FEDERAL MINISTRY OF HEALTH

National Quality Assurance Policy For Medicines and Other Health Products

FEDERAL MINISTRY OF HEALTH

August2015

Foreword

The National Policy on Quality Assurance for Medicines and other Health Products (NQAP) is a legacy befitting the management of the Federal Ministry of Health and its development partners, such as USAID/Nigeria, USP/PQM and others. It marks a very important and timely step in the development of the national health sector toward ensuring that health products in our country are not only quality-assured but effective, affordable, and safe for use. Although there are policies addressing various sectors in the Nigerian health care industry, such as the National Drug Policy (2005), National Drug Distribution Policy, National Pharmacovigilance Policy and more, there is the need to provide a document on the topic of quality assurance of medicines and other health care products.

This is to clearly spell out the various activities and their sequence in the handling of these vital products as a means of assuring the quality of products and services in the national health and pharmaceutical sectors, and securing the supply chain from falsified or substandard medicines and other health products for the management of critical diseases such as malaria, HIV/AIDS, tuberculosis, leprosy, and neglected tropical diseases.

This policy is directed primarily at manufacturers, supply entities, procurement entities, quality assurance organizations, regulators, policy makers, and other stakeholders. Furthermore, this policy also ensures that there exists in Nigeria a reliable assurance process for medicines and other health products—from the point of design through manufacture/production, procurement, storage, distribution, dispensing to consumers, and post-marketing surveillance. It is designed to operate within the legal framework of the National Agency for Food and Drug Administration and Control decree of 1993 and the Food and Drug Act of 1990, among others, and makes reference to existing guidelines, standards, regulations, other policies, and a compendium of standard operating procedures, as relevant.

This policy provides the foundational principles for engaging stakeholders and partners (either governmental or nongovernmental) in the activity chain of providing medicines and other health products in Nigeria, and it further reinforces the commitment of the Federal Government of Nigeria to systematic and coordinated maintenance of a national quality assurance system for medicines and other health products. In order to ensure maximum credibility, relevance and completeness and also to ensure widespread ownership of the document, the development of the National Quality Assurance Policy (NQAP) document has taken into account all the central issues affecting the availability of quality medicines and other health products to the consumer and has followed a carefully planned, consultative process involving all stakeholders.

The successful implementation of the NQAP will require the sustained involvement and input of many stakeholders and partners. I therefore urge all concerned to study the

document carefully and identify the most practical ways in which they may collaborate in contributing towards achieving its aims and objectives.

A policy should be dynamic and responsive to changing circumstances, as is the National Quality Assurance Policy for Medicines and other Health Products. I therefore invite all stakeholders and partners to become actively involved in the monitoring and evaluation of the implementation of the NQAP and any future revisions of the policy.

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Linus Awute, mni
Permanent Secretary
Federal Ministry of Health, Nigeria, 2015

Preface

The publication of this first comprehensive and detailed National Quality Assurance Policy (NQAP) marks a significant step forward in the overall development of quality assurance measures for medicines and other health products in Nigeria. With this in place, we now have available a vital reference point and a basis for planning necessary, appropriate interventions to make a significant positive impact on the extent and quality of medicines, pharmaceutical sector services, and importation and donation of products, as well as a process toward maintenance of the quality system.

The document as presented covers the quality assurance of medicines and other health products from the point of design through manufacture/production, procurement, distribution, quality control and dispensing to the consumer. It provides the foundational principles for engaging stakeholders and partners (either governmental or nongovernmental) in the activity chain of providing medicines and other health products in Nigeria. It also contains a glossary of terms explaining how they are used within the document.

Although the regular and reliable provision of essential medicines and health supplies is not the sole requirement for the provision of a quality assurance system, it is nevertheless the most visible and obvious sign that health system and supply chain activity interactions are working. Thus it is essential for all concerned that the design, manufacture, procurement, distribution, and so forth of medicines and other health products are of the highest quality possible within the limitations of the available resources and that such services should be available and accessible at all levels of the health system.

The Federal Ministry of Health is fully committed to the provision of a good quality assurance system guided by the goals and strategies of the NQAP. As a sign of this commitment, the coordination and supervision of implementation of activities under the NQAP will be strengthened by establishment of relevant coordinating and strategic units, both at the federal and local levels of the ministry. Although the issues of drug quality assurance have been captured within the National Drug Policy and other authoritative statutes, these documents have become increasingly inadequate to address the many concerns affecting the pharmaceutical sector as well as local and international health support initiatives.

This NQAP is therefore not only highly relevant, comprehensive and complete, but it forms a vital and realistic foundation for the quality assurance of medicines and other health products available in Nigeria while streamlining the activities of all stakeholders in the sector. The NQAP is a clear and detailed statement of the commitment of the Federal Government of Nigeria to the systematic and coordinated maintenance of a national quality assurance system that is an integral part of the overall National Health Policy. The NQAP will now be used as a basis for the preparation of NQAP Implementation Plans and associated yearly Priority Action Plans by all stakeholders.

The NQAP is offered primarily as a tool — to be used in whole or in part — to facilitate establishment of systems for quality assurance in organizations where no such formal systems exist, or for improvement of existing systems. Where resources or other

constraints limit the immediate application of some of the principles outlined in the policy, it is hoped that the document can serve as a "road map" for the future.

The policy has been developed based on operational principles, methodologies, systems, and conditions in Nigeria to meet and suit national needs. In considering the impact of interventions carried out under the NQAP, the bottom line should always be:Has the consumer received the required level and quality of medicines and other health products? Put more simply, has the patient received the required health product of good quality with the correct dosage regimen and with all the necessary information and advice? The Federal Ministry of Health is committed to ensuring that the supply chain is secured from substandard or falsified medicines and other health products, and the NQAP will assure that process.

It is therefore up to the government, nongovernmental stakeholders/partners, and others in the health sector to ensure that effective implementation of the NQAP is facilitated by offering full cooperation and support to the various activities and initiatives that will be undertaken to achieve this goal. This document is a dynamic document and therefore subject to constant review, update, and revision as required.

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DEFINITIONS

Medicines and Other Health Products

Medicines

Medicines, also termed drugs, includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state, or the symptoms thereof, in man or in animals; restoring, correcting or modifying organic functions in man or in animals; disinfection, or the control of vermin, insects or pests; or contraception (National Drug Policy, 2005)

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Other Health Products

Other Health Products refers to health-related products or devices. A health product could be a diagnostic tool and reagent for clinical testing, medical device, health monitoring device, surgical material, dietary supplement, herbal product, nutraceutical, biologic or vaccine.

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Diagnostic tools and reagents

Kits, reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body (21 CFR 809.3)

Herbal products
Preparations used to treat diseases that are made from plant parts, which may include roots, leaves, and other parts

Nutraceuticals
Food or food products that provide health benefits including prevention and treatment of diseases

Pharmaceutical products
Drugs that are suitably formulated and packaged for use for the treatment and prevention of ailments

Radiopharmaceuticals
Unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy

Counterfeit products
Products deliberately and fraudulently mislabelled with respect to identity and or source. Counterfeits can be branded or generic products. They may include products with correct or incorrect ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging. Related terminology include falsified or substandard.

Imported products
Products that are manufactured outside Nigeria

Local products
Products that are manufactured and/or packaged in Nigeria

Market Authorization Holder (MAH)
An entity licensed by the National Regulatory Authorities that is responsible for placing a medicine and other health product in the market

National Regulatory Authorities (NRA)
These are departments and agencies of a government that have the authority to enforce policies, standards, or guidelines presented in official documents. In Nigeria, such bodies include National Agency for Food and Drug Administration and Control (NAFDAC), Pharmacists Council of Nigeria (PCN), Medical Laboratory Science Council of Nigeria (MLSCN), Standards Organization of Nigeria (SON), and other relevant organizations.

Partners
Individuals or organizations that provide financial or technical support to government ministries/agencies or those in need of such assistance

Quality Control Laboratory
A laboratory providing testing services that generates analytical data within a quality system framework to provide clients with an accurate and representative portrayal of a sample's constituents, enabling them to meet their regulatory and monitoring commitments. This includes medical diagnostic laboratories.

Stakeholders
May be partners, government ministries, departments, or agencies

Substandard products
Genuine products that do not meet the quality specifications set for them, usually due to lack of expertise, poor manufacturing practices, or insufficient infrastructure.

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Policy Statement

The National Quality Assurance Policy for Medicines and Other Health Products as assures that consumers have access to medicines and other health products that meet the accepted standards of quality, safety, and efficacy.

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Background and Preamble

The Nigerian health sector has gone through a series of landmark advancements in the past couple of decades in the area of assuring quality of products and services. The Federal Government of Nigeria has catalyzed these processes through some timely interventions and programs to solve specific needs. These include the establishment of various regulatory bodies, such as the Pharmacists Council of Nigeria (PCN), Medical Laboratory Science Council of Nigeria (MLSCN), Standard Organisation of Nigeria (SON), Institute of Public Analysts of Nigeria (IPAN),National Agency for Food and Drug Administration and Control (NAFDAC), and the development of tools, such as the Essential Medicines List (EML), Essential Veterinary Drug List (EVDL), National Drug Policy (NDP), National Drug Formulary (NDF)and various program guidelines.

Despite these efforts, a gap exists due to the absence of a national quality assurance policy on medicines and other health products. This has become very necessary, especially with the explosion of activities in the Nigerian pharmaceutical manufacturing sector, continuous influx of imported medicines and health products, and numerous donor-funded health programs in the country, and with the ever-present threat of poor quality, falsified, and substandard products entering the country. Therefore, there is a need to standardize and formulate a National Quality Assurance Policy (NQAP) which

will apply to medicines and other health products distributed in Nigeria, whether imported, locally manufactured, or donated. This policy will assist in streamlining and strengthening current procedures and processes in the availability of medicines and other health products. (National Health Policy, Revised National Health Policy, September 2004)

Quality assurance is a process-centered approach to ensuring that the consumers of medicines and other health products have access to safe, efficacious and good quality products through the development of criteria based on specified and acceptable standards of practice, irrespective of their route of entry into the market.

The quality of products is ensured by the technical and managerial activities of the quality system. The technical activities include ensuring good manufacturing practices, evaluating product documentation, performing or reviewing quality control laboratory tests, and monitoring product performance.

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The managerial activities include ensuring quality assurance processes and procedures throughout the product design and manufacture, selection of reliable suppliers, preparation of contract terms, monitoring of supplier performance and performance of inspection procedures through the distribution networks, as well as securing the supply chain activity. This should include training and supervision of personnel at all levels of the product life cycle. Quality assurance aims at maintaining the delivery of quality products and services to consumers within established policies and legal frameworks.

Scope

The NQAP covers all forms of activities involved in the availability of safe, efficacious, and quality medicines and other health products in Nigeria, whether they are locally manufactured or imported.

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This policy is implemented through the systems laid down by relevant governing bodies in Nigeria and covers products for which a prescription is required by patients, products that may be provided to patients without a prescription and other health products. This policy covers all medicines and other health products available or intended for use in Nigeria irrespective of their mode or route of entry.

Aims and Objectives

The primary aim of the NQAP is to establish a uniform system that works in conjunction with other applicable guidelines, rules, regulations, and policies to ensure the quality, safety and efficacy of medicines and other health products within Nigeria.

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This system is subject to the appropriate standards and laws established in the country.

The specific objectives are to ensure that:

1. Medicines and other health products distributed in Nigeria are in accordance with regulatory requirements and fit for intended use.
2. Procurement meets predetermined norms and standards in terms of safety, quality and effectiveness.
3. The quality of products are monitored and maintained throughout their life cycle.
4. Consumers receive medicines and other health products appropriate to their health needs.
5. The policy is adequately financed, implemented, monitored and evaluated in collaboration with national and international partners as well as other relevant stakeholders.
6. The integrity of partnering providers is upstanding.
7. Partners' participation is in line with the country's needs and health strategies.

The following targets are expected to be met by2022:

1. 90% of medicines and other health products circulating in the country meet the accepted standards in terms of safety, quality and efficacy.
2. 100% of storage facilities meet the standards required to maintain the quality of products.

3. At least six (6) quality control laboratories, in addition to NAFDAC facilities, receive support from government and/or partners to obtain international accreditation.
4. 95% of prescriptions and use of other health products comply with the National Standard Treatment Guidelines and other relevant guidelines.
5. 95% of patients receive adequately labeled medicines and other health products.
6. 100% of the implementation plan for this policy is financed.
7. 100% of the implementation plan for this policy is achieved.

Manufacture and Design

The NQAP assures quality and safety in the manufacture and design of medicines and other health products.

Quality assurance for medicines and other health products is a very important aspect in the manufacture of medicines and other health products. In this approach, medicines and other health products are certified to be safe and compliant with all standards, regulations, and requirements of the national regulatory authority (NRA), NAFDAC, and other governing bodies. The system of quality assurance is designed to produce medicines and other health products that are of good quality and to prevent any type of noncompliance. Quality assurance pertains to all aspects of production, including in-process, finished product, and the quality of ingredients used to make the medicines or other health products, such that it comply to good manufacturing practices (GMP), good laboratory practices (GLP), and good distribution practices (GDP). Personnel are expected to be morally responsible, knowledgeable, and well trained to ensure that all requirements, standard operating procedures (SOPs), guidelines, and other applicable procedures and systems are met.

Quality assurance in the manufacture and design of medicines includes systems for raw material dispensing, addition of active ingredients, volume make-up and weight variation of bulks, in-process fill weight and fill volume checks, quality control of raw materials, in-process and finished products to the release of batch, online packing line check list, stability testing and post-marketing surveillance.

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In order to assure the quality of their products, manufacturers should provide to vendors complete guidelines for managing their quality and should annually conduct a surveillance audit of their products to ensure that their quality is being properly maintained. Vigorous evaluation of quality assurance systems is crucial to validate their complete effectiveness, thus, a validated process should be adapted at each and every point in the quality assurance system. Complete process validation is established by following GMPs and GLPs to assure the quality of all processes in place.

Other areas that contribute to quality assurance of medicines and other health products include cleaning, personnel hygiene, personnel training, line clearance, and validation.

It is expected that the manufacture and design meet all applicable rigorous quality assurance processes, standards, SOPs, guidelines and requirements before medicines or health products are released for use by consumers.

This policy requires that all medicines and other health products available/intended for use in Nigeria meet all standards of quality for production set by the NRA, such as GMP, World Health Organization (WHO) Prequalification, International Conference on Harmonisation (ICH)Guidelines, or relevant ISO accreditations for manufacturing sites of medical devices and diagnostics as relevant.[See definitions section where defined.

Procurement

The NQAP assures quality in the procurement of medicines and other health products.

Understanding the sources of medicines and other health products is an important aspect of the health care delivery services used to obtain products of satisfactory quality.

Procurement represents the single largest health expenditure by a country after personnel costs. Procurement of medicines and other health products begins with identifying reliable sources for products as well as accurate forecasting of quantities

Procurement represents the single largest health expenditure by a country after personnel costs. Procurement of medicines and other health products begins with identifying reliable sources for products as well as accurate forecasting of quantities(see National Procurement Guidelines and Manuals 2006).

The processes to achieve this should include:

- Identification and selection of products based on the national EML or EVDL;
- Quantification based on country's demographics, consumption and/or morbidity data;
- Ensuring that medicines and other health products to be sourced are registered by NAFDAC;
- Supporting expert guidance on the selection and procurement of diagnostics and other health products; and
- Adherence to WHO and national guidelines for evaluation of other health products to ensure access to the most suitable products, especially when they are not listed in the national or WHO recommended list. There should be adequate information on such products to aid in their evaluation and assessment.

An effective procurement process should:

- Ensure transparency, declaration of conflict of interest, and adequate documentation for all transactions;
- Seek to manage the buyer-seller relationship in a transparent and ethical manner in line with the government's commitment to Good Pharmaceutical Procurement Practices (GPPP);
- Facilitate procurement of the right medicines and other health products in the right quantities and at the right price;
- Ensure that all products to be procured meet the regulatory requirements of the NRA;
- Ensure supplier reliability with respect to service and quality;
- Ensure that procurement of medicines and other health products delegated to a third party will be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract that includes detailed product quality specifications; and
- Confirm that such third-party contracts define the responsibilities of each party, including observance of applicable standards and that sub-contracting may be permissible, subject to the written approval of the contract giver, providing the subcontractor is qualified for the job and authorized for the function.

Distribution

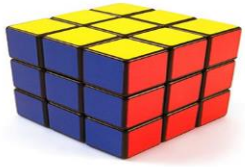
The NQAP assures quality and safety in the distribution of medicine and other health products.

Distribution of medicines and health products involves the following activities: receipt and inspection of products; storage;

Distribution of medicines and health products involves the following activities: receipt and inspection of products; storage; Packaging; transportation; and monitoring of facilities (see National Drug Distribution Guidelines (2013), National Supply Chain Risk Management Practices, NIST).

Receipt of products

The purpose of the receiving function is to ensure that the arriving consignment is correct, that such products originate from approved suppliers and that products have not been visibly damaged during transport. To provide quality assurance:



Incoming consignments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are

1. Incoming consignments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, condition monitoring devices have not been compromised, labeling is intact and products have not been damaged during transport.
2. Records of consignments should contain enough information to enable traceability and facilitate the recall of a batch of a product, if necessary, as well as the investigation of spurious, falsely-labeled, falsified, counterfeit (SFFC) or potentially counterfeit products.
3. Receiving and dispatch bays should protect medicines and other health products from adverse weather conditions.
4. Inventory control records should be initiated and maintained.

Hence, under the direction of the Federal Ministry of Health (FMOH), a unit will be able to assure that there is a method in place for ensuring traceability of medical products, serialization, and more.

Storage

1. Medicines and other health products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors.
2. Medicines and other health products should be handled and stored in such a manner as to prevent spillage, breakage, contamination, cross-contamination and mix-ups.
3. The required storage conditions for medicine and other health products should be maintained within the defined limits prescribed by the manufacturer or as written on the outer packaging. Monitoring devices should have alarm systems for out- of-range (OOR) reading, and/or capacity to track changes and provide history of the monitored parameter.

Medicines and other health products should not be stored directly on the floor.

4. Medicines and other health products should not be stored directly on the floor.
5. Stock should be stored and issued according to the first expiry, first out (FEFO) principle. Measures should be in place to ensure that this principle is adhered to. Exceptions should be documented.
6. Facilities should be available for the storage of all products under appropriate conditions. Records should be maintained of these conditions if they are critical for the maintenance of the quality of the product. All monitoring records should be kept for at least the shelf-life of the stored product plus one year.
7. Storage areas should be clean and free from accumulated waste and vermin. The pest control agents used should be safe and there should be no risk of contamination of medicines and other health products.
8.

Medicines and other health products that are thirty days to expiration date should be withdrawn immediately from stock.

- Medicines and other health products intended for destruction should be appropriately identified, held separately and securely, handled, transported and disposed in accordance with relevant guidelines.
- Medicines and other health products containing radioactive materials must comply with established protocols for handling.
- The providers of radiopharmaceuticals and other health products with radioactive components should provide adequate storage facilities.
- Fire safety equipment should be available and accessible, and personnel should be trained to use it.
- National, zonal/axial, state storage facilities or warehouses should have comprehensive insurance to cover all medicines and other health products against fire, flood, theft and other adverse climatic or hazardous conditions.

9. The storage of medicines and other health products which is delegated to a third party should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.
10. The contract should define the responsibilities of each party including observance of applicable standards. Sub-contracting may be permissible, subject to the written approval of the contract giver; however, the subcontractors should be qualified for the job and authorized for the function.
11. A planned preventive maintenance (PPM) system should be in place in warehouses and other storage facilities for adequate and proper ongoing maintenance of the facilities.

Packaging and labeling

1. Bulk haulage of medicines and other health products should be in containers that do not adversely affect the quality of the products and offer adequate protection from external influences, including contamination.

Containers should bear labels providing sufficient information about handling and storage requirements as well as enabling identification of the contents of the containers and the source

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3. Containers should bear labels providing sufficient information about handling and storage requirements as well as enabling identification of the contents of the containers and the source.
4. Direct packaging of medicines and other health products should meet the requirements of the national regulatory authorities.
5. In situations where compounding of medicines at the end-user stage, such preparations should be done according to official standards such as the U.S.

Pharmacopeia (USP), British Pharmacopoeia (BP), International Pharmacopoeia (Ph. Int.), African Pharmacopeia (AP), or a similar authority.

6. Packaging and labeling of herbal medicines/dietary supplements should meet the requirements of a stringent national regulatory authority.
7. Packaging of blood and blood products should meet the requirements under specified standards (see National blood Policy, 2005).

Transportation

1. During transportation, medicines and other health products should be prevented from exposure to conditions that could affect their quality and packaging integrity.
2. Medicines and other health products should be protected against breakage and adulteration during transportation.

Regardless of the mode of transport, the procurement entity should be able to demonstrate that the products have not been exposed to conditions that may compromise their quality and integrity.

3. Regardless of the mode of transport, the procurement entity should be able to demonstrate that the products have not been exposed to conditions that may compromise their quality and integrity.
4. The required storage conditions for medicines and other health products should be maintained during transportation within the defined limits prescribed by the manufacturer or written on the outer packaging.
5. For vaccines and other temperature-sensitive products, if the transportation route includes unloading and reloading, transloading or transit storage, particular attention should be paid to temperature monitoring to ensure maintenance of cold chain conditions, cleanliness and the security of any intermediate storage facilities.

6. Monitoring devices should have alarm systems for out-of-range (OOR) reading, and/or capacity to track changes and provide history of the monitored parameter.
7. Medicines and other health products should not be left in unauthorized premises. Deliveries should be made to the address stated on the delivery note and into the care of the consignee.
8. The transportation of medicines and other health products which are delegated to a third party should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.
9. The contract should define the responsibilities of each party, including observance of applicable standards. Sub-contracting may be permissible, subject to the written approval of the contract giver; however, the subcontractors should be qualified for the job and authorized for the function.

Vehicles and equipment

10. Vehicles and equipment used for distribution, storage or handling of medicines and other health products should be suitable for their intended purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination and cross-contamination.

Dedicated vehicles and equipment should be used when handling medicines and health products.

11. Dedicated vehicles and equipment should be used when handling medicines and health products.
12. Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment.
13. Where third-party logistics providers are used, the procurement entities should develop written agreements to ensure that appropriate measures are taken to safeguard medicines and health products, including maintaining appropriate documentation and records.
14. Vehicles, containers, and equipment should not constitute sources of contamination and cross-contamination, and should be kept free from rodents, vermin, birds and other pests. There should be written programs and records for

such pest control. The cleaning and fumigation agents used should not adversely affect the product quality.

15. Where special storage conditions (e.g., temperature and/or relative humidity, different from or limiting the expected environmental conditions) are required during transportation, such should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year.
16. Equipment used for monitoring conditions, e.g., temperature and humidity, within vehicles and containers should be calibrated at regular intervals (see monitoring devices under "Transportation, #6").

Falsified or Substandard Products

Products detected to be falsified or substandard are those that failed the quality assurance processes and are considered illegal in the market. Such products should not be sold or consumed.

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Medicines and other health products should adhere to the various laws that regulate the products against counterfeit or substandard products in Nigeria such as:

a. Poisons and Pharmacy Act, Cap 366 of 1990;
b. Food and Drugs Act, Cap 150 of 1990;
c. Counterfeit and Fake Drugs (miscellaneous provisions) Act, Cap 73 of 1990;
d. Pharmacists Council of Nigeria, Decree 91 of 1992;
e. National Agency for Food and Drug Administration and Control Act,Decree No. 15 of 1993; and
f. Drugs and Related Products (Registration), Decree No. 19 of 1993.

To avoid counterfeit products, partners/stakeholders should procure medicines and other health products from dealers, manufacturer's representatives or manufacturers

duly registered with NAFDAC, or other regulatory bodies as fit and legally qualified to procure medicines and other health products.

Partners/stakeholders should educate consumers via media such as radio, newspapers, TV, billboards, posters or flyers to purchase medicines and other health products from legally registered pharmacies, stores, or entities, etc.

State task forces on counterfeit and fake drugs that are not in existence should be reconstituted and invigorated. The task forces should be adequately funded to be able to acquire the necessary facilities for their operations.

Stakeholders/partners should be disseminating information about suspected counterfeiting activity to the relevant NRA or law enforcement agents.

Partnering entities and manufacturers of medicines and other health products should have established surveillance units to monitor the quality of their products.

Partners/stakeholders are encouraged to provide financial or technical support in identified areas to assist in eradicating counterfeit or substandard medicines or other health products in Nigeria.

Recall of Defective or Falsified Products

All complaints concerning a defective or falsified product should be recorded and thoroughly investigated by relevant stakeholders to identify the origin, reason for and extent of the defect.

1. All complaints concerning a defective or falsified product should be recorded and thoroughly investigated by relevant stakeholders to identify the origin, reason for and extent of the defect.
2. Products known or suspected to be defective or falsified should be promptly recalled following the manufacturer's recall procedure and/or that of the national regulatory authorities.
3. The NRA, manufacturer and/or marketing authorization holder should be informed in the event of a recall.
4. All recalled medicines and other health products should be stored in a secure and segregated area during storage and transit.

5. SFFC products should be kept apart from other products to avoid any mix-up. They should be secured and clearly labeled as "NOT FOR SALE/CONSUMPTION."
6. Customers to whom a given product may have been distributed should be informed promptly of any intention to recall such product because it is, or is suspected to be, defective or counterfeit.
7. Records of all returned, rejected and/or destroyed medicines and other health products should be kept for a predetermined period.

Quality Control

Quality control (QC]

ensures that the necessary and relevant tests are carried out, and that materials or products are not released for use until their quality has been proved to be in accordance with their specifications and intended purpose.

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1. Each entity that manufactures, procures, and distributes medicines and other health products should have basic quality control units where identity can be ascertained.
2. Each entity that manufactures, procures, and distributes medicines and other health products must be capable of undertaking the tests required, or of managing any subcontracting of such work to third parties while retaining responsibility for the quality of the work done.

3. The contracted quality control laboratory must be in Nigeria and must have valid good laboratory practices(GLP) certifications by the relevant national regulatory authority. Such laboratories include highly skilled QC laboratories existing in Nigeria's tertiary and research institutions. The performance of contracted laboratories should be continuously monitored for compliance with GLP, accreditation status and other certifications by the contracting entity. Results from such laboratories should be accepted by all stakeholders.

4. Consignments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and condition monitoring devices are not compromised, that labeling is intact and that the products are not damaged during transportation.

5. Each batch of medicines and other health products should be tested for identity using basic tests upon receipt.

6. Each batch of finished product with high health impacts and the greatest risk of having quality problems should be tested in a laboratory to determine that it conforms satisfactorily to its finished product specification, prior to supply. These include but are not limited to the following:

    a. Medicines with narrow therapeutic indices;
    b. Medicines with inherent bioavailability and stability problems;
    c. Modified release preparations;
    d. Sterile preparations; and
    e. New suppliers or suppliers with product quality problems in the past.

7. There shall be additional stringent evaluation and testing for health products, including diagnostic tools and reagents, that are outside of the WHO or national guideline recommended list, to ensure that the health products meet the expected national/WHO quality standards.

8. Quality monitoring activities should be conducted during storage, distribution, and use, to ensure that health products, especially diagnostics, continue to conform to the manufacturer's established quality specifications.

9. Sampling and testing of all medicines and other health products should be done according to a batch randomization testing protocol in line with defined/official sampling standards for each product. (see National Health Policy, 2004, current GDP, National Drug Policy, and other related applicable policies)

Dispensing of Medicines and Other Health Products

1. Dispensing units or entities should procure or purchase medicines from a legally registered manufacturer or wholesaler.

Suspicious products upon purchase should be reported to NAFDAC and/or other governing bodies immediately.

2. Suspicious products upon purchase should be reported to NAFDAC and/or other governing bodies immediately.
3. Dispensing should ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, with clear instructions and in a package that maintains the potency of medicines.
4. There should be sufficient space in the dispensary to ensure an efficient flow of work and the dispensing area should be adequately structured to promote effective communication between the dispenser and the patient.
5. Containers used in dispensing should be appropriate to the particular product being dispensed and should protect the contents from the adverse effects of moisture, sunlight, transportation and handling by the patient.
6. Dispensing aids used to count and measure medicines should be provided to guard against contact with skin and should be kept clean to avoid cross-contamination.
7. Labels should contain information about the medicine and its correct use, and the labeling and instructions for use should be appropriate to the needs and understanding of the patient.
8. Other health products such as medical devices, diagnostic tools and reagents should be dispensed in accordance with relevant protocols.
9. Dispensing records should be kept at the pharmacy in order to promote accountability, traceability, good management and monitoring.
10. Where products require special technique(s) for dispensing, the provider(s) should undertake training of the personnel involved in this function.
11. Radiopharmaceuticals should be handled and dispensed by trained personnel.
12. Each provider should be responsible for the total cost of training, installation, commissioning, servicing of medical devices, as well as, supplying the necessary reagents and calibrators required for its appropriate use.

Waste Management

Wastes are products identified for disposal or those generated from manufacturing processes, distribution and/or storage.

- *Medicines and other health products that are considered wastes should be appropriately identified, documented, held separately and securely, handled, transported and disposed of in*

- Medicines and other health products that are considered wastes should be appropriately identified, documented, held separately and securely, handled, transported and disposed of in accordance with relevant guidelines.
- Medicines and other health products containing radioactive materials must comply with established protocols for handling and disposal.

Personnel

1. *All personnel working in manufacturing design, distribution and procurement for medicines and other health products should be trained and qualified in the requirements of quality assurance of the products, as applicable*

All personnel working in manufacturing design, distribution and procurement for medicines and other health products should be trained and qualified in the requirements of quality assurance of the products, as applicable.

2. Personnel should receive initial and continuing training relevant to their tasks, in accordance with a written training program. A record of all trainings, which include details of subjects covered and participants trained, should be kept. There should be evidence of maintenance of a written training program. Key personnel involved in the distribution of medicines and other health products should be licensed to perform their duties. For the distribution of medicines, in particular, a registered pharmacist must be responsible for maintenance of the quality of medicines at all stages of the supply chain.
3. There should be an adequate number of competent personnel involved in all stages of the life cycle of the medicines and other health products in order to ensure that the quality of the product is maintained.
4. Personnel involved in the manufacture and distribution of medicines and other health products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous products, including products containing materials that are radioactive, toxic, infectious, or sensitizing, should be provided with suitable personal protective equipment.
5. Each entity manufacturing and procuring medicines and other health products for further distribution should have quality assurance personnel whose responsibility will include ensuring that the quality assurance procedures are implemented and adhered to.

Self-inspection

Self-inspection is the internal auditing of adherence to the quality assurance of the entire system, which should be conducted to monitor implementation and compliance with the principles of the NQAP policy and to trigger corrective and preventive measures.

Self-inspection should be conducted in an independent and detailed way by a designated competent person. The result of all self-inspections should be recorded.

Reports should contain all non-conformities observed during the inspection and where applicable proposals and timelines for corrective and preventive measures. There should be an effective follow-up program. Management should evaluate the inspection report and ensure adequate corrective and preventive measures are taken. Records of the management review of the self-inspection should be kept.

Documentation

All processes/activities in manufacture, distribution, procurement, and storage must be *properly documented according to relevant guidelines and all such documents must be kept on site by all relevant stakeholders.*

All processes/activities in manufacture, distribution, procurement, and storage must be properly documented according to relevant guidelines and all such documents must be kept on site by all relevant stakeholders.

2. All records must be retained, stored, and readily retrievable using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.
3. All manufacturing, distribution, procurement, and storage entities should keep records of all medicines and other health products received. Records should contain at least the following information:
   a. Date of supply;
   b. Name of the product(s);
   c. Batch numbers of product(s) supplied;
   d. Manufacture and expiry dates of the product(s);
   e. Quantity received; and
   f. Name and address of the manufacturer and supplier.
4. Instructions and procedures relating to any activity that can adversely affect the quality of medicines and other health products upon receipt should be developed and distributed to relevant personnel.

5. Documented procedures should be in place for temperature monitoring of sensitive medicines and other health products using security services to prevent theft or tampering at the storage facilities, destruction of un-saleable or unusable stocks and on retention of the records.

Operational Research

Operational research is necessary for the successful implementation of the National Quality Assurance Policy for Medicines and Other Health Products.

The goal is to identify the best methods of designing, manufacturing, selecting, procuring, distributing and using safe, efficacious, and quality-assured medicines and other health products.

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Its application should lead to practical and cost-effective measures that would inform managerial, educational and regulatory interventions to improve access to and use of quality medicines and other health products.

Research will focus, in particular, on the following areas:

- Impact of the NQAP and its components on the national health system and health service delivery;
- Utilization of medicines and rational drug use at different levels of health care facilities;
- Economics of the supply of quality medicines and other health products;
- Social and cultural aspects of using medicines and other health products, such as self-medication, acceptability and attitudes of consumers of medicines and other health products;
- Impact and effectiveness of multisource generics in disease management and national health programs;
- Effect of storage of diagnostic tools and reagents on laboratory results;
- Impact of workload on personnel performance in the quality assurance program;
- Impact of training of personnel in the health care system;
- Assessment/evaluation of the impact of errors in quality control laboratories; and

- Appropriate monitoring of product use to obtain pharmacovigilance data.

Pharmacovigilance

The introduction of an adverse drug reaction reporting system is an essential component of a national quality assurance system.

As part of its pharmacovigilance system,

a Marketing Authorization Holder (MAH) should be encouraged to establish a quality system for pharmacovigilance which will cover organizational structure, responsibilities, procedures, processes and resources as well as appropriate resource, compliance and record management.

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The overall quality objectives of a pharmacovigilance system should include:

a. Complying with the legal requirements for pharmacovigilance tasks and responsibilities as articulated in the Nigeria National Pharmacovigilance Policy (2012) and the Good Pharmacovigilance Practice Guidelines for Industry(2015);

b. Preventing harm from adverse reactions in humans arising from the use of authorized medicinal products within or outside the terms of marketing authorization or from occupational exposure;
c. Promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public; and
d. Contributing to the protection of patients and the public health.

All drugs must be regularly monitored with respect to their efficacy, safety, and quality as well as adverse reactions to evaluate the need to change the conditions of their continuing registration or withdrawal from the market.

The Nigerian Government should be encouraged to establish adequately equipped pharmacovigilance units nationwide, and to collect, evaluate and disseminate relevant information on adverse drug reactions and poisoning.

- Market Authorization Holders should regularly monitor their medicines and other health products in accordance with regulatory requirements in Nigeria.
- Partners/stakeholders/suppliers should regularly monitor their medicines and other health products with respect to efficacy, safety, quality, and adverse drug reactions and should share information with the relevant national regulatory authority.
- Any medicine or other health product withdrawn or banned in many countries outside of Nigeria due to unacceptable health risk, shall be automatically withdrawn from distribution in Nigeria (National Drug Policy, 2005).

International Cooperation and Harmonization

This section aims to

ensure that all relevant forms of technical cooperation are scrutinized and promoted to maximize or complement local or national demands with the effective use of limited resources. This could be achieved through technical collaboration with international agencies.

ensure that all relevant forms of technical cooperation are scrutinized and promoted to maximize or complement local or national demands with the effective use of limited resources. This could be achieved through technical collaboration with international agencies.

Possibilities for further international and regional collaboration will be systematically identified and engaged.

Cooperation, particularly in the following areas, will be encouraged and supported:

- All partners/stakeholders supporting the supply chain management at the national level must operate within the management ambit of the National Product Supply Chain Management Program (NPSCMP).
- All partners/stakeholders supporting the supply chain management of a state must operate within the management ambit of the state Logistic Management Coordination Unit (LMCU).
- All partners/stakeholders manufacturing, distributing, procuring and/or donating medicines and other health products for use in a national health program must key into a centralized management system of warehousing in Nigeria under supervision of the FMOH or its parastatals or implementing agencies.
- For the evaluation of the quality of medicines and other health products:
  - Regional procurement systems and the exchange of information on medicines and other health products supply sources;
  - Quality control issues;
  - Computerization of stock control processes;
  - Production and formulation of medicines and other health products;
  - Transfer of appropriate technology;
  - Research and development;
  - Training and human resources development;
  - Studies on drug utilization;
  - Exchange of drug information;
  - Emergency situations, such as epidemics and disasters—Emergency donations of medicines and other health products in such cases should be guided by National Guidelines on Donated Medicines and other relevant regulations in Nigeria.
  - Support should be in accordance with the expressed country's needs.
  - The planning, implementation, evaluation, and monitoring should be receiver-driven based on pre-established protocols.
  - Quality control of medicines and other health products should be done in Nigeria where there is capacity for such activities.
  - Capacity-building should be provided by partners as part of the support.

This policy document shall be binding on all stakeholders.

Policy Implementation

The NQAP will be made available to relevant stakeholders, who are required to adhere to the stipulated standards.

- Drug management information systems and other relevant information for taking decisions on quality assurance policy should be institutionalized.
- All warehouses where medicines and other health products imported, manufactured, procured, or donated for use in the national health program should be under the supervision of the FMOH.

Each state Logistic Management Coordination Unit (LMCU) should be domiciled in the office of the state directorate of pharmaceutical services. This Policy shall be implemented by the following:

- Federal Ministry of Health, including its parastatals/implementing agencies, should produce the policies and monitor, implement, and enforce the use of policies by all concerned.

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- State Ministries of Health, including Federal Capital Territories (FCT), should establish the LMCU domiciled in their directorate of pharmaceutical services and ensure implementation of this policy by stakeholders operating in the state.
- Local government health departments should ensure implementation working within their local governments.
- Partners comply and implement in accordance with NQAP.

Roles and Responsibilities

Federal Ministry of Health will produce the NQAP document and disseminate it; create awareness, enforce implementation, monitor and evaluate the document; and provide the operational legal framework.

1. Federal Ministry of Health will produce the NQAP document and disseminate it; create awareness, enforce implementation, monitor and evaluate the document; and provide the operational legal framework.

2. Agencies under the FMOH will ensure implementation of this document by partners working with them.
3. Regulatory agencies will ensure implementation of this document within their given scope, such as:
   a. NAFDAC—regulatory issues of medicines and other health products as contained in NAFDAC Act CAP N1 LFN 2004;
   b. SON—laboratory (ISO) accreditation, GLP certification of QC labs in Nigeria and other regulatory issues as in SON Act CAPS9 LFN 2004;
   c. PCN—regulation, accreditation, and inspection of pharmacies and pharmacists as contained in PCN Act 91of 1992;
   d. MLSCN—regulation, inspection, and accreditation of medical laboratories as in Act 11, 2003; and
   e. IPAN—regulation of public analysts as in Act CAP 116 LFN 2004.
4. A manual of SOPs should be developed to enable the implementation of the NQAP.
5. A full policy review shall be conducted every five (5) years.

Monitoring and Evaluation

Monitoring and evaluation (M&E) serves as a basis for making decisions to institute corrective actions or determine early signs of possible deviations. M&E are critical components of medicine and other health products quality in a national quality assurance policy.

Monitoring and evaluation involves data collection, collation, analysis, and interpretation and report writing at all levels. This information is essential for the effective management and improvement of the quality of medicines and other health products.

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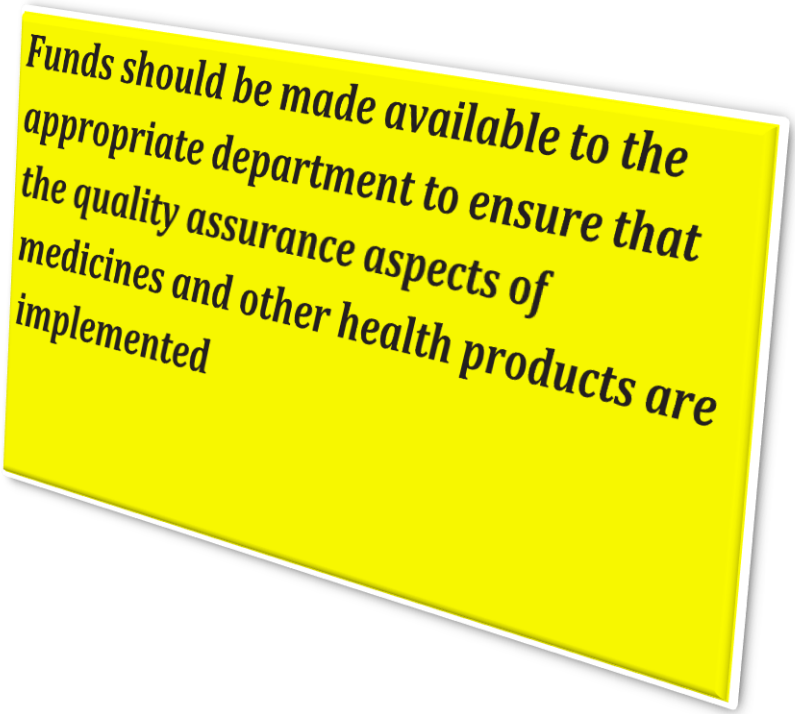
The following criteria should be considered:

- Appropriate indicators that conform to international standards for measuring outputs, outcomes, and impact of the quality assurance process should be developed and implemented.
- These indicators should be evaluated at all relevant levels of the health care delivery system.
- Routine assessment and progress of the NQAP for medicines and other health products implementation should be monitored at regular intervals.
- A full evaluation of the performance of the Policy should be conducted every two (2) years
- The Monitoring and evaluation of the NQAP should be keyed into the existing M&E framework of the FMOH.

Funding

Funding is critical to the successful implementation of the quality assurance system.



Funds should be made available to the appropriate department to ensure that the quality assurance aspects of medicines and other health products are implemented.

Monitoring and evaluation involves data collection, collation, analysis, and interpretation and report writing at all levels. This information is essential for the effective management and improvement of the quality of medicines and other health products.

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Adequate budgetary provisions should be appropriated for the sustainability of quality assurance maintenance at the federal and state levels.

- Government at all levels should make adequate annual budgetary provisions for quality assurance and its related activities.
- Stakeholders or affiliates should make available an agreed percentage of the total cost of the procured products for support towards quality assurance activities.
- Advocacy for funding to various stakeholders should be encouraged.
- Funding should be available to continue the process of quality assurance monitoring and evaluation, implementation, and policy review at the various levels of the health care delivery system.
- Funding should be made available annually for the production, distribution, and dissemination of quality assurance policy documents in the country.
- Funding should be made available annually for the training and re-training of personnel on quality assurance processes in the supply chain management.

Conflict of Interest

Where a conflict of interest exists or where there may reasonably be the perception of a conflict of interest based on certain criteria, the applicable partner(s)/stakeholder(s) must be excluded from participation/involvement in or influence on the decision-making process. Criteria, regulations and procedures must be established that allow for the disclosure of actual conflicts of interest or appearance of conflicts of interest, as well as the manner in which situations involving the conflict of interest shall be handled.

Any member of a stakeholder/partner entity that may be involved in activities, and/or holds interests that constitute a conflict of interest, or is perceived as such shall promptly declare such interest(s).

Such interest(s)/activities may include, but not necessarily be limited to the following:

- A possible conflict of interest is deemed to exist where the government employee or close relative, or a member of that person's household is an officer, director, employee, proprietary, partner, or trustee of the partner/stakeholders'

organization or affiliation or when aggregated with close relatives and members of that person's household is an employee of the partner/stakeholders' organization or affiliation.

- A possible conflict is also considered to exist where such a person is (or expects to be) retained as a paid consultant or contractor by an organization which seeks to do business with, and whenever a transaction will entail a payment of money or anything else of value to the official, member, to a close relative, or to a member of that person's household.

- A possible

conflict of interest exists when an individual affiliated with the government has an interest in an organization which is in competition with a firm seeking to do business with partners/stakeholders if the individual's position gives him or her access to proprietary or other privileged information which could benefit the partner or stakeholder in which he or she has an interest.

- A possible conflict of interest exists when an individual affiliated with a partner(s)/stakeholder(s) is a trustee, director, officer or employee of a not-for-profit organization which is seeking to do business with or have a significant connection with stakeholder(s)/partner(s) in government or is engaged in activities which could be said, in a business context, to be "in competition with" the programs of stakeholder(s)/partner(s).

REFERENCE DOCUMENTS

Essential Medicines List

Good Pharmacovigilance Practice Guidelines for Industry (2015)

Guidelines for Donation of Medicines and Health Care Equipment in Nigeria

National Blood Policy (2005)

National Drug Distribution Guidelines (2013)

National Drug Policy

National Health Policy 2004, Revised September 2004

Nigeria National Pharmacovigilance Policy (2012)

National Policy for Medical Laboratory Services

National Procurement Guidelines & Manuals (2006)

National Treatment Guidelines

Drug or Medicine-related Laws in Nigeria

1. ***Poisons and Pharmacy Act, CAP 366 of 1990.***

   This Act regulates the compounding, sale, distribution, supply and dispensing of drugs and provides different levels of control for different categories of drugs and poisons.

2. ***Food and Drugs Act CAP 150 of 1990***.

   This Act prohibits the sale of certain foods, drugs, cosmetics and devices as treatment for certain diseases. The Act prohibits the importation, exportation, distribution and sale of specified drugs. It also prohibits practices such as misleading packaging, labeling, and advertising, as well as manufacturing foods and drugs in unsanitary conditions. It conveys the power to appoint inspecting officers and food and drug analysts.

3. ***Counterfeit and Fake Drugs (miscellaneous provisions) Act, CAP 73 of 1990.***

   This Act prohibits the production, importation, manufacture, sale and distribution of any counterfeit, adulterated, banned or fake drugs. It also prohibits persons to sell any drug in an open market without permission from the proper authority.

4. ***Pharmacists Council of Nigeria, Decree 91 of 1992.***

[This repealed the Pharmacists Act of 1964.] This decree established the Pharmacists Council of Nigeria which is charged with the following responsibilities: (a) Determine the standard of knowledge and skill required of persons seeking to become registered members of the pharmacy profession; (b) Establish and maintain a register of persons qualified to practice as members of the pharmacy profession; (c) Prepare and review the code of conduct; and (d) Regulate and control the practice of the pharmacy profession. The Council has an investigating panel and disciplinary committee to discipline erring pharmacists as appropriate.

5. ***National Agency for Food and Drug Administration and Control Decree No. 15 of 1993.***

   This is the Decree establishing the National Agency for Food and Drug Administration and Control (NAFDAC). The Agency performs the following functions: (a) Regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of food, drugs, cosmetics, medical devices, bottled water and chemicals; (b) Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for the effective control of the quality of food, drugs, etc., as well as their raw materials and production, including processes in factories and other establishments; (c) Undertake appropriate investigations into the production premises and raw materials for food, drugs, etc., and establish relevant quality assurance systems, including certification of the production sites and regulated products; (d) Undertake inspection of food, drugs, etc.; (e) Compile standard specifications and regulations and guidelines for the production, importation, exportation, sale and distribution of food, drugs, etc.; (f) Undertake registration of food, drugs, etc.; (g) Establish and maintain relevant laboratory or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions. The Federal Task Force on Counterfeit and Fake Drugs established under the provisions of the counterfeit and fake drugs (miscellaneous provisions) Act operates within NAFDAC.

6. ***Drugs and Related Products (Registration) Decree No. 19 of 1993.***

   This Decree makes provisions for the prohibition of the manufacture, importation, exportation, advertisement, sale or distribution of a drug, drug product, cosmetic or medical device unless it has been registered in accordance with the provisions of the Decree. It also stipulates the procedure for applying for registration of a drug product, conditions under which information supplied by an applicant is disclosed, and provisions for the suspension or cancellation of certificates of registration and clinical trials. Penalties for contravention of provisions of this decree are also stipulated therein.

ACRONYMS

AP	African Pharmacopeia
AWACIO	Aids for Women, Adolescents, and Children International Organization
BP	British Pharmacopeia
CFR	Code of Federal Regulation
EML	Essential Medicines List
EVDL	Essential Veterinary Drugs List
FCT	Federal Capital Territories
FEFO	First Expiry, First Out
FMOH	Federal Ministry of Health
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPPP	Good Pharmaceutical Procurement Practices
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IPAN	Institute of Public Analysts of Nigeria
LFN	Laws of the Federal Republic of Nigeria
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
NASCP	National Aids and STDs Control Program
NDF	National Drug Formulary
NDP	National Drug Policy
NIPRD	National Institute for Pharmaceutical Research and Development
NIST	National Institute of Standard Technology
NMEP	National Malaria Elimination Program
NPSCMP	National Product Supply Chain Management Program
NPHCDA	National Primary Health Care Development Agency
NQAP	National Quality Assurance Policy

NRA	National Regulatory Authority
NSCIP	National Supply Chain Integration Project
PCN	Pharmacists Council of Nigeria
Ph. Int.	International Pharmacopeia
PMG-MAN	Pharmaceutical Manufacturing Group of the Manufacturing Association of Nigeria
PQM	Promoting the Quality of Medicines
QA	Quality Assurance
QC	Quality Control
SFFC	Spurious, Falsely-Labelled, Falsified Counterfeit
SON	Standards Organization of Nigeria
SOP	Standard Operating Procedure
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USP	U. S.Pharmacopeia
WHO	World Health Organization