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Consequences of the Increase of the Pharmaceutical Copayment in Spain: A New Material Deprivation

Implicaciones del aumento del copago farmacéutico en España: una nueva privación material

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Abstract: The law changes implemented by the Spanish government during the economic crisis started in 2007 have led to a restructuring of the pharmaceutical copayment system. The aim of this research is to analyze what legislative changes have been introduced in health policy in Spain and how these reforms are influencing access to medicines. A methodological triangulation has been developed through the review of the specialized bibliography, analysis of the legislative changes as regards the pharmaceutical copayment implemented by the Spanish government as well as the most relevant databases with our object of study. Our research confirms that a social polarization is taking place in the Spanish population in relation to access to drugs, improved by a system of copayment that is not very progressive and does not take the needs of each social group into account.

Key words: health policy, social security for health, social expenditure, right to health and citizenship.

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Resumen: Las reformas legislativas implementadas por el gobierno español durante la crisis económica iniciada en 2007 han supuesto una reestructuración del sistema de copago farmacéutico. El objetivo de esta investigación es analizar qué cambios legislativos se han introducido en la política de salud en España y cómo dichas reformas están influyendo en el acceso a los medicamentos. Para ello, se ha utilizado la triangulación metodológica para el desarrollo de la investigación, mediante la revisión de la bibliografía especializada, un examen de los cambios legislativos en materia de copago farmacéutico y un análisis de las bases de datos más relevantes respecto al objeto de estudio. La presente investigación confirma que se está produciendo

una polarización social en la ciudadanía en relación con el acceso a los medicamentos, favorecida por un sistema de copago poco progresivo que no tiene en cuenta las necesidades de cada grupo social.

Palabras clave: política de salud, Seguridad Social en salud, gasto social, derecho a la salud, ciudadanía.

Introduction

Health care is one of the cornerstones of the Welfare state in occidental countries after WWII. Such protection has to main sides: health care and pharmaceutical care. After the global economic crises that started in the 1970's, discourses that call the sustainability of such Welfare state into question have multiplied.

Sooner or later, the crisis that started in 2007 in the US ended up affecting industrialized countries and has meant a justification to restructure the Welfare state. One of its main strongholds in Spain is health care, being universal and gratuitous as of its inception. This system has produced a feeling of security among citizens together with pensions from Social security, the education system and, at present, social protection of people in dependence situation.

Some measures adopted by the Spanish government to face the economic crisis have focused on restricting the universality of health care for some collectives and increasing the pharmaceutical copayment for the whole citizenry. We face a possible change in the model of health care in Spain, which is characterized by lesser social responsibility, which may consolidate over the years, and even be exported to other countries in a similar economic situation.

The goal of this research is a dual one: 1) finding out the implications of legislative reforms as regards pharmaceutic issues in Spain; and, 2) analyze the possible consequences for citizens. Since this social phenomenon is recent, an approximation to the object of study was made by means of a combination of quantitative and qualitative methodological strategies. This methodological proposal favors approaching such social problem from various levels, enables debating the implications of regulation changes as regards drugs and allows finding out the way this reconfiguration of the system affects the citizens.

Restrictions in pharmaceutical copayment and new challenges for the Welfare state in Spain

Access to medication is an essential part of health care, and it is a fundamental right in the Spanish Magna Carta (article 43). In this way, not only do drugs facilitate the recovery or treatment, but are an indispensable part of health care. "Expenditures on medication is one of the main expense lines in health care in any country that wishes to maintain a Welfare state with minimal services" (Lago *et al*., 2012: 23). Therefore, access to drugs is part of the principles of social citizenship (Marshall, 1950) and equitable and democratic justice (Rawls, 1991).

In recent years, various measures have been implemented to rationalize health care budgets from a general level. The national State budget for medication accounts for an important share in *Sistema Nacional de Salud* [National Health Care System], which progressively increase due to the aging of the population and the more pressing need to assist poly-medicated chronic patients.

At the moment of analyzing the evolution of pharmaceutical expenditure within a territory, in this case Spain, we face a series of contradictory interests from the pharmaceutical industry. On one side, it has a privileged place to contribute to population's health and invests large amounts of money on innovation and research. On the other, from a mercantile standpoint, it looks for the maximization of profit, as any other business, on occasion conditioning the integrity of scientific research. Therefore, pharmaceutical industry is not isolated from the market and sometimes, it subordinates the population needs to economic profit (Páez, 2011).

The logic of pharmaceutical market is not in favor of poor people nor does it try to universalize access to drugs; its development and prosperity depends on sales, productivity, and potential consumers. Moreover, it is worth bearing in mind that pharmaceutical industry is controlled by multinational corporations, "whose financial power is enormous and when extending their business globally, they do it in very unequitable and advantageous manners" (Páez, 2016: 208).

The vision of disease-cure by means of medication is framed into the classic curative medical model, which makes drugs protagonists in health recovery. However, from a critical standpoint of biomedicine, this classic model makes the possibilities difficult to develop a preventive model, which considers determinate individual factors linked to life style and nutrition (Lifshitz, 2014), and that contests the role of pharmaceutical industry in the access to drugs and medication by citizens.

Pharmaceutical copayment is not new for Spanish citizens, as it was configured in 1966. The present regulation is mainly established in the Royal Decree – Law 16/2012, of April 20th (BOE, 2012a) and the Royal Legislative Decree 1/2015, of July 24th (BOE, 2015). These juridical norms are part of the austerity policies set up by the Spanish government in the set of Welfare systems as of the passing of Royal Decree – Law 20/2012, of July 13th (BOE, 2012b). All of these have redefined the social protection system and increased the households' impoverishment likelihood. As regards changes in medication, Freire (2014: 359) suggests that "RD Law 16/2012 worsened the status of the population's health care coverage leaving aside the only reform in it that is coherent with democratic values and public health care, and with the experience of most exemplary countries: to positively claim universal and equal health care coverage for everyone". The implications of regulation changes for pharmaceutical protection in Spain are being approached by researchers such as Garrido (2014), Cantero (2014), Jiménez-Martín and Viola (2014, 2016), from heterogenous perspectives. The state intervenes regulating the prices of drugs so that there are no conflicts of interest and health is not subjected to economic interests. In developed countries, "access, production, promotion and prices of medication are controlled because the market is not capable" (Ortún, 2008: 112).

In a global society characterized by an increase in the pauperization of labor conditions and unemployment, the access to pharmaceutical benefits may be turning into a privileged benefit, which not everyone receives. "From the standpoint of equality, such copayments may negatively affect some population sectors, especially the chronically diseased and those with the lowest incomes" (Saludas, 2013: 43).

The growing economic difficulties of the population, adding to the incidence of the pharmaceutical copayment have propitiated that the "number of households that have stopped buying drugs, keeping diets or treatments due to economic problems are now almost three times in terms of population, reaching 15,5%" (Foessa, 2014: 162). Plus, there is evidence that pharmaceutical copayment does not affect all in equal manner, but negatively affects the least favored (Aron-Dine *et al*., 2013). A study carried out in 2005 observed that "patients respond differently to an increase in the copayment for prescribed medication depending on the condition, the absolute increase in prices and availability of treatment alternatives" (Landsman *et al*., 2005: 627). Therefore, there is an interconnection of factors in the use of drugs and any other analysis has to consider the set of variables.

A large part of the measures destined for the reduction of pharmaceutical expenditures is focused on increasing copayments and reducing the range of drugs. However, there are other alternatives such as "creating a new regulatory framework, more stable and transparent, which makes explicit and hierarchizes the considered criteria, supported on economic assessment studies carried out by an independent government agency" (Cabiedes, 2013: 412). That is to say, focusing measures on the increase of health care copayment and the exclusion of drugs from the pharmaceutical catalogue does not seem to be neither a feasible nor fair long-term solution.

Other management proposals are aimed at reorienting pharmaceutical prescriptions toward rational use. "This approach may be an opportunity to reduce squandering and improve the efficiency of *Sistema Nacional de Salud*, though nowadays, is mainly an opportunity to improve our patients' health and welfare" (Sanfélix-Gimeno *et al*., 2011: 66).

In Spain, there is a health care copayment via taxes: progressively through *Impuesto sobre la Renta a las Personas Físicas*, IRPF (Tax on Incomes for natural persons) or proportional, via value added tax. Albeit, access to drugs is conditioned by direct copayment made by patients when acquiring one. The increase in this copayment may produce its own exclusion. In point of fact, there are research works that evince the factors that interfere in the patients' decisions of buying drugs or not, being the cost one of the variables (Rodríguez and Puig-Junoy, 2013).

On this line, other studies (Saludas, 2013; Cortès-Franch and González, 2014) show that pharmaceutic copayment disincentivize the consumption of unnecessary or replaceable medication, which the patients themselves rationalize their consumption. In this way, a self-valuation of the need to acquire medication, in virtue of economic capability, relegates the improvement drugs may produce on health to a second place. The various legislative reforms to health care systems entail a reduction of health care coverage and broaden the inequality divide among citizens (Foessa, 2014).

Puig-Junoy (2007) advocates for the establishment of differential copayments: 1) reduced copayment for essential medication; 2) another higher for preferential drugs; and, 3) an even higher third for those non-preferential and least efficacious. "One of the additional advantages of differential copayments is that they foster competence between therapeutic replacements to be included in the most reduced copayment groups and at once, facilitates decentralized price negotiations (discount or return) among funders and the pharmaceutical industry" (Puig-Junoy, 2007: 157-158).

After legislative reforms there is risk that pharmaceutical copayment ends up becoming a "tax on disease" and that is of no use for changing the tendency to increase prescriptions [...]. The crisis seems to be making access to health care services difficult for the most unfavored socioeconomic groups, including individuals with irregular migration status" (Cortès-Franch and González, 2014: 3). Adding to the modifications in pharmaceutical protection being extremely severe, which exhibits the inequality of opportunities, as well as the creation of new barriers to attain social citizenship. Changes in health care regulations are ruled by an inversely proportional law: "the more health care attention an individual or group needs, the lower their actual access to quality health care" (Navarro *et al.*, 2016: 1271).

Material deprivation in medications is an instance of the increase of poverty tendencies and inequality, as a consequence of the development of neoliberal policies that affect people in poverty situation more intensely. Recently, Oxfam (2016: 40) in order to reduce inequality in this regard put forward the following mechanism: "modify the global system of research and development and price fixation for drugs with a view to ensuring full access to adequate and affordable drugs". The current economic and social scenario may be propitiating new poverty profiles, which might be associated with certain levels of material deprivation, among them health care deprivation due to the inability to afford medication.

Methodology

The approximation to the object of study has been carried out from a methodological triangulation. We start from the premise that in social sciences, there is no method better than the rest, and that a combination of them, by means of a plurality of approaches, allows better approaching social reality. The methodological triangulation, from the combination of data, methodologies or theories (Denzin, 1978), enables "acquiring better and deeper knowledge of the object of analysis" (Cantor, 2002: 59). Triangulation has important advantages, as it improves confidence in results and stimulates the invention or introduction of new methods (Samaja, 2018).

This research approaches a new phenomenon in Spain, which needs to be studied from a number of perspectives to have an integral conception of it. Since we are trying to find out the implications of legislative changes for the Spanish population, if we followed a single approach, the information about the social problem would be biased and partial. Owing to this, a

methodological triangulation was used from theoretical analysis and the combination of data analysis methods, using qualitative and quantitative techniques in sequential stages.

At first, there was a theoretical review on the state of play, paying special attention to health care as a right, to the role the Welfare state has in the regulation of drugs and to the most recent studies on restrictions in accessing them in the current economic and social Spanish context.

Later on, from a qualitative side, the various legislative reforms in relation to medication access in Spain over the last five years are studied from a comparative standpoint regarding those started in 1966. To do so, legislative novelties in this regard were consulted, published in *Boletín Oficial del Estado*, BOE [State's Official Bulletin]. The main analysis elements are: 1) number of strata defined for health care copayment; 2) income ranges for each stratum; 3) participation percentage and upper limits for each stratum; 4) exclusion of drugs protected by *Sistema Nacional de Salud*; and, 5) social protection for particularly vulnerable collectives (pensioners with low incomes and, mainly, the unemployed).

Finally, and from a qualitative standpoint, the most distinguishable data sources were analyzed as regards the object of study, particularly *Barómetro Sanitario* [Health Care Barometer] and EAE Business School's publications on this subject. *Barómetro Sanitario* is an annual opinion survey by *Ministerio de Sanidad, Servicios Sociales e Igualdad* [Ministry of Health Care, Social Services and Equality] and *Centro de Investigaciones Sociológicas* [Center for Sociological Research]; it helps find out, among other topics, the degree of satisfaction citizens have about public health care services over time. For its part, "pharmaceutical expenditure in Spain in 2016" is a report by EAE Business School (2016), oriented to the study of public and private pharmaceutical expenditure, influencing on its evolution in various Spanish regions, and the effort the families make to afford these drugs. We focus our analysis on data on three key elements: 1) investment on drugs after the introduction of legislative reforms in Spain; 2) drug expenses per inhabitant; and, 3) profile and percentage of population that cannot afford prescribed medication as it is in social vulnerability.

The temporary context analyzed was broad, mainly in the case of legislation regarding pharmacology to understand the changes that took place, particularly considering the beginning of the economic crisis (2007) and the introduction of austerity measures that affected this sector in 2012.

Historic outline of pharmaceutical copayment participation[1]

The most important legislative referents in health care protection are found in Article 43 of the Spanish Constitution and in *Ley General de Sanidad* [General Law on Health Care] passed in 1986 (BOE, 1986), whereby *Sistema Nacional de Salud* [National Health Care System] was established in Spain. Twenty years later, Law 29/2006 of July 26th, was passed, it dealt with guarantees and rational use of drugs and health care products (BOE, 2006a). However, the regulation background for pharmaceutical support go further back in time.

The earliest vestige of pharmaceutical copayment in Spain is in Decree 3157/1966 of December 23rd (BOE, 1966), which regulates the supply of pharmaceutical specialties into *Régimen General de la Seguridad Social* [General Social Security Regime]. Article 3 explicitly expressed that pharmaceutical assistance would be gratuitous when it was offered in public health care institutions ort concerted or which came from labor accidents or professional diseases. Moreover, that same article established a copayment for medication depending on the price, that is, cheaper, more expensive or equal to 30 pesetas. In any case, the least copayment for drugs was established at five pesetas, that is to say, at least 16,6%. The copayment percentage may increase in one peseta per each ten of medication without exceeding 50 pesetas in any case. It is worth underscoring that no gratuity or discount was established for any collective, not even pensioners.

Later, Royal Decree 945/1978 of April 14th was passed (BOE, 1978); it defined a new regulation for the contributions of social security beneficiaries in the supply of pharmaceutical specialties. This juridical regulation incorporates significant innovations. On one side, it recognizes the exemption of copayment for Social Security pensioners, and for the first time, provisionally disabled workers due to a common disease or non-labor accident. Moreover, this juridical regulation included an annex of drugs (largely for chronic conditions) that would be ruled by the 1996 regulation. The rest would be applied a copayment of 30% of the medication.

Two years later, the Royal Decree 1605/1980 of July 31st was legislated (BOE, 1980); it modified the sorts of contribution in unemployment,

1 In the analysis of the regulation in this section, we specify that the legislative hierarchical order in Spain is as follows: Spanish Constitution, Organic Law, (Ordinary) Law, Royal Decree Law, Royal Legislative Decree, regulations, resolutions, as well as lower rank regulations. Before the approval of the Spanish Constitution of 1978, juridical regulations mainly adopted as Law, Decree and Order.

Seguridad Social y Fondo de Garantía Salarial [Social Security and Wage Guarantee Fund], and revises the participation percentage for beneficiaries in the price of certain drugs. This Royal Decree incorporates an important modification: as of that moment, participation in the pharmaceutical system for people not excluded from copayment would reach 40%.

In 2006, Law 29/2006 of July 26th was passed (BOE, 2006a); on guarantees and rational use of drugs and health care products, which later became the Royal Decree 1030/2006 of September 15th (BOE, 2006b), whereby the portfolio of common services of *Sistema Nacional de Salud* and the updating procedure are established. The most important modifications incorporated by this juridical regulation are, in the first place, the exclusion of the following drugs in Social Security protection: a) cosmetic and diet products, mineral waters, elixirs, dentifrices and similar products; b) drugs deemed publicity; c) drugs in the therapeutic groups or subgroups excluded from the funding in the current regulation; d) homeopathic products; e) the purposes and products publicized for the general public. Secondly, the following copayment criteria are established; on one side, there is a general system called "regular contribution", which reaches 40% of the cost of the product, in line with the previous regulation. On the other, another modality is established: "reduced contribution", in which patients would have to contribute only with 10% of the product without exceeding in any case 2,64€.[2] Plus, the group of people, treatments and products excluded in these contributions are specified: 1) pensioners and assimilated collectives, affected by toxic syndrome and disabled people according to considerations in the specific regulation; 2) treatments due to labor accidents and conditions from professional activities; and, 3) products supplied at the health care centers and services.

Once the economic crisis started and expenditure restriction policies were set, a juridical regulation with a broader scope for the protection of pharmacological assistance was passed, namely: Royal Decree-Law 16/2012 of April 20th (BOE, 2012a); on new urgent measures to ensure the sustainability of *Sistema Nacional de Salud* and improve the quality and stability of benefits. Such Royal Decree-Law incorporates significant modifications in the Law 29/2006 of July 26th (BOE, 2006a) on the

2 It is necessary to add this sort of contribution as follows: a) medication for chronic or grave conditions, classified in therapeutic groups or subgroups in the current regulation and according to the established conditions; b) results and accessories that belong to legally established groups: c) drugs provided by *Sistema Nacional de Salud*, by means of the official prescription for AIDS infected.

guarantees and rational use of drugs and health care products, especially, in Article 94 bis, which links pharmaceutical copayment with economic capacity. As a general rule, from that moment forward, users will pay 60% of the drugs' retail price (RP) as long as they declare earnings equal or greater than 100.000 € in the income tax return of natural persons; while for those with incomes between 18.000 and 100.000 €, the contribution will be 50% RP. For their part, employed people with this insurance with incomes under 18.000 € shall contribute with 40% RP. Finally, Social Security pensioners will pay 10% RP, as long as they not earn 100.000 € or more.

This juridical norm gathers a series of guarantees for pensioners with long-term treatments with a view to facilitating access to medication. To do so, a series of copayment limits was set, fixing maximum amounts for the free acquisition of drugs. In the case of pensioners who use medications in ATC[3] groups and with reduced contributions, would pay 10% of the price of the drugs, i.e., 2,64€ for 2012.

For pensioners with incomes under 18.000 €, the limit is 8 €. In the case of those who receive 18.000 € or more, and up to 100.000 €, the limit is 18 €. Finally, for pensioners with incomes equal or greater than 100.000 €, the highest contribution will be 60 €. These amounts are reassessed each year according to the consumer price index (CPI). Moreover, there was also a series of exemptions for certain collectives such as: 1) toxic syndrome affected and people with disability in the suppositions considered in the specific regulation; 2) people who receive social integration incomes; 3) people who receive non-contributive pensions; 4) unemployed individuals who have lost the right to unemployment insurance for as long as the situation lasts; and, 5) treatments due to labor accidents and professional-related diseases.

This juridical regulation is also the Royal Decree 1718/2010 of December 17th (BOE, 2010), on medical prescription and medication supply with codes to establish pharmaceutical copayment. These would be considered as follows: a) code TSI 001 for users free from contributions; b) code TSI 002 for users with a 10-percent reduction in contributions; c) code TSI 003 for users with a contribution of 40%; d) code TSI 004 for users with 50-percent contributions; e) code TSI 005 for user with 60-percent contributions; f) ATEP for prescriptions for labor accidents or professional disease; g) NOFIN for non-funded health care products and drugs. The most relevant changes introduced in regard to pharmaceutical benefits as of its first regulation up to the present appear in Table I.[4]

3 Codified listing of substances organized by active component and drugs, according to the affected organ or system.

4 All the graphs and tables are at the end of the article in Annex.

Three years later, the Royal Legislative Decree 1/2015 of July 24th was legislated (BOE, 2015) by means of which the text consolidated in Ley de *garantías y uso racional de los medicamentos y productos sanitarios*. This regulation does not include substantial changes in relation to copayment, save the updating of the highest price for the participation in the system, according to the patients' economic capacity. The Spanish copayment system was established after these reforms as show un Table II.

Plus, it is worth pointing at a very noticeable element, which, in spite of not being considered in pharmaceutical copayment, is connected to it: the exclusion of drugs from the health care system. This deed was enabled by the approval of the Resolution of August 2nd, 2012 (BOE, 2012c), of *Dirección General de Cartera Básica de Servicios del Sistema Nacional de Salud y Farmacia* [General Directorate of the Basic Portfolio of Services of the National Health Care System and Pharmacy], by means of which the drugs excluded from the pharmaceutical benefits of *Sistema Nacional de Salud* are updated. A total of 417 stopped being covered by the Social Security system, entailing savings of 450 million Euros (Ministerio de Sanidad, Política Social e Igualdad, 2012).

Among medicines, one might find products closely related to common ailments such as antacids, laxatives, antidiarrheal and products destined for muscle problems, for coughs, allergies or pneumological conditions. Therefore, there was an increase in pharmaceutical copayment due to action, as the participation of patients in the cost of these products increases, and omission, by excluding an amalgam of common use and chronical drugs from the health care coverage.[5]

Even if a stratified system is established, it lacks the necessary strips to be considered equitable. It seems relevant to further stratify population beyond the income thresholds currently recognized (under 18.000 euros; from 18.000 to 100.000 euros; over 100.000 euros), it would be important to consider, in addition to income levels, patrimonial wealth of the various individuals as well" (Lucas, 2016: 67).

It is difficult to account for the total impact of legislative modification regarding drugs. What is obvious is that it entailed a change in the existing protection model, devaluating acquired rights, increasing the difficulty to obtain a staple basic resource, augmenting the social inequality of people in poverty situation or inserted in social exclusion processes.

5 Some of these drugs are usual in our first aid kits such as Almax, Fortasec, Fastum, Calmatel, Movilisin, Zenavan, Rinomax, Mucosan or Pectox.

The evolution of pharmaceutical expenditure in Spain

If we approach the various funding models for the pharmaceutical benefit we may notice its diversity: from those that represent strong public and social responsibility in drug access, to those that support on the family as the main supplier. Given the current global economic context, it is not surprising that some countries —Greece, Ireland, Italy, Portugal, among others— have made adjustments in health care expenditures, including drugs, with a view to reducing their deficits by means of introducing pharmaceutical copayment or reducing the mean expense per prescription, among others (EAE Business School, 2016).

However, what for some is a measure to improve public expenditure efficiency and make it sustainable, for others is a way of weakening the benefits from the Welfare state, which ends up worsening the situation of the most vulnerable and cannot access, or do so with difficulty, the drugs prescribed.

In 2014, it accounted for medication, material and other pharmaceutical products up to Spain's Gross Domestic Product (GDP) (EAE Business School, 2016). Inside this percentage, public expenditures and private expenses have experienced an opposing tendency over the last nine years. Public expenditure has significantly reduced after 2009, while private has increased regarding these products. The variation in the total expenditure on drugs and other pharmaceutical products reduced in 0,77% between 2009 and 2014 in Spain. Nevertheless, interannual variation regarding 2013 produces a reduction over 3,4% (EAE Business School, 2016).

Once the Spanish situation was defined as regards pharmaceutical expenditures, it is significant to study the evolution of public and household expenses in recent years. Over this period, as previously mentioned, situations of economic and financial crises are being experienced, which have made many territories reduce expenditures in certain budgetary entries. This sort of management implies contesting acquired rights and fosters social inequality, as the Welfare state weakens. "At a micro level, disease creates poverty and this poverty, more disease [...] At macro, the vicious cycle is even more important; increase in health care problems demands an increase in these health care resources" (Navarro *et al*., 2016: 1271). Obviating these realities entails being blind to the way budgetary restrictions for the acquisition of drugs are a component that generates social inequalities.

Public and personal expenditures by the households on medicines have experienced over this period a conflicted evolution. While the households'

personal efforts on this sort of goods did not stop growing from 2012 to 2015, public expenditure dropped ceaselessly between 2010 and 2013, to slightly increase in the last two analyzed years, but with figures still far from 2007. The drop for the entire period surpasses 50 euros.

For their part, households have had to contribute more in order to be able to afford prescription drugs, thus entailing an increase of almost 16% in these eight years. In the final triennial, it has been noticed how the expense figures of some and the others have come closer (EAE Business School, 2016) (see Graph 1).

However, not everyone has witnessed in the same manner the increase in these pharmaceutical invoices. Data from the report "*El gasto farmacéutico en España en 2016*" [Pharmaceutical expenditures in Spain in 2016] (EAE Business School, 2016) indicate women, regardless of their age, have heavier expenses on this sort of products, especially in 2013, after "*Reforma de Salud*" [Health Care Reform] came into force. People older than 65 years spend the most on these products; plus, men older than this age are the ones that have seen to a larger extent this pharmaceutical expense increase during these eight years virtually 39%. The analysis of the average expenditure by sort of household discloses that the largest increase over these years corresponded to households of single individuals of 65 years of age and older, reaching an increase of more than 54%, which made them afford a pharmaceutical expense over 365 euros a year in 2015 (EAE Business School, 2016).

All of this has implied an increase in the citizens' investment on pharmaceutical products and has influenced on the percentage of people who over the last 12 months have stopped taking medications prescribed by public health care as they cannot afford them due to their economic resources. The analyzed data from *Barómetros Sanitarios*, produced by the Spain's Ministerio de Sanidad, Servicios Sociales e Igualdad (2014-2017), allow us noticing that after the coming into force of the so-called "Reforma de Salud", a percentage of people who cannot access prescription drugs of 5% was noticed. This figure will decrease over the following two years to increase again in 2016 (see Graph 2).

However, the increase of this health care copayment has not homogeneously affected the citizens; groups more vulnerable than others have been found in the face of its implementation. In 2016, young women (18-24 years) and people between 45 and 54 concentrate this higher risk (Ministerio de Sanidad, Servicios Sociales e Igualdad, 2017). If these groups were traditionally characterized by lack in the payment of utility bills (electricity, water, municipal taxes) or related to housing, presently those

uncapable of providing themselves with certain quality health care are on the increase. An unlike what might be thought, the elderly do not have to be the ones in the worst relative position (due to their scarce amounts in pensions), as the highest increase in the rates of poverty and social exclusion have taken place in the employed population (Instituto Nacional de Estadística, 2017). Unmet needs related to drugs are health care deprivation, contesting the social citizenship and one of the strongholds of the Welfare state in Spain.

Conclusions and discussion

One of the most distinctive features at the time of analyzing Welfare states is the degree of social protection it offers the citizenship. Together with education, social services and pensions, health care implies one of the fundamental pillars of this protection system in Spain. In spite of this importance and the universal access that has traditionally defined these services, it seems we are at a moment of "model change". This is characterized by lesser social participation and an increase in individualism in social protection. The characteristics proper to the Spanish Welfare state —characterized by intense familism— and the reforms introduced after the global economic crisis have weakened the extension of the existing model.

In the particular sphere of health care, pharmaceutical benefits have been restricted with various juridical regulations coming into force, mainly after the approval of Royal Decree Law 16/2012 (BOE, 2012a). The implications for citizens have been numerous, nevertheless two are worth mentioning. In the first place, an increase in the amount of copayment has taken place among the citizens in a poorly progressive way. Secondly, a large number of drugs has been excluded from the coverage of *Sistema Nacional de Salud*, which entails pharmaceutical expenses for citizens. Therefore, they have had to face such increase in conditions of inequality, which has led to the increase of social inequality and undermine acquired rights. Such measures implied savings in public treasury, but also raised criticisms, since there were other proposals to rationalize expenditures that do not affect the citizens' welfare as directly. All of this became a diminution in the contribution to pharmaceutical expenditure according to GPD in Spain.

The increase of this expense at the households has not been homogeneous. Poly-medicated individuals, and especially older than 65, pay more expensive drug bills. However, these individuals do not face the most difficulties to access their medication. According to *Barómetro Sanitario* 2016, the youngest people and those between 45 and 54 years to

a large extent claim they cannot access drugs prescribed by their facultative due to economic problems. This fact has a greater influence on Spanish women than men, being them who also afford a greater expense in this regard (Ministerio de Sanidad, Servicios Sociales e Igualdad, 2017).

The increase in pharmaceutical copayment is being carried out at a time when the rest of social benefits derive from the social protection system have reduced and there are high unemployment figures. As a consequence, inequality and poverty levels are increasing and favoring an increasingly polarized society that does not ensure the quality of life of its citizens.

Moreover, the participation in pharmaceutical expenditures especially falls on people with chronic condition, poly-medicated, with low incomes and at risk of losing access to such drugs. Even if the participation measures of the beneficiaries in the cost of these products might bring rationality and balance to public treasury, the dissuasive effect on this necessity good, in a socioeconomic context of increasing poverty and social exclusion tendencies in Spain poses a barrier for people who aspire to enjoy minimal quality standards as regard health care. And what is most important, no emphasis is made on the need to approach a change in the pharmaceutical copayment management model.

References

Aron-Dine *et al.* (2013), "The RAND health insurance experiment, three decades later", en *The Journal of Economic Perspectives,* núm. 27, vol. 1, Estados Unidos: American Economic Association.

BOE [Boletín Oficial del Estado] (1966), *Decreto 3157/1966, de 23 de diciembre, por el que se regula la dispensación de especialidades farmacéuticas en el Régimen General de la Seguridad Social,* España: BOE. Disponible en: http://www.boe.es/buscar/doc.php?id=BOE-A-1966-21115 [1 de julio de 2017].

BOE [Boletín Oficial del Estado] (1978), *Real Decreto 945/1978, de 14 de abril por el que se da nueva regulación a la aportación del beneficiario de la Seguridad Social en la dispensación de las especialidades farmacéuticas*, España: BOE. Disponible en: http://www.boe.es/buscar/doc.php?id=BOE-A-1978-13676 [1 de julio de 2017].

BOE [Boletín Oficial del Estado] (1980), *Real Decreto 1605/1980, de 31 de julio, por el que se modifican los tipos de cotización para desempleo, Seguridad Social y Fondo de Garantía Salarial y se revisa el porcentaje de participación de los beneficiarios en el precio de determinados medicamentos*, España: BOE. Disponible en: http://www.boe.es/buscar/doc.php?id=BOE-A-1980-16601 [1 de julio de 2017].

BOE [Boletín Oficial del Estado] (1986), *Ley 14/1986, de 25 de abril, General de sanidad,* España: BOE. Disponible en: https://www.boe.es/buscar/act.php?id=BOE-A-1986-10499 [1 de julio de 2017].

BOE [Boletín Oficial del Estado] (2006a), *Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*, España: BOE. Disponible en: http://www.boe.es/buscar/act.php?id=BOE-A-2006-13554 [15 de julio de 2017].

BOE [Boletín Oficial del Estado] (2006b), *Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización*, España: BOE. Disponible en: http://www.boe.es/buscar/act.php?id=BOE-A-2006-16212 [1 de agosto de 2017].

BOE [Boletín Oficial del Estado] (2010), *Real Decreto 1718/2010, de 17 de diciembre, sobre receta médica y órdenes de dispensación*, España: BOE. Disponible en: http://www.boe.es/buscar/act.php?id=BOE-A-2011-1013 [15 de agosto de 2017].

BOE [Boletín Oficial del Estado] (2012a), *Real Decreto-ley 16/2012, de 20 de abril, de medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridad de sus prestaciones*, España: BOE. Disponible en: http://www.boe.es/buscar/act.php?id=BOE-A-2012-5403 [16 de agosto de 2017].

BOE [Boletín Oficial del Estado] (2012b), *Real Decreto-ley 20/2012, de 13 de julio, de medidas para garantizar la estabilidad presupuestaria y de fomento de la competitividad*, España: BOE. Disponible en: http://www.boe.es/buscar/doc.php?id=BOE-A-2012-9364 [16 de agosto de 2017].

BOE [Boletín Oficial del Estado] (2012c), *Resolución de 2 de agosto de 2012, de la Dirección General de Cartera Básica de Servicios del Sistema Nacional de Salud y Farmacia, por la que se procede a la actualización de la lista de medicamentos que quedan excluidos de la prestación farmacéutica en el Sistema Nacional de Salud*, España: BOE. Disponible en: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2012-10952 [07 de septiembre de 2017].

BOE [Boletín Oficial del Estado] (2015), *Real Decreto Legislativo 1/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios*, España: BOE. Disponible en: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2015-8343 [16 de agosto de 2017].

Cabiedes, Laura (2013), "Nuevas perspectivas sobre el precio de los medicamentos: El caso español", en *Estudios de Economía Aplicada,* núm. 31, vol. 2, España: Universidad de Valladolid.

Cantero, Josefa (2014), "Constitución y derecho a la protección de la salud", en *Revista CESCO de Derecho de Consumo,* núm. 8, España: Universidad de Castilla-La Mancha.

Cantor, Guillermo (2002), "La triangulación metodológica en las ciencias sociales", en *Cinta de Moebio*, núm. 13, Chile: Universidad de Chile.

Cortès-Franch, Inma y González, Beatriz (2014), "Crisis económica-financiera y salud en España. Evidencia y perspectivas. Informe SESPAS 2014", en *Gaceta Sanitaria*, núm. 28 (S1), España: Sociedad Española de Salud Pública y Administración Sanitaria (SESPAS).

Denzin, Norman (1978), *The research act. A theoretical introduction to sociological methods*, Estados Unidos: Mc Graw Hill.

EAE Business School (2016), *El gasto farmacéutico en España en 2016. Evolución internacional y situación desde el punto de vista nacional.* Disponible en: http://static.correofarmaceutico.com/docs/2016/09/05/gasto-farmaceutico-2016.pdf [07 de septiembre de 2017].

Fomento de Estudios Sociales y de Sociología Aplicada (Foessa) (2014), *VII Informe sobre exclusión social y desarrollo social en Andalucía y España,* España: Fomento de Estudios Sociales y de Sociología Aplicada (Foessa). Disponible en: http://www.foessa2014.es/informe/uploaded/descargas/VII_INFORME.pdf [23 de septiembre de 2017].

Freire, José Manuel (2014), "Los retos de las reformas sanitarias en el Sistema Nacional de Salud", en *Mediterráneo económico*, núm. 26, España: Cajamar.

Garrido, Nuria María (2014), "Hacia una construcción del derecho a la salud como contenido del derecho fundamental a una vida digna y de calidad: el 'mínimo vital' como límite de la sostenibilidad económica", en Balaguer, Francisco y Arana, Estanislao [comps.], *Libro homenaje al profesor Rafael Barranco Vela*, España: Thomson Reuters-Civitas.

Instituto Nacional de Estadística [INE] (2017), *Encuesta de condiciones de vida*. Disponible en: https://www.ine.es/dyngs/INEbase/es/operacion.htm?c=Estadistica_ C&cid=1254736176807&menu=resultados&idp=1254735976608 [18 de octubre de 2017].

Jiménez-Martín, Sergi y Viola, Analía Andrea (2014), "El sistema de salud en España en perspectiva comparada", en *Observatorio de la Sanidad FEDEA,* España: Fundación de Estudios de Economía Aplicada (FEDEA). Disponible en: http://www.sanidad.fedea.net/docs/ informe.pdf [16 de septiembre de 2017].

Jiménez-Martín, Sergi y Viola, Analía Andrea (2016), "Consumo de medicamentos y copago farmacéutico", en *Observatorio de la Sanidad FEDEA,* España: Fundación de Estudios de Economía Aplicada (FEDEA). Disponible en: http://www.documentos.fedea.net/pubs/eee/eee2016-06.pdf [16 de septiembre de 2017].

Lago, Juan Aitor *et al.* (2012), *El gasto farmacéutico en España. Evolución internacional, situación nacional y medidas de control del gasto*, España: Escuela de Administración de Empresas Business School. Disponible en: htpp://www.redaccionmedica.com/contenido/images/eae_gastofarmaceutico.pdf [16 de septiembre de 2017].

Landsman, Pamela *et al.* (2005), "Impact of 3-tier-pharmacy benefit design and increased consumer cost-sharing on drug utilization", en *The American Journal of Managed Care*, núm. 11, vol. 10, Estados Unidos: The American Journal of Managed Care (AJMC).

Lifshitz, Alberto (2014), "La medicina curativa y la medicina preventiva: alcances y limitaciones", en *Medicina Interna de México*, núm. 30, México: Colegio de Medicina Interna de México.

Lucas, Manuel Lucas (2016), "Copago farmacéutico: reflexiones jurídicas en aras a su eventual reforma", en *Nueva fiscalidad*, núm. 4, España: Dykinson.

Marshall, Thomas Humphrey (1950), *Citizenship and social class*, Reino Unido: The syndics of the Cambridge University Press.

Ministerio de Sanidad, Servicios Sociales e Igualdad (2012), "Nota de Prensa: Resolución por la que se revisa la lista de medicamentos con financiación pública." Disponible en: http://www.mscbs.gob.es/gabinete/notasPrensa. do?id=2532 [07 de octubre de 2017].

Ministerio de Sanidad, Servicios Sociales e Igualdad (2014-2017), *Barómetros Sanitarios (2013-2016).* Disponible en: https://www.mscbs.gob.es/estadEstudios/estadisticas/inforRecopilaciones/barometro/home.htm [20 de noviembre de 2017].

Navarro, María Dolores *et al.* (2016), "Equilibrio entre salud y sanidad", en Torres, Cristóbal [comps.], *España 2015, Situación Social*, España: Centro de Investigaciones Sociológicas.

Ortún, Vicente (2008), "El impacto de los medicamentos en el bienestar. Informe SESPAS 2008", en *Gaceta Sanitaria*, núm. 22, España: Sociedad Española de Salud Pública y Administración Sanitaria.

Oxfam (2016), *Una economía al servicio del 1%*, España: Oxfam. Disponible en:http://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp210economyonepercenttax-havens-180116-es_0.pdf [16 de septiembre de 2017].

Páez, Ricardo (2011), "La investigación de la industria farmacéutica: condicionada por los intereses del mercado", en *Acta Bioethica*, núm. 11, vol. 2, Chile: Universidad de Chile.

Páez, Ricardo (2016), **"**La investigación internacional de nuevos medicamentos: una valoración desde la justicia global", en *Revista Latinoamericana de Bioética*, núm. 16, vol. 2, Colombia: Universidad Militar Nueva Granada.

Puig-Junoy, Jaume (2007), "La corresponsabilidad individual en la financiación de medicamentos: evidencia y recomendaciones", en Puig-Junoy, Jaume [comp.], *La corresponsabilidad individual en la financiación pública de la atención sanitaria,* España: Fundación Rafael Campalans. Disponible en: http://www.fcampalans.cat/publicacions_detall.php?id=8&idpubli=84 [16 de septiembre de 2017].

Rawls, John (1991), *Teoría de la justicia*, México: Fondo de Cultura Económica.

Rodríguez, Marisol y Puig-Junoy, Jaume (2013), "Cuando hay que pagar, a veces lo urgente puede esperar", en *Emergencias*, núm. 25, vol. 6, España: Revista Científica de la Sociedad Española de Medicina de Urgencias y Emergencias.

Samaja, Juan (2018), "La triangulación metodológica. (Pasos para la comprensión dialéctica de la combinación de métodos)", en *Revista Cubana de Salud Pública*, núm. 44, vol. 2, Cuba: Sociedad Cubana de Salud Pública.

Saludas, José Manuel (2013), "Efecto de los copagos en la sanidad: teoría y evidencia", en *Boletín Económico de ICE,* núm. 3035, España: Ministerio de Economía y Competitividad. Disponible en: http://www.revistasice.com/es-ES/BICE/Paginas/Todos-los-Boletines.aspx [22 de diciembre de 2017].

Sanfélix-Gimeno, Gabriel *et al.* (2011), "La prescripción farmacéutica en Atención Primaria. Mucho más que un problema de gasto", en Ortún, Vicente [comp.], *La refundación de la atención primaria,* España: Acta Sanitaria. Disponible en: https://link.springer.com/book/10.1007/978-84-938062-5-5 [26 de diciembre de 2017].

Annex

Table I

Most relevant legislative changes regarding pharmaceutical copayment in Spain

Juridical regulation	Most relevant legal modifications
Decree 3157/1966 of December 23rd	Gratuity of pharmaceutical assistance in health care institutions It includes pharmaceutical copayment defining 30 pesetas as the limit and 5, lower limit (16,6%) and with a maximum upper limit of 50 pesetas. No discount was offered for collectives.
Royal Decree 945/1978, of April 14th	It establishes discounts in pharmaceutical copayment for pensioners and disabled individuals. It establishes a general 30-percent copayment (with the exception of a catalogue of drugs still ruled by the previous regulation).
Royal Decree 1605/1980 of July 31st	A general 40-percent copayment is established. The exemption for individuals considered in the previous regulation is maintained.
Law 29/2006 of July 26th	It excludes drugs from the pharmaceutical protection catalogue (aesthetic, commercial, homeopathical, etcetera). A "regular contribution" of 40 percent is established. A "reduced contribution" is established, where 10% will be deposited, with an upper limit of 2,64€. Inclusion of more collectives free from copayment.

Royal Decree -Law 16/2012 of April 20th	Copayment is defined by economic capacity. Income equal or greater than 100.000 €: contribution of 60% of the product. Income between 18.000-100.00€: copayment of 50% of the product. Income under 18.000€: contribution of 40% of the product. Pensioners (as a general rule): contribution of 10% of the product, defining limits for participation: - When they take drugs belonging to ATC group, they will contribute with 10% without surpassing 2,64€ at all cases. - Incomes below 18.000€: 8€. - Incomes between 18.000€ and 100.000: 18€. - If incomes are equal or greater than 100.000€: 60€. Other exceptions, adding to pensioners, are defined, among them individuals who receive social integration incomes, non-contributive pensions, or subsidies from unemployment. No exemption for unemployed individuals who receive unemployment benefits.

Source: BOE (1966; 1978, 1980, 2006, 2012), own elaboration.

Table II

Pharmaceutical copayment system

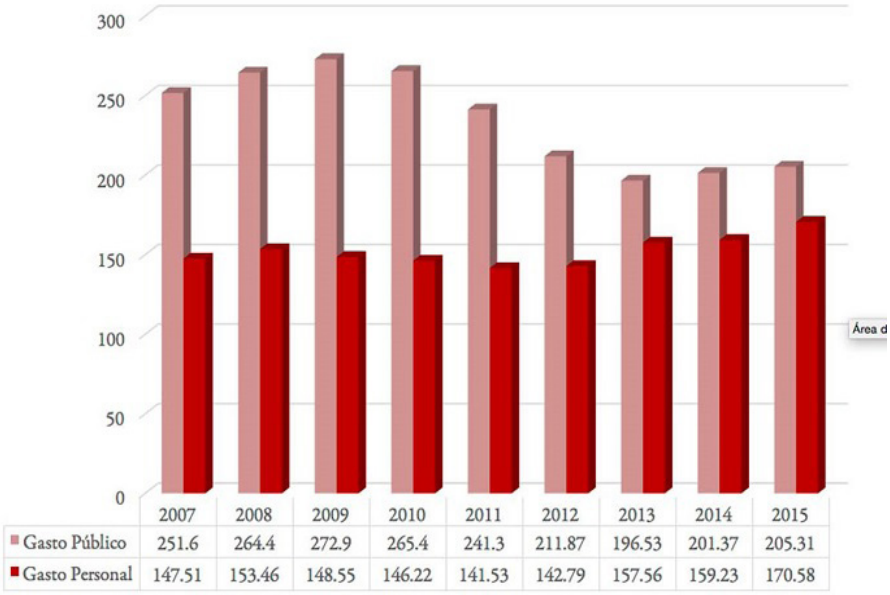
TSI CODE	Collective	Copayment according to PVP
001	Non-contributive pensions and their benefits	0 %
	Unemployed who lost he right to receive unemployment subsidy for as long as their situation remains (inscribed in employment demand)	
	Affected by toxic syndrome	
	Recipients of social integration incomes	
	Treatments from labor accidents and occupational disease	
002**	Pensioners with incomes under 18.000 euros a year, with a monthly limit of 8,23€*	10%
	Pensioners with incomes between 18.000-100.000 euros a year, with a monthly limit of 18,52€	
003	Active workers and their beneficiaries with incomes under 18.000€	40%
004	Active workers and their beneficiaries with incomes between 18.000 and 100.000 euro a year	50%
005	Active workers and their beneficiaries with incomes over 100.000 euro	60%
	Pensioners with incomes over 100.000 euro a year, with a monthly limit of 61,75€*	
006	Mutualists and passive strata (functionaries of Estado, Instituto Social de las Fuerzas Armadas y la Mutualidad General Judicial)	30%

* These amounts will be revalued annually following CI variations. ** In the case of reduced contribution drugs and ATC groups will add a maximum of 4,24€ per prescription.

Source: BOE (2015), own elaboration.

Graph 1

Evolution of the pharmaceutical public and personal expenditure per inhabitant in euros

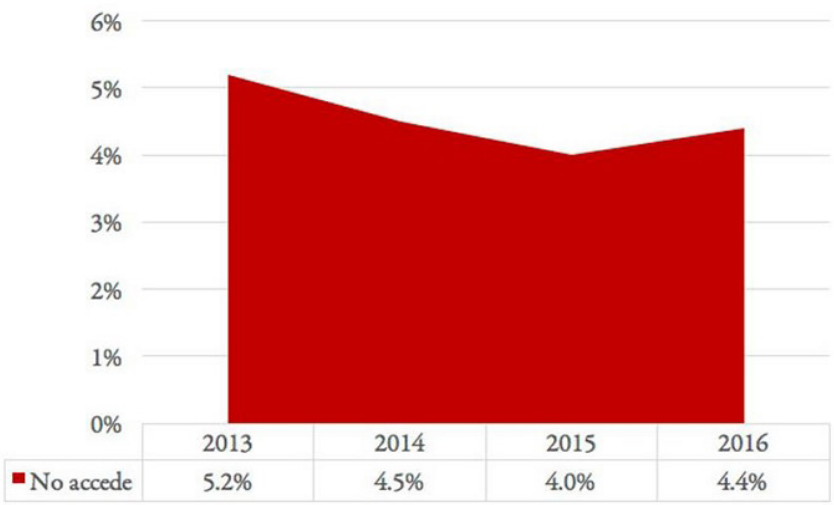


	2007	2008	2009	2010	2011	2012	2013	2014	2015
Gasto Público	251.6	264.4	272.9	265.4	241.3	211.87	196.53	201.37	205.31
Gasto Personal	147.51	153.46	148.55	146.22	141.53	142.79	157.56	159.23	170.58

Source: EAE Business School (2016), own elaboration.

Graph 2

Evolution of the percentage of individuals that cannot access prescribed drugs in Spain



Source: Barómetro sanitario of Ministerio de Sanidad, Servicios Sociales e Igualdad (2014-2017), own elaboration.

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