



Pricing & Reimbursement

2019

Second Edition

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CONTENTS

Preface	Edward J. Dougherty, <i>Dentons US LLP</i>	
Country chapters		
Angola	Francisca Paulouro & Pedro Fontes, <i>VdA</i>	1
Australia	Greg Williams, Colin Loveday & Sheena McKie, <i>Clayton Utz</i>	9
Belgium	Pieter Wyckmans & Julie De Keukeleire, <i>Quinz</i>	23
Brazil	Rodrigo Augusto Oliveira Rocci, <i>Dannemann, Siemsen Advogados</i>	37
Canada	Sara Zborovski, Christopher A. Guerreiro & Ian Trimble, <i>Norton Rose Fulbright Canada LLP</i>	50
China	Nicolas Zhu, <i>CMS China</i>	57
France	Catherine Mateu, <i>Armengaud Guerlain</i>	65
Germany	Dr. Ulrich Reese & Carolin Kemmner, <i>Clifford Chance LLP</i>	84
India	Archana Sahadeva & Deepshikha Malhotra, <i>Advocates</i>	99
Ireland	Marie Doyle-Rossi & Maree Gallagher, <i>Covington & Burling</i>	110
Italy	Sonia Selletti & Mauro Putignano, <i>Astolfi e Associati, Studio Legale</i>	120
Japan	Kazuhiro Kobayashi, <i>Oh-Ebashi LPC & Partners</i>	134
Korea	Kyung Shik Roh & Kyungsun Kyle Choi, <i>Kim & Chang</i>	145
Mozambique	Francisca Paulouro & Pedro Fontes, <i>VdA</i>	151
Poland	Agata Zalewska-Gawrych & Marta Skomorowska, <i>Food & Pharma Legal Wawrzyniak Zalewska Radcy Prawni sp.j.</i>	159
Portugal	Francisca Paulouro & Pedro Fontes, <i>VdA</i>	165
Spain	Jordi Faus, <i>Faus & Moliner</i>	177
Sweden	Odd Swarting & Camilla Appelgren, <i>Calissendorff Swarting Advokatbyrå KB</i>	192
Switzerland	Oliver Künzler, Carlo Conti & Martina Braun, <i>Wenger Plattner</i>	203
Ukraine	Nina Moshynska & Olga Kovalenko, <i>Gorodissky & Partners Ukraine</i>	211
United Kingdom	Grant Castle, Brian Kelly & Raj Gathani, <i>Covington & Burling LLP</i>	215
USA	Edward J. Dougherty, <i>Dentons US LLP</i>	227

Mozambique

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Mozambique has a very basic Pricing and Reimbursement system. Recent legislative developments show a growing and encouraging concern with access to medicinal products. However, further regulation, as well as improvement of the country's general economic conditions, are required before the system can become more sophisticated and effective.

Market introduction/overview

Mozambique is a large country in East Africa, with an area of 801,590 km² and an estimated population of 28,861,863 inhabitants.

The health and pharmaceutical sector in Mozambique is still small and lacking in diversification. However, it is rapidly expanding.

Mozambique is a country with a tropical climate which is prone to natural disasters. Recently this year, on 15th March, the Province of Sofala was severely affected by Cyclone Idai and the country is facing the consequences of this natural disaster.

Cyclone Idai was the strongest tropical cyclone to hit Mozambique since Jokwe in 2008. Idai brought strong winds and caused severe flooding in the entire region, striking not only Mozambique, but also Madagascar, Malawi and Zimbabwe.

Information released by the National Institute of Management of Disasters ("INGC") indicates that Cyclone Idai affected over 800,00 people in central Mozambique, with current casualties estimated at 468.

The number of rescued people has risen from 127,626 to 135,827. They have all taken refuge in 161 shelters.

The National Directorate of Health in Mozambique has sent a team to work on the ground with the afflicted and to identify the main diseases that are arising from this natural disaster. A high rate of water-related diseases was identified, such as diarrhea, due to the consumption of turbid water and malaria. Outbreaks of cholera were also detected in several points affected by the cyclone.

This team has intervened and worked with the local population through the transmission of information on measures to be taken for water treatment, and has distributed chlorine and "Certeza", a product used in Mozambique for water purification.

The international community has spared no effort to support Mozambique, with Unicef estimating that around US\$10 million is needed for the most urgent needs of children. The United Nations and its partners have called for US\$40.8 million assistance to people affected by Idai in Mozambique.

Healthcare services are provided by: (i) the public sector, under the National Health Service

(“NHS”), which is the most geographically extensive and technically advanced; (ii) the private sector, which is divided into a profitable part, with almost exclusive presence in the urban areas, and a non-profitable part, comprising national and international NGOs with strong links to the public sector; and (iii) traditional medicine practitioners (an important part of which is represented by the Association of Traditional Doctors of Mozambique, “AMETRAMO”), widely accepted by local communities, offering non-allopathic and complementary medicine and medications.

The performance of these sectors is still below their potential for growth, due to the various limitations that affect the market, such as undeveloped medical facilities, shortage of medicines, and lack of qualified human resources. Studies carried out in 2014 indicated that the country had only 4.9 physicians and 25.2 nurses per 100,000 inhabitants, a proportion that is among the lowest in the world.

Even though the NHS has benefited from major progress in the last few years, healthcare units still only cover about half of the population, and some of them lack adequate conditions to provide healthcare services, including medicine distribution. In addition, the NHS is under-funded, and heavily dependent on external financing to purchase medicines. In September 2013, the Ministry of Health approved a Strategic Plan for the Health Sector 2014–2019 which defined several strategies and reforms aimed at solving the main problems in the health and pharmaceutical sectors.

Recent improvements in Mozambique’s standard of living, and a public commitment to the creation of an enhanced health system, offer promising signs of improvement.

Pharmaceutical pricing and reimbursement

Regulatory classification

Regulation of pharmaceutical products is governed by Law no. 12/2017 of 8th September (“Law 12/2017”), which establishes the rules applicable to the production, distribution, use and marketing of medicines, vaccines, biological products and health products. Medicines are generally subject to medical prescription. Medicines that are not subject to medical prescription are those included in a list that is periodically approved by the Ministry of Health.

Medicines can only be purchased by and used within the NHS if they are included in the National Medicine Form or in the List of Essential Medicines. Both the National Medicine Form and the List of Essential Medicines are periodically revised and published by the Ministry of Health, which is also responsible for ensuring that the medicines included in these documents are, in fact, used. Only private sector providers of healthcare services can prescribe medicines and other health products that are not included in these documents, provided that these products are included in the list of medicines that are registered and authorised in Mozambique.

Reimbursement of medicines is not specifically regulated by Mozambican laws. The applicable legislation does, however, establish situations in which medicines can be provided free of charge. Law no. 2/77 of 27th September (“Law 2/77”) establishes that medicines for hospitalised patients should be provided free of charge. Law 2/77 also establishes that “basic medicines” may be provided free of charge for outpatient treatment, and that such medicines would be indicated in a List to be defined by the Ministry of Health and the Ministry of Finances.

The said list was later approved by Ministerial Order no. 24/85 of 3rd July (“Ministerial

Order 24/85”). Ministerial Order 24/85 further established that all medicines distributed by Community Health Workers (a network of healthcare providers in remote areas) would be free of charge, and that medicines dispensed by the primary care network in rural areas would have a single price of 20 MT per prescription (and should be paid by the State in the price exceeding that amount). Medicines provided free of charge pursuant to Law 2/77 and Ministerial Order 24/85 may only be distributed at medicine distribution points and pharmacies of the Government which are attached to the healthcare units where such medicines are prescribed. Medicines which are part of the National Medicines List and which are not included in the list of medicines provided for free pursuant to Ministerial Order 24/85 are purchased at their approved sales price.

Additionally, Decree no. 16/88 of 27th December created a Social Fund for paediatric medicines and food supplements, whereby population groups in need of economic support because they suffer from chronic conditions or because they belong to economically deprived groups (physically handicapped, elderly, unemployed, etc.) have access, in NHS pharmacies, to medicines subsidised by the State (the State contribution to the price of medicines varies between 100%, 80% and 50% of their public sales price).

Who is/are the payer(s)?

The funding of the pharmaceutical and health sector of Mozambique comes from multiple sources and is greatly dependent on external resources, including donations. According to a report from the Medicines and Medical Supplies Department of the Ministry of Health, in 2012, the implementation rate of funding allocated for medicines was 99.9%. The main source of funding is public – the State Budget allocated by the Ministry of Finance, which includes: direct contributions from donor countries to Mozambique’s State Budget; funds from Mozambique’s Common Fund of Support for the Health Sector (designated in Portuguese as “PROSAÚDE”); and funds from vertical programmes. There are other, less documented funding sources such as private contributions and contributions from families through payments in private clinics and hospitals and co-payments in State hospitals, among others. Apart from the State budget and PROSAÚDE, funds are controlled by the Ministry of Health, including earmarked revenue.

One of the strategies envisaged by the Strategic Plan for the Health Sector 2014–2019 approved by the Ministry of Health in September 2013 is to identify and document the gaps in the funding of medicine and liaise within the Ministry of Health and partner countries in order to obtain more funds. This Strategic Plan further designs a specific Funding Strategy for the health sector, which includes the exploration of more funding mechanisms.

Medicines can also be donated by other countries and foreign organisations to NHS institutions, as well as to other public or private institutions which are not part of the NHS, as provided for in Order of 3rd February 2010. In principle, the Government can only accept donations of medicines included in the National Medicines List.

Public institutions purchase medicines pursuant to public procurement procedures.

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

Since the Mozambican legislation does not currently establish a specific regime for reimbursement of medicines, there is no reimbursement procedure to be followed by pharmaceutical companies. When medicines are provided free of charge pursuant to Law 2/77 and Ministerial Order 24/85, the selection and payment of medicines are entirely handled by the Ministry of Health and the Ministry of Finances. The law does not specifically allow companies or suppliers to request that their medicines be included in the

List. As for paediatric medicines and food supplements that are funded through the Social Fund, approved by Decree 16/88, the person belonging to a disadvantaged group is required to submit a request in his/her local pharmacy (or the place where they will retrieve the medicines) to gain access to the applicable co-payment.

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

As we have seen, there is not a specific reimbursement framework or methodology. The criteria for providing medicines free of charge to outpatients pursuant to Law 2/77 is the inclusion in a list of “basic medicines” approved by the Ministry of Health. In the case of funding of medicines pursuant to Decree 16/88, the percentage of funding attributed depends on the condition or status of the person receiving the medicines.

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

Law 12/2017 created a National Regulatory Authority of Medicines (designated in Portuguese as “ANARME”), replacing the Medicines Council created by the previous regime.

A new price regime was also approved by Ministerial Order 21/2017 of 13th March (“Ministerial Order 21/2017”). The former regime established different criteria for price calculation. The methodology differed in accordance with the category of the medicine. A reference prices system was also in force, based on a price comparison with the average price of reference countries, and the price of medicines whose active substance already existed in the market (and generics) depended on the price of medicines that were currently on the market.

The regime enacted by Ministerial Order 21/2017 does not, however, consider these aspects, and is rather focused on simplifying price-setting, and adapting it to the particular costs associated with importing medicines to Mozambique.

Pursuant to Law 12/2017, ANARME is the authority responsible for proposing the pricing of medicines, vaccines and biological products, while the Council of Ministers is responsible for regulating the public sales price of medicines, profit margins and price-revision mechanisms.

The pricing of medicines, as noted above, is regulated by Ministerial Order 21/2017. The Public Sales Price of medicines is set by the Pharmaceutical Department of the Ministry of Health for all national territory, based on a proposal by the Importer-Wholesaler. This proposal should contain the following elements:

- (i) indication of the Free on Board (“FOB”) Price;
- (ii) indication of the Cost, Insurance and Freight (“CIF”) Price;
- (iii) indication of the Wholesale Price;
- (iv) indication of the Retailer Sales Price;
- (v) indication of the Public Sales Price; and
- (vi) indication of the Sales Price to FARMAC Pharmacies (FARMAC – *Empresa Estatal de Farmácias, E.E.* is the State Pharmacies Company that runs several public street pharmacies).

Ministerial Order 21/2017 further defines the criteria to calculate the Wholesale Price, the Retail Sales Price, Public Sales Price and the Sales Price to FARMAC pharmacies. The Wholesale Price is calculated based on the CIF Price, with the addition of bank, customs clearance and harbour expenses, as well as other direct import fees charged up to the distributor warehouse, until a maximum of 9% of the CIF price.

The Retailer Sales Price is calculated based on the Wholesale Price, to which accrues the Importer-Wholesaler trade margin, which is set at 23.5% of the CIF Price, and the trade margin of the distributor (to cover transportation costs to the entire country), which is set at 5% of the CIF Price.

The Public Sales Price is calculated based on the Retailer Sales Price, to which accrues the retailer trade margin, which is set at 66.3% of the CIF price. The Public Sales Price of medicines dispensed in FARMAC Pharmacies is discounted by 7%. Ministerial Order 21/2017 expressly forbids the sale of medicines at a different price than the prices set therein, except if medicines are dispensed in pharmacies attached to NHS health units. Notwithstanding, importers-wholesalers are entitled to submit a request (to charge higher prices) before the Pharmaceutical Department of the Ministry of Health if they consider that the prices are unacceptably low.

Issues that affect pricing

Several issues affect the pricing of medicines in Mozambique. Lack of control and monitoring of the price throughout the supply chain, as well as the lack of more developed legislation, affects the price of medicines, since it increases the risk of medicines being sold at a higher price than they should, for instance, by the application of random mark-ups or by the adjustment of mark-ups according to the demand for specific medicines.

In addition, disparities in costs can lead to differences in prices based on geographical location, with a tendency for higher prices in urban areas. Surges in prices prevent the population from purchasing medicines at affordable prices, which in turn fosters the black market and counterfeiting of medicines. Furthermore, the lack of a Pharmaceutical Policy, the insufficient revision of the National List of Medicines, and the virtual absence of quality control due to limited capacity, give rise to quality issues. Indeed, only medicines that raise suspicion are monitored. Irrational prescription and consumption also affect the market and negatively influence the prices of medicines.

Policy issues that affect pricing and reimbursement

Demographics, health care costs and political factors may influence the pricing of medicines in Mozambique.

The country suffers from a high incidence of HIV/AIDS and associated diseases, such as tuberculosis, which plagues most Mozambican families. Apart from infectious diseases, the country is also beset by diseases that are characteristic of tropical countries, such as malaria, as well as seasonal, warm weather diseases, such as cholera, which had a serious outbreak in the north of the country at the beginning of 2018. These diseases affect young people in the economically active range. For 2019, the Government foresees an increase in the number of people living with HIV, but also of antiretroviral therapy coverage, from 1,069,593 and 86,508 in 2017, to 1,271,649 and 104,229 in 2019, respectively.

Elderly people represent 5.6% of the population. Most of them suffer from diseases such as hypertension, diabetes, cancer, osteoporosis, among others, aggravated by nutritional problems and physical inactivity.

Access to healthcare is extremely limited, especially in rural areas where the only health care providers are public. In urban areas, there is already a shift in this paradigm of supply, and private healthcare providers are increasing and becoming more visible.

Pursuant to the Strategic Plan for the Health Sector 2014–2019, the total expenditure on health was estimated at 6.2% of GDP and is increasing. Nevertheless, the system is still

underfunded, since the GDP *per capita* spent on health is below regional averages, and below the value that is recommended by the World Health Organization and the World Bank to finance a basic level of care. Politically, the legal and political environment is favourable to the prosecution of health objectives, however, there are still situations of overlap, fragmentation and lack of coordination between laws and policies that hinder the creation and development of laws and policies regarding the pharmaceutical sector, including price and reimbursement of medicines.

Emerging trends

The Strategic Plan for the Health Sector 2014–2019 is still the best indicator of health-related trends in Mozambique. The Plan’s main goals and strategies do not concern pricing and reimbursement. Nevertheless, this Strategic Plan did anticipate the revision and approval of a legal framework of medicines regulation. This goal seems to have been achieved with the entry into force of the new Medicines Law, approved by Law 12/2017, as well as the approval of a new pricing regime of medicines by Ministerial Order 21/2017. However, the new pricing regime is strictly based on the costs of freight. There is room for additional sophistication and fine-tuning, namely in the regulation of prices in accordance with the medicine’s category or therapeutic indication. There is therefore a chance that the regime will be updated and replaced by a more ambitious regime in the next few years and, when these conditions are met, there may be a shift to reimbursement.

The Parliament’s Annual Social and Economic Plan for 2018 recommends an increase in antiretroviral therapies for pregnant women, and an increase in child vaccination coverage.

In 2019, the Government expects a growth of health expenditure to 4.7% of GDP, which should allow an increase in external consultations, institutional births and hospitalisations, as well as an increase in the number of beneficiaries of social protection programmes (children, elderly people, persons with disabilities and female heads of households).

The Government also intends to appoint about 2,126 new health professionals, 80 of whom will be physicians, 100 superior and 1,946 medium healthcare technicians, in order to improve the quality of health services.

The Government’s Economic and Social Plan for 2019 also features the strategic objective to expand access and improve the quality of health services. To achieve these goals, the Government sets out to:

- (i) introduce new vaccines, namely PCV (Pneumococcal Vaccine), Rotavirus and HPV (Human Papilloma Virus Vaccine);
- (ii) enhance the prevention, diagnosis, treatment and fight against malaria throughout the country;
- (iii) strengthen medicine supply and improve diet in health units;
- (iv) expand the services of prevention and diagnosis and treatment of Tuberculosis, including Multi-resistant (“MDR”) and Extremely resistant (“XDR”);
- (v) expand HIV prevention and diagnosis services;
- (vi) increase the number of health units that offer antiretroviral therapy and increase their access; and
- (vii) introduce a radiotherapy service at Maputo Central Hospital.

On 19th March 2019 the President of the Republic of Mozambique, Filipe Nyusi, launched the “National Dialogue about Tuberculosis”, saying that the major target of this campaign is to prevent and significantly reduce tuberculosis by 2030.

A significant market trend has also recently emerged. A large part of the Mozambican population of the upper middle class has been seeking healthcare in neighbouring South Africa. This cross-border movement is a clear sign that the population's standard of living is increasing, and that demand for quality healthcare is higher than supply. The country is bound to advance in this area, and the creation of private clinics, the construction of hospital infrastructures in rural areas, and the importation of medicines are stimulated by this tendency.

Successful market access

The primary success factors for entering into Mozambique's pricing and reimbursement market are to engage with local stakeholders. Interested parties should also monitor international calls for tender, considering that Mozambique's Government often invites foreign companies to bid for tenders for the supply of medicines, which may provide a relevant opportunity for companies to enter in the market.

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