An evaluation of pharmaceutical co-payment reforms in Spain

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The sudden fall of public revenues after the long-lasting economic crisis that began in 2008 has led many public health systems in European countries to cut public health financing through high copayments or coinsurance rates on drug prescriptions dispensed in pharmacies. This is especially the case in Spain, where until July 2012 nearly three out of four prescriptions were dispensed free of charge, Spain being until then one of the European countries with a relatively high number of prescriptions per capita[1]. Spanish health authorities have long sought to control public-sector pharmaceutical expenditure, but the economic crisis exacerbated this, and severe pressures were exerted on the public sector. After more than three decades of medicines being offered free to the elderly, this led in mid 2012 to a new co-payment policy being adopted.

Bountiful backing until 2012

From 1978 to July 2012, the Spanish national health system (NHS) provided generous free healthcare coverage to all Spanish residents, with the exception of a non-refundable coinsurance rate for outpatient prescription pharmaceuticals. The general co-payment rate had been 40% of the retail price since the early 1980s. A lower coinsurance rate of 10% was applied to medicines mainly prescribed for chronic diseases, with a price cap of €2.64 per prescription. Thus, effective coinsurance rates for insured patients ranged from 40% to a rate slightly above zero for highly priced medicines under the lower coinsurance rate. In addition, drugs provided to hospitalised patients were provided free of charge.

Pensioners and their dependants were exempted from the coinsurance scheme, so the aforementioned coinsurance rates were applied only to economically active people and their dependants, independently of their socio-economic characteristics. Caps or ceilings on maximum out-of-pocket expenditure did not exist either. Thus active individuals who transited into retirement or received an incapacity pension, independently of their age, as well as all their dependants, were automatically exempted from the pharmaceutical coinsurance

scheme and got free access to outpatient prescription medicines[2]. It is worth noting that civil servants were the exception to the general rule, since they incurred a co-payment rate of 30% of the full retail price, which was applied to both active individuals and pensioners.

Nominal coinsurance rates (40% and 10%) had remained unchanged in the two decades prior to the 2012 reform, although the effective average coinsurance rate had halved since the eighties (from 15% in 1980 to 7% in 2009). The increasing ageing population might explain the reduction in effective cost sharing, as well as the increasing number of medicines with a 10% coinsurance rate and the fraud (pensioners could obtain prescriptions for other household members who were not exempt from copayments)[3].

Puig-Junoy, García and Casado[4] previously examined the impact of the coinsurance exemption for prescription medicines applied to elderly individuals in Spain after retirement using an administrative dataset that linked pharmaceutical consumption and hospital discharge records for the full population aged 58 to 65 years in January 2004. This population was covered by the public insurer in Catalonia. In the study, a 'difference-in-differences' strategy was used and the eligibility age for Social Security to control for the endogeneity of the retirement decision was exploited.

The published results showed that this uniform exemption increased the consumption of prescription medicines on average by 17.5%, total pharmaceutical expenditure by 25% and the costs borne by the insurer by 60.4%, without evidence of any offset effect in the form of lower short-term probability of hospitalisation.

Free medication for all Spanish pensioners has also been shown to be clearly inequitable. Since it was independent of financial circumstances, a pensioner who received a large pension or had assets worth millions would pay nothing, while an unemployed person or a family with young children and an income of barely €1,000 per month, would pay their share. Half of all the cost sharing contributed by patients is concentrated in a small group of sick people: it was provided by just 5% of users, for whom it can represent a heavy burden.

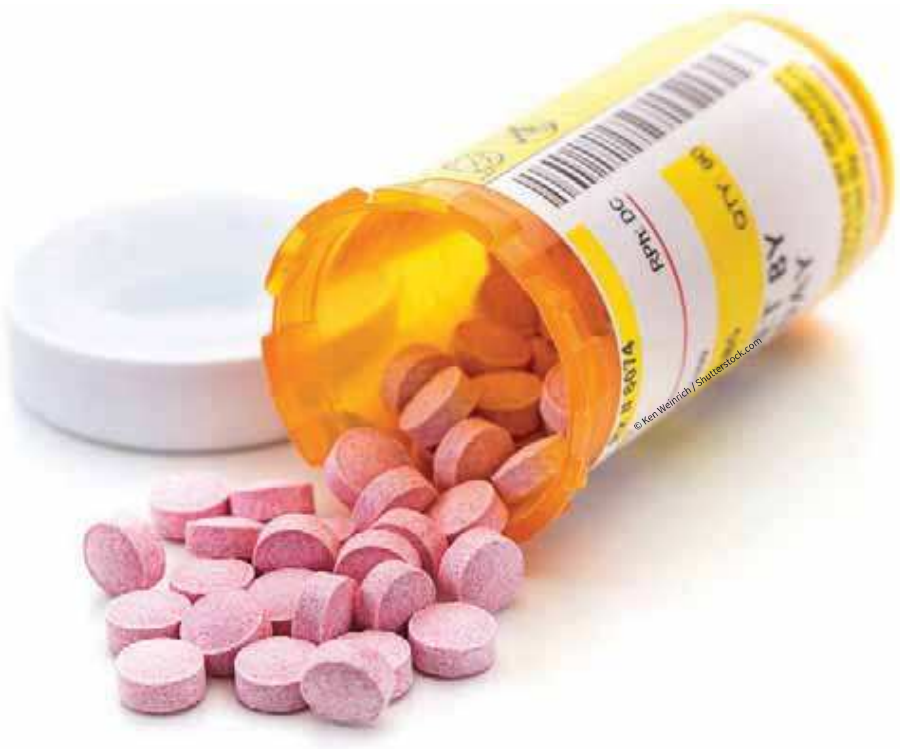
> "Nearly half (40%) of the population think that the new scheme is more fair"

Three-pronged reform approach

In June 2012 the co-payment for outpatient prescription drugs was reformed in depth, and three types of policies ('three-payment reforms') came into effect nearly concurrently between late June and early October 2012. These policies were: (i) the temporary introduction of a regional one-euro fee per prescription in Catalunya and Madrid until it was suspended by the Constitutional Court; (ii) reform of national co-payment provisions, in which cost-free arrangements for all pensioners' drugs were replaced with a 10% co-payment subject to a monthly cap, and non-pensioners' 40% co-insurance rate with a 50 or 60% co-payment, depending on income; and (iii) the de-listing of a broad spectrum of over 400 drugs, including most in certain categories (nearly all for minor ailments).

The main aim of the reform, in a country where drug consumption rates per capita are among the world's highest, has been to enhance public awareness that 'universal' does not mean cost-free. However, there are shortcomings to the reform. For example, the existence of differential treatment within each income and need for patients with serious diseases are issues, since the co-insurance rate is very high and there is no cap on total expenditure in place. Another shortcoming is non-pensioners' co-insurance, contrary to the intention, does not depend on income. The initial inability to apply pensioners' cap at the point of sale is not only embarrassingly expensive, but overrides the reduction of financial risk pursued.

Despite issues like these, the reforms did induce a spectacular decline in the number of prescription drugs dispensed by pharmacies for the first time in over 30 years. A study of prescriptions and nation-wide spending in Spain between January 2003 and August 2013[5] revealed that the number of post-reform prescriptions was 12.8% lower than the counterfactual number assuming absence of reforms.



Puig-Junoy *et al.*[6] ran 17 univariate ARIMA analyses, one for each autonomous region, covering the period from January 2003 to July 2013. Dynamic forecasts were calculated to estimate the counterfactual number of prescriptions that would have been issued in each region in the absence of reform measures. The response variable was the joint impact of the measures adopted in each region calculated as the difference, expressed in per-centage, between the cumulative number of prescriptions actually recorded after 3, 6, 12 and 14 months, and the (contrafactual) number predicted by the respective models.

The findings revealed that after the steep and steady 10 year climb in the number of prescriptions

dispensed in Spain before the reform, there has been: (i) a drastic decline of over 20% of prescriptions in the 14 months after the reform in Catalunya, Valencia and Galicia; (ii) drops of over 15% in nine other regions; and (iii) drops larger than 10% in 15 of Spain's 17 autonomous regions.

Puig-Junoy *et al.*[6] also detected substantial inter-regional variability in the impact of Royal Decree 16/2012 on the number of prescriptions, because its provisions were not uniformly applied (the Basque Country did not apply the change in co-payments in the period studied) and because some regions established one-euro per prescription co-payments of their own (subsequently overruled by the Constitutional Court). The study provided evidence of the high price-sensitivity of prescription drug demand and the huge potential impact of a small linear co-payment (€1 per prescription) on drug use. These results were consistent with the hypothesis that the first euro of co-insurance has a sizeable effect on drug consumption[7].

Nonetheless, by the end of the time series, the effect of the Royal Decree appeared to have been 'diluted', although this observation was not statistically conclusive at the time.

Additional analyses showed short-lived effect

Subsequently, throughout February 2014, the same authors[8] analysed prescription numbers over a longer time series, running ARIMA segmented regression analyses for each autonomous region and for Spain as a whole. A significant finding was that the effect of higher co-payments was short-lived: they induced a drastic but transient decline in NHS prescriptions without varying the underlying upward trend. While the number of prescriptions was observed to be lower than it would have been if co-insurance had not been reformed, the model predicted that the effect of the reform on prescriptions would disappear entirely in a few years' time in certain regions and in Spain as a whole. In other words, although the co-payments introduced in mid-2012 managed to reduce NHS prescriptions drastically in the short term, since they had no impact on the prior upward trend, the numbers would tend to creep back up to former levels.

A survey to the general population questions the social acceptance of the new copayment stablished in the RDL16/2012[9]. Opinions on the justice of the new regulation, on the protection to disadvantaged social groups and on the adequacy of the copayment burden to the economic level of the patient were gathered. It was found that nearly half (40%) of the population think that the new scheme is more fair and that it better protects the disadvantaged groups. However, most of the population consider than there should be more defined income brackets to differentiate copayment rates. 73% of those who had used the public NHS and 81% of non users answered in that direction.

The survey also questions whether the individual failed to follow a medical treatment prescribed by a public doctor in the last 12 months because he could not afford it economically. A small but noteworthy 5.3% of the surveyed answered affirmatively (6.3% of those that had used the public healthcare network). Since we do not have data for the year before the new regulation, we cannot stablish a cause-effect relationship. We profiled the groups experiencing economic barriers to medicines; they are predominantly active (employed and unemployed) with low income, as one would expect given the design of the copayment scheme.

Final comments

Given the high sensitivity to prescription prices, information is urgently needed on which groups of patients and drugs contributed most to the aforementioned drastic reduction. Such data are instrumental to assessing the potential decline in overuse attributable to zero cost and its impact on adherence to treatment, access to necessary and effective treatment, and ultimately health. Health authorities' scant understanding of and lack of interest in the impact of a measure with such far-reaching social effects (the typical "why waste time evaluating?" attitude) is surprising. Little or nothing is known about patients' and doctors' decision-making mechanisms when it comes to reducing the number of prescriptions dispensed or their effects on necessary/unnecessary consumption, adherence to treatment and the use of other healthcare services or health.

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