides useful data that guide vaccines procurement, supply, distribution and utilisation in the country that is largely dependent on imports and donors. This process shall be in line with the utilisation endpoints to encourage and synchronise vaccines data with procurement, distribution and utilisation.

1.5.3. Distribution Plan for Vaccines

Efficient vaccines distribution plans play a crucial role in the prevention and control of VPDs. An effective planning of vaccines delivery in Nigeria shall involve the fulfilment of storage requirements and distribution logistics. Nigeria shall ensure proper supply chain mechanism for vaccines distribution to various target groups. In addition, appropriate technology shall be used to provide much needed technical support for vaccines distribution protocol. Plans should be made for alternative transport in case of a breakdown while in transit.

1.5.4. Vaccines Donations

Vaccines donations shall be guided by the Guidelines for Donations and Healthcare Equipment in Nigeria 2007.

1.5.5. Vaccines Cold Chain

The Federal Government through the NPHCDA shall make adequate arrangements to strengthen the Cold Chain System in order to cope with the storage requirements of the various vaccines. Therefore, the Government shall:

- i. Deploy more resources to the procurement of more Cold Chain Equipment
- ii. Intensify training and capacity building for Cold Chain Managers and Operators at all levels
- iii. Improve infrastructure such as power supply in order to ensure that vaccines are well stored and preserved to minimise wastages
- iv. Put in place mechanisms and systems for independent auditing of cold chain capacity in the country
- v. Adopt and circulate global standards for vaccines storage across all levels
- vi. Ensure regular self-assessment of cold chains and vaccines management using standard global effective Vaccines Management Tool.

1.6. Vaccines Quality Control and Regulation

The National Agency for Food and Drug Administration and Control (NAFDAC) shall be responsible for assuring the quality of vaccines through laboratory analysis and lot release of vaccines alongside regulatory inspections for Good Manufacturing Practice of the facilities where these vaccines are manufactured. In view of the entrance of newer and less known vaccines into the country, the NAFDAC shall:

- i. Review and modernise its guideline and system of laboratory tests
- ii. Procure new technologies to improve its efficiency in the face of increasing emergencies

- iii. Maintain appropriate records, data and information on its activities to provide researchers with proper support in their work
- iv. Grant permission for the conduct of clinical trials
- v. Register and control the quality of imported vaccines
- vi. Work closely with other relevant Agencies such as NNMDA, NIPRD, NIMR and NABDA to assess and validate the quality of imported and locally produced vaccines
- vii. Collaborate with foreign partners to conduct assessments of imported and locally produced vaccines where local capacity is inadequate and the cost is justified.

1.7. Vaccines Use

1.7.1. Guidelines for Vaccines Use

Guidelines for the use of vaccines shall be developed to cover the following thematic areas:

1. Administration, preparation and timely disposal
2. Infection control and sterile technique
3. Healthcare provider exposure to vaccine components
4. Safe use of needles and syringes
5. Route of administration
6. Report of ADRs and AEFIs.

1.7.2. Information Management System

All vaccines use data shall leverage on the existing National Health Logistics Management Information System (NHLMIS) platform which is linked to the District Health Information System (DHIS) of the country that takes care of logistics data and service data.

1.7.3. Designation of Levels of Care for Vaccines Administration

Vaccines administration cuts across both private and public health facilities. Nigeria has three levels of healthcare delivery systems; primary, secondary and tertiary healthcare. Of the three, the primary health care which is closest to the people is majorly saddled with the responsibility of vaccines administration. Therefore, the primary health care system shall be fully optimised to adequately manage vaccines administration.

1.7.4. Adverse Reactions to Vaccines – Clinical Reporting and Management

Adverse Drug Reactions (ADRs) and Adverse Events Following Immunisation (AEFIs) shall be reported using ADR Report Forms (Yellow Form) provided by NAFDAC. Proper reporting mechanisms shall be adopted with the provision of the four (4) main parameters: name of the patient, name of reporting officer, suspected adverse reaction and responsible drug (vaccine). In this light, healthcare providers across all levels shall be trained on Pharmacovigilance and reporting systems to effectively record and forward all AEFIs to NAFDAC for collation and further action.

There shall be a guideline categorising ADRs intensities including detailing protocols to be followed in handling such reporting.

1.7.5. Vaccines Handling

Capacity building of stakeholders on maintaining the integrity and quality of vaccines across the supply chain is crucial. This can be achieved through continuous training and re-training of relevant stakeholders, attendance of relevant conferences, seminars and workshops. It is for this reason that Nigeria shall ensure that institutions and facilities involved in vaccines management, implement and

maintain a functional quality management system including use of guidelines and procedures, and proper maintenance of records.

1.7.6. National and Community Response to Ineffective Vaccines

Once vaccines are suspected to be non-effective, usage shall immediately be suspended and the relevant regulatory authority, NAFDAC shall be alerted. NAFDAC and NCDC shall undertake investigations and sampling of such products for laboratory analysis and pronouncement on the quality and efficacy of the said products. In a situation where there is confirmation of defectiveness of the product, it shall be removed from circulation and other appropriate regulatory actions shall be taken. Procurement shall be halted and a recall and mop-up process will be initiated across the nation, with the publication of alerts where relevant. Manufacturers shall be notified of findings and responsibility for recall and mop up shall be carried out by all relevant stakeholders.

1.7.7. Vaccines Wastage and Disposal

Vaccines wastage is inevitable. However, efforts should be made to minimise wastage because of the cost implication. All expired and deteriorated vaccines must be disposed-off properly to avoid the vaccines being used by unscrupulous persons. The following steps shall be taken:

- i. Efficient forecasting, selection, quantification and procurement of vaccines
- ii. Vaccination schedule at vaccination points shall consider product pack sizes, especially for multiple-dose vaccines
- iii. Procuring vaccines with a reasonable shelf life
- iv. Efficient storage of vaccines and the use of appropriate Cold Chain Equipment
- v. Regular stock taking to ensure vaccines that are about to expire are used first
- vi. Efficient information system to track the availability and use of vaccines.

1.7.8. Vaccines Export

Locally produced vaccines could be exported after local needs have been met.

1.7.9. Intellectual Property Rights (IPR)

- i. The Patents and Designs Act of 1970. Cap 344 of Laws of the Federation of Nigeria 1990 is the guiding Patent Law in Nigeria. The grant of a Patent for an invention enables the Patentee monopoly in respect of that invention for a limited period of time. This monopoly excludes others from using that invention. The granting of Patents is in order to encourage technological development and to serve as an incentive to the inventor allowing him/her limited time and the right to exploit the invention. However, the country shall also ensure that inventions which could improve the quality of life of the citizenry are exploited to the good of the greatest number of people especially as it concerns public health
- ii. The Patentee, whose Patent has been infringed, shall be entitled to the remedies of damages, injunction and accounts. In order words, any Vaccine Manufacturer whose products are being infringed upon has the right according to the Act to seek redress in the courts. The Federal High Court has the exclusive jurisdiction for entertaining actions brought under the Patents and Designs Act. Therefore, patents infringement actions can be filed in the Federal High Court.

2. SECTION NINE: VACCINES ADVOCACY

Vaccine Advocacy shall be the responsibility of Governments at all levels with the support of other relevant stakeholders:

- i. Advocacy to raise funds and resources to execute the implementation of the Vaccine Policy with the active involvement of the TWG on Resource Mobilisation
- ii. Advocacy to the Legislators to enact appropriate legislation to address the implementation of the Vaccine Policy or to strengthen existing legislation as the case may be which shall be spearheaded by the Nigeria Vaccine Policy Governing Council
- iii. Advocacy and public enlightenment to mitigate vaccines hesitancy/resistance to opinion leaders and communities across the country by various groups including government officials, advocacy groups, civil society organisations, donors, media and religious/traditional leaders.

3. SECTION TEN: VACCINES RESEARCH AND DEVELOPMENT (R&D)

3.1. Research and Development

Research is central to many discoveries and inventions and provides the platform for developments in virtually every field. The national response to vaccine challenges for vaccines preventable diseases has exposed gaps in vaccines need, pandemic preparedness, and revealed opportunities to enhance global vaccines development by exposing the need to leverage on novel technologies and prioritising vaccine research efforts. Therefore, the Nigeria Vaccine Policy Governing Council through its TWG on Research and Development shall:

- i. Supervise and harvest the benefits of vaccines research and development for vaccines preventable diseases in Nigeria and in pandemic situations
- ii. Examine the technological and scientific advances from the global response to Vaccines Preventable Diseases (VPD) outbreaks in vaccines research, development, and manufacturing, including the use of platform technologies, and recommend strategies to harness the science, technology, policy and practice required to improve national pandemic preparedness and response
- iii. Identify and recommend Government institutions, Research Institutions and Scientific bodies including the Academia to be sponsored for vaccines research
- iv. Provide recommendations for the disbursement of all funds meant for vaccines research and development and document the progress being made yearly. .

Specifically, the TWG on vaccines research and development shall:

- 1) Ensure that the R&D institutions engage in the science and technology most contemporary to prevailing and emerging vaccines development for the best product output
- 2) Assess how lessons from prior epidemics have impacted the research and development planning, including innovative trial design approaches, regulatory approval mechanisms, and R&D capacity in resource-limited settings
- 3) Distinguish pandemic - level response from VPDs vaccines development and delivery, identify overlapping regulatory and policy concerns, and review need for novel vaccines development platforms beyond traditional processes
- 4) Discuss implications of the existing seasonal VPDs responses and pandemics and consider how emerging technologies can be applied to the management of seasonal or pandemic outbreaks

- 5) Recommend actions to strengthen and diversify the use of vaccines production facilities and novel vaccines technologies, and strategies that are sustainable and could be rapidly adapted to address prevailing VPDs and emerging pandemics
- 6) Consider the impacts of issues such as viral drift, vaccination effects, vaccines effectiveness, and intellectual property rights upon the technical, regulatory, and policy feasibility of recommended actions
- 7) Recommend ways to build capacity for accelerated vaccines development and delivery against pandemics
- 8) Consider mechanisms to better coordinate and integrate research and development processes for newly developed vaccines with cohesive vaccines distribution and post-approval surveillance.

These considerations shall include streamlining vaccines clinical testing, intellectual property management, and other national and international policy barriers that may impede or delay vaccines development.

3.2. Examples of areas of work, outputs, and advisory structures to support vaccines development and evidence-based global policy:

3.2.1. Institutional Research Capacity

Vaccines development and use require infrastructural, human, instrumentation and contemporary knowledge. These ensure that national acquisition and use of vaccines meet the requirements for their deployment and use in the population. It is for these reasons that:

- Nigeria will encourage indigenous development of vaccines and ensure priority patronage for locally developed vaccines
- GoN shall provide dedicated funding to support institutional development in human and relevant infrastructural facilities to support vaccines research and development
- GoN shall encourage research collaboration among scientists in the African Region and also globally in order to encourage the development and use of vaccines for new and re/emergent VPDs of public health interest
- GoN shall continue to support and strengthen institutional capacity through the constant engagement of multiple stakeholders and the maintenance of relevant structures for effective development, acquisition and /or use of vaccines.

3.2.2. Institutional Mapping of Research Capacity for effective vaccines development

The mapping of institutions involved in vaccines research and development (R&D) activities in the country shall be carried out regularly to assess the strengths, gaps in order to streamline efforts while avoiding duplication. This will also help in selection of potential candidates for development and maximise opportunities to reduce resource-intensive demand of vaccines R&D.

The participation of government, private institutions and industries that have human and material resources in the area of vaccines research will be given a platform through the meeting of the national advisory committees and sub-committees for synergy of ideas. These institutional collaborations shall be encouraged to develop vaccines needed for use in Nigeria with vaccines development grants, shared infrastructures, expert manpower, biological materials and intellectual property rights from international groups working on similar vaccines. The partnerships between vaccine manufacturers and technology providers, for instance, will accelerate the development of purpose-built solutions while leveraging on the core competencies and insights of each partner.

4. SECTION ELEVEN: VACCINES CLINICAL TRIALS

4.1. Clinical Research /Trials

A clinical trial is a prerequisite to providing acceptable, safe, effective and efficacious vaccines. In this regard, the GON shall:

- Ensure that relevant agencies certify the safety and efficacy of new and existing vaccines
- Ensure that Vaccines Data and Safety Monitoring Board, Safety Monitoring Committees and Independent Safety Monitors adequately document and evaluate adverse events and side effects and continually provide oversight for adverse effects/events as well as document challenges in vaccines use
- Ensure that proper evaluation is applied for new or modified local and international clinical research regulations and policies for impact on vaccines use, research and development
- Emphasise the need for post marketing surveillance of all vaccines used in the country in order to track adverse events or any other development in connection with vaccines use.

4.2. Science of Vaccine Production Development

4.2.1. Vaccine Quality Assessment

The GoN through the Federal Ministry of Health shall strengthen all Institutions like NAFDAC, NIPRD, Biologics Division, NIMR, Universities and other research institutions engaged in laboratory testing especially of new generation of vaccines

The Government of Nigeria through NAFDAC shall:

- Approve and pronounce on the quality of vaccines manufactured locally or imported for National use
- Ensure that locally manufactured vaccines meet global quality standards
- Conduct Laboratory testing of all manufactured and imported vaccines to ascertain their quality
- Ensure that all laboratories for the testing of vaccines are duly accredited according to internationally accepted ISO standards
- Conduct regular training and capacity building for personnel engaged in laboratory testing of vaccines
- Align Nigeria's prequalification standards with WHO-UNICEF standards to operate in a single-window system in order to avoid unnecessary delays in regulatory clearances of all vaccines
- Stick to national and global agreements to facilitate importation and clearance of vaccines needed in emergencies.

4.2.2. Operational Research

- i. The Nigeria Vaccine Policy Governing Council in collaboration with FMoH and relevant stakeholder will conduct vaccines operations research to provide critical analysis of the efficiency and effectiveness of the processes of vaccine production, procurement, distribution and use. Such studies are required to determine the extent to which issues with vaccines distribution, cold chain and others affect the outcome of immunisation or vaccination programmes
- ii. Operations research studies in vaccines safety would determine if the benefits of vaccines produced locally or imported for use in Nigeria outweigh the risks
- iii. The studies would also identify the side effects and adverse events that are directly linked to a vaccine, thereby enhancing the role and impact of Pharmacovigilance.

4.2.3. Surveillance and Monitoring of Vaccines

The government shall: Ensure that necessary mechanisms are put in place for regular surveillance and monitoring of vaccines at all stages of vaccines management.

4.2.4. Adverse Events Following Immunisation (AEFI)

- i. NPHCDA and NAFDAC shall conduct regular AEFI surveillance in line with the national operational guidelines on AEFI.

4.2.5. Vaccines Response in Disaster and Outbreak Situation

Government shall: Prepare in advance for vaccines against certain diseases with potentials to cause outbreaks and ensure effective response to emergency disease outbreaks and disasters with relevant stakeholders by:

- i. Safeguarding the country against outbreaks and disasters through fast-tracking local manufacturing of vaccines to cushion the impact of emergencies
- ii. Planning for vaccines in the long term against the emergence of novel and re-emerging pathogens
- iii. Conduct efficient fast-tracked assessments and approvals for vaccines using risk-based approaches to ensure vaccines security.

4.2.6. Vaccines Research Funding

- i. Funding for vaccines research shall be drawn from the Vaccines Policy Funds and disbursed, and its utilisation monitored by the TWG on Research and Development
- ii. Records of all funds disbursed to the vaccines research institutions must be properly maintained and all such funds must be accounted for by the institutions in accordance to government policies and guidelines
- iii. Annual auditing of disbursed research funds shall be in line with government laid down policies, procedures and guidelines.

5. SECTION TWELVE: VACCINES BIO-REPOSITORY

In countries with well-developed vaccines programmes, bio-repositories are created or established to bank biological samples comprising usually of both sera and organisms collected during surveillance of disease, epidemics or clinical trials. Bio-repositories are a valuable source of materials that can be used retrospectively in identifying biomarkers, the make-up of genes or changes in the disease-causing organisms especially in re-emerging diseases. The Government of Nigeria shall:

- i. Through National Biotechnology Development Agency (NABDA) and NCDC establish Bio-repository which shall be governed by existing guidelines on the functioning of a National Bio-repository in line with global best practices
- ii. Draft a Nigeria specific Standard Operating Procedures and Guidelines with appropriate linkages to different programmes
- iii. Equip the Bio-repository with fingerprinting sequencing for analysis of the genetic makeup of the organism, and freeze-drying facility for long-term storage
- iv. Accredite and link the established Repository with the International Repository System and other discovery research units within the country

- v. Link all data generated with other national programmes.

6. SECTION THIRTEEN: IMPLEMENTATION FRAMEWORK

6.1. General Implementation Requirement

6.1.1. Dissemination of the Policy

6.1.1.1. The FMoH will determine when dissemination will take place

6.1.1.2. The FMoH shall ensure the dissemination of this Policy and associated documents to relevant stakeholders through appropriate channels.

6.1.2. State Level Buy-in to the Policy

6.1.2.1. All States and the FCT Administration shall be encouraged to buy-in to the Policy and support its dissemination.

6.1.3. Stakeholders Roles and Responsibilities

Table 1: Stakeholders Roles and Responsibilities

S/No	Stakeholder	Roles and Responsibility
1.	Government of Nigeria	<ul style="list-style-type: none"> ● Approve the Nigeria Vaccine Policy ● Establish the Vaccines Governing Council ● Make laws and legislation in respect of vaccines ● Make budgetary provisions ● Establish a dedicated vaccines Funds ● Support resource mobilisation for vaccines ● Create conducive environment to attract Foreign Direct Investments (FDIs) ● Serve as guarantor for both local and international PPP MoUs ● Enter into bilateral/multilateral agreements with foreign governments and institutions in support of local vaccines production, imports, exports, research and development ● Invoke the uptake of WTO TRIPS flexibilities and waivers for local production of vaccines under Patent ● Ensure advocacy and public enlightenment on vaccines uptake, hesitancy and resistance ● Provide adequate support to Ministries and Agencies in their roles in vaccine policy implementation ● Institutionalise patronage of locally produced vaccines ● Ensure effective vaccines supply chain management.
2.	State Governments	<ul style="list-style-type: none"> ● Buy-in to the NVP ● Make budgetary provisions and ensure release of funds

		<ul style="list-style-type: none"> ● Support resource mobilisation for vaccines ● Create conducive environment to attract Foreign Direct Investments (FDIs) ● Enter into bilateral/multilateral agreements with foreign governments and institutions in support of local vaccines production, imports, exports, research and development ● Support the advocacy and public enlightenment on vaccines uptake, hesitancy and resistance ● Provide adequate support to Ministries and Agencies in their roles in vaccine policy implementation ● Institutionalise patronage of locally produced vaccines ● Ensure effective vaccine supply chain management. ● Participate in policy implementation and review processes
3.	Local Governments	<ul style="list-style-type: none"> ● Buy-in to the NVP ● Make budgetary provisions and ensure release of funds ● Support resource mobilisation for vaccines ● Create conducive environment to attract Foreign Direct Investments (FDIs) ● Enter into bilateral/multilateral agreements with foreign governments and institutions in support of local vaccines production, imports, exports, research and development ● Support the sensitisation, advocacy and community mobilisation on vaccines uptake, hesitancy and resistance ● Provide adequate support to departments in their roles in vaccine policy implementation ● Institutionalise patronage of locally produced vaccines ● Ensure effective vaccine supply chain management. ● Participate in policy implementation and review processes
4.	FMoH (Department of Food and Drug Services)	<ul style="list-style-type: none"> ● Secure approval of Nigeria Vaccine Policy document across all levels ● Printing and presentation of the document to the public ● Dissemination of document ● Establish the vaccines secretariat ● Appoint a desk officer to man the NVP Governing Council Secretariat ● Coordinate the implementation and review of the policy every five years ● Supervise Monitoring and Evaluation Processes

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		<ul style="list-style-type: none"> ● Advocacy to strategic leaders and other relevant stakeholders on vaccines uptake, hesitancy and resistance ● Initiate the budgeting process for vaccines policy
5.	Vaccine Governing Council (VGC)/TWGs	<ul style="list-style-type: none"> ● Implementation of the Nigeria Vaccine Policy ● Establish appropriate Technical Working Groups (TWGs) to drive the process of policy implementation ● Support, supervise and review the roles of the TWGs especially in respect of local vaccines production, resource mobilisation, supply chain management, research and development ● Participate in policy implementation and initiate the process of policy review (every 5 years)
6.	NPHCDA	<ul style="list-style-type: none"> ● Conduct vaccines forecast, quantification and procurement ● Handle vaccines logistics to ensure availability of good quality and efficacious vaccines ● Monitor the storage, distribution and use of vaccines at all levels ● Maintain adequate data of vaccines uptake during immunisations ● Support the advocacy for resource mobilisation ● Participate in policy implementation and review processes
7.	NCDC	<ul style="list-style-type: none"> ● Collaborate with GoN, FMOH and its agencies in vaccines management and protocols ● Provide scientific guidance for local production of vaccines ● Monitor and support processes of vaccines uptake and immunisation ● Advocacy to whittle down vaccines hesitancy and resistance ● Maintain data on vaccines efficacy and uptake ● Participate in policy implementation and review processes
8.	NAFDAC	<ul style="list-style-type: none"> ● Vaccine licensing and approval ● Approval of vaccines imports, exports and use ● Pronouncement of vaccines quality ● Post-marketing surveillance of vaccines ● Support the ethical committee to provide guidance and approval on the conduct of clinical trials and clinical trial sites

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		<ul style="list-style-type: none"> ● Pharmacovigilance tracking ● Disposal of expired and ineffective vaccines ● Participate in policy implementation and review processes
9.	NIMR	<ul style="list-style-type: none"> ● Participate in vaccines research and development ● Provide leadership in clinical trials ● Participate in policy implementation and review processes
10.	NIPRD	<ul style="list-style-type: none"> ● Provide leadership in vaccines research and development ● Support and monitor clinical trials ● Support in vaccines assessment, analysis and quality control ● Participate in processes of Vaccine Policy review
11.	FMoF/ Budget Office	<ul style="list-style-type: none"> ● Support the budgetary process for vaccines financing ● Support the establishment of a dedicated vaccines fund ● Prompt release of cash backings for vaccine policy implementation ● Approve waivers where and when necessary for vaccines imports and for machineries for local vaccines production and research ● Support advocacy for resource mobilisation ● Support bilateral/multilateral agreements for vaccines ● Advise GoN on all aspects of funding for vaccines ● Participate in policy implementation and review processes
12.	MoFA	<ul style="list-style-type: none"> ● Support in identifying foreign investors for DFIs in local vaccines production ● Participate in bilateral and multilateral agreements in support of the Nigeria vaccines project ● Support in mobilising Nigerians in diaspora to invest in the vaccines project ● Support in technology transfer processes ● Participate in policy implementation and review processes
13.	FMoTI	<ul style="list-style-type: none"> ● Coordinate FDIs for local vaccines production in Nigeria ● Participate in policy implementation and review processes

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14.	Diaspora Commission	<ul style="list-style-type: none"> ● Harness the potentials from the diaspora in support of local vaccines production, research and development (in collaboration with MoFA) ● Participate in policy implementation and review processes
15.	PCN	<ul style="list-style-type: none"> ● Licensing and regulation of vaccines manufacturing and warehousing/storage facilities ● Regulate professional practice ● Support training and capacity development of professionals ● Participate in policy implementation and review processes
16.	NVRI	<ul style="list-style-type: none"> ● Support research and development of vaccines ● Support the processes of policy review ● Maintain data on all zoonotic diseases and their modes of transmission to humans ● Monitor the health of all animals within the human environment ● Participate in policy implementation and review processes
17.	NABDA	<ul style="list-style-type: none"> ● Support research and development of vaccines ● Publish and disseminate research findings on vaccines development ● Participate in policy implementation and review processes
18.	Other Related Government Agencies	<ul style="list-style-type: none"> ● Customs: Facilitate smooth administrative procedures for the importation of machines and materials for vaccines production and distribution ● Police: Support in the arrests and prosecution of those engaged in vaccines mismanagement, such as faking and other vaccines related illegal activities ● Police: Provide security for NRAs in their vaccines monitoring activities ● DSS: Support in the tracking down of those engaged in vaccines mismanagement and other vaccines related illegal activities ● Participate in policy implementation and review processes
19.	Nigerian Judiciary	<ul style="list-style-type: none"> ● Ensure quick dispensation of justice in matters relating to vaccines mismanagement and abuses

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		<ul style="list-style-type: none"> ● Participate in policy implementation and review processes
20.	Nigerian Legislature	<ul style="list-style-type: none"> ● Expedited passage of bills on legislations related to vaccines including those involved with the invocation of the WTO, facilitate the domestication of TRIPS Flexibilities and Waivers
21.	PMGMAN	<ul style="list-style-type: none"> ● Engage in local production of vaccines ● Support in the maintenance and monitoring of the GMP of all locally produced vaccines ● Lead in the advocacy for patronage of all locally produced vaccines ● Support advocacy for resource mobilisation for the implementation of the vaccine policy ● Support local research and development of vaccines ● Participate in the implementation and review of the vaccine policy
22.	Foreign Governments	<ul style="list-style-type: none"> ● Honour bilateral/multilateral agreements in support of vaccines policy ● Support the local vaccines production initiative of GoN ● Provide technical and financial support towards vaccines research and development ● Promote FDIs in support of local vaccines production, research and development ● Support technology transfer for local production of vaccines ● Share relevant information on global vaccines situation
23.	Development Partners/Donors	<ul style="list-style-type: none"> ● Support the implementation of the Nigeria Vaccine Policy ● Provide support for the Nigeria Vaccine Policy review ● Support training and capacity building for vaccines human resource ● Facilitate technology transfer for local production of vaccines

7. SECTION FOURTEEN: MONITORING AND EVALUATION (M&E) FRAMEWORK

7.1.1. Purpose of the M & E Plan

The Nigeria Vaccine Policy is aimed at achieving availability, self-sufficiency and vaccine security in the country. The monitoring and evaluation framework developed based on the Policy objectives will be used in monitoring progress on periodic basis.

7.2. Data Collection

Data collection tools to be developed by the Federal Ministry of Health in collaboration with relevant stakeholders. The instrument will serve as a means of collecting secondary data for indicators already being tracked by NPHCDA. This will entail reviewing existing data collection system and tools including electronic platforms and adopt or adapt accordingly.

With respect to primary data collection and survey data, FMOH in collaboration with NPHCDA and NAFDAC will coordinate the data collection, and conduct trend analysis to inform performance review which will guide the direction for implementation and other necessary decisions. The FMOH will leverage on the polio legacy through the NPHCDA for reporting vaccines use and the implementation of the vaccine policy.

The scope of the data collection shall be the entire country depending on the indicator to be measured.

Data quality audit will be part of the data collection process in order to validate and ascertain the level of data reported on implementation of the Nigeria Vaccine Policy.

7.3. Data Flow Process

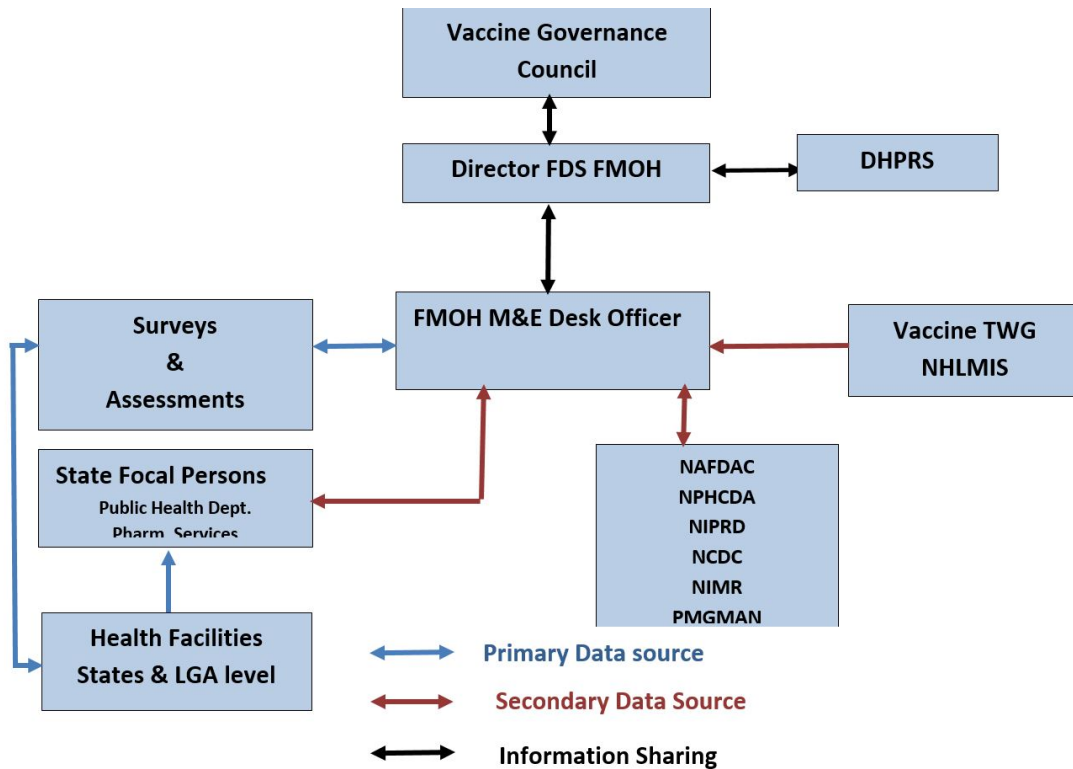


Figure 1: Data Flow Process

Monitoring Plan

Routine collection of relevant secondary data will be done on a monthly basis while the reporting will be on a quarterly basis to the Director Food and Drug Services in the Federal Ministry of Health who will in turn report to the Vaccine Governing Council.

Survey or assessment will be conducted at least once a year from primary data source and reported accordingly.

The overall performance of the implementation will be reviewed twice a year to guide implementation and provide insight into necessary changes needed for improvement.

7.3.1. Evaluation Plan

The evaluation of the implementation of the vaccine policy will focus on the following;

1. Policy environment
2. Stakeholder engagement
3. Financing of policy implementation
4. Outcome of implementation after 5 years.

The implementation will start with a baseline assessment to collect baseline data and intermediate/midterm evaluation after two and a half years of implementation of the policy. Lessons learnt from the evaluation will be used to improve implementation of the policy or to make changes in the implementation with the approval of the Vaccines Governing Council.

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Table 2: Implementation Plan of Nigeria Vaccine Policy

Activities	Indicators	Definition of Indicator	Data Source	Target	Frequency of Data Collection	Means of Verification	Responsible Person
Objective 1: To establish appropriate structures for effective implementation of the Nigeria Vaccine Policy towards achieving local vaccine production and ownership							
i. Establishment of the Vaccines Governing Council	Governing Council established by Mar 2022	Governing Council, TWG, Council secretariat and appointment of desk officer completed	Desk Officer's Quarterly report	Governing Council, Council Secretariat established and appointment of desk officer completed	Measured once by Mar 2022	Inauguration Report	Director FDS
ii. Establishment of TWGs	TWGs established by Mar 2022					Inauguration Report	Director FDS
iii. Establishment of Council Secretariat	Council Secretariat established in FDS by Mar 2022					Inauguration Report	Director FDS
iv. Appointment of Desk Officer	Desk officer appointed in FDS Dept. by Dec 2021					Appointment letter of Desk officer	Director FDS
Objective 2. To achieve local production and uptake of vaccines that meet all global quality standards and ensure vaccines security in line with the requirements of the Sustainable Development Goals and Universal Health Coverage							
Vaccines Manufactured through the BVNL	Operational Vaccines Manufacturing plant from the JVA commissioned for production		FMOH & BVNL Report	Commissioned manufacturing plant	Dec 2023	Commissioning Report	BVNL
Production of local vaccines through BVNL	Percentage of dossier(s) of identified vaccines developed and registration number approved for production by Dec 2023	Numerator: Number of vaccines dossiers developed & approved for production with their registration number Denominator : Total number of Vaccines identified for	Annual Report of BVN or any other company established for that purpose Or Report from NAFDAC data based	30% of Vaccines dossiers developed & registered for local production	Bi-annual	Sighted/Verified dossiers and NAFDAC registration certificate	

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		local production					
Engagement of international collaborators to undertake local vaccines production through PPP arrangement	Proportion of international collaborators engaged to undertake local vaccines production that leads to signing of MOU by March 2023	Number of international collaborators engaged. Denominator Number of international collaborators identified for engagement	FMOH Report/memo details approving the MOU	MOU signed with at least one international collaborator engaged. Report of agreement signing	biannually	Sight MOU	
Promote patronage of locally produced vaccines	Proportion of vaccines locally produced and procured locally	Numerator - Number of vaccines procured locally Denominator - Number of vaccines manufactured locally	FMOH Report	At least one seminar/workshop organized per quarter	Quarterly	Report of seminars/workshops	
Employed WTO's TRIPS Flexibilities and Waivers to engage in local production of vaccines under Patent in the interest of Public Health	Proportion of locally produced vaccines that received WTO's TRIP waiver under patent in public interest	Numerator - Number of vaccines produced based on the WTO waiver granted Denominator - Total number locally vaccines produced in country	Production report from manufacturer	Production of at least one vaccine	Quarterly from March 2023	Report of Vaccines production	
Strengthen NAFDAC capacity to regulate local production of vaccines	NAFDAC achieve maturity level three (ML3) in WHO Global Benchmarking of regulatory system	NAFDAC having demonstrated capacity to regulate local production of vaccines in line with ML3 in WHO Global Benchmarking of regulatory system	NAFDAC report on Global Benchmarking	Achieve ML3 by Dec 2021	Measured once by December 2022	Sight Award of ML 3 to NAFDAC	FMOH NAFDAC
Strengthen institutionalization of	Number of states with functional	Number of states where NAFDAC is	Quarterly report from NAFDAC	PV and traceability functional in	Quarterly	Sight NAFDAC quarterly	FMOH NAFDAC

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Pharmacovigilance and Traceability technology to support detection of ADR and substandard and falsified vaccines products throughout the country	Traceability operationalised	implementing Traceability on vaccines using the GS1 technology		50% of the states by December 2024		report from NAFDAC	
Objective 3: To achieve ownership of all vaccines supply chain management processes in order to improve accessibility of vaccines to optimise utilisation							
Conduct staff skill and capacity assessment to carry out effective vaccines supply chain tasks	Number of staff with required supply chain skill set on vaccines supply chain management	Number of staff with vaccines supply chain management skill. NOTE ref the skill set required for vaccines supply management in supply chain policy or guideline.	Assessment report collated by Vaccines Desk officer	50% of the staff has required skill set required to manage vaccines supply chain.	Annually Measured once by Jun 2022	Sight approved assessment report	FMOH, NPHCDA, NAFDAC, PCN, Customs, development & donor partners
Optimize the vaccines supply chain management process for effective vaccines selection, quantification, procurement distribution and use	Framework for vaccines supply chain optimization developed by June 2022	NA	Vaccines supply chain optimization framework	Framework for vaccines supply chain optimization developed	review biannually	Supply chain report on quantification, procurement and distribution	FMOH, NPHCDA
Conduct regular training and capacity building for supply chain management staff	Percentage of staff identified for training and trained on vaccines supply chain management annually	Numerator: Number of staff trained on vaccines supply chain management annually Denominator: Total number of staff	Training reports from agencies	80% of staff identified for capacity building trained by Dec, 2023	Annually	Sight training report	FMOH, NPHCDA,

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		identified annually that need vaccine supply training.					
Maintain appropriate data of all vaccines' procurement, use and link with the NHIS Data bank	Proportion of vaccines procurement and use data collected and linked with NHIS annually	Number of vaccines data on procurement and use collected and linked with NHIS Total number of approved data set on vaccines procurement and used required.	50 % of data reported NHIS data platform	FMOH & NHIS Annual report	Annually	NHIS data platform	FMOH, NPHCDA, NHIS
Objective 4: To support vaccines research and development towards the introduction of new and improved vaccines using innovative technologies							
i. Vaccines research and development TWG established with TOR and functional	Availability of vaccines research development TWG that meet quarterly	Existence of VRD TWG that meet statutory requirement as stated in the vaccine policy	As indicated in Objective Report of VRD TWG	As indicated in Objective 1	Measured once	As indicated in Objective 1 Report of VRD TWG	Director DFDS
ii. Designate Institutions for the conduct of vaccines research and development	Number of Vaccines research and development institutions designated by Dec 2021		Memo for approval of the designation of institution	Vaccines research and development institutions designated	Measured once by Dec 2021	Designation memo sighted	GoN, FMOH
iii. Provide appropriate funding for vaccines research and development	Percentage of required funds for research and development budgeted and released	Numerator: Total amount of funding for Vaccines research and funding released Denominator: Total amount of funding for vaccines research and development budgeted	FMOH budget	At least 80% of funding for vaccines research released	Dec 2022 and conducted yearly	FMOH annual fiscal report	GoN, FMOH, NAFDAC, SON, VGC, , TWGs Donors, Foreign Governments, International Investors , Nigerians

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							in Diaspora, etc.
iv. Support technology transfer for vaccines research and development	Proportion of vaccines production technology transfer that was successfully completed within timeline	Numerator: Number of vaccines production technology transfer that was successfully completed within timeline Total number of transfer technology for vaccines production that was initiated.	Production company annual report	At least 80% of targeted number of technology transfer initiated and completed.	Measured annually from Dec 2024	Sight Production company annual report	FMOH, BVN and any other vaccines producing companies
Objective 5: To engender sustainable access to funding for local vaccines production and availability and for research and development using innovative technologies							
i. Make sustainable budgetary provisions	Percentage of annual budget estimate set aside for vaccines funding that was released.	Percentage of annual budget estimate set aside for vaccines funding that was released	Annual Budget act	100% of funding set aside released	Annually from Dec. 2022	FMOH annual report	GoN, NPHCDA FMOH, FMOF VGC, TWG on resource mobilization, Legislature, FDIs, Donors, Nigerians in Diaspora, etc.
ii. Undertake vigorous advocacy for resource mobilization	Number of resource mobilization activities for local production of vaccines carried out annually	Number of resource mobilization activities for local production of vaccines carried out annually	FMOH/NPHCDA report	At least 1 activity per quarter	Annually starting from Dec 2021	FMOH annual report	
iii. Provide conducive atmosphere for Foreign Direct Investments (FDI) through ease of doing business for vaccine	Number of FDI for local vaccines manufacturing in Nigeria	Total number of FDI for local vaccines manufacturing in Nigeria	PEBEC report on ease of doing business	FDI on local vaccines manufacturing increased by 25% by Dec 2024	Annually starting from Dec 2022	PEBEC Annual report	FMOH, FMOF, MFA, PEBEC FMOFI

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manufacturing							
Objective 6: To strengthen bilateral/multilateral cooperation and to encourage public/private partnerships for the local production of vaccines and for vaccines research and development.							
Engage foreign government on local vaccines production in terms of partnerships, investments, technology transfer including value chain addition	Number of MoU signed between FGoN and foreign governments or multilateral/bilateral cooperation	The number of engagement of foreign government that resulted in the signing of memorandum of understanding between the foreign governments or multilateral/bilateral cooperation	Vaccines Desk officer annual report	Annually	At least one MOU signed annually	FMOH annual report on local vaccines production	GoN, FMOH, MFA, FMOI, VGC, Donors partners, Diaspora Commission,

APPENDIX

1. Different Types of Vaccines

There are different types of vaccines which include:

- I. **Live Attenuated Vaccines:** This is a type of vaccine that is derived from the weakened pathogen that can cause a mild form of the disease that can produce immunity to the disease which may be transient or long-lasting. This immune response is similar to natural infection and is often strong and long-lasting. Examples include vaccines for viruses (Measles, Mumps, Rubella, Rabies, Poliomyelitis, Yellow Fever, Varicella, Rotavirus, Influenza) and bacteria (Bacille Calmette Guerin and Typhoid vaccines).
- II. **Inactivated Vaccines:** Contains dead or partially dead versions of the pathogen which cannot cause infection on their own (These vaccines trigger protective and shorter lasting immunity). More doses are often required and usually need a booster dose after a few years. Examples are Hepatitis A, Rabies, some Influenza vaccines, Polio (Salk), Hepatitis B, HPV and Hib vaccines.
- III. **Subunit, Recombinant, Polysaccharide, and Conjugate Vaccines:** these groups of vaccines often contain parts of the pathogen and/or antigenic parts required to trigger protective immunity. A conjugate vaccine uses a strong antigen combined with a weak antigen to trigger a stronger immune response. Recombinant vaccines are DNA based vaccines that elicit antigens which triggers protective immunity. Polysaccharide vaccines are made up of long chains of sugar molecules that trigger protective immunity in the presence of pathogens.
- IV. **Toxoid Vaccines:** They are derived from toxins produced by bacteria which have been made harmless by heat or chemical. (E.g. Tetanus or Diphtheria).

2. BVNL

It is a joint venture between the Federal Government of Nigeria and May and Baker Plc with equity share of 49% and 51% respectively.

3. List of Documents Consulted in the Development of Nigeria Vaccine Policy

- I. National Vaccine Policy India
- II. Nigeria National Immunisation Policy
- III. Nigeria National Drug Policy
- IV. Informed Consent Form - NHREC's National Code of Health Research Ethics
- V. Clinical Trial Applications - NAFDAC's Clinical Trial Regulations (2007)
- VI. Checklist for Approval to Conduct Clinical Trial in Nigeria
- VII. Documentation Guidelines for Registration of Vaccines/Biological in Nigeria
- VIII. Selection and Study of Vaccines
- IX. Material Transfer Agreements
- X. Guidelines for Introduction of New Vaccines

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