Chapter

5

# Medical products and health technologies

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## Abbreviations

AMA..... African Medicines Agency
CAC..... Corporate Affairs Commission
CMS ..... central medical stores
DRF..... Drug Revolving Fund
FDS ..... Department of Food and Drug Services
FMOH..... Federal Ministry of Health
IP..... intellectual property
MAS ..... Mobile Authentication Service
MDDC..... mega drug distribution centre
NAFDAC..... National Agency for Food and Drug Administration and Control
NCS..... Nigeria Customs Service
NDDG..... National Drug Distribution Guidelines
NNRA ..... Nigerian Nuclear Regulatory Authority
PCN..... Pharmacy Council of Nigeria
PCPSR ..... Presidential Committee on Pharmaceutical Sector Reform
PHC..... primary health care
PMG-MAN..... Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria
PPMV..... patent and proprietary medicine vendor
PVG/FDIC ..... Pharmacovigilance/Food and Drug Information Centre
SDDC..... state drug distribution centre
TCAMCN..... Traditional, Complementary and Alternative Medicine Council of Nigeria
VAT..... value-added tax
WHO..... World Health Organization

## Chapter 5 key messages

- National policies and guidelines on medical product regulation and distribution exist but are poorly implemented and audited. Nigeria's National Agency for Food and Drug Administration and Control plays a critical role in regulation, market authorization and supply. More stringent policy implementation, tighter policy evaluation structures and the stipulation of sanctions are needed to support supply-side regulation.
- Nigeria has about 150 local pharmaceutical manufacturing companies, but they meet only 30% of the country's needs. This limited national capacity to produce medical products has resulted in over-reliance on imported pharmaceuticals and medical supplies. Foreign direct investment in the pharmaceutical sector, the provision of critical manufacturing infrastructure and tax incentives for local producers could improve domestic production capacity.
- Policies and guidelines exist to strengthen supply chain management. However, the lack of a systematic, well-regulated drug distribution system results in the deterioration of drugs during storage, stock shortages and the circulation of fake products. If effectively implemented, the National Drug Distribution Guidelines could improve supply and distribution nationwide.
- Despite policy intervention efforts, overprescription of branded medicines remains prevalent. Loss of patient and prescriber confidence in generic medicines and the absence of a national prescription policy and sufficient drug use training remain obstacles.
- Poor availability of medical technologies for diagnosis and limited capacity to maintain existing health technologies affect quality of care.
- The majority of Nigerians in rural and semi-urban areas receive health care from traditional medical practitioners. Standardization and formal integration of traditional medicine into the health system is under way but incomplete.

# 5.1 Governance and regulation

## Legislation and national policies

A range of national policies guides the regulation of medical products and technologies (FMOH, 2022a). See Table 5.1.a for a list of legislation and policies currently in place.

**Table 5.1.a** Legislation and national policies

| Policy | Year introduced | Objective | Implementation |
|---|---|---|---|
| Zero-tax Policy on Pharmaceuticals | 2024 | To strengthen the health care value chain, addressing rising drug prices and the depreciation of the Nigerian naira | This is being implemented across the nation and has led to a marked reduction in the cost of imported medicines |
| Nigeria Standard Treatment Guidelines (third edition) | 2022 | To assist prescribers in deciding on appropriate treatments for specific clinical problems, aiming to beneficially influence prescribing behaviour at all levels of care | This has been disseminated but not widely enough to ensure usage by all formal health providers at all levels of care in Nigeria |
| National Drug Policy | 2021 | To guide domestic drug production and procurement | There are low prescription rates for generic medications in Nigeria, and, currently, no law regulates the prescription of drugs, although the government has recently inaugurated a steering committee for a national prescription policy |
| Nigerian Vaccine Policy (first edition) | 2021 | To encourage local production of vaccines and to ensure self-sufficiency in vaccine availability, which will further boost the existing National Immunization Policy | Funds are currently being sourced for the necessary equipment and partnership to commence vaccine production |

**Table 5.1.a** Continued

| Policy | Year introduced | Objective | Implementation |
|---|---|---|---|
| Guideline for Donated Medical Products in Nigeria | 2021 | To guide NAFDAC's mechanism for pharmacovigilance and safety monitoring, regulation of medical products and health technology donations | This is being implemented |
| National Health Supply Chain Strategic and Implementation Plan (NHSCSIP) | 2021–2025 | To provide direction for medicine supply chain systems to accurately quantify, procure and cost-effectively distribute high-quality medicines and other health products down to the last mile | This is being implemented by some state ministries at the subnational level, but most stakeholders frequently ignore stipulated supply chain functions and processes, leading to poor coordination, integration and harmonization of multiple supply chains and their activities |
| Nigeria Essential Medicines List for Children (first edition) | 2020 | To prevent inappropriate prescriptions for children less than 12 years, over- and underprescription, use of inadequate preparations and dosage, and the use of expensive new drugs instead of cheaper alternatives | This has been implemented and has found to be useful |
| Nigeria Essential Medicines List (seventh edition) | 2020 | To prevent inappropriate prescription, over- and underprescription and the use of expensive new drugs instead of the cheaper alternatives | This is available and comprehensive enough for use at all levels of health care in Nigeria but needs to reach all primary health care facilities in Nigeria |
| Nigerian National Pharmacovigilance Policy and Implementation Framework | 2020 | To support monitoring of adverse events and guide drug safety monitoring in Nigeria | This is being implemented across the country<br>Sort codes need to be made available for all medicines in the country for easy reporting |

**Table 5.1.a** Continued

| Policy | Year introduced | Objective | Implementation |
|---|---|---|---|
| Bill establishing a council for traditional, alternative and complementary medicine practice | 2020 | To create an environment conducive for the development of traditional complementary and alternative medicines for national health system development and economic benefits | This is being implemented and it helps protect the traditional concept of ownership of traditional medicines |
| Five Plus Five-Year Validity (Migration to Local Production) policy | 2019 | To enhance local production of pharmaceuticals in Nigeria | This has not been fully implemented, as most medicines are not licensed for local production of their raw ingredients |
| Guidelines for Handling and Disposal of Unwholesome Medicines and NAFDAC Regulated Products (Food, Medicines, Medical Devices, Cosmetics, etc.) in Nigeria | 2018 | To properly manage unwholesome medicines and NAFDAC-regulated products at a facility level | Poor compliance with the national guidelines for expired medication disposal is prevalent, despite the threat of confiscation and arrest of those in possession of expired drugs by officials of the Nigeria Customs Service (NCS) and NAFDAC |
| National Policy for Controlled Medicines | 2017 | To enhance regulated accessibility to controlled medicines for medical purposes | This is being implemented across the country |
| Nigeria Supply Chain Policy for Pharmaceuticals and other Health Care Products | 2016 | To set policies and guidelines for the planning and forecasting of medical products and health technologies | This has been partially implemented, but the lack of a systematic, well-regulated supply chain system results in the deterioration of drugs during storage and stock shortages |
| Counterfeit and Fake Drugs and Unwholesome Processed Food (Miscellaneous Provision) Act (Amendment) Bill, 2015 | 2016 | To enable the regulation of fake and counterfeit drug circulation in Nigeria, to reduce treatment failures | This has been only partially implemented because of logistical issues with monitoring |

**Table 5.1.a** Continued

| Policy | Year introduced | Objective | Implementation |
|---|---|---|---|
| National Quality Assurance Policy for Medicines and Other Health Products | 2015 | To ensure that medicines and health products are quality-assured, effective, affordable and safe for use, and to protect the supply chain from falsified or substandard medicines and other health products | This has been only partially implemented, as adequate funds are lacking for the monitoring required |
| National Drug Distribution Guidelines | 2012 | To guide drug supply and distribution nationwide | This has been partially implemented, but the lack of a systematic, well-regulated drug distribution system results in the deterioration of drugs during storage and stock shortages<br>Despite the use of third-party logistics, long waiting times still persist |
| Guidelines for Donation of Medicines and Health Care Equipment in Nigeria | 2007 | To guide pharmacovigilance and safety monitoring, regulation of medical products and health technology donations | This is being implemented across the country |
| Traditional Medicine Policy | 2007 | To empower NAFDAC, as the regulatory authority for traditional medicines in Nigeria, to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of traditional medicines and products | This has been partially implemented, but some traditional medicines without NAFDAC approval are still sold in the country, due to inadequate monitoring |
| Guidelines on Medical Equipment Management in Nigeria | 2005 | To provide guidance to health facilities to support the maintenance of records of medical equipment and calibration and quality control procedures to track history and use and identify problems | This has been only partially implemented due to a lack of funds for the logistics of reaching all health facilities |

**Note:** NAFDAC = National Agency for Food and Drug Administration and Control.

Policies are formulated and revised at intervals based on need. Nigeria has not yet signed, ratified or deposited the treaty establishing the African Medicines Agency (AMA). The approval process is under way, and stakeholder consultation is still ongoing, with delays attributed to Nigeria's signing and ratification procedures. The AMA, when fully operational, is expected to improve medicine regulation and access by permitting more bulk imports, bringing down medicine prices and thus limiting the supply of substandard and fake medicines. It will also enable local pharmaceutical manufacturers to increase production and export more products.

## Regulatory system and responsible regulatory bodies

The regulation, licensing and standardization of medical products and health technologies are implemented by various government agencies (FMOH, 2022a). Key agencies and their roles are highlighted in Table 5.1.b.

**Table 5.1.b** Roles of key agencies responsible for the regulation of medical products and health technologies

| Agency | Key role | Source |
|---|---|---|
| Federal Ministry of Health (FMOH), Department of Food and Drug Services (FDS) | • Formulation of policies and guidelines on medical products and health technologies. | FMOH, 2022a |
| National Agency for Food and Drug Administration and Control (NAFDAC) | • The national regulatory authority for medical products and health technologies. The NAFDAC Act Cap N.1 LFN 2004 authorizes NAFDAC to regulate the manufacture, importation, exportation, distribution, marketing and use of medical products and health technologies in Nigeria<br>• This includes oversight for clinical trials and guidelines for regulating medical products and donated health technologies. It also inspects manufacturing facilities and distribution channels and outlets. It is responsible for advertisement control, pharmacovigilance, post-market surveillance, import and export control, and quality control laboratories for medicines, vaccines and other biologics, including traditional medicines and products | NAFDAC, 2017a |

**Table 5.1.b** Continued

| Agency | Key role | Source |
|---|---|---|
| National Institute for Pharmaceutical Research and Development (NIPRD) | • Researches and develops medicines, vaccines, diagnostics, biological products and pharmaceutical products. Conducts quality control and quality assurance tests for medicines, food, cosmetics, herbal products and raw materials and sets the standards and specifications for the manufacture of pharmaceuticals | NIPRD, 2020 |
| Pharmacy Council of Nigeria (PCN) | • Registers and licenses pharmacists and pharmaceutical premises in Nigeria<br>• Issues permits to pharmacy technicians, registers and licenses PPMVs, and regulates the marketing of pharmaceutical products | PCN, 2021a |
| Institute of Chartered Chemists of Nigeria (ICCON) | • Regulates the teaching, learning and practice of chemists in Nigeria with regard to chemical products and drugs | ICCON, 2020 |
| Institute of Public Analysts of Nigeria (IPAN) | • Analyses and standardizes medical products and health technologies<br>• Certifies product composition, safety and use | IPAN, 2022 |
| Nigerian Nuclear Regulatory Authority (NNRA) | • Approves the registration of medical diagnostic and imaging technologies, medical devices and aids | NNRA, 2020 |
| Nigeria Natural Medicine Development Agency (NNMDA) | • Responsible for research, development, documentation and promotion of Nigeria's indigenous medicine for sustainable integration into the national health care delivery system | NNMDA, 2019 |

**Note:** PPMV = patent and proprietary medicine vendor.

## Market authorization of medicines and health technologies

Market authorization for medical products and health technologies requires product registration with the National Agency for Food and Drug Administration and Control (NAFDAC) and the issuing of a NAFDAC registration number, which takes about 120 days (NAFDAC, 2017b), or 21 days for life-saving commodities (WHO, 2016). Product advertisements require advert approval from NAFDAC and vetting approval from the Advertising Practitioners Council of Nigeria. The Investigation and Enforcement Directorate of NAFDAC keeps track of compliance

with regulations. The directorate manages the disposal of NAFDAC-regulated products that are defective, unsafe, false, sub-par, expired, adulterated and/or unwholesome (NAFDAC, 2017b). Consumers can file drug-related complaints using the pharmacovigilance rapid alert system by sending a prepaid short text message with the name of the medicine and the problem or reaction to a short code (20543). They can also utilize the Mobile Authentication Service (MAS), which consists of a scratch-off code and texting capabilities to verify the authenticity of medicines prior to use (WHO, 2016).

## Regulation of medical devices and aids

NAFDAC regulates health technologies including medical diagnostic and imaging technologies and medical devices and aids via the national regulatory framework for medical devices. The framework prohibits medical device production, importation, exportation, marketing or distribution without registration (NAFDAC, 2018). Registration can be approved by NAFDAC, the FMOH or the Nigerian Nuclear Regulatory Authority (NNRA) (WHO, 2016). The registration process entails a manufacturing quality assessment of the medical device, inspection of legal documents, approval of the device by the relevant regulatory body and issuance of a NAFDAC identification number (NAFDAC, 2018). The registration process takes three to six months and is valid for one to five years (WHO, 2016; NAFDAC, 2018). Medical devices require registration with NAFDAC before import (WHO, 2016). The Drug Registration and Regulatory Affairs Directorate approves and certifies medical devices and directs national legislation to regulate medical devices (WHO, 2016). The NNRA formulates policy and regulates medical equipment with sources of radiation. It monitors nuclear safety and radiological protection and can administer approval certificates for medical devices with radiation sources (Idowu and Okedere, 2020). The Standards Organisation of Nigeria verifies and certifies that imported medical devices and aids meet acceptable Nigerian industrial standards. A medical device requires Standards Organisation of Nigeria Conformity Assessment Programme certification to get the approval of the Bureau of Public Procurement, needed for inclusion in the national list of approved medical devices and manufacturers (WHO, 2016).

## Regulation of wholesalers, pharmacies and vendors

The Pharmacy Council of Nigeria (PCN) registers all forms of pharmacy premises ranging from retail, wholesale and manufacturing to hospital and online pharmacies (PCN, 2021b), as well as the premises covered by the Corporate Affairs Commission (CAC) (PCN, 2004). The CAC incorporates and registers new businesses in Nigeria. PCN registration requires premises to meet PCN location and size requirements. The operation of online and mail order pharmacies is permissible only through a registered community pharmacy and in line with the regulations and guidelines of the PCN. Advertisement of pharmaceutical products is regulated by information and communications technology (ICT) laws such as the National Information Technology Development Agency Act and the Cyber Crime (Prohibition and Prevention) Act (PCN, 2021b).

Requirements for the registration of manufacturing premises are similar to those for new retail, distribution or importation premises, together with the list of products to be manufactured, company organigram and staff qualifications and duties (PCN, 2021b). The PCN ensures that coordinated wholesale centres meet personnel, storage facility and good storage practice requirements (PCN, 2021b). Only licensed pharmacists, operating from licensed premises, are authorized to trade in drugs and supply and dispense drugs to the populace (PCN, 2004). Premises are regularly inspected by PCN pharmaceutical inspectors (PCN, 2021a). However, over-the-counter medications can be sold in patent medicine stores controlled by patent and proprietary medicine vendor licences. All donated medicines and health technologies must meet the regulation requirements stipulated in the Guideline for Donated Medical Products in Nigeria (NAFDAC, 2021).

The FMOH is responsible for federal medical warehouses, federal central medical stores (CMS), and warehouse and distribution coordinating units. It supervises the activities of federal and zonal warehouses across the country to ensure the proper warehousing of medicines and health products procured for or donated to the country (FMOH, 2022a). All medical stores must have quality control laboratories and be suitably located, well constructed and well equipped, with storage facilities maintained at appropriate temperatures at every level of the medicine distribution system under the supervision of a pharmacist (FMOH, 2021e). Although a central computerized inventory control system has been established by the Department of Food and Drug Services (FDS) to effectively manage medical products and health technologies, this is difficult to fully operationalize because Nigeria has medical stores at the

national, state and local government area levels, with federal health institutions operating autonomously.

## Pricing, tax and reimbursement regulations

The regulation and market authorization of medicines and health technologies depend on their clinical trial profiles. However, to improve the affordability of medical products, strategies such as the Drug Revolving Fund (DRF) are used within the public sector (FMOH, 2022a; USAID, 2022b). Procurement from local manufacturers is encouraged and price markups are controlled based on the production cost of the medical product. A 10% price markup is allowed on expensive medical products such as anticancer agents, while as much as a 20–50% markup is permitted on more affordable medical products.

Medical and pharmaceutical products, instruments and appliances used in medical, dental or veterinary sciences and health care-related services are exempt from value-added tax (VAT). Essential medical equipment and supplies are exempt from import duty and VAT for an initial six-month period. In addition, the raw materials used in manufacturing pharmaceutical products are also exempt from VAT (FIRS, 2022). Nigerian regulatory requirements do not include mandatory clawback stipulations.

Reimbursement for medicines, vaccines, biologics and medical devices does not currently abide by established processes. However, the government makes payments for equipment and services supplied directly to local distributors. Foreign suppliers receive payments through negotiations with their local partners (export.gov, 2019).

## Clinical trials and quality control regulations

NAFDAC provides oversight for clinical trials in Nigeria and has also issued guidelines to supplement the NAFDAC Act. All clinical trials should be conducted in line with the approved protocol, good clinical practice and NAFDAC requirements (NAFDAC, 2017b). NAFDAC is responsible for pharmacovigilance and safety monitoring, regulation of medical products and health technology donation. According to NAFDAC's Guideline for Donated Medical Products in Nigeria, the recipient organization must demonstrate the capacity to handle the type and quantity of the donated drug product. At the

same time, the pharmacovigilance unit monitors any adverse drug reactions associated with the product's use (NAFDAC, 2021). The FMOH has produced the Guidelines on Medical Equipment Management in Nigeria (2005). Health facilities are expected to maintain records of medical equipment to track history and use. A similar record of calibration and quality control procedures must be maintained to track and identify episodes that may have led to problems (FMOH, 2005a).

## 5.2 Planning and forecasting

Policies and guidelines for the planning and forecasting of medical product and health technology needs in Nigeria include the National Drug Policy, the National Drug Distribution Guidelines (NDDG) and the Nigeria Supply Chain Policy for Pharmaceuticals (FMOH, 2018b). The annual procurement plans for medical products and health technologies are coordinated and prepared by the Department of Procurement of the FMOH for the ministries, departments and agencies. The procurement of medicines follows the drug supply chain as stipulated in the National Drug Policy and is based on the Essential Medicines List. The planning process for medical products is carried out using requisition lists received from all relevant programmes, departments and agencies. The FDS, through the National Product Supply Chain Programme, coordinates, manages and supervises the supply chain of pharmaceuticals and other health care products in Nigeria (FMOH, 2022a). The FDS also harmonizes the supply chains of all health care programmes in the country. Assessments of the quantities of medical products needed are based on past consumption patterns, and shortages are prevented by subjecting suppliers to a competitive bidding process through a DRF technical committee, where applicable, or a pharmacy technical committee.

### Disease-specific procurement

For HIV/AIDS drugs, Nigeria uses the Pooled Procurement Mechanism established by the Global Fund and the United States President's Emergency Plan For AIDS Relief. These drugs are reserved for national programmes and are made available at no cost at designated treatment health facilities in Nigeria. HIV/AIDS and tuberculosis drugs are also available in pharmacies supplied

by independent marketers, but without government or donor involvement. For malaria medicines, many locally manufactured medicines are available, and normal planning and quantification processes for essential medicines at all health care levels are followed. However, malaria medicines from the Global Fund are also procured through public–private mix approaches from World Health Organization (WHO) prequalified pharmacies, while other malaria medicines are purchased from local pharmacies and are usually given out for free during designated programme activities.

## 5.3 Domestic production and procurement

### Domestic production and procurement policies

The National Drug Policy 2021 guides domestic production and procurement. In 2019, NAFDAC introduced the Five Plus Five-Year Validity (Migration to Local Production) policy, to encourage the production of essential medicines locally. As of 1 May 2019, imported medical products capable of being produced locally are given a maximum of 10 years (initial registration period of five years and then renewal of registration for another five years) to transition to local production. Partnership with a Nigerian company is acceptable (Fatokun, 2020). The Migration to Local Production directive applies to manufactured pharmaceutical products, pharmaceutical ingredients (both active and non-active) and packaging materials. Failure to abide by migration guidelines results in a product's registration being cancelled, thus preventing distribution and even importation into the country (Fatokun, 2020). The Five Plus Five-Year Validity (Migration to Local Production) policy aims to decrease and discourage the import of pharmaceutical products over time and to increase the capacity to utilize local manufacturing facilities, thereby encouraging the production of essential medicines locally. However, the policy currently faces significant implementation challenges.

In 2016, the Economic Community of West African States Common External Tariff on pharmaceutical raw materials was removed. A 20% import adjustment tax was then added to four groups of imported drugs capable of being produced by local manufacturers: vitamins, antimalarials, antibiotics and alkaloid derivatives (Fatokun, 2020). In addition, Federal Executive Order No. 003 stipulated in 2017 that at least 40% of the government's procurement expenditure should be for locally manufactured goods or services. Nevertheless,

the policy acknowledged that not every product can be manufactured locally, and some imports are necessary.

The Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) is an umbrella organization of 150 manufacturers that advocates for national self-sufficiency in producing high-quality, safe and affordable medicines (Ezeobi, 2022). The group has called for policies that encourage private investors and sustain local manufacturers. An expedited medicines access programme, a partnership between the FMOH and local manufacturers, has been proposed.

The government came under pressure from the Pharmaceutical Society of Nigeria (PSN) to control the preponderance of fake drugs in Nigeria. A counterfeit and fake drugs decree was introduced in 1988 to make sales and distribution in open markets illegal without a registration licence (Erhun et al., 2001). A task force was set up to enforce this, and penalties meted out to offenders. The decree was amended subsequently to overcome shortcomings, including inadequate empowerment of NAFDAC to carry out its responsibilities and insufficient penalties for offenders. The bill was passed into law in November 2016 to make comprehensive provisions for the prohibition and control of counterfeit and fake medical products. These provisions are now being implemented and NAFDAC has been empowered to impose stiffer penalties on offenders.

Evidence suggests that policies facilitating the abolition of the import licence system and VAT on pharmaceutical raw materials and the decrease in tariffs on raw materials have encouraged local production (Ogbonna et al., 2015). A two-year executive order introducing zero tariffs, excise duties and VAT on imported pharmaceuticals, aimed at revitalizing Nigeria's health sector, came into effect in June 2024.

## Local capacity for production

Nigeria's pharmaceutical sector has a 60% production capacity (Okereke et al., 2021). However, approximately 70% of drugs consumed in Nigeria are imported (Fatokun, 2020; Olutuase et al., 2022). About 150 local pharmaceutical manufacturing companies meet only 30% of Nigeria's needs (Ezeobi, 2022). Challenges identified by PMG-MAN include the "brain drain", the high cost of production, diesel costs and uncollectable loans (Ezeobi, 2022). These factors undermine the sector's capacity to produce and thrive. A customized package of

fiscal and non-fiscal incentives could facilitate local pharmaceutical production at a competitive price (Fatokun, 2020; PharmAccess, 2022).

## What is produced and by whom?

Nigeria is the largest pharmaceutical manufacturing country in West Africa, accounting for more than 60–65% of local drug production (Obasanjo et al., 2015; Onyebuchi, 2016). In 2021, there were approximately 600 pharmaceutical manufacturers in Africa, 80% of which were concentrated in eight countries (South Africa, Egypt, Algeria, Morocco, Nigeria, Tunisia, Kenya and Ghana), with Nigeria ranking fifth based on market size (Ussai et al., 2022; Intelligence, 2023). The 150 registered local manufacturers in Nigeria compete with imported brands. Local production began in Nigeria in 1944 with the establishment of May and Baker Nigeria plc, Nigeria's first pharmaceutical company.

**Table 5.3.a** Top 10 Nigerian pharmaceutical manufacturers by total revenue

| Rank (from highest to lowest revenue) | Manufacturer |
|---|---|
| 1 | GlaxoSmithKline Nigeria |
| 2 | May and Baker Nigeria plc |
| 3 | Fidson Healthcare plc |
| 4 | Emzor Pharmaceutical Industries Ltd |
| 5 | Juhel Nigeria Ltd |
| 6 | Evans Medical plc |
| 7 | Swiss Pharma Nigeria Ltd |
| 8 | Nigerian-German Chemicals plc |
| 9 | Ranbaxy Nigeria Ltd |
| 10 | Vitabiotics Nigeria Ltd |

**Source:** Data from UNIDO, 2011

Nigerian manufacturers currently produce drugs including antimalarials, analgesics, antiretrovirals, herbal preparations and drugs for sickle cell disease. However, the current tax environment remains a constraining influence on the pharmaceutical sector and local manufacturers.

## Import requirements and procedures

Companies intending to clear imported drugs, controlled/psychotropic substances and/or drug precursors from the ports must submit an application to the Director-General of NAFDAC, signed by the Superintendent Pharmacist.

Import application requirements are as follows (NAFDAC,2024):

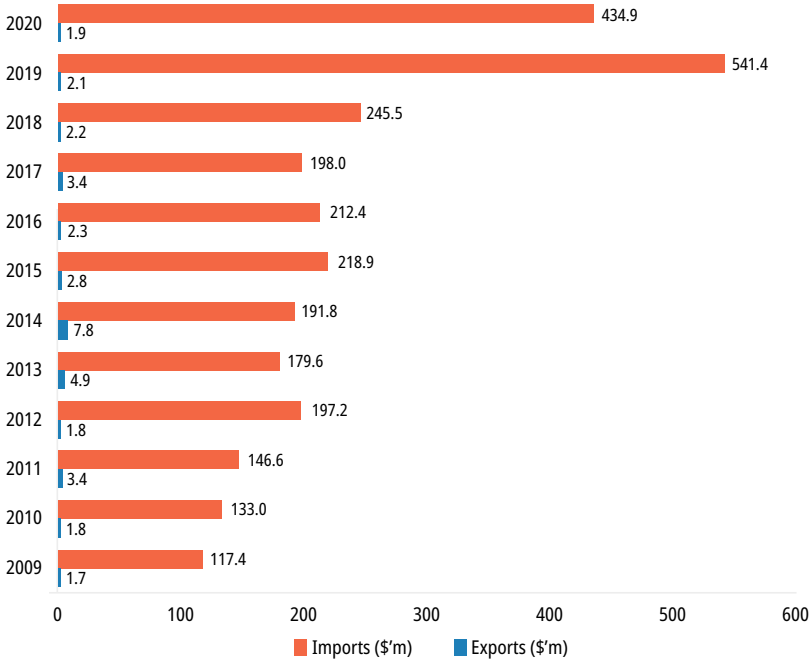
- name
- quantity of each item
- port of entry
- single goods declaration form
- commercial invoice
- pre-arrival assessment report
- manufacturer's certificate of analysis
- clean report of inspection and analysis for shipments from China, Egypt and India
- packing list
- form M (a legal document that importers must complete to import goods into Nigeria)
- bill of loading/airway bill
- photocopy of permit to import
- evidence of product registration/letter of recommendation from Registration and Regulatory Affairs (new applicants only)
- evidence of payment of stipulated fee.

## Procurement systems

Different procurement systems exist for different health programmes. Some programmes are centrally procured at the national level and distributed to the CMS of the various states. This is widely used for national programmes and is beneficial in terms of the improved availability, accessibility and affordability of high-quality drugs. However, procurement and key supply chain decisions are made at the ministry level without engaging state decision-makers, resulting in an inefficient system. Open tenders and direct procurement are widely used by some programmes. Payment delays for past orders lead to stock-outs of essential drugs at public health facilities. Unfortunately, drugs expire and spoil during peripheral storage due to poor storage facilities and lack of personnel.

In addition, delays in clearance by NAFDAC and the Nigeria Customs Service (NCS) result in medicines arriving at storage facilities close to their expiry dates, thus leading to expired drugs along the downstream supply chain.

**Figure 5.3.1** Exports and imports of medical and pharmaceutical products in million US dollars, 2012–2020




**Source:** UN Trade and Development and CEIC data taken from PharmAccess, 2022

Due to lack of data, Figure 5.3.1 shows the values, in US dollars, of medical and pharmaceutical products imported to and exported from Nigeria between 2012 and 2020, rather than the "Annual amounts spent on procurement of medical products and health technologies as a proportion of THE (total health expenditure)" which would usually form part of our template description of a country's health system and services . Additionally, Figure 5.3.2, "Annual amounts spent on procurement of medical products and health technologies by source of funding", which would also usually form part of our template description, has been excluded again due to a lack of data.

Chapter 3, Section 3.7.1, provides further details on external sources of funds and institutional donor engagement. Data on total product expenditure by

funding source (public, private and external sources) are currently unavailable. Chapter 6, Section 6.3, contains further information on health infrastructure procurement.

Supply-side constraints, such as limited domestic production, have led to high costs of medicines, and distribution bottlenecks have negatively affected health service delivery, resulting in poor clinical outcomes, inhibiting progress towards achieving universal health coverage.

## 5.4 Storage and distribution

Drugs are stored centrally and then distributed to peripheral points. Temperature monitoring equipment is available to ensure acceptable standards and temperatures are maintained in medicine storage facilities. However, this equipment is not available in all facilities and medicines are often stored in conditions that exacerbate deterioration and the degradation of their active ingredients. Unreliable electricity supply also affects storage and reduces potency, thus resulting in drug deterioration (Olutuase et al., 2022).

Drugs are distributed from central storage points via road transport. Vehicle shortages significantly affect distribution. The absence of a functioning drug management information system to effectively coordinate the public drug supply and poor staff performance regarding monitoring and evaluation also negatively affect distribution (NHW, 2022). However, to mitigate this shortcoming, last-mile distribution of health products has been privatized to third-party logistics providers and this has been very successful in terms of reducing drug stock-outs.

The lack of effective system coordination falls short of the drug supply management stipulated by the National Drug Policy. For this reason, the federal government established the Presidential Committee on Pharmaceutical Sector Reform (PCPSR) in 2003. The committee is mandated to develop strategies to facilitate an effective drug distribution system in Nigeria and has developed NDDG. The National Health Supply Chain Strategic and Implementation Plan 2021–2025 has also been developed and is being implemented in some states at the subnational level. It harmonizes existing policies to develop an evidence-based guideline intended to strengthen governance and improve quality and coordination in supply chain management (NHW, 2022).

Chapter 6, Section 6.2, provides further information on laboratory, diagnostic and medical equipment infrastructure, including distribution

and maintenance, and systems for handling donated equipment. Chapter 8, Section 8.2, also provides information on digital systems for handling supply chains.

## Warehousing and distribution policies

The drug distribution guidelines developed by the PCPSR assign clear roles and responsibilities. Manufacturers and importers are responsible for ensuring drug availability; they sell to only mega drug distribution centres (MDDCs) in the country's six geopolitical zones and state drug distribution centres (SDDCs). MDDCs are driven by the private sector and sell to only wholesalers. In contrast, the SDDCs service the public sector at the state level (Ojo, 2014) and are also permitted to sell to national health programmes and wholesalers. Wholesalers are important because they can sell to public and primary health care (PHC) facilities, community pharmacies and private health institutions and directly to end users/consumers (Onyebuchi, 2016). Community pharmacies are also permitted to sell to private health facilities. All stakeholders are subject to professional disciplinary measures for non-compliance as defined by the regulatory bodies, namely the PCN and NAFDAC (Ogbonna et al., 2015).

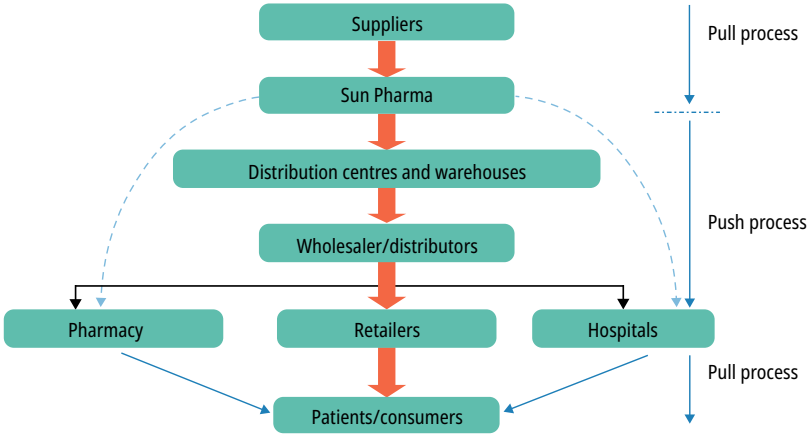
At the state level, drug supply to the public being undertaken through the CMS contributes to the out-of-stock syndrome seen in government hospitals, since these hospitals cannot purchase directly from reliable companies, nor can they undertake emergency purchases; instead, they rely solely on supplies from the CMS. The drug distribution network is chaotic because stakeholders fail to adhere to guidelines (NAFDAC, 2019b). Open market stakeholders, including community pharmacies, patent and proprietary medicine vendors (PPMVs), private and public hospitals, importers, pharmaceutical manufacturers and distributors, and wholesalers, frequently ignore stipulated responsibilities in terms of supply chain functions and processes. The coordination, integration and harmonization of multiple supply chains and their activities is also poor (NAFDAC, 2019b).

PPMVs do not have formal education, and most have little or no training, yet they make diagnoses, treat patients and prescribe and dispense medicines based on practical experience. Statutorily, they should sell only over-the-counter drugs but, in practice, they sell all types of drugs. Drugs are sold on the streets, in the market and even on buses. Evidence suggests that most drugs sold informally are adulterated, substandard or fake (Onyebuchi, 2016).

## Warehousing and distribution practices

The drug distribution framework uses the pull-and-push process (see Fig. 5.4.a). There is a pull from the suppliers for raw materials for production, then the pharmacies produce medicines, which they push to the distribution centres and wholesalers who then push them to the hospitals, pharmacies and retailers. The patients then pull from these sources by buying from them as recommended by the Nigeria Supply Chain Integration Project in 2014.

**Figure 5.4.a** Drug distribution framework at a glance: pull-and-push process




**Source:** Manikandan and Sundarakani, 2019

## Warehousing and distribution capacity

Good warehousing practices and distribution capacities across supply chain operations should ensure effective coordination of warehouse operations to supply health programme commodities to health facilities. This process should include:

- appropriate and timely stock replenishment and warehouse space utilization;
- ensuring temperature monitoring equipment is available and functional and temperatures comply with acceptable standards;
- monitoring the distribution activities of third-party logistics service providers;

- adequate transport;
- maintaining relevant documentation (e.g. a quarantine tracker, expiry tracker and pallet utilization tracker) to provide routine summary reports as required.

Capacity in Nigeria is underutilized and suboptimal, with health facilities often purchasing directly from the CMS, to avoid long waiting periods for supplies.

## Stock-outs and shortages

The major procurement methods used – open tender and direct procurement – are prone to delayed payments for previous orders, leading to stock-outs of essential drugs at public health facilities. Drug expiry at central or peripheral storage points further contributes to stock-outs. Studies have shown that 87% of health facilities have experienced stock-outs. Of these, 69.5%, of which 85.2% were hospitals, experienced stock-outs of vital and essential medicines (Chukwu et al., 2017).

Drug demand and supply issues are mostly attributed to a lack of raw materials for manufacturing, problems with logistics and manufacturing, seasonal demand, unpredictable demand and high product-specific demand. A unified definition of drug shortage is lacking, which has been identified as a barrier to effectively addressing the issue.

WHO established global mitigation strategies to curb drug shortages in 2016. These include operational improvements to lower the risk of shortages and to activate early warnings, governmental policy changes, and training health professionals to avoid and manage shortages (WHO, 2016; Shukar et al., 2021; Olutuase et al., 2022). While these are currently being implemented in the Nigerian context, there are no structures for policy evaluation and there is a lack of strict punishment for defaulters and an absence of funds to conduct regular training.

## Management of expired products

The most common expiry date management approach is the "first expired, first out" method (Johnston et al., 2014). In theory, this approach is adopted to reduce the rate of drug expiration and spoilage. However, this method is not

always appropriate because of improper storage/filing of drugs and limited training of drug-handling personnel.

NAFDAC uses incineration to dispose of expired drugs at the central level, alongside a state-run disposal system. Expired substances are separated from in-date and in-use drugs, labelled "expired" and included in inventory reports (NAFDAC, 2019a). Best practice is, however, rarely followed in drug warehouses, given that poor compliance with the national guidelines for expired medication disposal is prevalent, despite the threat of confiscation and arrest of those in possession of expired drugs by officials of the NCS and NAFDAC. Others dispose of expired drugs via rubbish bins, the general municipal waste system and burning and by pouring expired liquid medicines down sinks.

### Waste management

Despite the large volume of medical waste generated, a standardized evaluation and management framework is currently lacking. Waste segregation is not commonly practised. Waste storage is also suboptimal, with many bins lacking lids. The rating of health care waste management practice was found to be level 0, unsustainable with regards to segregation, storage and packaging (Abah and Ohimain, 2011). Waste is collected at centralized open dumpsites, and either burnt or buried. Hospital waste, including human body parts, used swabs and expired drugs, is usually disposed of with the general waste, without prior treatment. Burning and burying medical waste, especially needles and other sharp items, is widespread, despite managed incineration being preferable (Aigbavboa and Mbohwa, 2020).

## 5.5 Stewardship and use

### Rational use of health products and technologies

The FMOH coordinates the development of policies to guide and encourage the rational use of health products and technologies. The National Drug Policy, National Supply Chain Policy for Pharmaceuticals, NDDG, Nigeria Essential Medicines List (seventh edition 2020), Nigeria Essential Medicines List for Children (first edition 2020), National Vaccine Policy, National Action Plan for Antimicrobial Resistance 2017–2022, Nigerian Standard Treatment Guidelines

(third edition, 2022) and the National Drug Control Master Plan 2021–2025 are examples of such policies. The licensing and regulation of human resource development for health, together with the training and continued medical education of health personnel, are practices carried out to encourage the rational use of health products and technologies across Nigeria's health services and communities (Olutuase et al., 2022).

## Government supervision and monitoring of rational use

The Nigeria Essential Medicines List (seventh edition 2020) and the National Drug Policy seek to prevent inappropriate prescription, over- and underprescription and the use of expensive new drugs instead of cheaper alternatives. The concept of an essential medicines programme was introduced with the National Drug Formulary and Essential Drugs List Act (1989) to help improve rational prescribing and reduce health care costs. In 2017, the FMOH developed the National Policy for Controlled Medicines to enhance regulated accessibility to controlled medicines for medical purposes.

NAFDAC and the PCN jointly regulate drug supply, distribution, stock and sale in Nigeria. The PCN sets practice standards, including monitoring and supervision, to encourage rational use of medicines at the national, subnational, facility and shop levels. Supervision and monitoring practices are not well defined or standardized across all levels. Medicines and therapeutic committees are formed in health facilities and monitoring is done through surveillance. The National Primary Health Care Development Agency coordinates and supervises vaccine delivery and rational use at the PHC level using reporting forms. The DHIS2 platform also supports supervision and data collection through mobile technology at the national and subnational levels.

Concerted efforts in this area have been made by government at all levels by providing training in rational drug use for health personnel involved in diagnosis and the prescription and dispensing of drugs and also for consumers. Standard treatment guidelines and the national formulary are provided for all prescribers according to the level of care (primary, secondary or tertiary care), although health worker retraining in this area is needed (Mostafa et al., 2021).

Rational use practice is regulated through supportive supervision from relevant professional bodies and senior colleagues. To improve drug use practices, health institutions rely on feedback collected through communication

between staff and patients, hospital complaint boxes and the public posting of the phone numbers of key management staff. Moreover, efforts are being made by the FMOH and PCN to strengthen prescription practices by developing a prescription policy, increasing monitoring and ensuring that only licensed pharmacies dispense prescribed drugs. Prescription errors are common, including prescribing incomplete doses, omitting details of dosage by age and duration of drug use, and prescribing medications that could adversely interact with each other. Utilization of the WHO prescription guide (De Vries et al., 1994) as a reference standard for regular clinical audits could help assess prescription quality across the country.

## Monitoring adverse events

The Nigerian National Pharmacovigilance Policy and Implementation Framework was developed in 2012 and revised in 2020 to support the monitoring of adverse events and guide drug safety monitoring in Nigeria (FMOH, 2020h). Monitoring is coordinated by the National Pharmacovigilance Centre or Pharmacovigilance/Food and Drug Information Centre (PVG/FDIC) at NAFDAC, which was established in 2004 as part of NAFDAC and is affiliated with the WHO Collaborating Centre for International Drug Monitoring. PVG/FDIC has developed guidelines for monitoring the safety of health products and technologies in Nigeria. Pharmacovigilance units have been established nationwide to collect, evaluate and disseminate information on adverse drug events. Reporting can be done by any health worker or marketing authorization holder by texting details of the problem to 20543, a toll-free short code. The Med Safety app (WEB-RADR) can also be used for adverse drug reaction reporting in Nigeria, and there is a functional national database on adverse drug reactions and other medicine-related problems (NNPPIF, 2020).

## Prescribing patterns: generic or branded

Policies to encourage the use of medicines in their generic rather than branded forms have been designed to minimize expenditure on medicines and improve access to affordable and essential medicines (Hassali et al., 2012; Mostafa et al., 2021). However, in practice, prescribing branded medicine is still prevalent in many public health institutions, despite the specifications of the Essential

Drug Act (Government of Nigeria, 1990), now superseded by the National Drug Policy. This practice has held back the expected gains of the essential drugs programme. Likewise, low prescription rates for generic medications contradict the Nigeria Standard Treatment Guidelines (Fadare et al., 2016). Currently, no law regulates the prescription of drugs, although the government has recently inaugurated the Steering Committee for a National Prescription Policy.

Most hospital pharmacies are stocked based on the Essential Drugs List, with dispensing based on the generic medicines available. On the other hand, profit-led community pharmacies stock mostly branded medicines, given that their clients usually present prescriptions with specific brand-name medicines. Prescribing patterns are shown in Table 5.5.1. Note that the private sector is expected to align with the national treatment guidelines.

## 5.6 Traditional medicines and products

### Governance and regulation

The Federal Government of Nigeria, through the FMOH, established the Traditional Medicine Policy in 2007. The policy empowers NAFDAC, as the regulatory authority for traditional medicines in Nigeria, to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of traditional medicines and products (FMOH, 2005c).

In addition, a traditional, complementary, and alternative medicines department was created at the FMOH in 2018 to develop, implement, review and monitor compliance with policies; initiate the development of legislation relating to traditional, complementary and alternative medicines; promote the development and commercialization of indigenous traditional medicines; and integrate traditional, complementary and alternative medicines into the national health care system (FMOH, 2018d, 2022). The department collaborates with NAFDAC and the Traditional, Complementary and Alternative Medicine Council of Nigeria (TCAMCN), to strengthen cooperation between traditional medicine and other health care providers. It also provides reliable information to consumers on the proper use of available traditional medicine products (FMOH, 2022a).

The Drug Registration and Regulatory Affairs Directorate of NAFDAC coordinates the registration/listing of, labelling of, advertisement of, inspection

of manufacturing facilities for, laboratory analysis of and post-marketing and safety monitoring of traditional herbal medicines in Nigeria using the Guidelines for the Registration and Control of Herbal, Medicinal Products and Related Substances in Nigeria. Approximately 1035 traditional medicines and products have been registered by NAFDAC, according to its drug product database (FMOH, 2018d). The registration status of each product should be renewed every five years. The traditional herbal medicines listed are those whose therapeutic/medicinal claims have not been assessed through clinical trials and whose listed status should be renewed every two years (WHO African Region, 2022c).

Some state governments have enacted a traditional medicine board law allowing traditional medicine to be practised legally. State-level laws are guided by the Nigerian Traditional Medicine Practitioners' Council Act. The practitioners liaise with state boards of traditional medicine to ensure compliance with the policies and guidelines outlined in the Federal Traditional Medicine Board Act, then they establish model traditional medicine clinics, herbal farms, botanical gardens and traditional medicine manufacturing units in various regions of the country, working with organizations that have similar interests.

## Research, development and manufacturing

The National Institute for Pharmaceutical Research and Development conducts research on phytomedicines. It identifies, collects, processes, conserves and standardizes medicinal plants and herbal medicines through its Department of Medicinal Plant Research and Traditional Medicine (NIPRD, 2020). The Centre for Research in Traditional, Complementary and Alternative Medicine collaborates with the Nigerian Council of Physicians of Natural Medicine and other traditional medical practitioners to coordinate research that will ensure safety and show the efficacy of potential herbal remedies. It also trains researchers from governmental and nongovernmental institutions and traditional medical practitioners (Balogun, 2022). Other privately and publicly funded research institutes, universities and pharmaceutical manufacturing firms also form partnerships and contract research to foster the development of traditional medicines. Although the scientific literature on traditional medicines in Nigeria has expanded recently, information on emerging developments and promising medicinal plants is still very limited (Balogun, 2022).

## Organization and practices

Organization and provision differ across the country. Traditional health care practitioners differ by ethnic group. The Igbos call them dibia and the Yorubas call them babalawos, while the Hausas call them boka. Traditional medicine providers vary in nature and include traditional bonesetters, birth attendants, traditional doctors, herbalists and spiritual healers and others associated with alternative and complementary treatments.

Numerous herbal medicines are in circulation. While some have approval from the country's drug regulator – NAFDAC – others are sold illegally (Oladipupo-Okorie and Viatonu, 2014). Manufacturers are free to advertise their products; however, NAFDAC requires that advertisements be accurate, complete, clear and designed to promote credibility and trust among the general public and health care practitioners. There are two main classes of traditional medicine suppliers: local producers and distributors of imported products, most of which are from the south-west and south-east geopolitical zones.

There are several herbal medicine and homeopathy training institutions, including the Federal College of Alternative and Complementary Medicine in Lagos. Most modern traditional health practitioners combine their knowledge with mainstream skills and abilities in processing and preserving herbal medicines, as well as in the management of illnesses.

## Acceptance and use

Traditional medicines and products are widely used in Nigeria and continue to gain acceptance, particularly in remote, rural and peri-urban areas of the country, where they are used by up to 80% of the population (Balogun, 2022). The ratio of traditional healers per head of population in these settings is much higher than that of medical doctors per head of population. Different reasons drive the use of herbal medicine by people of all classes. Some see it as the only affordable, easily accessible form of health care; others turn to it when conventional medicine has failed them. The use of Islamic medicine mixed with traditional Hausa medicine to treat ailments is gaining popularity, especially in the northern parts of the country (Oladipupo, 2021).

To accelerate the health agenda in Nigeria, there is a focus on institutionalizing traditional medicine alongside orthodox medicine in health care provision. Traditional medicine products have yet to be included in the

Nigeria Essential Medicines List. However, there are plans to develop a national essential list of complementary and alternative medicines for Nigeria (FMOH, 2018d). The Medical and Dental Council of Nigeria is also contemplating integrating homeopathy into the country's health care delivery.

### Knowledge and intellectual property rights

The government assures traditional medicine practitioners' intellectual property (IP) rights for their products. However, traditional healers gain little from the current IP regime due to a lack of IP awareness, the lack of globally recognized IP regimes and difficulties obtaining patents in the informal sector (Ekong, 2021). The Nigeria Natural Medicine Development Agency has institutionalized and provides a protective mechanism for traditional medical knowledge and has raised awareness of and sensitized stakeholders to the issue. A draft policy and draft IP framework have been developed. This is being implemented by the Traditional, Complementary and Alternative Medicines Department of the Federal Ministry of Health and Social Welfare. The scope of protection provided extends to traditional knowledge that is generated, conserved and transmitted in a traditional and intergenerational context, as well as through biological resources. A further bill to protect the traditional concept of ownership, which is usually communal, was approved by the federal government in 2020 and allows for the establishment of a council for traditional, alternative and complementary medicine practice in Nigeria. These policies and frameworks are being implemented by the TCAMCN of the Federal Ministry of Health and Social Welfare.

## 5.7 Recent reforms

The Health Sector Reform Committee was established in 2022 to improve diagnosis and health care delivery by addressing infrastructure and equipment deficiencies. The committee began by commissioning a diagnostic needs assessment of the health sector. The findings are expected to improve diagnostics in Nigeria's public health facilities.

Second, the DRF system, a concept that promotes access to and ensures the availability and affordability of drugs, guarantees the sustainability of drug supplies and services. The DRF scheme is also linked with community voice and

accountability mechanisms to ensure responsiveness and promote equity and the rational use of drugs, based on the Essential Medicines List. It was adopted in 1988 based on the Bamako Initiative – a regional public health strategy aimed at increasing the availability of essential drugs and services across the continent – and reviewed in 2007. However, weak political, socioeconomic, managerial and administrative structures negatively impact the DRF system's operations in Nigeria (Ogbonna et al., 2015). Various organizations and projects have recently invested in reviving the DRF in some states. The introduction of state social health insurance schemes and the implementation of the Basic Health Care Provision Fund in the country have helped to improve the availability of essential medicines and reduce stock-outs. The FMOH has embarked on a comprehensive overhaul of the failing DRF scheme across health care facilities with a view to strengthening sustainable service delivery. It is also working on the development of a national DRF policy. Unchecked theft from the DRF account has been a major challenge for the scheme, and legislation has been recommended by various interest groups, such as the PSN and Association of Hospital and Administrative Pharmacists of Nigeria, as a solution.

MAS scratch codes for all antimalarials and antibiotics were introduced nationwide in 2012 to stop the retailing of fake medicines. However, challenges in implementation have been attributed to context issues, including mobile network issues and constant power outages. Low literacy levels and limited phone ownership have also contributed to low MAS success rates (Oyetunde et al., 2019). More information is available in Chapter 8, Section 8.2.

NAFDAC has introduced the implementation of pharmaceutical traceability using Global Standards 1 to secure the supply chain by enabling the visibility of movement of medical products. In this way, the history of a product or the intended route of a product can be tracked (NAFDAC, 2022).

Innovative approaches to strengthening local production capacity – such as the implementation of the zero-tax policy for importation of medicines and pharmaceuticals, including equipment and low-interest loans for such purposes – should be applauded and embraced by pharmaceutical companies. Building the capacity of health workers in supply chain management at the federal and state ministries of health and facility levels, as well as dissemination of these current policies and guidelines to the end users, will improve current practice in the country. There is also a need for technology adoption to enhance the production of medicines and vaccines.

## Chapter summary

Chapter 5 describes Nigeria's policies and practices relevant to the range of medical products and health technologies needed for the effective provision of essential health care services. National policies and guidelines govern the production, procurement, distribution and use of medical products and health technologies in Nigeria, with NAFDAC playing a pivotal role in regulation, market authorization and supply. However, policy implementation and auditing of progress remain weak.

Annual procurement plans for medical products and health technologies are coordinated and prepared by the FMOH's Department of Procurement, for the ministries, departments and agencies. Assessing the quantities of medical products that need to be produced and imported is based on past consumption patterns. More stringent policy implementation, tighter policy evaluation structures and the stipulation of sanctions are needed to support supply-side regulation.

Existing national production capacity meets just 30% of the country's needs, making Nigeria overly reliant on imported pharmaceuticals and medical supplies. The lack of a systematic, well-regulated drug distribution system results in the deterioration of drugs during storage, stock shortages and the circulation of fake products. Prescribing branded medicines is still prevalent in many health institutions, despite the specifications of the National Drug Policy to prescribe generic versions of drugs. Limited availability of medical technologies for diagnosis and limited capacity to maintain existing health technologies affect the quality of care, as does underinvestment in health technologies.

Most Nigerians in rural and semi-urban areas receive health care from traditional medical practitioners. The standardization and formal integration of traditional medicine into the health system is under way but is still incomplete.

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