

Embassy of India, Luanda भारत का दूतावास, लुआंडा

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# REPORT ON HEALTH SECTOR IN ANGOLA

May 2022





## **Foreword**

It is with great pleasure I present a report prepared by Mr. Aditya Vats, Second Secretary (Economics & Commerce) on the health sector in Angola. In this report, Mr. Vats has compiled all the information available in open sources for easy reference of interested Indian companies.



- 2. The objective of this report is to give an idea of potential opportunities in the health sector. The report gives the information about Angola's health care system, its various organs and the available infrastructure, National government's Health policy framework, health indicators, a brief SWOT analysis, prospects for market access by Indian companies, and the rules and regulations for entry into the Angolan market especially in Healthcare, Pharmaceuticals and Medical equipment. The report provides a capsule of information that will be useful for Indian businesses to explore and take advantages of the capabilities and opportunities, in a focused and comprehensive manner.
- 3. Angola and India share historic and friendly bilateral relations based on mutual trust and respect. Both countries are striving to diversify their economic relations and strengthen cooperation in the areas of health and pharmaceuticals, agriculture and food processing, energy, mineral resources and technology. India is Angola's 3rd largest trading partner sharing about 10% of Angola's external trade mainly on account of bulk crude oil purchase.
- 4. The Embassy of India in Angola has been active in organizing various webinars and virtual events to strengthen trade and investment between both countries. The Embassy also strives to spread information about business and investment opportunities in both the countries through economic newsletters and sector specific reports, which are available on the Embassy's website. You are encouraged to send your economic and commercial queries and inputs to our commercial wing at the following email ids sscom.luanda@mea.gov.in, com.luanda@mea.gov.in

(Pratibha Parkar) Ambassador Embassy of India , Luanda

#### Introduction



Angola is an upper middle-income country of 33 million inhabitants that is 67 percent urban. The country will graduate from its least developed country status to a developing country in 2024. The population by gender, comprises 49.4 percent male and 50.6 percent female. Angola has a large working force with 52% of its population in the age group of 15-64 years. Poverty is estimated to be around 48.4 percent, as per latest data of 2019, using the US\$ 1.9 per person per day. The Health Expenditure of Angola is 3% of GDP with US\$ 71

per capita being spent on Health. Life Expectancy at Birth in Angola is 63.1 years and a high fertility rate of 5.6 births per woman.

## **Health Care System**

Angola's healthcare system is comprised of public and private services. As per Angolan law, public health services, from primary care to specialized services, are available at no cost. However, the public system suffers from shortages of doctors, medicines, nurses, primary health care workers, as well as inadequate training and a lack of a computerized information management system to efficiently track historical records of patients. As a result, access to healthcare services and to pharmaceuticals for most of the population is limited. The best quality health services are found in Luanda and in the other major cities of Benguela, Lobito, Lubango and Huambo.

Most middle and upper middle class Angolans use private healthcare services that generally offer higher quality and fee-based care. Four major private clinics are located in Luanda: Girassol (affiliated with state oil company Sonangol), Sagrada Esperança (affiliated with the state diamond company Endiama), Multiperfil (affiliated with the Presidency), and the Luanda Medical Center. Numerous small private clinics are also available. Professional and upper class Angolans typically travel to Namibia, South Africa, Cuba, Spain and Portugal for more complex medical treatments. However, such international health travel has become more difficult due to increased costs with the local currency devaluation and severe restrictions on foreign exchange. Many Angolans also have started preferring India for medical treatments.

## **Government organisations / National Health System**

The Ministry of Health (MINSA) is the entity responsible for formulating and conducting the policy in Angola, constituting the National Health Development Plan (PNDS 2012-2025) its main strategic instrument, with direct effects on the improvement of the main indicators of health. However, the health and well-being of populations in Angola are correlated with the social determinants of health, namely nutritional status, conditions of access to water drinking water, basic sanitation services and the improvement of accessibility to large areas of the territory national. The implementation of health policy requires, as such, an integration with several areas and levels of governance.



MINSA has Health Guardianship Entities, which are autonomous organizations that act in cooperation with MINSA through its Council. These entities are not necessarily founded by the Ministry, but are incorporated by the Government under the validity of the Constitution. These include:

- National Institute for Health Research (INIS), which is a national institute for scientific research, technological development and innovation.
- National Anti-drug Institute (INALUD), which is dedicated to dealing with matters that ii) relate to the misuse of psychotropic substances, whether legal or illegal.
- iii) National Institute of Opthamology of Angola (IONA), provides health care in the field of prevention, diagnosis and specialized treatment of eye pathologies, as well as the training of specialist doctors and other professionals.

The National Health System (NHS) covers the National Health Service, which operates under the supervision and methodological guidance of MINSA and is managed by provincial governors and municipal administrators. The following subsystems and supplementary services also form part of the national system and are responsible for Health infrastructure in Angola.

- i) The Health Service of the Angolan Armed Forces (DSS/EMG/FAA), which is the biggest national partner of the Ministry of Health with respect to assistance to communities and services of major public companies (SONANGOL, ENDIAMA and others).
- The National Civil Protection Service (SNPC) of the Ministry of Interior, which takes the ii) lead in organizing a response to natural disasters and emergencies, including public health emergencies. It is also responsible for health surveillance interventions organized by the National Police Force in areas relating to oversight, economic activities and border control.
- National Directorate of Public Health (DNSP) The National Directorate of Public Health iii) shall be the direct executive service which regulates, guides and coordinates all health promotion, disease prevention and control activities. and disease control.
- iv) **General Health Inspectorate (IGS)** - The General Inspection of Health is the technical support service that monitors, supervises and evaluates the functioning of the National Health National Health System, especially in what concerns the legality of acts, efficiency and performance of services, proposing or detenninating measures for connection and improvement.
- **The National Health Board** is the technical support service which ensures the evaluation of v) the physical and mental status, incapacity for the evacuation of sick people outside the country.

- vi) National Directorate of Hospitals/Services - The National Directorate of Hospitals is the direct executive board that draws up public hospital policies and coordinates the organization of the health infra-structures and institutions that develop health care activities.
- Medicines and Health Technologies Regulatory Agency (ARMED) The Regulatory Agency vii) for Medicines and Health Technologies, is a public establishment with legal personality and capacity, endowed with administrative, patrimonial and financial autonomy, in charge of carrying out regulatory, regulatory, guidance, licensing, inspection and control of activities in the field of medicines for human use and health technologies, with a view to guaranteeing their quality, efficacy and safety. (Article 1 of Presidential Decree No. 136/21 of 1 June). It aims to develop actions for regulation, regulation, guidance, licensing, supervision and control of activities in the field of medicines for human use and health technologies, with a view to guaranteeing their quality and safety.
- viii) Central Medicines Procurement and Supply (CECOMA) - Is a public institute responsible to develop the acquisition, distribution and maintenance of medical instruments in coordination with other organs of the Ministry of Health
- ix) Other participating entities include Hospitals/Services
  - a) **Provincial Health Offices and Provincial Government run Provincial Hospitals**
  - Municipal Health Directorate and Municipal Administrations run Municipal b) Hospital, Health Care Centers and Posts;
  - The health education sub-system, which covers technical and professional c) institutions as well as public and private medical schools. Like the National School of Public Health: A public institution dedicated for technical-professional specialization, post-graduation and -professional, in public health, as well as to promote the technical level of health professionals
  - d) Health and non-profit making private health services (essentially run by religious institutions and NGOs).
  - Community and Health Development Agents; e)
  - d) Other Ministries and viz. M/Education (MED); M/o Higher Education Science Technology and Innovation (MESCTI); M/o Your and Sports (MINJUD); M/o Social Action and Women Promotion (MASFAMU); M/o Interior (MININT); M/o Justice and Human Rights (MJDH); M/o Tecommunications, IT and communication (MINTICS); M/ o Agriculture and Fisheries (MINAGRIF); M/o Industry and Commerce (MINCO) etc.

## **Health Policy framework**



Rights to health care are enshrined in Angola's Constitution, in its latest amendment passed in 2010. Article 21 provides Health care under the 'Fundamental tasks of the State' which include to promote policies that will make primary health care universal and free; and to make strategic, large-scale, permanent investments in human capital, with particular emphasis on the full development of children and young people, as well as in education, health care, the primary and secondary economy and other sectors that structure self-sustainable development. Further, Article 77 of the Constitution, guarantees Health and Social Protection.

Angola's National Development Plan for 2018-2022 (PND) and National Health Development Plan for 2012-2025 (PNDS) outline the government's priorities. These include: rehabilitating and

expanding public healthcare infrastructure and capacity, especially for rural and underserved urban populations; expanding healthcare professional training; and disease prevention.

Angola's Health development goals are also included in Government's Long-Term Development Strategy (ELP Angola) 2025, titled "Angola a Country With A Future Sustainability, Equity and Modernity", aiming to "combat poverty and promote the improvement of the health status of the Angolan population, providing more direct support to the groups disadvantaged and poor social groups, ensuring the population a greater healthy longevity".

The PNDS 2012-2025 aims to promote compliance with the right to health enshrined in the Constitution, universal access to health care, improving the management and financing mechanisms of the National Health System (NHS), providing services of quality, timely and humanized, with a view to combating poverty and strengthening the well-being of the population.

The PNDS has been developed on the basis of the following priorities for the sustainable development: Increased life expectancy at birth; Accelerated reduction of maternal, infant and childto-juvenile mortality; Improvement of the Human Development Index and promotion of the achievement of the Millennium Goals; Consolidation of legislative and organizational reform of the NHS as well as institutional capacity; Health improvement at all levels; Elaboration of strategic plans for the training of technicians and health professionals in the short, medium and long term and distribution of human resources in accordance with the needs and objectives of the Plan; Updating the incentive plan for health professionals; Adoption of new health technologies; Health allocation of adequate and sustainable funding; Efficient and modern management of the resources of the NHS.

The PND 2018-2022 establishes the following intervention priorities for the health sector: Expand and improve access to health care, through the creation, rehabilitation and modernization of health units and the strengthening of human resources, with a focus on Primary Health Care; Promote the integrated and articulated organization between the health units of the three levels of attention, ensuring the availability of means of diagnosis, efficient management of medicines, vaccines and essential medical devices; Improve and strengthen maternal and child health care and nutrition;

Reduce morbidity and mortality from communicable and non-communicable diseases through promotion, prevention, comprehensive treatment and rehabilitation measures, as well as the improvement intersectoral interventions with regard to the social determinants of health; Reinforce the Health Information and Management System, through the modernization.

In addition to these strategic guidelines, the definition of health policy is part of the objectives of the African Union Agenda 2063: "Healthy, well-nourished citizens with a long hope of life" and "Citizens with access to quality and affordable health services, with access to universal sexual and reproductive health information, available to all women and groups vulnerable", with two priority areas of intervention: "Poverty, Inequality and Hunger" and "Health and Nutrition".

Health is also a central element of the objectives of the 2030 Agenda, namely "ensuring access to quality healthcare and promote well-being for all at all ages" (SDG 3) and "eradicate hunger, achieve food security, improve nutrition and promote agriculture sustainable development, thus contributing to an improvement in public health" (SDG 2).

For the achievement of above objectives, following aims stand out in Angola's health policy development:

- i) Combat diseases, namely those of communicable and parasitic origin and chronic diseases, with relative weight in the national nosological framework, as well as emerging and reemerging ones;
- ii) Protect maternal health and support reproductive health;
- iii) Substantially reduce infant mortality and under-5 mortality;
- iv) Develop and organize the primary health care network, taking into account the population and the geographical area, as well as the particularities of rural and urban areas;
- v) Expand the secondary healthcare network (General – Provincial Hospitals), as a second priority;
- vi) Consolidate the tertiary health care network (more differentiated Hospital Units), as National Reference Units, based on the needs of differentiated care, according to the national framework;
- vii) Create a tertiary health care network, based on private initiative and PPP;
- viii) Substantially increase, in quantity and quality, human resources in the health sector, privileging the national offer, including that found in the diaspora;
- ix) Make the financing model evolve from a situation with wide domain of the public sector and of international aid to a situation of plurality of funding sources, in which, however, primary care remains largely publicly funded;
- x) Build, progressively, a model of organization and management of the National Health Service, matrix type, given the intersectoral and intra-sectoral relationships

## **SWOT Analysis**



The National Health Development Plan (PNDS) vision configures health as an primary factor in the country's overall development and social justice, promoting universal access to equal health care, improving the management and financing mechanisms of the NHS. It offers quality, timely and humanized services, with a view to combating poverty and strengthening the National well-being. PNDS objectives are ambitious in all areas of the NHS, including strengthening the

fight against transmissible and chronic diseases, mother and child care, improved services, etc. PNDS is a key management document and an essential integration tool to sustain the NHS in the medium and long term politically, technically and financially. It is presented as the strategic-operational document to materialize the strategic guidelines set out in the "Angola 2025" Long-Term Development Strategy and the National Health Policy, as well as in the priorities of the Executive, transforming them into concrete actions and interventions to be executed during its term.

## The Strengths of Angolan Sustainability are:

- i) Political Will on the Importance of Nutrition;
- ii) National Nutrition Programme;
- iii) National Nutrition Strategy for childhood and the for Food and Nutrition Security;
- iv) Integrated Municipal Programme for Rural Development and Combating Poverty;
- v) National Council for Food and Nutrition Security;
- vi) Intersectoral coordination and partnership;
- vii) Sensitized national and international partners;
- viii) Economic growth of the country.

The health needs and the current problems facing the NHS are mainly related to:

- i) insufficient health coverage and poor maintenance of the Health Centre;
- ii) the weak system of reference and against reference among the three levels of the NHS;
- iii) human and technical health personnel with limited quantitative and qualitative expression and poor distribution of personnel in rural and peri-urban areas;
- iv) weaknesses in the Health Management System, including the information, logistics and communication system;
- v) insufficient financial resources and inadequacy of the financing model; and
- vi) reduced access to drinking water, sanitation and energy.

The PNDS projected that about \$5.2 billion would be invested in the public system per year for the period 2013 to 2025. Angola's National Budget (OGE) 2021 provided 12% of its primary fiscal expenditure spending on Health, an increase of 3% over previous year 2020, amounting to a total of US\$ 2 billion, making the above targets defined in PNDS, PND and ELP difficult to attain.

#### As per latest available data, some health indicators are as follows:

1	Life expectancy at birth (years)	63.1
2	Fertility rate	5.6 births per wom- an
3	Neonatal mortality rate (per 1000 live births) (2016)	24
4	Under-five mortality rate (probability of dying by age 5 per 1000 live births) (2016)	68
5	Maternal mortality ratio (per 100 000 live births) (2015)	239
6	Diphtheria tetanus toxoid and pertussis (DTP3) im- munization coverage among 1-year-olds	31%
7	Infants exclusively breastfed for the first six months of life (%)	38%
8	Child deliveries in health facilities	51%
9	Births attended by skilled health personnel	57%
10	hospital beds per 1,000 people,	approximately 0.1
11	Doctors per 1,000 inhabitants,	about 0.08
12	Nurses/midwives per 1,000 inhabitants	0.01
13	Population using improved drinking water sources (%) (Censo 2014)	13 (Rural) 51.4 (Urban) 36.1 (Total)
14	Population using improved sanitation facilities (%) (2015)	81 (Urban) 60 (Total) 25.9 (Rural)

(Source: WHO 2018 report and World Bank latest data)

In the field of health, there have been improvements in infant mortality rates (80 per thousand in compared to 180 per thousand in 2009) and mortality of children under five years (120 per thousand compared to 300 per thousand at the beginning of the century). There was a decrease in the rate of morbidity due to Malaria (which has dropped from 25% to 15%), Poliomyelitis is eradicated and Leprosy almost. The Ebola prevention operation was successful. However, there is still a considerable scope for progression, evident in the numerous cases of cholera and, more recently from Yellow Fever and Malaria. The nutritional status of Angolans is also a concern, with 38% of children showing moderate chronic malnutrition and 15% with severe malnutrition, a situation that worsens in rural areas.

## **Cooperation with India**



India and Angola have signed a Memorandum of Understanding for cooperation in the field of Health and Medicine in 2022, which has set pace for forging enhanced bilateral cooperation. The MoU provides for exchanges in health sector, to explore and take advantages of the capabilities and opportunities in a focussed and comprehensive manner, develop joint initiatives and partnerships, technology development and capacity building.

The MoU has paved the way forward for exchanges and training of medical doctors and other health professionals, assistance in the development of human resources and setting up of health care facilities, regulation of pharmaceuticals, medical devices and cosmetics and exchange of information, procurement of medicines and medical equipment and other areas towards enhancing cooperation.

#### **Market Access**

Angola offers medium-term business opportunities for Indian companies. Given its challenging business environment, and consistent attention needed to develop market presence, companies should consider the necessary time and financial commitments required to succeed in Angola. The long-established presence by Portuguese companies in Angola provide opportunities for collaboration, and also poses stiff competition for new market entrants. A strong Angolan business partner who is well aware of the local business procedures and is established in the industry with financial strength and established clients is essential to business success. Companies should perform thorough due diligence on potential business partners and establish contractual arrangements conformant to Indian and Angolan laws. The best prospects include in Medical equipment (diagnostic and imaging); Instruments; Consumables; Pharmaceuticals; Training and management services and technology; Hospital and clinic design and construction; Distance medicine services and technologies.

#### **Pharmaceuticals**



local manufacturing Increasing basic primary pharmaceuticals is a government priority as articulated in Presidential Decree 180/10 which established the country's National Pharmaceutical Policy. The Ministry of Health reports that pharmaceutical purchases, primarily imports, total over \$60 million per year. Leading suppliers of pharmaceutical imports into Angola are China, India, and Portugal. According to the Angolan Pharmaceutical Society,

there are over 221 importers and distributors of pharmaceuticals and medical devices. Local production is limited to Nova Angomédica, a joint venture between the Angolan Ministry of Health and private company Suninvest. Nova Angomédica produces anti-anemic, analgesic, antimalarial, anti-inflammatories, anti-tuberculosis, anti-allergic (in pill and syrup forms), as well as saline solution and ointments.

Pharmaceuticals are distributed through pharmacies, public hospitals, and private clinics. The quality of products, prices, and service vary according to location. Small pharmacies in the outskirts of major cities tend to sell unregulated, lower cost pharmaceuticals, often from India and China. Higher quality and fully registered pharmaceuticals are more common in urban centers. Pharmacies in public hospitals generally provide generic pharmaceuticals, while private pharmacies generally carry branded pharmaceuticals.

Counterfeit pharmaceuticals are a concern in Angola. The National Institute for Consumer Protection (INADEC) with Regulatory Agency for Medicines and Health Technologies (ARMED), are responsible for enforcing registration requirements and keeping non-conforming pharmaceuticals and counterfeit products out of the market.

## **Medical Equipment**



Angola relies primarily on imported medical equipment, devices, supplies and consumables to meet local demand. Medical solutions and equipment are distributed to hospitals, clinics, medical centers and practitioners through a small network of local importers and distributors. There is nominal local manufacturing of medical supplies and consumables in Angola.

Several specialized cardiology centers are equipped for diagnostic capability as outpatients care; however, very few

have the infrastructure or equipment for interventions and surgeries. Angola currently offers limited opportunities for sales of cardiology devices and equipment, but this should expand in the future as diagnosis and treatment capacity improves.

#### **Healthcare Infrastructure**



Angola's public healthcare sector holds potential for Indian companies given the government's priority on expanding public healthcare infrastructure and providing efficient primary healthcare delivery. Private healthcare will continue to grow as a portion of the overall health services network in Angola to meet demand for quality healthcare by the middle and upper classes, many of whom currently rely on healthcare treatments outside of Angola.

In the retail area, Angola has been experiencing an upswing in the establishment of comprehensive, well-stocked pharmacies offering prescription and over-the-counter medicines, personal hygiene, self-improvement health products, smoking cessation, first aid supplies, basic outpatient immunization and diagnosis services. Leading pharmacies in Angola include: Mecofarma, Moniz Silva, Novassol, Central, and Mediang. These pharmacies could become promising clients for Indian suppliers. Medical equipment including instruments, diagnostic and imaging are also needed in the market. Post-Covid, opportunities should open for design, construction, and equipping of public health facilities to expand capacity in Luanda and other provinces where healthcare services are limited.

### Telemedicine

Several healthcare facilities are utilizing telemedicine to extend health care service to rural areas and lower income urban populations, groups who typically depend on traditional medicine. However, these services are challenged by limited internet access among poorer populations and inconsistent internet connectivity outside of major population areas, as well as by government budget shortfalls. Examples of telemedicine solutions in Angola include: Girassol Clinic's five-year contract with Portuguese company PT Inovação e Sistemas to provide medical care and remote specialty consultations, as well as training for the health care professionals throughout the country;

Pediatric Hospital David Bernardino in Luanda partners with PT Inovacao e Sistemas telemedicine system to access international medical expertise to diagnose and treat children with heart problems; Nossa Senhora da Paz Hospital in Benguela Province accesses expertise and training on infectious diseases using telemedicine with the Vall d'Hebron Institute of Research in Spain; and, the Luanda Medical Center deploys patient monitoring technologies from Israeli company Shahal Medical Services Ltd.

Under the e-VidyaBharati and e-AarogyaBharati (E-VBAB) Network Project, India has offered capacity building and training for Angolan youth and professionals through telemedicine and tele-education, which is under consideration of Angolan side.

## **Registration Process**

The Ministry's National Regulatory Agency for Medicines and Health Technologies (ARMED) is the regulatory body, set up under Article 1 of Presidential Decree No. 136/21 of 1 June, 2020 and is responsible for establishing the criteria for pharmaceuticals and medical equipment entry into Angola. ARMED is a public establishment with legal capacity, and endowed with administrative, patrimonial and financial autonomy, in charge of carrying out regulatory, regulatory, guidance, licensing, inspection and control of activities in the field of medicines for human use and health technologies, with a view to guaranteeing their quality, efficacy and safety. ARMED regulates and authorizes clinical trials of medicines and health technologies, working together with the Ethics Committee of the Ministry of Health.

ARMED has authorized 179 importers and 48 distributors of pharmaceuticals and medical devices as of 1 April, 2022. To import into Angola, pharmaceutical products must be registered with the Ministry of Health, submitted for laboratory tests to meet compliance to norms and standards, and be labelled in Portuguese. There are 14 private DNME certified pharmaceutical laboratories in Angola: AstraZeneca, Bayer Health Care, Bial, BluePharma, Dafra Farma, Edol, GSK, Labesfal, Laboratórios Azevedos, Merck Serono, Sandoz, Sanofi, Shalina and Tecnifar. Health authorities are also planning to develop a public pharmaceutical laboratory that will have the capacity to analyze the quality of pharmaceutical products before entering Angola.

#### **Customs Clearance**

The following are requirements for the customs clearance of medicines and other pharmaceutical products:

1. For medicines in general and herbal medicines (including industrialized natural medicines):



- Batch quality control certificate;
- Invoice in Portuguese;
- Certificate of Origin of the products;
  - Information leaflets in Portuguese;
- In the case of narcotics, psychotropics, precursor substances and other products subject to control by the Ministry of Health, a copy of the Import Certificate issued by ARMED must also be attached.

#### 2. For medical equipment:

- a) Invoice in Portuguese;
- b) Certificate of origin of the Products;
- In the case of rapid tests for the diagnosis of infectious diseases, the Copy of the c) Import Certificate issued by ARMED must also be attached.
- 3. The request for customs clearance of the requests referred to in paragraphs 1, 2 and 3 must contain the following data:
  - a) Exercise Authorization Number;
  - b) Tax Identification Number;
  - c) Commercial Invoice Number;
  - d) Origin of the goods (country specification);
  - Country of Origin (of manufacture); e)
- For medicines received at the Angola Post Office, DHL and/or purchased via the internet for personal use, you must attach the justification (medical prescription) signed by the attending physician, including the respective number of the Order of Physicians, with legible signature and purchase invoice from the country of origin.
- 5. The application form can be downloaded from the link: https://armed.gov.ao/wp-content/ uploads/2022/04/REQUERIMENTO-para-desalfandegamento.pdf

## Import certificates

There is a requirement for issuance of import certificates of medicines and health products under the special control by the Ministry of Health. In order to request authorization for import, the following requirements must be met with the Regulatory Agency for Medicines and Health Technologies (ARMED):

- 1. Import request addressed to ARMED, including the Pharmaceutical Practice Authorization number and the Tax Identification Number, which must be signed by the Technical Director of the importing entity
- 2. Export authorization issued by the competent authorities of the country of origin
- 3. Opinion of the National Directorate of Public Health for the importation of antituberculous drugs





- 4. Opinion of the National Institute for the Fight against AIDS for the importation of antiretrovirals
- 5. Copy of the validation issued by the National Institute for Health Research, for the import of Rapid Diagnostic Tests for screening and diagnosis of infectious diseases
- 6. Original letter from the hospital addressed to the importer, signed and stamped by the General Director of the hospital unit, for the importation of narcotics.
- 7. Proforma invoice of the products to be imported, in Portuguese (alternatively in English/French or Spanish);
- 8. Certificate of Good Manufacturing Practices (GMP)
- 9. Copy of the Information Leaflet, the label that accompanies the medicine, must include the Portuguese language

After the product enters Angola, the importer must send ARMED a copy of the export certificate issued by the competent authorities of the country of origin within eight days, under the risk of being penalized in future imports.

The list of products subject to the special control by the Ministry of Health are as follows:

- 1. Anabolic steroids
- 2. Anaesthetics
- 3. Anti-retroviral drugs
- 4. **Blood Products**
- 5. Rapid diagnostic tests for screening and diagnosis of infectious diseases
- 6. Vaccines
- 7. Anti-poison serums and antidotes
- 8. **Immunoglobolins**
- 9. Misoprostol and derivatives
- Sildenafil and derivatives 10.
- 11. Tramadol
- 12. Citotec
- 13. Acamprosate
- 14. Alcohol
- 15. Supplements containing anabolic substances
- 16. Raw materials and packaging materials for the pharmaceutical industry
- 17. Drugs or health products for clinical trials
- 18. Plants or parts thereof having a therapeutic effect
- 19. Medicinal products used in erectile dysfunction

The lists of Narcotics, Psychotropics and Precursor Substances subject to control by the International Narcotics Control Board can be accessed through the link (INCB). The application form can be downloaded from the link https://armed.gov.ao/wp-content/uploads/2022/04/ REQUERIMENTO-produtos-controlados-.pdf

### **Market Authorisation**

Marketing Authorization, is the authorization to commercialize a certain drug in the national market, after its evaluation by the Regulatory Agency for Medicines and Health Technologies, culminating in the issuance of an Introduction Authorization Certificate on the Market (CAIM), valid for five years.

The procedures for applying for AIM are set out in article 10/annex III of Presidential Decree No. 315/20 of 17 December, 2020.

Under the Registration of medicinal products procedure adopted by ARMED, it consists of evaluating the technical documentation of the medicinal product, inspection of manufacturing facilities and laboratory evaluation of samples of the medicinal product proposed for registration, including pharmacological evaluation.

#### MANUFACTURING ACTIVITY

For authorization to exercise the manufacturing activity of health products in Angola, a dossier is to be submitted to the Ministry of Health / ARMED under following Heads:

- i) Documentation required for the implementation of the manufacturing unit
- ii) Manufacturing unit implementation project
- iii) Manufacturing unit
- iv) Written procedures
- Project related to staff v)

When submitting the dossier, only the documentation referred to in point i will be sent and points ii to v will be evaluated during the inspection of the installations.

## Setting up a Pharmacy / Herbalist Shop

An application addressed to the Director General of the Regulatory Agency for Medicines and Health Technologies, including the Tax Identitifciation Number NIF is required to be submitted with following:

- i) Color copy of the applicant's identification document.
- ii) Deed of Incorporation of a Company (for companies).
- iii) Plant with quotas of the installations, accompanied with sketches of Location.
- iv) Disclaimer of the authenticated Technical Director and the original OFA Declaration.
- Proof of payment of fees. v)

## Opening a drug/equipment depot

An application addressed to the Director General of the Regulatory Agency for Medicines and Health Technologies, including the Tax Identitifciation Number NIF is required to be submitted with following:

- i) Color copy of the applicant's identification document.
- ii) Deed of Incorporation of a Company (for companies).
- iii) Plant with quotas of the installations, accompanied with sketches of Location.
- iv) Disclaimer of the authenticated Technical Director and the original OFA Declaration.
- Proof of payment of fees. v)

#### **Barriers**

Testing Requirements: Imports of pharmaceutical products are subject to testing during customs clearance, and after customs clearance are subject to additional oversight by the Ministries of Commerce and Health. To import medical devices into Angola, the registered importer must present a Certificate of Origin, a Certificate of Free of Sale, and a certificate proving compliance with ISO 9001 quality norms to the Ministry of Health, which is responsible for processing the required import license.

Severe delays in access to foreign exchange combined with the limited public sector healthcare budget is impeding some Angolan importers and distributors from introducing new product lines and stocking product inventory.

#### **Procurement & Tenders**

Most imports of pharmaceuticals and medical equipment are managed by the Angolan private sector. Private health institutions purchase directly from overseas suppliers or through their designated local distributors. CECOMA is the Ministry of Health's official procurement agencies. The public sector depends on the central government medical procurement center (CECOMA) which centralizes all orders and manages stocks for all public health institutions nationwide. The tenders of the Ministry of Health can be accessed through CECOMA or MINSA websites as below or media newspaper like Jornal de Angola.

## **Government Links**

Ministry of Health - https://minsa.gov.ao/ao/

National Health Plan 2012-2025 - http://extwprlegs1.fao.org/docs/pdf/ang169620.pdf

National Regulatory Agency for Medicines and Health Technologies (ARMED) - https:// armed.gov.ao/. More details on ARMED are available at https://armed.gov.ao/. Contact details of ARMEDm are Rua Comandante Che-Guevara n° 86/86A, B° Maculusso, Ingombotas, Luanda - Angola | Tel.:+244 945 817 227 | TIN:5000767115 | Email: armed@minsa.gov.ao

Jornal De Angola: https://www.jornaldeangola.ao/ao/

## **Main Hospital and Clinics**

Luanda Medical Center: https://www.lmc.co.ao/ Congressos da Clinica Girassol: www.girassol.co.ao Clínica Multiperfil: www.multiperfileventos.com/pt

Clinica Sagrada Esperanca: https://www.clinicasagradaesperanca.co.ao

#### **Local Associations**

Ordem dos Médicos de Angola: www.ordemdosmedicosdeangola.org Ordem dos Farmacêuticos de Angola: www.ordemfarmaceuticosangola.org Associação dos Farmacêuticos de Língua Portuguesa: http://www.afplp.org Ordem dos Enfermeiros de Angola: www.ordenfa.amawebs.com

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