

A report from The Economist Intelligence Unit

Value-based healthcare in Portugal

Necessity is the mother of invention



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About this report

Value-based healthcare in Portugal: Necessity is the mother of invention is an Economist Intelligence Unit (EIU) report, commissioned by Gilead Sciences. Value-based healthcare looks at health outcomes of treatment relative to cost. In this particular paper, The EIU examines the way in which the recent economic and financial crisis has shaped health technology assessment in Portugal; the role of the hospital sector as a decentralised power source; and promising initiatives in integrated care, family health units and a new process for the re-evaluation of health technologies.

In November-December 2015 The EIU conducted three interviews with experts on value-based healthcare in Portugal. The insights from these in-depth interviews appear throughout the report. The EIU would like to thank the following individuals (listed alphabetically) for sharing their insight and experience:

- Pedro Pita Barros, professor, Nova Business School in Lisbon
- Ricardo Baptista Leite, former member of the Portuguese parliament
- Carlos Gouveia Pinto, professor, Lisbon School of Economics and Management

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Introduction

Despite being one of the smaller and less affluent countries in the EU, Portugal has been ahead of many of its neighbours in making value measurement an active part of its health technology assessment (HTA) process. As one of the EU states most adversely affected by the global financial crisis of 2007-08, Portugal has also been forced to adapt to economic constraints that have, in turn, helped to frame the evolution of its approach to HTA.

Portugal's economy was guided by a demanding Memorandum of Understanding (MoU) with the troika—the European Commission, the European Central Bank (ECB) and the International Monetary Fund—between 2011 and 2014, which put the country under severe economic constraints, according to Ricardo Baptista Leite, a former member of the Portuguese parliament and an infectious-disease and public-health expert.

With a health system that is financed primarily through general taxation and a population of just under 11m people, Portugal's total (private and public) expenditure on healthcare reached 9.1% of GDP in 2013, according to the latest available OECD data. This is above the OECD average and was the 14th-highest level of spending as a share of GDP in the 34-member OECD in that year. However, in per-capita terms (at constant prices and assuming purchasing power parity), healthcare spending in Portugal ranked only 25th, with spending falling since 2011, when the MoU was introduced.

“But despite the fact that the troika does a lot of lip service on value-based health, all of the measures applied to the Portuguese health system were merely financial,” Dr Leite says. “Of course, we complied with that, but we also had a clear view, and what we decided to do was to achieve not only financial solvency but also sustainability.”

Efforts to increase efficiency and a greater emphasis on generic drugs have been counterbalanced by increasing consumption of healthcare, making it harder to rein in costs. Continued concerns about escalating healthcare costs, as well as the desire to get the most out of limited resources, have led to a series of reforms of the health system, including more integrated health delivery, greater autonomy for healthcare providers setting up their own primary health clinics and, most recently, an overhaul of the country's HTA system.

In addition to investing more in preventive healthcare, Dr Leite explains, “we have tried to shift the way we were financing not just hospitals, but also access to innovation. That has been a slower process, but we did achieve some important changes.”

This paper will first look at the evolution of Portugal's reimbursement and pricing system against the backdrop of the economic and financial crisis and will then examine the post-crisis era of reform.

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Chapter 1: Evolution of a system in crisis

Portugal's health technology assessment (HTA) process has traditionally been limited to pharmaceutical products. However, one of the country's newest reform initiatives aims to put medical devices through similar evaluations. The country is also unusual in the way in which responsibility for healthcare spending is arranged. Although the central administration of the health system, the Administração Central do Sistema de Saúde (ACSS), is charged with setting budgets, hospitals have significant power over the allocation of funding.

A system of cost-sharing

Portuguese healthcare is delivered through three co-existing and overlapping systems. One of these is universal, while the other two are characterised by more limited access. These systems encompass both private and public providers and different levels of cost-sharing.

Portugal's national health service, the Serviço Nacional de Saúde (SNS), has offered universal healthcare coverage since 1979 and is funded through general taxation. It includes a range of public and private providers. However, there is no comprehensive coverage for all services.

Certain professions have access to special public and private insurance schemes known as "health sub-systems", which provide comprehensive or

partial coverage to between one-fifth and one-quarter of the population. The plans are financed through employee and employer contributions, including state contributions for those employed in the public sector.¹

Finally, a further 10-20% are covered by private insurance funds or voluntary health insurance (VHI).

The level of cost-sharing for healthcare is highest for pharmaceutical products, with reimbursement levels ranging from 0% to 100% and reduced co-payments by certain population groups, such as pensioners. Patients with conditions that have a major impact on quality of life, including cancer and some chronic diseases, are eligible for full reimbursement of essential or life-saving medication, such as insulin.²

Authorisation, regulation, distribution and surveillance of pharmaceuticals and medical devices are concentrated within the National Authority of Medicines and Health Products, the Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED), which was established in 1993 as part of the Ministry of Health. INFARMED conducts HTAs and recommends reimbursement for pharmaceutical products only; as we will see in Chapter 2, reforms of the HTA system introduced in 2014 will allow it

¹ Barros, PP, Machado, SR *et al*, "Portugal Health System Review", *Health Systems in Transition*, Vol. 13, No. 4, 2011, European Observatory on Health Systems and Policies, p. xvi.

² *Ibid.*

to undertake economic evaluations of both drugs and medical devices.

INFARMED is responsible for both reimbursement decisions and the periodic re-evaluation of approved technologies based on a comparative efficacy, safety and cost-effectiveness profile, a process that can lead to a change or reduction in price or the reimbursement rate as well as the removal from the list of reimbursable drugs. Decisions on whether to reimburse a drug are based on the type of disease and the specifics of the patient's situation, including the severity of the disease or the importance of prolonging life.

The agency began issuing guidelines for carrying out cost-effectiveness studies on drugs for sale in pharmacies as early as 1998, making it one of the first HTA agencies in Europe to do so.³ In 2006 this mandate was extended to hospital drugs.

The outpatient list of approved medicines, which is updated monthly, includes more than 7,200 drugs, of which 4,300 are considered to be essential. Non-essential drugs are subject to substantial co-payments of between 31% and 85%.⁴

In the inpatient sector, for prescribing, drugs must be included in both the National Hospital Pharmaceutical Formulary and local hospital formularies; if this is not the case, prescribers must provide a justification for using the medicine in question. These requirements may result in access inequalities across hospitals and/or regions.

INFARMED has responsibility for determining the maximum manufacturer price of outpatient prescription medicines. The agency has used international reference pricing based on the average price in selected EU countries since 2003. Starting in 2007, it used prices from four countries—Spain, France, Italy and Greece. In 2015 these reference countries were changed to include France, Spain and Slovakia, with the average of the three used for the retail market and the lowest for hospital prices.⁵ International

reference pricing is used for all drugs except generics.

In the case of medicines for hospital use only, a similar combination of reference pricing and central reimbursement evaluation is used; however, once this reimbursement is approved, individual hospitals have the ability to review the use of a drug and establish a purchasing contract with the manufacturer. Central reimbursement decision is not followed by funding allocation to drugs. Hence hospitals are the budget holders of drugs. Hospitals are not permitted to purchase drugs or negotiate for their use if they have not been approved nationally for reimbursement. In 2007 the Portuguese parliament passed legislation introducing maximum prices, based on the lowest price of the basket of reference countries and budget controls for new drugs in public hospitals, requiring assessment of new drugs based on therapeutic added value and cost-effectiveness.⁶

Still, by 2008 Portugal's pharmaceutical expenditure, not including hospital medicines, was around 2.1% of GDP, comparably higher than in many other OECD countries.

Health budgeting in an age of austerity

The government has regularly negotiated with pharmaceutical companies in an effort to reduce its overall spending. Since 1997 the industry has signed regular framework agreements with the ministries of health and finance committing to reforms, limits of expenditure and industry financial contributions. In 2014 the payback from the industry amounted to €160m (US\$173m), and for 2015 it was agreed to be €180m.⁷ This represents over 7% of the total annual medicines bill (in retail prices).

Moreover, the government has repeatedly introduced price cuts for medicines, including a 30% reduction for generics in 2008; a 6% mandatory discount in the retail price of all reimbursed drugs; a 7.5% reduction in biologics in 2010; and a cut in 1,400 branded drugs in 2013.

³ *Ibid.*, p. 45.

⁴ Vogler S and Leopold C, "Access to essential medicines in Portugal", commissioned by Health Action International Europe, July 2009, pp. 27 and 32.

⁵ Ministry of Health, Decreto-Lei n. 97/2015, June 1st 2015. Available at: http://www.portaldasauade.pt/NR/rdonlyres/96677839-3EB3-4ABF-B7E8-B9CDF2B43D3D/0/Decreto_Lei97_2015_SiNATS.pdf

⁶ Barros *et al*, "Portugal Health System Review", p. 45.

⁷ IMS, "Portugal: Compromise Reached over Payback Agreement", *IMS Pharma Pricing & Reimbursement*, January 2015, Vol. 20, No. 1, p. 18.

Under the agreement with the troika—the European Commission, the European Central Bank (ECB) and the International Monetary Fund—reached in 2011, the government agreed to cap drug expenditure at 1.25% of GDP in 2012 and to around 1% of GDP in 2013 and 2014, according to Carlos Gouveia Pinto, a professor at the Lisbon School of Economics and Management.

Portugal's efforts to reform its drug pricing policy have contributed to significant reductions in pharmaceutical spending since 2010. Total expenditure on retail medicines in the Portuguese SNS stabilised at below €1.2bn annually between 2012 and 2014, down from more than €1.6bn in 2010.⁸ OECD data show that in Portugal per-capita pharmaceutical expenditure in real terms fell by an annual average of 6.8% during 2010-13, while sales remained relatively stable in the OECD on average over the same period.⁹

Generic drugs have been a key part of the focus on cost control in Portuguese pharmaceutical policy, which has combined both price reductions and an increase in reimbursement rates to provide incentives. The market share of generic medicines reached 22.6% of the total value of pharmaceutical market sales (at ex-factory prices) in Portugal in 2013—above countries such as Greece (15.1%) and Spain (18.5%), but below Italy (41.5%) and Poland (54.8%)—according to data from the European Federation of Pharmaceutical Industries and Associations (EFPIA).¹⁰

But while efforts to control expenditure have been more effective in the ambulatory sector, they have been less so in the hospital sector, according to Professor Gouveia Pinto.

The hospital sector: A decentralised power source

The hospital sector has traditionally had a significant amount of autonomy and been less subject to performance indicators than other

parts of the Portuguese healthcare system.

The finance ministry provides the health ministry with a global budget for the health service, which is allocated to individual institutions within the system, including public hospitals. The ministry introduced diagnosis-related groups (DRGs) gradually from 1997 to 2002. Since 2003 they have been used to establish total funding for SNS hospitals and inpatient care, accounting for 75-85% of public hospitals' inpatient budget.¹¹ The Portuguese authorities use DRGs to set hospital budgets, rather than to define payments for sequences of treatments. Because the DRG system requires the collection of data on an individual patient basis, the resulting improvement of available information helps hospitals to adjust their budgeting for case-mix and other factors specific to hospitals, thereby allowing resources to be allocated more evenly.¹²

The health service has invested in making clinical trials within hospitals part of its health strategy, allowing both engagement with the pharmaceutical industry and early access to new technologies for compassionate use. Yet the fact that hospital boards could negotiate directly with the pharmaceutical companies creates its own problems, Dr Leite notes.

"Most of the time, for most pathologies, there are three or four first-line drugs, and this leads to regional disparities, which is bad for the SNS because it makes it difficult to negotiate on price volume," he says. At the same time, he argues, hospital administrators are unwilling to relinquish this source of power. "A regional system would work better, as agencies could supervise one another and show they could compare prices."

Hospitals have been successful in some cases at negotiating further price discounts to the maximum price approved by the government, according to Pedro Pita Barros, an economics professor at Nova Business School in Lisbon. He adds that some hospitals have also managed

⁸ INFARMED and ACSS from presentation by João Almeida Lopes, president of the Portuguese Pharmaceutical Industry Association (APIFARMA), to *Rethinking Pharma* conference, 2015.

⁹ OECD, *OECD Health Statistics 2015*.

¹⁰ EFPIA, *The Pharmaceutical Industry in Figures, Key Data 2015*, p. 17. Available at: http://www.efpia.eu/uploads/Figures_2015_Key_data.pdf

¹¹ Barros *et al*, "Portugal Health System Review", pp. xvii, 70-71.

¹² *Ibid.*, p. 70.

to create consortia to achieve higher volumes to improve negotiations with pharmaceutical companies.

Portugal has made efforts in recent years to reform the hospital sector and improve the quality of care, including through the introduction of new management models, payment systems and safety standards.

As part of this process, hospitals have instituted a number of performance indicators that reflect access, quality, productivity and financing. The OECD praises the Portuguese approach to quality monitoring and improvement as “particularly sophisticated”, employing disease-specific registers and electronic patient records to help drive reforms.¹³

However, despite compiling extensive data on hospital activities and outcomes of care, Portugal has yet to significantly link financial incentives to the quality of hospital services—

just 5% of hospital revenue is related to relevant performance indicators.¹⁴

In some specific cases the government has been trying to move away from the current global budgeting system to models in which hospitals are financed through contracts paid per patient. Dr Leite refers to the treatment of HIV, where hospitals are eligible for higher reimbursement rates if they improve patients’ health, such as keeping virus counts low and CD4 counts (which are an important part of the human immune system) high in HIV patients. “It’s an interesting example,” he says, “and it’s a model that needs to be perfected, but I believe it’s going in the right direction.”

Yet problems persist with maintaining consistent clinical practices across the sector, the OECD points out, adding that Portuguese healthcare is still “over-reliant” on the hospital sector.¹⁵

¹³ “Portugal: Raising Standards,” *OECD Reviews of Health Care Quality*, May 27th 2015, p. 3.

¹⁴ *Ibid.*, p. 33.

¹⁵ *Ibid.*, pp. 14 and 19.

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Chapter 2: The post-crisis era of reform

The impact of the global financial crisis and the particular restrictions introduced as a result of the troika negotiations with Portugal have provided the catalyst for a series of reforms, starting in 2010.

In particular, hospitals were forced to present a strategy for reducing their expenditure, and healthcare providers were encouraged to deliver more integrated care. At the same time, the health ministry hired retired physicians to deal with a shortage of doctors and established a group for primary healthcare reform, along with a new governance model to shape the reforms.¹⁶

These policies have been underpinned by efforts to empower patients, including the greater use of websites and other ways of informing health consumers. More recently, the government has undertaken an ambitious plan to overhaul its system of conducting HTA.

Integrated care

Compared with many of its European neighbours, Portugal has been in the vanguard of OECD countries in introducing a more integrated delivery of healthcare services.

The government began to develop integrated care pathways to deal with an ageing population and increasing rates of chronic illnesses in

2008, publishing its new guidelines in 2013. The pathways involve co-ordinating medical and nursing services in hospitals, primary healthcare and long-term care.¹⁷

As part of this process, the government has set up integrated disease management programmes, characterised by a balance between incentives and sanctions to improve care for conditions such as obesity, chronic renal disease and pulmonary hypertension.¹⁸

“The integrated approach won’t be applicable to everyone, but if it is a disease with high prevalence or high impact on the budget, it may make sense to have a programme integrating all services and to make sure the financing system isn’t funding administrative procedures,” notes Dr Leite. The approach is especially important for diseases such as diabetes, which still has a 13% prevalence in Portugal, significantly higher than the OECD average, he adds.

It remains difficult, however, to draw a conclusion at this point about whether the integrated care structure has led to improved outcomes for patients, according to Professor Pita Barros. “Partial evaluations seem to point to not much difference in outcomes and in outputs, although a more comprehensive review is required in my view, and care needs to be taken to compare

¹⁶ *Ibid.*, pp. 17ff.

¹⁷ *Ibid.*, p. 14.

¹⁸ *Ibid.*, p. 19.

appropriately," he says. This is in part because a focus on patient outcomes is still not as widely accepted within the system, he adds.

Family health units

Portugal has traditionally placed a high priority on specialist hospital care, but the health system has suffered from a relatively low number of general practitioners (GPs) compared with other countries. At the same time, the health service restricts access to specialist care, with GPs playing the role of gatekeepers, leading many to bypass their local surgery and visit emergency departments.¹⁹ Recent healthcare reforms have attempted to correct this and to improve efficiency gains in healthcare delivery.²⁰

In particular, there has been an effort to look more closely at efficiency and outcomes in the primary-care system, which is currently dominated by two different models: primary healthcare units (PHCUs) and family health units (FHUs). PHCUs, the traditional form of primary-care delivery in Portugal, operate under a chain of command with decisions made by regional health administrators and healthcare professionals employed as civil servants. In 2007 the government established a newer model—family health units—with the aim of increasing co-ordination between multidisciplinary providers, giving GPs and primary-care nurses greater flexibility and bringing GPs closer to patients. FHUs generally comprise between three and eight GPs and a similar number of family nurses, who are invited to volunteer to form their own partnership groups to deliver primary care together.

There are a number of other differences between FHUs and PHCUs. Acute cases are treated in separate GP-staffed facilities in some PHCUs, while FHUs treat acute cases during the GPs' normal working hours. PHCUs only handle medical consultations, while FHUs also offer regular appointments with nurses.²¹ Under the system FHU teams receive performance-related payments that reward accessibility and quality, including their success in controlling

hypertension, avoiding diabetic complications in patients or other health indicators.²²

The OECD notes that the reforms "have been successful in improving accessibility, efficiency, quality and continuity of care, as well as increasing the satisfaction of both professionals and citizens".²³ However, challenges remain. According to the OECD, FHUs appear to consistently outperform PHCUs, so that parts of the population have higher-quality access to care than others. The OECD argues that the government could do more to encourage traditional PHCUs to transform themselves into FHUs, including by introducing incentives.²⁴ This is particularly crucial in view of the impending shortage of GPs as many retire, and given the potential gains to be reaped from developing the role of the family nurse.

Now we have to really consider how to motivate those who are not yet interested in moving into the new system because the evidence is so clear," Dr Leite says, calling the programme a "real-life clinical trial in austerity times".

SiNATS: A continuous process of evaluation

The most notable recent reform to the Portuguese health system has been the introduction of a new national system of health technology assessment, the Sistema Nacional de Avaliação de Tecnologias de Saúde (SiNATS), as part of INFARMED in 2014.

Previously, as we have seen, INFARMED used HTA to help determine pricing and reimbursement of medicines as well as to control expenditure, using both relative effectiveness and cost-effectiveness measures.

SiNATS extends the evaluation system to all types of technologies, starting with medical devices, and gives priority to contract-based financing agreements with manufacturers. The evaluation process is expected to look at the feasibility of risk-sharing agreements and the need for additional monitoring of medicines. Under the

¹⁹ *Ibid.*, p. 99.

²⁰ Barros *et al.*, "Portugal Health System Review", p. xviii.

²¹ *Portugal: Raising Standards*, p. 25.

²² *Ibid.*, p. 19.

²³ *Ibid.*, p. 14.

²⁴ *Ibid.*, p. 25.

more formal contract system, pharmaceutical companies will be required to pay back the excess if they exceed budget projections, and cost-effectiveness is calculated both pre- and post-marketing.

The most crucial change brought in by the new initiative is that HTA will now be used to help to re-evaluate the health technologies that are already authorised and funded by the national health service. SiNATS will reassess existing technologies in comparison with alternatives, using both manufacturers' information and data on patient outcomes from national registries of patients treated on the SNS for conditions such as cancer and HIV/AIDS.²⁵ "The idea is to have a continuous process of evaluation," Professor Gouveia Pinto says.

One key issue that SiNATS seeks to solve is the existing flawed reimbursement model, which tends to be inconsistent and political, according to Dr Leite. "The truth is that, at the end of the day, since the model isn't as perfect as we would like it to be, the question is whether the state will reimburse the drug despite the fact that it passed the HTA challenge," he says.

Consequently, SiNATS seeks to ensure that the HTA process becomes more transparent and streamlined and that it involves a wider range of stakeholders, including patient associations.

Professor Gouveia Pinto argues that the introduction of SiNATS was motivated by the government's belief that the regulation of hospital drug expenditure was ineffective. "While doctors agree more with systems of efficiency, SiNATS is taking into account results, not just cost-containment," he observes.

The creation of SiNATS and its new evaluation procedures have the potential to create additional delays to decisions about new technologies, especially during the pricing and reimbursement process. This challenge is expected to have a greater impact on branded hospital medicines, such as those for cancer and

rare diseases, although INFARMED has said that it is looking into providing a route for accelerated access to innovative medicines that appear to be promising.

One key factor that will determine the success of SiNATS is its ability to be ruthless about taking technologies whose efficacy is no longer supported by scientific evidence off the market, Dr Leite says. "The only way I think we are going to fix the reimbursement issue is to establish a cap on overall drug expenditure and negotiate with all partners within the industry. We need to establish fully transparent rules, and there needs to be assurance from the state that they will comply.

Professor Gouveia Pinto notes that "although SiNATS allows for disinvestment, and there is a specific law on that, the concrete way this will be put forward is not clear".

Building a better information and decision-making infrastructure

As it looks to implement this more evidence-based approach to assessing new technologies, Portugal can make use of a "rich information infrastructure" that is significantly more expansive across its healthcare system than is the case in other countries. This includes not only disease registers and electronic patient identifiers but also the Portuguese Health Data Platform, including a patient, professional and institutional portal.²⁶

In 2003, as part of efforts to ensure a high-quality primary-care service, the government created a new regulatory body, the Health Regulatory Agency (HRA). The agency focuses on promoting patients' rights through providing quality-of-care indicators and other information to allow for informed choice in the selection of care providers; the regulation of market failure, including fighting inequality in access to healthcare; and the regulation of the economic interaction between different parts of the healthcare system through increased competition.²⁷

²⁵ *Ibid.*, p. 2.

²⁶ *Ibid.*, p. 21.

²⁷ European Observatory on Health Systems and Policies, *Health Systems in Transition (HiT)*; profile of Portugal.

Conclusion

In developing its system for evaluating and authorising new technologies, Portugal has taken into account cost-benefit analysis well before many wealthier neighbouring countries. Years of economic austerity and restrictions imposed by the troika have forced the country to find more innovative ways of getting the most value out of this process.

In the course of experimentation, Portugal has also implemented significant reforms in primary healthcare and integrated care delivery, although both of these areas are works in progress.

But there are positive signs from the reform initiatives: according to OECD survey data, the percentage of the Portuguese population

who think that the health system requires fundamental change or even a complete revamp fell to 54% in 2015, from 80% in 2002. This compares with an average of 51% across the EU.²⁸

Portugal will face the challenge of accelerating reforms in the hospital sector to improve outcomes further and to ensure that the funding system is an incentive to increase health outcomes. Moreover, it will have to perfect the SiNATS initiative to ensure that an ongoing and more comprehensive evaluation system for new technologies does not hamper access for the patients who need them. And finally, the link between reimbursement decision and funding allocation remains a challenge to be resolved.

²⁸ *Portugal: Raising Standards*, p. 22.

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LONDON

20 Cabot Square
London
E14 4QW
United Kingdom
Tel: (44.20) 7576 8000
Fax: (44.20) 7576 8500
E-mail: london@eiu.com

NEW YORK

750 Third Avenue
5th Floor
New York, NY 10017
United States
Tel: (1.212) 554 0600
Fax: (1.212) 586 1181/2
E-mail: newyork@eiu.com

HONG KONG

1301 Cityplaza Four
12 Taikoo Wan Road,
Taikoo Shing
Hong Kong
Tel: (852) 2585 3888
Fax: (852) 2802 7638
E-mail: hongkong@eiu.com

GENEVA

Rue de l'Athénée 32
1206 Geneva
Switzerland
Tel: (41) 22 566 2470
Fax: (41) 22 346 93 47
E-mail: geneva@eiu.com