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HEALTHCARE & LIFE SCIENCES REVIEW

PORTUGAL

TURNING THE PAGE

Portugal experienced the best economic growth in a decade in 2017, up 1.2 percent on the previous year to 2.9 percent, and the Bank of Portugal reports 2018 will see 2.8 percent growth. Adalberto Campos Fernandes, the minister of health, comments "We are performing favorably; we see remarkable GDP growth, low rates of unemployment and enjoy a more stable budget (...) These steps forward contrast sharply with the difficult period between 2011-2014."

Further evidence of an economic revival includes healthcare spending growing to 8.9 percent of GDP—which lags behind more developed EU economies such as France and Switzerland but aligns closely with Northern Europe and Scandinavia. Manuel Heitor, the minister of science and technology, explains that the entire life sciences sector stands to benefit, and a change in strategy will drive progress in science. "Portugal has since diverged from the European averages to show an increase in R&D and innovation. The official data is clear; public expenditure in R&D increased by EUR 40 million (USD 46 million) last year, and private spending increased by EUR 90 million (USD 105 million)." Critics explain that the resurgence is primarily due to continued favorable international investment conditions, whereby fiscal incentives, a highly skilled talent pool and a good quality of life have attracted foreign investment and increased private sector consumption.

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PHARMA FOOTS THE BILL

Adalberto Campos Fernandes, minister of health; Manuel Heitor, minister of science, technology and higher education; Heitor Costa, executive director, Apifarma

While Portugal exited its bailout programme in May 2014 without the need for a new financial package, government austerity measures curbed pharmaceutical reimbursement, and pharmaceutical companies made a display of solidarity. The executive director of APIFARMA, the Portuguese industry association for innovative medicine companies, Heitor Costa, explains how pharmaceutical companies collaborated with the government by agreeing to a market cap, and they now intend to regain their former position: "Following the crisis, Troika's restrictions sought to downsize the market. However, since Portugal exited Troika, we no longer battle with these measures. The testament to our long history of cooperation with government and stakeholders was made clear in 2016, upon signing on an agreement that no longer features a cap. The agreement established rational market developments, and as such, we pay a contribution to the system's sustainability – similar to a tax – and for the past two years, we have seen steady growth."

Nonetheless, following the crisis, several companies found managing an affiliate in Lisbon a Sisyphean task in the face of the government's decision to cut pharmaceutical costs. Of the Top 100 pharmaceutical companies in Portugal, over 15 pharma MNCs have effectively withdrawn from Portugal to establish Iberian headquarters across the border in Madrid, Spain. Nelson Pires, general manager for Portugal, the UK, and Ireland at Jaba Recordati, explains "the 'Iberianization' of Portugal is a serious risk which undermines the relevance of the Portuguese market for European affiliates." Salvador Lopez, general manager of Mundipharma, comments that "In 2014, Mundipharma confronted a challenging market that had been heavily impacted by the Troika economic crisis; the healthcare system, in particular, faced many constraints."

Numerous commentators agree that Portugal's economic revival is yet to impact the pharmaceutical industry. Antonio

Leão, general manager for Lilly, acknowledges that although the outlook is promising, there is still much to be done. "The total market is worth roughly EUR 2.9 billion (USD 3.4 billion), and if we look back to the crisis period, the retail market was severely hit and lost approximately a third of its total value. Only now is it starting to regain some of what has been lost."

Nelson Pires, general manager, Jaba Recordati; Antonio Leão, country manager, Lilly; Antonio Cabral, general manager, Medicinalia Cormedica

THE TROIKA EFFECT

The brunt of this economic impact was not confined to the pharmaceutical sphere; from medical devices to contract research organizations (CROs), the Troika intervention sparked a chain reaction of challenges across healthcare. Antonio Cabral, general manager of Medicinalia Cormedica, one of the most significant Portuguese medical devices company, notes that "We have excellent doctors, nurses and healthcare professionals but sometimes we lag behind in the delivery of sophisticated medical devices, which is exacerbated by our recent exit from the economic difficulties." Maria Queiroz, CEO of Eurotrials, a Portuguese homegrown CRO, comments that "During the crisis, the national healthcare system and physicians felt the pressure to be 300 percent focused on patients and patient evaluations, and naturally, research efforts took a back-seat role. As we exit the crisis, the physicians' gaze will once again turn to the importance of translational research and clinical trials."

José Aranda da Silva, a key opinion leader and the first president of INFARMED in 1993 offers a balanced view: "The crisis had a huge impact on the healthcare sector, and between 2009 and 2015 Portugal experienced cuts of around 30 percent. However, the country is now recovering strongly, and the healthcare budget is beginning to grow. Unfortunately, this success is not enough, and there is a consensus among many politicians who believe that the amount of money allocated to healthcare needs to increase." The debate continues

José Aranda da Silva, president, health and national health service foundation; Antonio Portela, CEO, Bial; Filipa Costa, general manager, Janssen

as pharmaceutical companies wait with baited breath to reap the rewards of their collaborative efforts from 2011 to 2015. Although an economic revival is underway, there is a long way to go before the pharmaceutical landscape will realize the benefit. In the meantime, Antonio Portela, the third generation of the Portela family to manage Portugal's leading pharmaceutical company, Bial, argues that the onus is on pharmaceutical companies to take the initiative and drive change: "We, as an industry, must attract venture capitalists to consider Portugal, but they will only do that if market conditions are attractive: if prices, timelines, and payments are competitive on the European standing."

While Portugal experiences a revival, challenges to the pharmaceutical industry take on many forms, from a chronically underfunded healthcare system to a rise in generic penetration, to tackling more market access hurdles than many other Mediterranean countries could handle. As Filipa Costa, country manager from Janssen comments, " If we consider the portfolio, the European medicines are generally made available in Portugal, although sadly there is a considerable delay in market access relative to other European countries. The time taken from EMA approval to access in Portugal, (granted by INFARMED), to hospitals (which have their autonomous procedures), is closer to the two-year mark than the legislated 200 days."

GENERICS TO THE RESCUE

The healthcare market dynamics have shifted away from a brand-oriented market, whereby healthcare professionals prescribed more originator drugs, leading to an increase in generic consumption. The share of generics has risen from 45 to 49 percent penetration in the past three years, and the trend looks to continue. Paulo Lilaia, the President of APOGEN, the Portuguese Generic and Biosimilar Association and CEO for Generis, a local generics company acquired by Aurobindo in 2017 conveys, "The generics and biosimilars role in the healthcare system

TOP 20 PHARMA COMPANIES IN PORTUGAL

(MAT MARCH 2018)

		SALES (EUR)	MARKET SHARE
	TOTAL	2,751,203,489	100.0%
1	MSD	147,595,183	5.4%
2	MYLAN	127,228,600	4.6%
3	BAYER	118,775,655	4.3%
4	TEVA	117,285,083	4.3%
5	SANOFI	108,858,316	4.0%
6	ASTRAZENECA	108,800,505	4.0%
7	NOVARTIS FARMA	101,374,831	3.7%
8	GLAXOSMITHKLINE	97,455,921	3.5%
9	GENERIS	86,725,237	3.2%
10	BIAL	86,386,754	3.1%
11	BOEHRINGER INGELHEIM	76,250,736	2.8%
12	SERVIER	72,947,198	2.7%
13	MERCK SA	63,006,792	2.3%
14	PFIZER	60,400,406	2.2%
15	TECNIGEN	55,015,031	2.0%
16	JABA RECORDATI	48,761,334	1.8%
17	MENARINI	48,554,457	1.8%
18	GSK CONSUMER HEALTHCARE	48,130,550	1.7%
19	JANSSEN	44,586,362	1.6%
20	MEDINFAR	44,186,190	1.6%

Source: Health Market Research (HMR)

is vital: if we want to treat more patients with better value-added medicines, we have to economize in other areas. Generics create the necessary room to have money for investments in new and innovative products."

João Madeira, the experienced country manager for Mylan, comments "Portugal lacks the resources to treat as many patients as needed in the right timeframe and with the right product, so we need to make more efficient use of the available resources." In essence, prioritizing the generic medicine over the innovator following patent expiration saves money for the healthcare system. Mario Madeira, from a rival generic-innovator hybrid company, Teva, agrees that "The generics strategy paves the way for access to affordable medicines for healthcare professionals and patients." The strategy for rising generic penetration must stay the course, however, because as Madeira continues: "If we open room for doubt, we will never eradicate the stigma that still purveys in some regions of the market that says that 'generics are not as good as branded medicines.' Although the mindset has evolved, and it is far away from a total misunderstanding, today Portuguese people embrace generics, and the uptake is faster than it used to be. Today, we can confidently say that most Portuguese patients are treated with a generic medicine."

Paulo Lilaia, CEO, Generis; João Madeira, country manager, Mylan; Mario Madeira, general manager, Teva

Now with almost 50 percent market share, generics are one of the cornerstones of the Portuguese pharmaceutical market's development. According to APIFARMA's Costa, given the nature of the healthcare system, "The more generics present in the market; the more innovations have room to develop," especially because greater generic medicine usage frees up resources to be spent on reimbursement. There is one important caveat: "The golden rule with regards to generics is that we must respect patents and intellectual property; this is a non-negotiable red line for APIFARMA. If intellectual property rights are respected, then we allow room for innovation which is crucial to the healthcare system's success."

FREEING UP FUNDING FOR INNOVATION?

For Jaba Recordati's Pires, the solution is to "have a foot in both camps; generics and innovatives, then we can represent a complete solution to patients that requires more than just the monotherapy." RJ Lasek, former country manager for Takeda, (now vice-president, commercial planning, and pricing) outlines his ideal strategy in the face of a rising generic tide: "As a government partner, we want them to be able to manage the category better and improve patient outcomes. Consequently, we insisted that the innovation we offer is priced in a way that will enhance the government's overall cost per outcome. The trick is to strike a balance between innovation, biosimilars (or generics), and collaborate with the government. The government is open to this kind of debate, and there is room for innovation."

The introduction of biosimilars to the market from companies including Mylan, Amgen, Mundipharma and Teva will reinforce efforts to allocate more resources to value-added medicines. APOGEN's Lilai continues adding that "Although biosimilars require significant amounts of investment, they are a crucial part of generic pharmaceutical companies' business given the potential they represent." Mylan's Madeira mirrors this view, "The biosimilar business brings value to the national health system so that, with the same budget, it can treat more patients and at an earlier stage of the diseases."

RJ Lasek, country head, Takeda

José Aranda da Silva paints a detailed picture of the generic landscape in Portugal: "In the beginning, it was not easy for the system and for companies to adapt to this change in market dynamics. Nonetheless, most of the international companies have since entered the generics market, for example, Novartis and Pfizer; and we should see more companies like this entering Portugal. Generics will continue to grow." Overall, the increase in generic consumption and the arrival of biosimilars have granted the authorities the necessary breathing space to improve drug access, better target non-communicable diseases, and balance healthcare expenditure.

The Portuguese Flagbearers

Sérgio Luciano, CEO, Quilaban

Paulo Barradas Rebelo, CEO, Bluepharma

For local companies, the trick is to keep things simple in the face of numerous challenges and at times, high levels of bureaucracy. At Basi laboratories, a local success story led by Joaquim Matos Chaves, he often jokes that "I spend half my time insisting that people do not complicate procedures in Europe; if we keep things simple and focus on the vision of the product, then success is far more likely." Basi Laboratories recently received a EUR 40 million (USD 47 million) investment as part of Horizon 2020, which looks to "increase production output from four million units to roughly 100 million. For a small company, this is a vast increase in production." Indeed, Matos Chaves's ambitious vision is "to bring product manufacturing in line with prices in Indo-China." Intrinsic to this vision is an internationalization trajectory that expands from PALOPs countries (the group of Portuguese-speaking African countries), to as far afield as "the CIS, the Middle East, and French-speaking African countries." Sérgio Luciano, CEO for local diagnostics company, Quilaban, explains the usual route for ambitious Portuguese companies "our international expansion started by the African Portuguese speaking countries, namely into Angola and later on into Mozambique, Cape Verde and Guinea Bissau, given the convenience of shared language."

Basi Laboratories New Facilities

Bial exemplifies the need for Portuguese companies to create scale. Portela has "in the past five years, switched turnover from 70 percent domestic, 30 percent international to 70 percent worldwide, 30 percent Portugal." Bluepharma, a rival manufacturing company based in Coimbra, (Portugal's third city after Lisbon and Porto), also has plans to expand, as Paulo Barradas Rebelo, CEO looks to invest 15 million into a new industrial unit. "Our business in Portugal is small but important because this is where we see our portfolio app and flow and where we can train and learn new businesses before exporting to larger markets." There are opportunities to be had in Portugal, but the critical mark of a local company's success is international expansion.

For Basi, who has just received "the most significant investment that the pharmaceutical industry in Portugal has seen in recent years, and we are the first mid-cap sized Portuguese company to receive funding from EIB," international expansion and "being one of the reference manufacturers of choice in Europe," is an attainable goal.