Pricing & Reimbursement

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CONTENTS

Angola

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Angola does not yet have a Pricing and Reimbursement system in place. While there are encouraging signs that the country is willing to undertake legislative and administrative reform, general improvement of economic conditions must be achieved before an effective system can be implemented.

Market introduction/overview

The Republic of Angola is one of the largest countries on the African continent with a surface area of 1.2 million km^2, located on the west coast of sub-Saharan Africa. Recent population estimates are about 25 million inhabitants, comprising *ca*. 48% men and 52% women.

After almost four decades of conflict, ending in 2002, Angola experienced fast economic growth, mainly driven by its oil industry. The sharp decline in oil prices since mid-2014 and weak growth of the non-oil sector significantly impacted the economy and social services, resulting in a reduction of public revenues, severe tax and external imbalances (including forex shortages). Exports dropped by more than half, and the external accounts moved from surplus to deficit.

On top of this, there was the devaluation of the Angolan Kwanza. The state of Angola's economy is threatening the recent progress in terms of economic and social development, notably the long-term target of improving human development outcomes. Public spending on health has decreased since 2014 (however, this was already low compared to international standards), compromising previous increases in health expenditure by the public sector.

The National Health Service ("NHS") includes: (i) the Ministry of Health; (ii) Provincial Governments – with Provincial Health Directions and Provincial Hospitals; and (iii) Municipal Administrations – with Municipal Health Directions, Municipal Hospitals, Health Care Units and Posts. The Municipal Administrations have been assuming a progressively more dominant role in the primary healthcare network and basic healthcare activities, despite their limited administrative and technical know-how. Public expenditure at municipal level is high but struggles to achieve its goals.

Public health services provided by the NHS are free of charge and delivered through a three-layer pyramid: (a) first level – health centres and clinics, municipal hospitals, nursing stations and doctors' offices; (b) second level – general and monovalent hospitals; and (c) third level – central and specialised hospitals. The public health system also comprises the Army, the Ministry of Interior and public companies' health facilities. There are significant disparities in health facilities and access to care between urban and rural areas.

Pharmaceutical pricing and reimbursement

Regulatory classification

The regulation of medicinal products in Angola is still incipient and inconsistent.

The law establishes different types of medicines, but the system has not matured enough to associate a specific regime to each type.

Medicinal products are regulated by the Ministry of Health. Medicines are controlled and monitored by the General Health Inspection ("IGS"), which is responsible for inspecting pharmaceutical products. Among other aspects, IGS monitors the quality of imported pharmaceuticals.

The National Directorate of Health ("DNME") regulates pharmaceutical activity, and oversees the application of administrative and technical regulations to the sector. Medicines cannot be legally supplied and purchased without being registered in Angola through a procedure managed by the DNME. The registry is valid for five years and is renewable.

Generics and biosimilar medicines do not yet have a legal definition. However, the law does define "therapeutic equivalents" to the reference product. The law establishes that the Ministry of Health should promote generic substitution in pharmacies, and that medicines should be purchased at the best available price. Additionally, it is stated that generics should benefit from simpler and cheaper registration procedures. However, all these aspects reflect legal intentions; neither the law, nor any regulation, provides for any specific regime. Government plans also set out that the acquisition of generics is a priority.

An important feature of pharmaceutical regulation is inclusion in the National List of Essential Medicines ("List"). The List outlines the medicines that Angolan authorities deem necessary to treat the most pressing conditions from a public health perspective – and a significant share of the market concerns the sale and purchase of those medicines. The law provides that the List should contain medicines that are indicated for treatment of prevalent diseases, and are safe and efficacious. Given the abstract nature of these criteria, the inclusion of medicines in the List is rather subject to the Ministry of Health's discretion.

Most medicines are purchased by the State. Reimbursement of pharmaceutical products has not yet been regulated, despite several indications that this is a public policy priority that should advance soon. As for medical prescription, the foundation of the regime has been laid, but additional regulation is required to define which medicines are subject to medical prescription.

Indeed, while the law provides that suppliers of medicinal products can obtain a Marketing Authorisation after the request is assessed by the National Directorate of Medicines and approved by the Ministry of Health, specific marketing authorisation legislation is yet to be enacted. Subjection to medical prescription is typically assessed and decided in the Marketing Authorisation procedure. If such procedure is not legally provided for, subjection to medical prescription is not assessed by the authorities in a legally foreseen procedure.

Notwithstanding, the law does determine that medicines are subject to medical prescription if they fulfil one of the following requirements:

(i) raise direct or indirect risks when used without medical supervision;

(ii) are, or can be, widely used for a different purpose than intended, and such purpose poses a direct or indirect risk to public health;

(iii) contain substances, or combinations that include substances, with sensitive side effects; and

(iv) are prescribed by a doctor to be administered by a parent.

Medicines subject to medical prescription can be classified as: common (if they fulfil the requirements to be subject to medical prescription, and do not fall into other special categories); medicines subject to *renewable prescription* (that are intended for diseases with extended treatment, and where the prescription may be used more than once without raising safety concerns); medicines subject to *special prescription* (medicines that raise substance abuse, addiction, or misuse concerns); and medicines subject to *restricted medical concerns* (medicines that are exclusively used in a hospital or otherwise monitored setting because of their adverse effects).

A comprehensive list of prescription-only medicines in Angola is yet to be approved. The Ministry of Health has, however, issued an Order (731/17, of December 29), where it provides that the following medicines cannot be dispensed without medical prescription:

(i) antibiotics, including antituberculotic medicines and 3rd generation antibiotics;

(ii) Misoprostol;

(iii) Sildenafil, Tadalafil and Vardenafil; and

(iv) narcotic and psychotropic medicines.

Additional medicines can be included in such a list in the future or, alternatively, the Ministry of Health can decide on a general procedure whereby the medicine's subjection to medical prescription is assessed and decided.

The Ministry of Health recently appointed, through Order no. 56/18, of 6 March, a National Commission of Medicines and Health Products. The Commission works as an advisory body of the National Directorate of Medicines, and, among other tasks, is responsible for approving and updating the National List of Essential Medicines and for assessing the list of medicines that may be sold without medical prescription. While the Commission was appointed in March 2018, neither of these lists have been approved or updated since then.

Who is/Who are the payer(s)?

While a small private sector is gaining traction, the great majority of medicine purchases in the country are conducted by the State.

What is the process for securing reimbursement for a new pharmaceutical product?

There are indications that a pricing regime for pharmaceutical products – and, possibly, for reimbursement – is being prepared. However, the law does not currently provide for a process to secure reimbursement. Admittedly, reimbursement can be secured exceptionally, through an *ad hoc* decision of the Ministry of Health. However, at this stage, such a decision would not follow a predetermined legal procedure.

How is the reimbursement amount set? What methodology is used?

The law does not currently provide for a reimbursement procedure, and hence it does not provide a methodology to set the reimbursement amount.

How are drug prices set? What is the relationship between pricing and reimbursement?

The prices are not set linearly.

The General Framework for National Pharmaceutical Policy foresees the creation of a Commission for Price Regulation with the purpose of creating or changing the laws and regulations applicable to the pricing of pharmaceutical products. Even though the law dates from 2010, this Commission has not been created so far. Because of the delay in creating or changing these laws and regulations, a Law dating from 1974 is technically still in force,

but is considered inapplicable due to it being incompatible with inflation and overall market evolution.

Medicinal products are therefore, in practice, subject to the same regulation as any other product, pursuant to the National Pricing System. The National Pricing System is managed by the Pricing and Competition Institute which works under the supervision of the Ministry of Finance. Because no special regulation currently applies to medicinal products, they are bought and sold under a free pricing regime, where the margins are not administratively set.

No regulation is foreseen regarding hospital medicines. For this reason, prices are determined via public procurement procedures launched to purchase hospital medicines.

Tender award procedures for medicinal products are launched by a Centralized Medicine Purchase Authority ("CECOMA"). CECOMA is a public authority, working under the supervision of the Ministry of Health, charged with developing and managing the system of purchase, distribution and maintenance of goods for the National Health Service. In other words, CECOMA purchases and stores medicines and carries out their distribution to health facilities all over the country.

Prior to making a purchase, CECOMA submits an inventory with the available stock to said health facilities, who prepare an annual estimate of their needs. Based on the information provided, CECOMA then proceeds to contact local and international suppliers, and launches tender procedures to award supply contracts that correspond to the identified needs. Each healthcare facility provides their estimates within the budget that is allocated to them and allocated to each healthcare facility.

In the call for tenders, CECOMA determines the maximum price it is willing to pay for a certain product. While the maximum price will be decided by CECOMA, the product's final sale price should result from the tender procedure, and will depend on whether there is competition in the tender.

Private health institutions purchase directly from their suppliers or through their designated local distributors.

Issues that affect pricing

Lack of regulation and scarcity of medicines are the main problems. Medicines are dispensed for free in public healthcare facilities. However, the National Health System is clearly unable to meet demand, and hospitals are frequently out of stock. The National Health Services' insufficiency, together with structurally unregulated prices, cause private pharmacies to charge very high prices for medicinal products.

While it is difficult to assess, these conditions also foster a very active black market, with severe counterfeiting issues. The country's size and deficient health coverage further contribute to this outcome. Direct importation of products therefore remains a relevant concern.

The National Health Development Plan for 2012–2025 (the "Plan") sets out to increase the use of generic medicines. While this may contribute to decreasing medicine prices in the future, the country currently lacks the institutional framework to ensure or promote the substitution of branded medicines by generics.

Direct import is also a relevant concern. Even though CECOMA is the procurement agency in charge of the acquisition, storage and distribution of medicines for the public sector, some private actors and Provincial Governments may carry out procurement on their own, which also gives rise to price surges.

Policy issues that affect pricing and reimbursement

Children aged under five account for 15% of the population, and those under 15 account for 48%. In addition, 47% of inhabitants live in urban areas, while 49% are based in rural areas. Though significant improvements have occurred, the estimated average life expectancy in 2015 was only 51 years for men and 54 for women.

There is a clear need for improvement in the quality of primary healthcare service delivery, notably for underprivileged groups and rural areas. These quality failures are mainly due to a defective health system, e.g. dysfunctional health posts and hospitals, outdated classifications of healthcare professionals, lack of trained staff, a restricted number of individuals with appropriate academic background, lack of incentives linked to performance (outputs or service quality), work delays and absence, etc. In addition, the health system is exposed to disease outbreaks. Angola's epidemiological surveillance system has detected several epidemics since 2013, namely: yellow fever; malaria; measles; human and animal rabies; cholera diarrhea (bloody stool and viral); dengue fever; and chikungunya. Some of these occurrences are a sign of patchy vaccination coverage.

Due to the lack of a strict testing mechanism, the quality of pharmaceutical products is worrying. The country does not have a national quality-control laboratory: 10 small-sized laboratories screen the quality of medicines at entry points and are not enough to cover the whole supply of imported pharmaceuticals. Storage conditions are often deficient, notably for products which require temperature control.

Communicable diseases account for over 50% of deaths recorded within the population. Even with the improvements attained in the past decade, the child mortality rate, neonatal and maternal mortality, estimated at 48/1000 and 477/1000 live births respectively (2017), remain high. Malaria endures as a major public health concern, being the main cause of death, disease and absenteeism. Tuberculosis also has a negative impact on public health and development, affecting mainly individuals in the labour force. Despite a relatively low HIV/Aids prevalence rate of 2.2%, the situation varies within the country, with some provinces more affected than others, the province with the highest prevalence being Bié.

Emerging trends

Angola has not enacted a coherent and comprehensive regulatory system. The existing legal framework is clearly insufficient and is not applicable in numerous aspects. Legal and administrative reforms are patently necessary. However, even though several plans and legal instruments have been approved, implementation remains a challenge.

While it is difficult to anticipate where the regulatory system is headed, it is nevertheless bound to become more sophisticated and predictable.

The National Health Development Plan for 2012–2025 (the "Plan") outlines the following priorities:

(i) rehabilitating and expanding public healthcare infrastructure and capacity, especially for rural and underserved urban populations;

(ii) expanding the training of healthcare professionals; and

(iii) preventing disease.

The Plan also foresees the transition of the health system from a government-financed model to a system with recourse to diversified revenue streams. However, considering the country's current stage of development, and according to the World Health Organization

(WHO), primary healthcare will continue to rely on public and external financial resources.

The Plan acknowledges that the medicinal products market lacks a global approach to address its most significant challenges, namely:

(i) supporting local production of medicines;

(ii) building a National Laboratory for Quality Control;

(iii) further developing the List (the National List of Essential Medicines);

(iv) preparing a National Form of Medicines and Therapeutic Guides, as an important tool to support the rational use of medicines; and

(v) developing the legal and technical framework of traditional medicines.

Presidential Decrees of 2010 establish an increase in local manufacturing of basic primary pharmaceuticals as a government priority. The self-sufficiency of the national market is deemed as the ideal scenario, and thus as the ultimate goal.

In the Plan, the State undertakes to guarantee the availability of "physical resources" – such as infrastructure, medicines, medical equipment, and human resources – of the health system, to the extent of its capacity.

The Government further intends to develop legislation and technical rules regarding the manufacture, acquisition, storage, distribution and rational usage of medicines, as well as pharmacovigilance, in order to ensure that the medicines are safe and accessible to the Angolan population.

Reimbursement of medicines is also mentioned as a priority. At the current stage of development, the Government considers that reimbursement is a "human rights" issue, which materialises the principle of the State bearing a significant share of the burden of health costs.

The Government further undertakes to develop the NHS. The Plan sets out the following guidelines for its reform:

(i) definition and reorganisation of the national health system and the National Health Service;

(ii) increased coverage and rational organisation of healthcare services (with a reference system between health centres, hospitals, and polyvalent hospitals);

(iii) lowering mother and child mortality rates;

(iv) lowering the death rate for chronic and most prevalent diseases (malaria, tuberculosis, trypanosomiasis, measles, tetanus, meningitis and poliomyelitis);

(v) coordination of the public and private sectors and traditional medicine;

(vi) standardisation, organisation and financing of healthcare services; and

(vii) promotion of scientific investigation.

Successful market access

Considering the structural lack of regulation and the unpredictability of the market, cooperation with the competent authorities plays a significant role. Interested parties have to try to anticipate market and regulatory trends and ensure their products are approved and placed on the market according to the authorities' interpretation of applicable laws. Interested parties would also do well to consider adjusting their portfolios or business plans to cater to the most pressing needs of the Angolan population.

Given the scarcity of resources and the Angolan system's level of maturity, it is natural that

successful market access will depend on the product being used to treat or prevent a disease whose treatment or prevention is deemed as a priority. Local collaboration can also help to accelerate or clarify procedures, which can be particularly lengthy or bureaucratic if they are managed remotely.

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