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IS BUDGET CAPPING A SUCCESSFUL MACRO POLICY TO CONTROL DRUG EXPENDITURE? THE SPANISH EXPERIENCE

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IS BUDGET CAPPING A SUCCESSFUL MACRO POLICY TO CONTROL DRUG EXPENDITURE? THE SPANISH EXPERIENCE

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Summary

In 2015, Spain implemented a pharmaceutical budget capping system aimed which links pharmaceutical expenditure to Gross Domestic Product (GDP). The Protocol signed between Farmaindustria (Spanish Pharmaceutical Industry Association) and the Spanish Government sets two limits to total public pharmaceutical expenditure for original medicines, namely, a reference rate of medium term GDP growth, and the annual rate of growth itself. From a conceptual standpoint, budget-capping policies, such as the one employed within Spain, are promising from a cost-containment, affordability and predictability perspective. While this policy seems to contribute to cost containment, it is doubtful that this type of macroeconomic policy contributes to efficiency, the diffusion of innovation or whether it provides the appropriate incentives for competition to take place where appropriate.

Introduction

Several national audits of the Spain's pharmaceutical sector have taken a highly critical view of the current pricing and reimbursement system. The evaluation and subsequent pricing of new technologies was found to lack both consistency and transparency. Further there has been an apparent unwillingness to apply and implement legislation on the use of economic evaluation in the pricing and reimbursement of medicines. Very recently, the Spanish Fiscal Authority (AIREF Spending Review on the Pharmaceutical sector (June 2019)), has emphasized again similar concerns about efficiency in the Spain's decision-making process in controlling drug expenditure.

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The issue of efficiency in the Spanish pharmaceutical sector is magnified by global trends in pharmaceutical markets. While an increasing number of innovative medicines have come to market that are potentially beneficial to patients, the associated high costs of these therapies have raised concerns over financial sustainability. Further, an ageing population and growth in non-communicable disease exert increasing fiscal pressure on health care systems (WHO, 2015).

In response to growing expenditures, policy makers across Europe have implemented cost-containment measures and policies aiming to improve efficiency in resource allocation, with particular emphasis on the pharmaceutical sector. A common policy across an increasing number of EU countries relates to the introduction and use of health technology assessment (HTA), whether this is taking place through the use of economic evaluation or clinical benefit assessment (WHO, 2015). This seems to be the preferred tool of health policy makers. Another common macro-economic measure mostly preferred apparently by those responsible of public finance has been to cap pharmaceutical expenditure. Budget capping shifts the risk of unsustainable growth from the payer to the industry. But while capping pharmaceutical expenditure may ensure affordability it does not necessarily promote efficiency (Garrison and Towse, 2003). This is the focus of our paper.

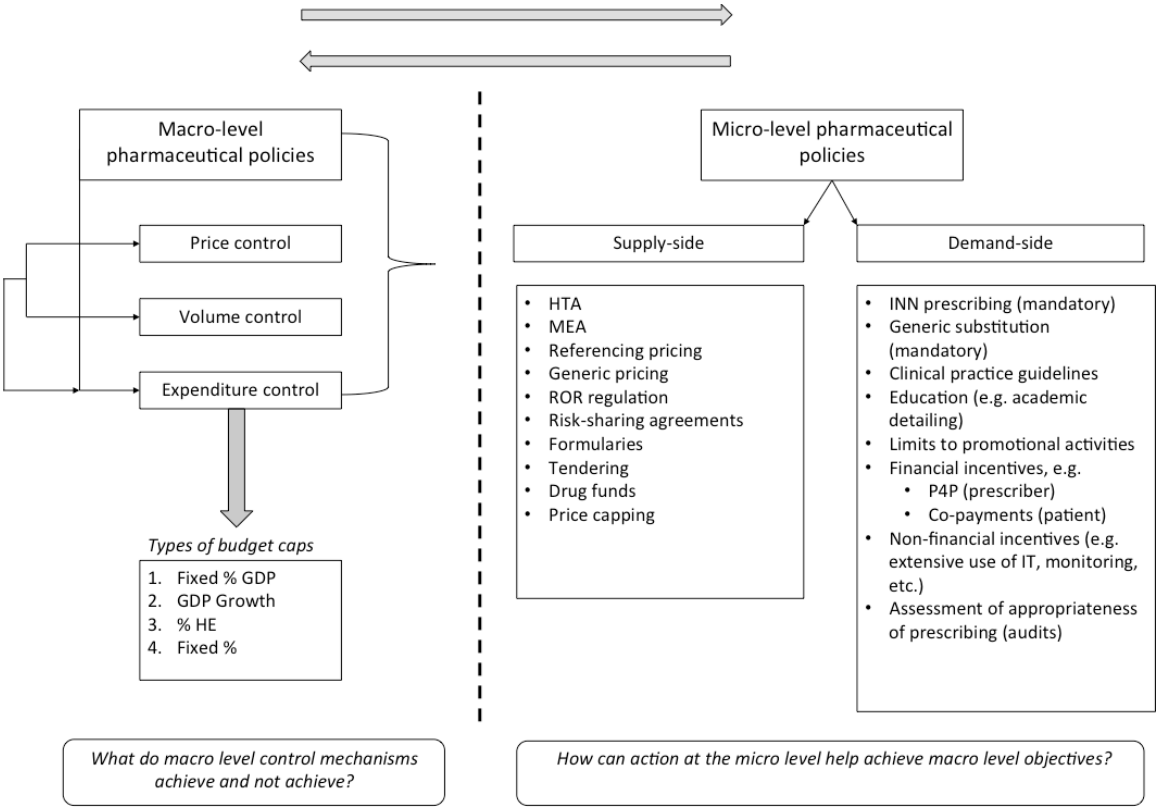
Background

Since 2015 Spain has employed a budget capping system, which links pharmaceutical expenditure to the Gross Domestic Product (GDP) growth rate. The Protocol signed between Farmaindustria (Spanish Pharmaceutical Industry Association) and the Spanish Government sets two limits to total public pharmaceutical expenditure for original medicines, namely, a reference rate of medium term GDP growth, and the annual rate of growth itself (Farmaindustria 2016a, Ministerio de Hacienda Y Administraciones Públicas 2015). From a conceptual standpoint, budget-capping policies seem to contribute to cost containment. In the preceding years the cost limit has been held and only this past year 2018, a devolution of 1,5% of GDP is being due (1.500 millions of euros) having pharmaceutical expenditure overpassed the GDP rate of growth. However,

it is doubtful that this type of macroeconomic policy contributes to efficiency, the diffusion of innovation or whether it provides the appropriate incentives for competition to take place where appropriate.

Traditionally, efficiency improvements, diffusion of innovation and competition can be promoted through various demand- and supply-side micro-economic policy tools (even if there is some evidence in Spain that not all these tools were effective in attaining their goals); these are not implemented in isolation, but rather in conjunction with macro-level policies (Carone et al. 2012).

Figure 1: Analytical framework



Source: The authors.

To face the increase ok pharmaceutical expenditure needs to address the following questions:

1. What are they key drivers of pharmaceutical expenditure?
2. What is their specific impact on public budgets?

3. Given some economic financial constraints, how this is affecting efficiency in the pharmaceutical sector at the macro and micro levels?

A global budget constrain is one of these last resort rough policies that finance ministers try to impose when other policies are not tried or do not work. Spain implemented in 2015 a pharmaceutical budget capping system aimed which links pharmaceutical expenditure to Gross Domestic Product (GDP). The Farmaindustria agreed a Protocol setting two limits to total public pharmaceutical expenditure for original medicines, namely, a reference rate of medium term GDP growth, and the annual rate of growth itself. We will search in this paper for the consequences of this policy based on both secondary and primary evidence. Targeted and comprehensive literature reviews are carried out to collect data on the impact of pharmaceutical policies on expenditure due to the budget capping systems[3]. In addition, some interviews to k-agents were performed[4].

Key trends in the Spanish Pharmaceutical sector

A number of trends emerge from the discussion on the drivers of pharmaceutical expenditure and from the discussion on the feasibility of pharmaceutical budget caps. First, relative to other European countries, Spain's health expenditure per capita and

[3] Targeted searches were carried out first in MEDLINE, ECONLIT and Google Scholar on generic policy, health technology assessment, price cuts, dispensing policy, prescribing policy, expenditure/budget capping, and risk sharing agreements. Peer-reviewed evidence was then supplemented with grey-literature obtained from websites of national health organizations, international organizations, and Google searches. In addition, publicly available data relating to health expenditure, pharmaceutical expenditure, new medicine uptake, generic uptake, and number of prescriptions was collected from OECD databases and Spanish Ministry of Health websites. The second phase of literature review focused on macroeconomic pharmaceutical budget caps. MEDLINE, ECONLIT and Google Scholar were searched for any papers with relevant evidence on the use of pharmaceutical budgets and payback or clawback schemes, since 2000. Search terms included combinations of 'pharmaceutical budgets', 'drug budgets', 'medicines budgets', 'pharmaceutical funds', 'medicines funds',' drug funds', 'payback, clawback', and 'rebate'. Evidence was systematically screened and assessed for strengths, weaknesses, opportunities and trends.

[4] Primary data was obtained from a meeting with expert stakeholders in March 2017 to gather feedback on budget capping policies across Europe and their impact on government healthcare policies. A limited number of follow-up interviews were conducted to clarify outstanding issues.

pharmaceutical expenditure per capita levels are well within EU averages and have remained so over the past 15 years.

Second, over the past 15 years, there are three distinct periods characterizing Spanish pharmaceutical expenditure (both, hospital and retail): (a) Steady spending growth (average of 6.2 % per annum from 2000-2009); (b) significant decline in spending (average of -7.35% per annum from 2010-2013); (c) modest growth in pharmaceutical spending (average of 2.59% from 2014-2016), and a new escalation in these recent years (2018-19).

Third, pharmaceutical expenditure in Spain seems to be responsive to both pricing and volume policies. Price cuts, generic substitution policies, and introduction of co-payments coincide with declines in pharmaceutical expenditure from 2010 to 2013, yet the results achieved appear to be temporary as additional pressures continue to inflate expenditure.

Fourth, the period from 2014-2017 is characterized by an overall increase in total, retail and hospital pharmaceutical expenditure. The largest variations are seen in hospital expenditure, predominantly due to the introduction of new hepatitis C treatments.

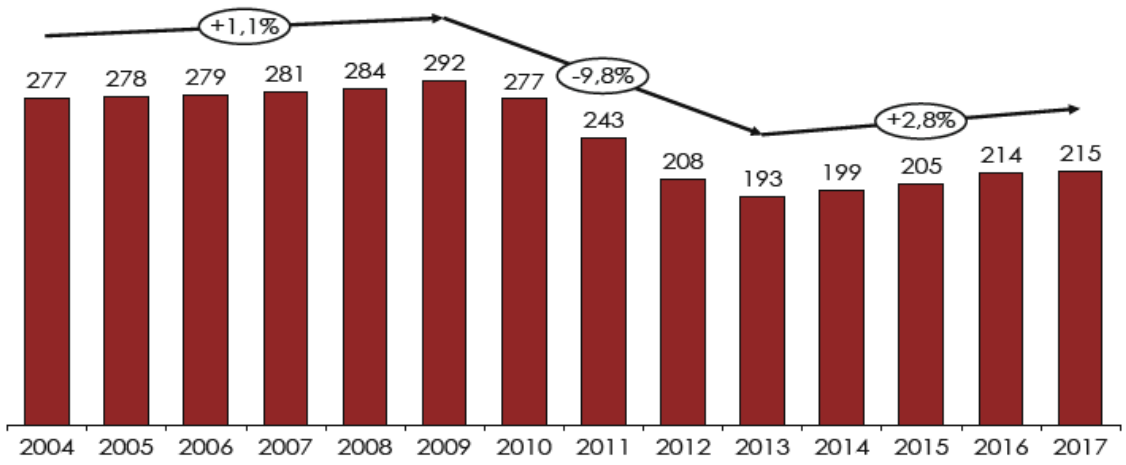
Fifth, while Spain has made significant improvements in generic policy over the past 15 years, its performance appears to fall short of other EU member states. The same occurs for biosimilars, for which uptake in Spain is lagging behind the other main EU countries. Targeting generic and biosimilar pricing and penetration have the potential to improve Spanish health system efficiency.

Sixth, the use of HTA in the Spanish context is very limited either as a tool to inform decision-making (particularly pricing and reimbursement decisions) at national level, or as tool to provide guidance on cost-effective prescribing amongst prescribing physicians. It appears that there is poor dissemination of HTA reports, most physicians are not aware of them and, consequently, are not able or compelled to use them in daily clinical practice.

Seventh, the economic crisis and implementation of aggressive policy reforms from 2009 to 2012 coincide with net decreases in the number of registered pharmaceutical

formulations. This is a result of both an increase in the delisting of products and a decrease in the registration of new formulations.

Figure 2.Per capita real Pharmaceutical expenditure 2004-17 (euros 2016) (*)



Source AIREF, June 2019 Retail. Expenditure on hospital dispensed drugs is estimated woul add an extra 30% to the above figures.

In addition to the former features, a relevant characteristic of the Spanish National Health System (NHS) is the decentralization of financing and provision. The responsibility is shared between the State and the regions ("Autonomous Communities"). In the pharmaceutical market, most of the key regulatory bodies operate at State level, such as pharmaceutical pricing and reimbursement, marketing and advertising of drugs, and the quality and manufacture of pharmaceutical products.

At State level, the Ministry of Health, Social Services and Equality (MoH) is the institution in charge of the pharmaceutical sector. The MoH monitors the pharmaceutical market through two main institutions: 1) the Directorate-General of Pharmacy and Health Care Products, in charge of the pharmaceutical policy, and 2) the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) which deals with the scientific tasks and marketing authorisation.

These regulations are aimed at achieving equilibrium between national health objectives, industry and public pharmaceutical expenditure (Piña-Mavarez and Suarez-Serrano, 2009). One of the most significant reforms was that of the patent system in

1986 and the Spanish Medicines Law in 1990. The latter was replaced by the new pharmaceutical law in 2006, "Guarantees and the Rational Use of Medicines and Health Products, Law 26/2006", which introduced a modified reference price system (Costa-Font and McDaid, 2007).

A further -relatively recent- development in the overall regulatory framework aiming to improve decision-making at pricing an reimbursement level is linked to Health Technology Assessment (HTA). Specifically, the HTA procedure is different for pharmaceuticals and medical devices[5]. On one hand, pharmaceutical pricing and reimbursement decisions are taken at national level through the Interministerial Commission on Pharmaceutical Prices [ICPP] (*Comisión Interministerial de Precios de Medicamentos*)[6]. On the other hand, HTA agencies are in charge of the assessment of medical devices. However, their decisions are not binding.

The Spanish pharmaceutical market is featured as being highly regulated, yet little is known about the extent to which such regulation is effective in satisfying key policy imperatives such as macro-economic efficiency, micro-economic efficiency, quality of care or equity.

Spanish pharmaceutical policy reforms since 2006

Over the past ten years there have been a series of notable reforms targeting price, volume and generic uptake. Figure 2 presents a chronology of policy reforms from 2006-2015. The first reforms were purely cost-containment initiatives through compulsory

[5] In the context of medical devices, in 2012 (RD law 16/2012), in order to improve coordination across HTA agencies, the "Spanish Network of Agencies for Assessing National Health System Technologies and Performance" (*Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud*) was created. This network is formed of the eight HTA Spanish agencies. The network is in charge of the assessment of medical techniques and procedures for the inclusion, exclusion or modification of their use within the NHS service portfolio. Their assessment is not binding and made after the technologies have been authorised and adopted.

[6] This Commission is formed by representatives of the Ministry of Finance and Civil Service, the Ministry of Health, Social Services and Equality, the Ministry of Economy, Industry and Competitiveness and, from 2011 (RD 200/2012), from two rotatory – every six months- Autonomous Communities. Until 2012, price agreements on new drugs were publicly available on the Ministry of Health, Social Services and Equality website, however, from 2012 onwards, these are not uploaded.

price cuts. In 2006, prior to the economic crisis, branded products without a generic competitor in Spain but available in other European countries received a flat 20% price reduction. In 2010, as part of the RDL 4/2010, this price reduction increased to 30% while it expanded its scope to publicly financed generic products. Generic products received a flat price reduction on the basis of reference pricing, leading to decreases of around 25-30%. Further, originator products received a price cut of 7.5%, orphan products a cut of 4% and incontinence products a cut of 20% (Lobo 2013).

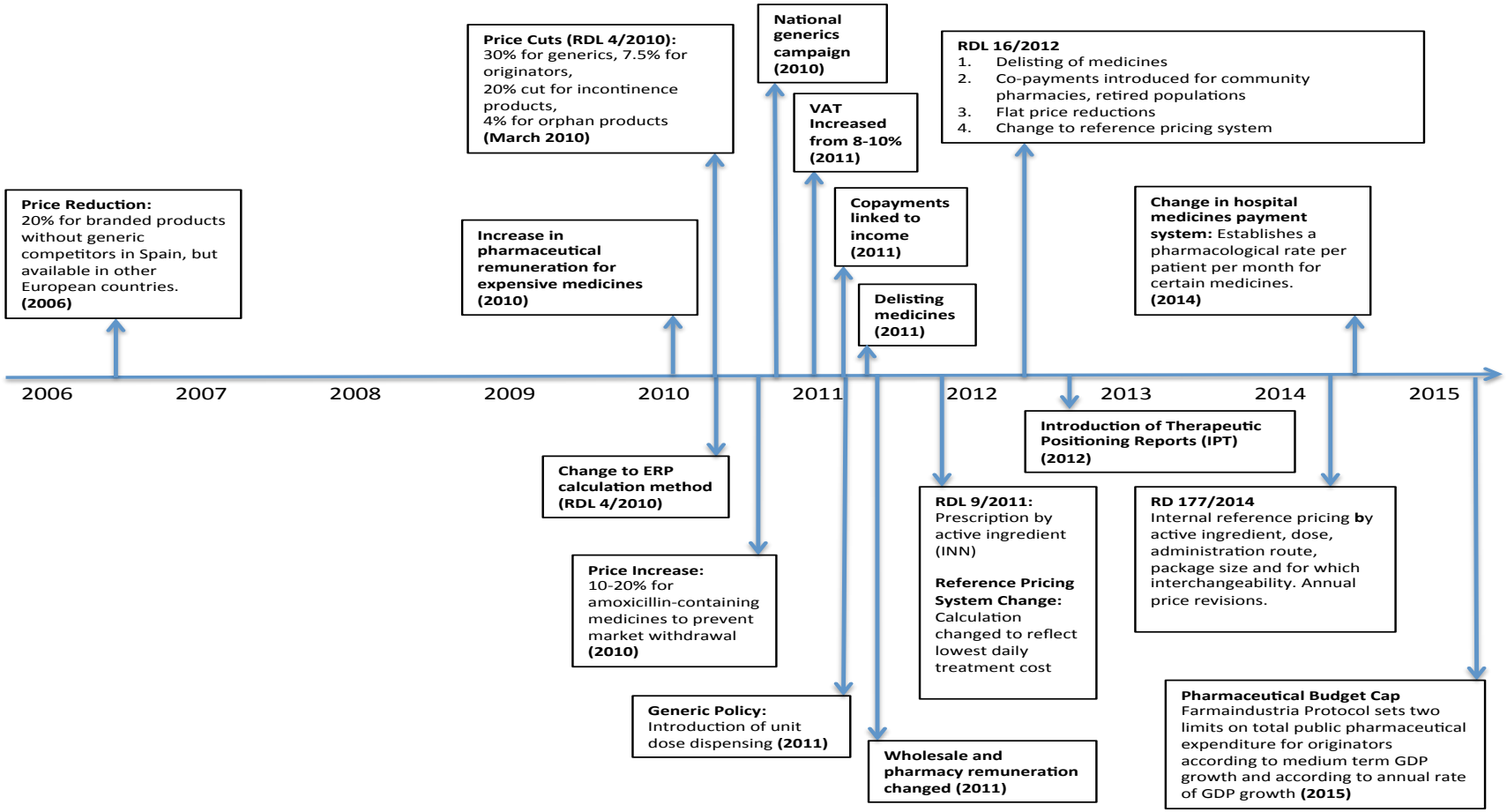
The next major reform occurred in 2011 through the RDL 9/2011, which introduced mandatory generic prescribing and required pharmacists to dispense the cheapest available product according to MoH drug groups. Additional reforms in 2011 included delisting of medicines and the introduction copayments linked to income.

Further changes were then made the following year with the passing of RDL 16/2012. Copayments in the public Spanish NHS are applied only to retail pharmaceutical products and there isn't any copayment for hospital products. In 2011 after the passing of the RDL, both the conditions and the personal limits changed to the 2012 situation. Effective copayment rates had been steadily diminishing for almost 24 years (15% in 1985, 7% in 2009 and 6% in 2012) (Lopez-Valcárcel & Puig-Junoy, 2016). The copayment rate for active population was fixed at 40% and 10% for chronic patients since 1980 while the retired population was exempt. This steady decline is explained by the ageing effect, the consumption of chronic patients and excessive consumption associated with moral hazard (Puig-Junoy, Garcia-Gomez, & Casado-Marin, 2011). After the RDL 16/2012, the retired population faced a 10% copayment rate with monthly limits depending on personal income, however, there was an opportunity to expand the scope of applicability of copayments. Beyond reforms to copayments, RDL 16/2012 introduced a number of other changes to the Spanish pharmaceutical sector. This included the delisting of a number of medicines for minor symptoms, cost-containment initiatives in the form of flat price reductions, increased generic utilization, and adjustments to the reference pricing system.

Between 2013 and 2014, only minor reforms were introduced in the Spanish pharmaceutical sector. This included the elimination of the copayment introduced in

2012 and never actually applied, changes in hospital medicines payment system and a change in internal reference pricing for off-patent medicines. Finally, in 2015, Spain introduced a budget cap linked to GDP growth on total pharmaceutical expenditure through the Farmaindustria Protocol (Farmaindustria 2016a, Ministerio de Hacienda Y Administraciones Públicas).

Figure 2: Chronology of pharmaceutical policy reforms in Spain (2006-15)



Pharmaceutical Budget Caps

Despite the implementation of several micro-level pricing and volume policies from 2010-2012, pharmaceutical expenditure began to rise again in 2013. As commented, in 2015, Spain implemented a pharmaceutical budget cap in order to limit the growth in pharmaceutical expenditure and link it to GDP growth.

Several different types of pharmaceutical budget caps have been identified in literature. Table 1 provides a list of the various pharmaceutical budget caps identified through literature review. Appendix A provides a detailed overview of the various types of budget capping systems. A cap on expenditure can either be 'global' or 'partial', where the former includes all aspects of healthcare, while the latter relates to certain section(s) within healthcare (Wolfe & Moran, 1993). Partial budgets are increasingly targeted at the pharmaceutical industry in light of increasing expenditure within the sector. Under this type of budget, governments can impose expenditure caps on total pharmaceutical expenditure (e.g. Spain Farmaindustria Protocol), impose caps for expenditure on individual products (e.g. price-volume agreements) or disease areas (e.g. UK Cancer Drugs Fund), or even impose caps on caps on prescribers. In addition, budgets can either by 'hard' or 'indicative' (Mossialos, Mrazek & Walley, 2004; Ess, Schneeweiss, & Szucs, 2003). Hard budgets can either enforce penalties (e.g. only partial reimbursement, or repayment of overspending) or offer rewards (e.g. allowing the physicians or practices to keep or reinvest surplus funds) (Mossialos, Mrazek & Walley, 2004). Under indicative budgets, data for prescribing at the physician/practice/organisation level is collected with information regarding under- or over-spending communicated to the agent. Unlike hard budgets, no immediate penalties or rewards are issued (Mossialos, Mrazek & Walley, 2004). Differences are seen in the mechanism of setting the budget cap. Expenditure can be fixed to GDP (e.g. Greece, Romania, Portugal) fixed as a % of total health expenditure (e.g. Italy), or fixed at a baseline level and subject to increases linked to GDP growth (e.g. Spain) or to fixed percentage increases (e.g. UK PPRS) (Carone et al. 2012; Department of Health 2013). If spending growth targets are exceeded, rebates often apply, but the type of rebate implemented can differentiate across products; for example, the latest PPRS agreement

in the UK explicitly excludes all new products launched during the 5 years of the agreement (2014-2018) (Department of Health, 2013). This is a clear indication by the regulator in favour of supporting innovation.

The Spanish Protocol establishes that, if pharmaceutical expenditures exceed the reference rate but not the actual growth rate, the industry will implement economic compensatory measures towards the NHS, which do not involve a monetary transfer. From the literature available, it is unclear what this economic compensatory measure will be and how this will be shared. On the contrary, if spending exceeds real annual GDP growth, compensation will be monetary. There are therefore two thresholds, the first of which is less stringent than the second (Farmaindustria 2016a, Ministerio de Hacienda y Administraciones Publicas 2015).

Table 1: Country experience with pharmaceutical expenditure capping

Country	Type of Pharmaceutical Capping	Pay pack scheme	Brief description
Spain	Fixed percentage of real GDP growth. Only on innovative and publicly funded expenditure. Base set at 2015 levels	The Farmaindustria Protocolo does not explicitly define a payback mechanism. It is assumed that manufacturers will payback 100% of the excess, but this not explicitly defined.	Spain has recently introduced this method for capping pharmaceutical expenditure with a base set at 2015 expenditure levels. Two budgets caps exist. The first is linked to a reference rate of medium term real GDP growth, and the second to the rate of real growth itself.
Italy	Fixed % of Health Expenditure - 13.3% in 2009, reduced to 13.1% in 2012 and 11.4% in 2013	60% payback from the pharmaceutical industry, wholesalers and pharmacies and 40% payback from state and regions.	First budget ceiling introduced in 1998, abolished in 2001. Second budget cap introduced in 2002 and was set at 13% of SSN expenditure.
New Zealand	Capping by product/therapeutic class	PHARMAC legally obliged to stay within budget. District Health Boards must cut expenditure elsewhere if PHARMAC spends over its budget.	PHARMAC has a Combined Pharmaceutical Budget which is developed in collaboration with DHBs and the Minister of Health.
Germany	Fixed budget (Calculation unclear)	Excess spending clawed back from physicians' association (up to the value of 142 million euro).	Budget caps for the 23 regions were introduced in 1993. Due to resistance from physicians, cap was abolished in 2001.
France	Budget caps for therapeutically related products	Drug manufacturers must contribute to a rebate scheme if the budget is overrun. The amount owed by each manufacturer is based on the drug's added therapeutic value and innovativeness of the drug.	Each year the French Parliament votes to approve a prospective budget for each category of health expenditure.
Greece	Fixed percentage of GDP – 1.33% in 2012, 1% in 2014	Payback agreement has been negotiated whereby industry pays every quarter if bi-monthly expenditure targets are surpassed.	In 2008 public expenditure on GDP in Greece was the highest in the EU. As part of a series of reforms through the Economic Adjustment Programme, a

Country	Type of Pharmaceutical Capping	Pay pack scheme	Brief description
			target of 1% of GDP was set for outpatient public spending on pharmaceuticals.
Portugal	Fixed percentage of GDP – 1.25% in 2012	Drug manufacturers pay back 100% of excess expenditure according to companies' individual market share.	Through Portuguese Economic Adjustment Programme, a target was set to reduce overall public spending on pharmaceuticals. Applies to both outpatient and inpatient.
Romania	Fixed percentage of GDP	Budgets implemented at the pharmacy level.	Up until 2009, Romania had in place monthly budget ceilings are the pharmacy level. Budgets were based on the number of pharmacists and their professional status, the number of pharmacy assistance, opening hours and location.
England	Earmarked Drug Fund	Under the 2014 PPRS, member companies have to pay back if NHS spending on branded medicines goes over pre-agreed growth rates	The Cancer Drugs Fund provides funding for cancer drugs that are not approved by NICE. In 2016, the Fund was revised and now operates within NICE. Now, it is a "managed access fund".
Scotland	Earmarked Drug Fund	Under the 2014 PPRS, member companies have to pay back if NHS spending on branded medicines goes over pre-agreed growth rates	The Scottish New Medicines Fund. The New Medicines Fund was set up in Scotland to provide additional coverage for orphan drugs, not available due to a negative SMC recommendation.
United Kingdom	As part of the most recent PPRS (2014) pharmaceutical expenditure, and due to austerity, there is a nil permitted increase in spend in 2014 & 2015, a fixed permitted % growth in expenditure	Excess spending is subject to PPRS. (1) It covers branded medicines sold to the NHS; generics are regulated separately. (2) PPRS is voluntary (and it covers around 80% of the branded sales to the NHS). (3) The alternative regulatory scheme regulates	The UK PPRS sets limits on the rate of return on capital employed (ROCE) by pharmaceutical firms.

Country	Type of Pharmaceutical Capping	Pay pack scheme	Brief description
	(PPRS): 1.8% in each of 2016 and 2017, with a permitted increase of 1.9% by 2018.	prices of medicines directly. The payments (payback), which is calculated based on the products that are on the market as of 31 December 2013. All new products launched after 1 January 2014 are not subject to PPRS payments. Exemption from PPRS payments is given to smaller companies with sales under £5 million. Paybacks are calculated on a company basis based on sales of branded medicines to the NHS. But the same percentage applies (for each year) to all companies in the PPRS.	

Source: Authors compilation from a variety of sources, including Carone et al. 2012, Department of Health 2013, Espin and Rovira 2007, Busse 1999, Busse 2008, and Anastasaki et al. 2014.

The Impact of pharmaceutical budget caps

Evidence on the impact of pharmaceutical budget caps is sparse. International comparisons of budget capping systems are limited by differences in microeconomic level policies and health system structure across countries.

From a macroeconomic standpoint, capping pharmaceutical expenditure is unlikely to result in an efficient allocation of resources. One of the key efficiency goals of health care systems is to determine the optimal allocation of the health care budget. From an economic perspective, a health care budget can be allocated among a series of inputs including drugs, hospital services, and physician services in order to produce a final output, which is health. In some cases these inputs act as complements and in other case as substitutes for the production of health. Increasingly, in the context of growing health expenditure, countries have been employing a silo-mentality to health care budget allocation. Rather than fixing budgets across the entire health care systems, countries have set budgets for individual inputs.

Literature suggests that silo budgeting, while helping to constrain costs within the context of the input, is unlikely to produce efficient outcomes across the entire health care system (Garrison and Towse 2003). Silo budgeting of individual inputs has the potential to distort production and produce inefficiencies across the entire health care system. For instance, a cap on pharmaceutical expenditure may require a reduction in expenditure in drugs, and subsequently more expenditure in hospital services that may be less effective at promoting patient health. Assigning budgets to silo inputs rather than the final output may prevent health care systems from achieving the optimal mix of services. It has also been argued that it is more efficient for expenditure control to be exercised at disease or therapeutic area level (Garrison and Towse 2003).

Nevertheless, pharmaceutical expenditure caps with payback mechanisms can be effective at controlling costs if they are transparent, hard, and enforce penalties/rewards (Kanavos, 2008). Evidence from Germany, Portugal, Italy, and France report that pharmaceutical capping and payback mechanisms have produced cost savings (Espin and Rovira 2007). Sood et al. also demonstrate that the implementation

of global pharmaceutical budget caps can have a substantial impact on pharmaceutical expenditure, accounting for a 6% reduction over a 12-year period; however measures such as negotiation of pharmaceutical prices are shown to be more effective at reducing pharmaceutical expenditure (Sood et al. 2009), among other policy options.

Moreover, on public financial terms is revenue elasticity rather than GDP growth in itself that guarantee a sustainable finance.

The effect of pharmaceutical budget caps on diffusion of innovation

Diffusion of innovation refers to the extent to which a country can promote uptake and access to new innovations to patients. We have showed that the uptake of new medicines is highly variable. Despite a decrease in the total number of new medicines marketed, in 2015, the number of new active principles has been higher than the average over the past ten years. While there is no evidence at present in the literature exploring the impact of budget capping on innovation, a few key concerns were highlighted through stakeholder consultations.

In Spain, indeed, pricing and reimbursement decisions are taken by the Inter-ministerial Commission for Pharmaceutical Prices. As such the presence of budget cap does not directly act as a barrier to the entry of new medicines. Nevertheless, budget caps can have indirect consequences on the diffusion and financing of innovation. First, at a broad level, silo budgets reduce flexibility in allocating the health care budget. Health is the product of a series of different inputs. The level of innovation in each input can vary. By fixing the budget for one input, it restricts the ability of countries to respond to transformative innovations in one input. In theory, if the level of innovation in the pharmaceutical sector, far exceeded that in the hospital services, it would be efficient to reinvest resources accordingly. However, through silo budgeting, this reinvestment is not possible, and resources cannot be fully used to finance health care inputs with the highest value.

Secondly, budget caps potentially punish innovation. Within the pharmaceutical sector, each year some innovative products will enter the market, some products in the market

will come off patent, and other products will become obsolete and leave the market. In principle, if expenditure levels are fixed, savings from disinvestment in obsolete products and savings from price cuts and generic substitution will provide some revenue to allow for the introduction of new medicines. However, there is no guarantee that these savings will provide sufficient funds to match the pace of innovation or to finance truly transformative innovations (e.g. new treatment for Hepatitis C). In a situation where the budget cap is exceeded, a payback is triggered and the effective price of all products across the market is lower. If the cap is exceeded by a substantial amount, the payback amount will increase. Therefore, everything else being equal, years with high numbers of innovative products will result in high payback by industry, while years with limited numbers of innovative products will result in lower payback.

Overall, it is unclear whether or not the combination of budget capping with clawbacks or rebates will directly impact the diffusion of innovation, unless there is explicit provision exempting new and innovative products from these (as is the case in the latest UK PPRS agreement). In general, budget caps reduce the ability of payers to reinvest resources across health care inputs and are potentially most punishing in situations where the level of innovation and amount of subsequent payback required is highest.

Stakeholder input on pharmaceutical budget caps

Stakeholder consultation revealed mixed reviews on Spain's pharmaceutical budget capping system. First and foremost, concern was raised over how the cap system was being implemented in practice. Within legislation, there was a lack of clarity on several important details relating to the scheme. Specifically, it was unclear how the payback would be structured in situations where the cap was exceeded. More information is required on what the non-monetary economic compensatory measures would be for exceeding the reference rate of medium term GDP growth. The first time to observe proceedings for year 2018 is still unknown.

Opponents of a budget cap linked to GDP, criticized the choice of GDP as an anchor for expenditure. Fundamentally, GDP is an aggregate measure that is not linked to any

specific drivers of healthcare expenditure. Problems with forecasting, due primarily to GDP volatility mean that prospective budgets will likely miss targets consistently. Further, such a cap can create heterogeneity across regions in Spain. Across regions, differences in GDP and differences in drivers of expenditure are not taken into account by such a system. It is unclear if all regions will be able to reach the cap. Tensions may arise across regions, in competing for share of the rebates. Experiences from Italy suggest that implementing a payback can be costly and challenging from a legal standpoint. For payers, it may be preferable and more efficient to implement measures that lower prices prospectively.

Proponents of a budget cap linked to GDP, stress that anchoring GDP ensures that pharmaceutical expenditure remains affordable. In situations of GDP growth, more spending will be available for pharmaceuticals. In situations of economic crisis, financial risk is minimized. Further, they stress that this type of budget gap is politically attractive and a relatively simple method of containing pharmaceutical expenditure. From an industry perspective, a payback system may be preferable to prospective price cuts owing to extensive external reference pricing systems across Europe. While a payback will not influence price and revenue in other countries, a lower price would trigger spill-over effects throughout other countries due to reference pricing. Nevertheless, proponents of utilizing a GDP-linked budget cap acknowledge that a budget cap alone is not sufficient to contain expenditure and that additional policies are needed to address the drivers of pharmaceutical expenditure within Spain.

What macro-level constraint ensures macroeconomic stability on medicines spending?

While this type of policy is relatively simple and attractive to a risk-averse policy maker, stakeholder consultations revealed several problems with it, which need to be addressed in a forward-looking way. First, the use of GDP growth as an anchor is arbitrary. GDP growth is not directly linked to either the volume or the prices of medicines, and therefore does not address any of the drivers of expenditure. Second, in

order for a cap to be set, GDP growth must be forecasted. GDP often tends to be quite volatile, and as such there is significant risk that the forecasted GDP growth and subsequent cap will be inaccurate. Clear methodologies must be put into place to ensure that the pharmaceutical budget cap is accurate. Third, it is also unclear how this cap will be transferred at regional level and this dimension carries significant weight in a country that relies on a federal system of governance. Both GDP and expenditure vary by region. Some regions may be better able to meet their expenditure cap than others. There is risk that a pharmaceutical budget cap, when applied at regional level will produce inequities in the health care system. Fourth, beyond issues of efficiency, the current budget capping system raises concerns about Spain's ability to promote innovation. Along with ensuring financial sustainability, Spain also should have a keen interest in contributing towards the continued development of innovative and cost-effective medications that improve the health and quality of life in their population and promoting their uptake and use. The importance of these two objectives needs to be weighed carefully.

As an alternative to a budget cap linked to GDP that carries all the above shortcomings, Spain might consider a model whereby expenditure growth is set at a fixed percentage and innovation accounts for a significant proportion of the growth element. There is comparable experience from the recent UK PPRS on this, whereby new products (innovative or not) launched during the lifetime of the latest PPRS agreement are not subject to PPRS payments (rebates) (Department of Health 2013). Another experience is France, where innovative medicines are excluded from the payback system. Out of the various budget-capping policies examined earlier, this offers the greatest stability and predictability to industry, the lowest volatility, and ensures sustained growth in innovation. Supply-side intervention through negotiation and the use of evidence-based techniques to assess value should ensure affordability, particularly in circumstances of fiscal restraint.

Another alternative would be the implementation of contingency funds, to be used in years where there are significant innovations entering the market. In years where

expenditure falls below the threshold, the difference is added to a contingency fund used to fund innovation in future years where expenditure thresholds are exceeded.

While a budget cap may ensure that expenditure does not reach unsustainable levels, additional measures are required to maximize health values within the existing budgets. More fundamentally, despite Spanish legislation that prioritizes Health Technology Assessment through economic evaluation, it is unclear whether any use is made of this tool to inform coverage decisions based on value.

Concluding remarks

While Spain's pharmaceutical expenditure levels are well within European averages there are several areas in which they could improve. The recently implemented budget capping system shouldn't be 'the' way forward if it is not evaluated and improved properly. It has been a first attempt to initiate in Spain a sustainability dialogue between the Government and pharmaceutical industry but It appears to be arbitrary, lacks clarity on payback mechanisms, suffers from methodological issues in GDP forecasting and raises concerns over efficiency and diffusion of innovation. A model similar to that of the UK PPRS, which sets targets on expenditure growth and exempts new products, may be more appropriate for promoting sustainable access to innovation within Spain. Moving to the microeconomic level, reforms in the use of health technology assessment and risk sharing agreements can help promote both efficiency and affordability. Despite recent improvements in generic policy, Spain would also benefit from the implementation of new tendering policies, provided that such implementation is well planned and managed. Generic utilization and appropriate drug use should also be targeted through demand side policy tools such as patient education programs and prescribing guidance. Finally, further efforts are likely needed to balance national objectives with regional needs and autonomy. Applying risk-adjustment to regional pharmaceutical budgets and implementing bundled payments for physician services at regional level could be a way forward.

In brief, strictly speaking, a pharmaceutical budget cap can promote affordability at the macroeconomic level within Spain but a number of other additional measures are needed to promote value for money, affordability and efficiency at local level. Further, changes may be required to the current capping mechanism to address concerns on methodology, efficiency, and diffusion of innovation. At any rate once you do, please evaluate and reassess.

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Appendix A – Overview of pharmaceutical budget capping systems

There are two types of pharmaceutical budgets and caps: global and partial. At a macroeconomic level, a number of countries have employed global limits to the total pharmaceutical expenditure (PE) over the past few decades, applying across the totality of drug spend. The rationale is clear and aims to restrict pharmaceutical spending growth. There is significant variation in the type of cap imposed, both in terms of the method of setting the cap and in terms of the consequences of exceeding the cap. Generally, global pharmaceutical caps fall under one of the following: i) PE capped at a fixed percentage of GDP; ii) (annual) PE growth linked to GDP growth; iii) PE set at a fixed proportion of health expenditure; iv) (annual) PE growth limited to a fixed percentage. In terms of partial pharmaceutical budgets (and caps) a number of countries implement earmarked drug funds for specific purposes or classes of medicines (e.g. orphans, cancer drugs, etc). An example of such earmarked funds is the Cancer Drugs Fund (CDF) in England.

A.1.1. Pharmaceutical expenditure capped as a fixed percentage of GDP

The simplest and perhaps most arbitrary method of determining a limit for pharmaceutical expenditure is to set it as a fixed percentage of GDP. Three countries employing pharmaceutical budget caps have explicitly set their pharmaceutical expenditure as a fixed percentage of GDP (Greece, Portugal, and Romania).

Prior to 2010, Greece had the highest pharmaceutical expenditure out of all EU member states at close to 1.9% of GDP (as well as the highest drug spend per capita). In response to national economic crisis, Greece implemented an Economic Adjustment programme with a series of reforms aimed at controlling health expenditure. Unsurprisingly public expenditure on pharmaceuticals was targeted as part of these reforms. A target of 1% of GDP was set for outpatient pharmaceutical expenditure in 2012. Unfortunately uptake of reforms was slow, and this was later revised to 1.33%, with a target of 1% set for 2014. A pay-back mechanism was negotiated for any excess expenditure.

Similar to Greece, Portugal was in the midst of financial crisis and through an economic adjustment programme also implemented targets for pharmaceutical expenditure that were linked to GDP. Portugal set a target of 1.25% for 2012 and 1% of GDP for 2013. Unlike Greece, who applied the target solely to outpatient pharmaceutical expenditure, in Portugal, targets were set for all pharmaceutical expenditure. A pay-back mechanism was negotiated for any excess expenditure.

Romania has also implemented a budget ceiling of around 1% of GDP, with a payback mechanism in place for any excess expenditure (Carone et al. 2012).

A.1.2 Pharmaceutical expenditure growth linked to GDP growth

An alternative to linking pharmaceutical expenditure to GDP is to set a base level of pharmaceutical expenditure and to link any future growth to GDP growth. Spain has recently introduced this method for capping pharmaceutical expenditure with a base set at 2015 expenditure levels. From this base, the percentage of pharmaceutical expenditure growth cannot exceed that of GDP growth. Any excess expenditure is to be paid back by industry according to companies' individual market share (further details are provided in section 4.3).

A.1.3. Pharmaceutical expenditure capped as a fixed percentage of health expenditure

The third method links pharmaceutical expenditure with health expenditure. Since 2002, Italy has set their pharmaceutical budget at 13% of total health expenditure. If this level is exceeded, payback is required from regions, industry, wholesalers and pharmacists. Regions are responsible for 40% of the payback, while industry and dispensers are responsible for 60%. The proportion of health expenditure was changed in 2009 to 13.3 %, then again lowered to 13.1% in 2012 and 11.4% in 2013.

A.1.4 Pharmaceutical expenditure growth fixed at a given percentage

An alternative option to linking pharmaceutical expenditure to GDP growth, is to set an arbitrary growth target for pharmaceutical expenditure, with any excess being paid back by industry according to market share. This scheme has been applied most recently by the UK in line with the 2014 PPRS. Under the latest PPRS agreement, pharmaceutical expenditure is set to remain constant for 2015, to increase by 1.8% in 2016 and 2017 and to increase by 1.9% in 2018.

In the past, Portugal also imposed limits on the growth rate of pharmaceutical expenditure. Between 2006 and 2007 growth rate for pharmaceutical expenditure was set at 0%. Interestingly, only 69.65% of the excess expenditure was to be paid back by industry. The literature was unclear on responsibility for the remaining 30%.

A.1.5. Earmarked drug funds

Pharmaceutical budgets are also found at the disease level through earmarked drug funds. These are specialized funds earmarked for particular types of products that historically have operated outside of traditional reimbursement systems. These funds are partial drug budgets, and were set up to provide access to specific therapies that are deemed clinically effective, but that have failed to receive a positive HTA because of poor cost-effectiveness and high levels of uncertainty (NHS 2016).

The Cancer Drugs Fund (CDF) in England was established in 2010 with an interim budget of £50 million. Initially 10 strategic health authorities in England operated the scheme at a local level. In 2013, NHS England took over the scheme and established a national list of products available through the cancer drugs fund. The scheme was established as a temporary measure to provide additional funding for cancer drugs until an alternative arrangement was made. In 2014, the scheme was extended for an additional 2 years. The budget was frequently exceeded, and by 2015/2016 was set at £340 million. In 2016, a new cancer drugs fund was established within National Institute for Health and Care Excellence (NICE). In the new CDF, NICE assesses all cancer drugs and determines whether or not a drug enters the CDF. The CDF provides temporary reimbursement for promising drugs that do not have sufficient evidence available for a positive NICE recommendation (NHS 2016).

Other examples of earmarked drug funds is the New Medicines Fund in Scotland, for rare diseases, and the Life Saving Drugs Fund in Australia for serious and rare medical conditions (Scottish Government 2015, Australian Government Department of Health 2016).

A.1.6 Variations in payback mechanisms

Typically budget or expenditure caps, if they are to be credible, are associated with a payback mechanism, clawback or rebate. There is some heterogeneity in the form of payback mechanisms, however, broadly these can be classified as: a) no payback, b) segmented payback, c) full payback, or d) payback with exemptions.

While in some cases, such as with earmarked drug funds, targets are set and not enforced, most countries implement some type of payback. In certain instances, full payback is required, however, in general, industry may not be responsible for the entire excess expenditure. This occurs in settings with multiple payors or in settings where decision-making is decentralized to regional levels. For instance, in the past, Belgium only required industry to pay back 72% of the excess, with the remainder being paid back by insurance organizations. Meanwhile within Italy, excess expenditure was found to be split between industry, wholesalers, pharmacists and regions (Espin and Rovira 2007). Other countries may impose additional flat rebates on all sales beyond the capped level of spending. Hungary, required full pay back and in the past included a flat 12% rebate on all pharmaceutical expenditure (Espin and Rovira 2007). Greece currently implements a payback whereby all excess spending is returned to the Ministry of Health.

Exemptions are frequently placed on paybacks for certain types of products. This provides countries with some flexibility in their payback schemes. The UK for instance, provides exemptions on payback in the PPRS for companies that have a market share under £5 million and for sales on vaccines or products that are centrally procured in case of national emergencies (ABPI 2014).

Overall, countries have several options to choose from when setting budget caps on pharmaceutical expenditure

A.1.7 Spanish and international pharmaceutical budget caps

Spain's pharmaceutical budget is linked to real GDP growth. Specifically, the Farmaindustria Protocol sets two limits to the total public pharmaceutical expenditure for original medicines: a reference rate of medium term GDP growth, and the annual rate of growth itself.

The Protocol establishes that, if pharmaceutical expenditures exceed the reference rate but not the actual growth rate, the industry will implement economic compensatory measures towards the NHS, which do not involve a monetary transfer. On the contrary, if spending exceeds real annual GDP growth, compensation will be monetary. There are therefore two thresholds, the first of which is less stringent than the second.

Abbreviations

ABPI	Association of the British Pharmaceutical Industry
AEMPS	Spanish Agency of Medicinal Products and Medical Devices
CDF	Cancer Drugs Fund (UK)
CHE	Current Health Expenditure
EU	European Union
GDP	Gross Domestic Product
GENESIS	Group for Innovation, Assessment, Standardisation and Research in Drugs Selection
HTA	Health Technology Assessment
ICPP	Interministerial Commission on Pharmaceutical Prices
ITB	Incremental Therapeutic Benefit
IPT	Informe de Posicionamiento Terapéutico
LSEH	London School of Economics and Political Science Health
MoH	Ministry of Health, Social Services and Equality (Spain)
NHS	National Health System
NICE	National Institute for Health and Care Excellence (England)
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-Counter
PE	Pharmaceutical Expenditure
PPRS	Pharmaceutical Price Regulation Scheme (UK)
QALY	Quality-Adjusted Life Year
R&D	Research and Development

RDL	Royal Law Decree
ROCE	Rate of Return on Capital Employed
RSA	Risk Sharing Agreements
SESPAS	Spanish Society of Public Health and Health Administration
SWOT	Strengths, Weaknesses, Opportunities and Threats
SAS	Servicio Andaluz de Salud (Andalusian Health Service)
THE	Total Health Expenditure
UPF	Univesitat Pompeu Fabra
WHO	World Health Organisation
WTP	Willingness to Pay

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