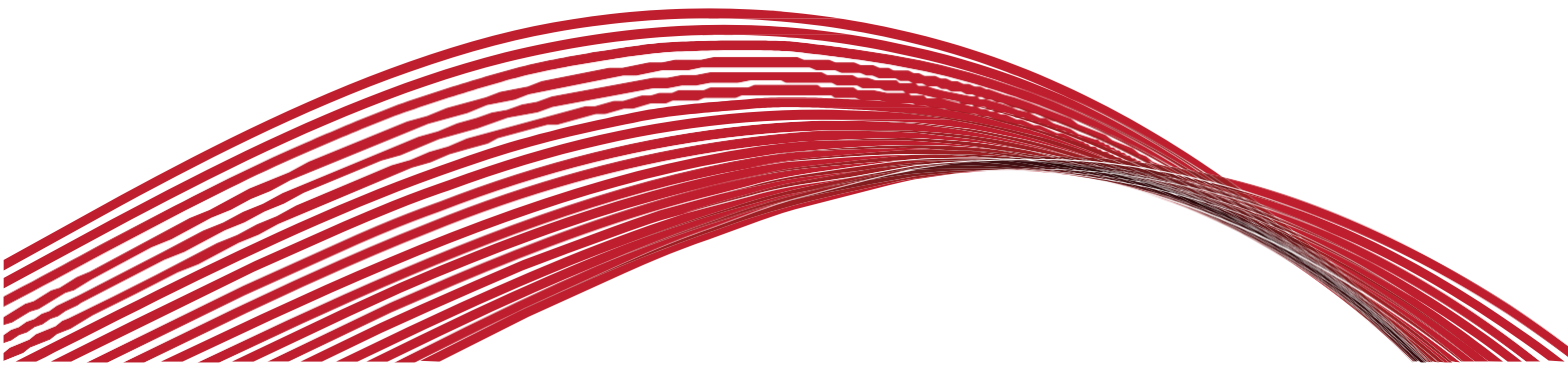
PUBLIC EXPENDITURE EVALUATION 2018

PROJECT 2 (PRESCRIPTIONS)

STUDY

MEDICATION DISPENSED THROUGH PRESCRIPTION



The Independent Authority for Fiscal Responsibility (AIReF by its Spanish acronym) was created with the mission of ensuring strict compliance with the principles of budgetary stability and financial sustainability set out in article 135 of the Spanish Constitution.

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CONCLUSION OF THE EVALUATION

Within the framework of the Spending Review, carried out by the Independent Authority for Fiscal Responsibility (AIReF) in Spain in 2018, public expenditure on prescriptions dispensed at pharmacies has been evaluated. Many agents are involved in this expenditure process, from the first research stages until the medicine is collected by the patient in the pharmacy with a public prescription. Therefore, a wide variety of issues are considered in the analysis carried out in this study.

For the reader to get an idea of the size of the expenditure item analysed, it is helpful to measure this in relation to Spain's Gross Domestic Product (GDP), total healthcare expenditure and total public expenditure on medicines, which also includes hospital medicine as well as medicines dispensed in pharmacies. In 2017, Spanish public healthcare expenditure was 72,813 million euros, of which around 16,264 million (1.4% GDP) was spent on medicines and over 62%, around 10,171 million, on prescriptions dispensed at the pharmacy.

In this study, AIReF focuses on those aspects of both supply and demand that determine this and on those aspects that the health authorities have the ability to influence. A wide range of issues are considered, including: the authorisation of medicines and their inclusion in public funding; pricing; procedures for the public purchase and selection of medicines; other aspects of pharmaceutical policy that affect healthcare professionals, especially regarding doctors' prescriptions and pharmacists' dispensation, and that affect patients, who ultimately are those who consume the medicines.

The analysis carried out by AIReF concludes that the Spanish National Health System (NHS) has room for improvement in terms of:

- Governance
- Procedural aspects, mainly related to the pricing of medicines.
- Efficiency
- Equity.

In terms of governance, the role of the Regions in determining which medicines are funded at which price does not correlate to the impact that these decisions have on their budgets.

In terms of procedural issues, there is no system for establishing the price that the NHS pays for medicines and the cost-benefit analysis is not a binding aspect when determining prices. In addition, the lack of human and technological resources needed to support these decisions means that the system focuses on the introduction of new medicines and dedicates less time on the re-evaluation of medicines in the portfolio. On the other hand, different reimbursement schemes would allow for less public expenditure on minor medicines by overcoming some of the drawbacks resulting from Spain being commonly included in the baskets that serve as international benchmarks for setting public funding prices for medicines.

Regarding the efficiency of the NHS:

- The Reference Price System (RPS), an instrument created to reduce the price of medicines for which there are equivalents, does not offer a comprehensive view of the price of treatments and therapies funded, since it only considers equivalence in terms of active ingredient and not in terms of therapeutic indication.

- There is a lack of contrast between prescriptions made and a great heterogeneity among the Regions in their prescription guidelines, which also has a negative effect on the system's efficiency.

- Overlapping actions to evaluate medicines in the Regions also does not favour optimal results in terms of efficiency: fragmented criteria hinder the work of the prescribers and do not favour rationality in the use of medicines.

- The example of Andalusia, where the medicine selection system (auction) has proved successful in achieving savings without compromising citizens' health, shows that it is possible to improve efficiency by establishing a nationwide medicine selection system.

Finally, in terms of the equity of the NHS, it was observed that the current co-payment model penalises active low-income workers, in comparison to pensioners with similar incomes, and is unequal in its treatment of particularly vulnerable people, such as recipients of minimum income benefits. In addition, it favours strategic behaviour that comes at a cost to the NHS.

Consequently, AIReF's proposals to the Government include:

1. Modifying the current composition of the Interministerial Commission on Medicine and Healthcare Product Prices, giving joint responsibility to the Regions regarding the decisions made within the Commission.

2. Creating an independent authority that supports decision-making on funding with appropriate human and technological means, incorporating cost-benefit information and forecasts for new therapies in reports provided to health authorities, while guaranteeing the systematic re-evaluation of medicines and monitoring of funding conditions.

3. Establishing a new RPS in which therapeutic indication is considered in addition to the active ingredient.

4. Applying medicine selection processes at the national level, taking inspiration from Andalusia's medicine selection system.

5. Modifying the current co-payment scheme, introducing improvements regarding equity and efficiency.

6. Incorporating avoidable co-payment systems, allowing citizens to be aware of the impact of their consumption decisions and allowing for improved billing prices for the NHS.

7. Linking prescriptions to the resolutions of the Interministerial Commission on Medicine Prices and introducing generalised programmes to monitor their use.

8. Increasing cooperation between the Spanish Agency of Medicine and Healthcare Products and the Regional Evaluation Agencies in the assessment of medicines and the preparation of clinical guidelines.

9. Developing healthcare education plans to encourage the rational use of medicines and adherence to treatments, with the participation of the primary care pharmacist and pharmacy.

AIReF's proposals could generate significant savings and efficiency improvements for the NHS. More specifically, the application of a national medicine selection system could save about 412 million euros by 2022; the establishment of a new RPS that considers both the active ingredient and therapeutic indication, about 507 million euros by 2022; the implementation of pharmacotherapeutic review and monitoring systems for prescriptions made, 485 million euros by 2022; and the introduction of periodic control systems to mitigate consumption deviations for high-impact medicine groups, 492 million euros by 2022. As some of the proposals would reduce the same aspects of inefficiency, the impact of each proposal is evaluated in isolation; their joint application would result in more modest savings. However, the potential savings derived from the application of AIReF's array of proposals is even greater, considering the budgetary impact of the rest of the proposals in this study, for which the existing information did not allow for a calculation of savings.

1
EVALUATION SUMMARY

1.1. Background

The purpose of Study 2 is to analyse the factors that determine public expenditure on prescription-dispensed medicines dispensed in pharmacies in Spain and to offer proposals that guarantee the sustainability and overall efficiency of the National Health System (hereinafter, NHS) in relation to this.

More specifically, expenditure on medicines[1] collected within pharmaceutical provision, not funded through a contribution from the user[2], but via public healthcare budgets, is analysed. For this reason, references to pharmacy expenditure in this report will be understood as references to public sector subsidisation[3] of expenditure on medicines prescribed by a public medical prescription and dispensed at pharmacies. Project 2 offers proposals that allow for an improvement in the efficiency of pharmacy expenditure and, therefore, the sustainability of the NHS.

A wide variety of sources of information have been used to carry out this study. These have mainly come from the *Administración General del Estado* (Central State Administration - AGE), as well as the *Ministerio de Sanidad, Consumo y Bienestar Social* (Ministry of Health, Consumption and Social Welfare - MSCBS)[4],

1 Although they are included within pharmaceutical provision, healthcare products are not included.
2 Art. 94.bis of Royal Decree-Law 16/2012, and art. 102 of the revised text of the Law on guarantees and rational use of medicines and healthcare products.
3 For the purposes of the SR in the definition of the Action Plan, a subsidy is understood as any outlay of funds without direct compensation or outside market conditions in the case of loans.
4 Nomenclature of medicines (2004-2017), Alcántara, broken down by Region and by Health Card Code; *Base de Datos de Centros de Atención Primaria* (Database of Primary Care Centres - BDCAP) 2014, 2015 and 2016 (BDCAP). For 2016, it contains information on prescriptions made in primary care centres in 7 Regions (Aragon, Galicia, Canary Islands, Asturias, Navarre, Cantabria and Extremadura) to around one million patients, their health problems, socio-economic information and their visits to primary and specialised care.

the *Agencia Española del Medicamento y Productos Sanitarios* (Spanish Agency of Medicine and Healthcare Products - AEMPS)[5], the *Ministerio de Hacienda y Administraciones Públicas* (Ministry of Finance and Public Administrations - MINHAP)[6], as well as information from the Regions[7].

In addition to quantitative information sources from the various public administrations (hereinafter, PAs) mentioned above, interviews have been carried out with: (i) experts in the field from the General Directorate of Pharmacies of the MSCBS and the Department of Medicine for Human Use of the AEMPS, as well as the pharmacy and budget directorates of the 17 Regions, (ii) representatives of the *Consejo General de Colegios Oficiales de Farmacéuticos* (General Council of Official Pharmacist Associations - CGCOF), Farmaindustria and the *Asociación Española de Medicamentos Genéricos* (Spanish Generic Medicines Association - AESEG), as well as (iii) other experts in the field of clinical pharmacology, health economics and law, who exercise their responsibilities in different areas. In addition, health reports and statistics have been consulted for different assessments, as well as academic and scientific literature that will be detailed more specifically throughout the document where necessary.

Furthermore, AIReF benefited from the collaboration of PwC consultants[8] and the scientific advice of the *Fundación de Estudios de Economía Aplicada* (Foundation for Applied Economics Studies - FEDEA), more specifically from Sergi Jiménez and Juan Oliva, in the realisation of this project.

The *Agencia Estatal de Administración Tributaria* (State Tax Administration Agency - AEAT) also collaborated. We thank all the public administrations and other organisations that have kindly collaborated with the Independent Authority for Fiscal Responsibility (AIReF), contributing their knowledge and experience on many of the issues analysed in this report, for which AIReF is ultimately exclusively responsible.

1.2. Overview

In Spain, healthcare, education and pensions, along with social care and care for dependants, constitute the four basic pillars of the welfare state, with public services being considered as a fundamental aspect.

5 Information on the medicine pipeline, which will lose patent or foreseeable authorisation protection in the short term.

6 Information on public expenditure on medicines and healthcare products available from 2014, prepared with information submitted by the Regions, INGESA, MUFACE and MUGEJU.

7 Questionnaire about the use of resources, by Region and Basic Health Zone (hereinafter BHZ) 2016 and 2017; Questionnaire about prescription control and rationalisation policies. With information from the resolutions of the Andalusian Health Service of the calls for the selection of medicines, a database has been prepared for the assessment of this procedure.

8 Consultant hiring was funded by the European Commission's Structural Reform Support Service (hereinafter, SRSS).

The protection of health and healthcare is the right of all citizens, as recognised in article 43 of the Spanish Constitution. The responsibility for executing, administering and managing healthcare rests with the Regions, which provide most of the expenditure linked to the provision of this service in their budgets. For its part, the AGE, via the MSCBS, exercises the basic management competences assigned to it by the legal framework[9].

Thus, the NHS figures as "the coordinated network of the AGE's and the Regions' healthcare services that includes all of the functions and healthcare benefits that, pursuant to the law, are the responsibility of public authorities".

In this framework, the NHS offers citizens a set of services, including pharmaceutical provision[10].

The study focuses on the analysis of both supply factors and demand factors. Most of the decisions that determine supply are the responsibility of the AGE, for example the authorisation to market medicines, their registration and the funding and public establishment of their prices, regulation of distribution and dispensation conditions, etc., whilst demand factors are mainly determined by the actions of the Regions.

In 2017, public healthcare expenditure in Spain amounted to 72,813 million euros, approximately 70.7% of total healthcare expenditure and 6.26% GDP. Total public expenditure on medicine exceeded 16,264 million euros, 1.4% GDP, of which over 62%, around 10,171 million euros, was pharmacy expenditure.

Since 2009, public expenditure on medicine has always evolved above the real GDP growth rate. This fact is determined by factors not only linked to the evolution of the cycle but also by structural, demographic and socio-economic factors, such as the increasing entry of high-cost therapeutic innovations, population ageing and the greater incidence of chronicity.

9 The responsibilities of the State regarding healthcare are: general bases and coordination of healthcare, external healthcare and the definition of basic regulations on pharmaceutical and healthcare products, and regulation linked to the economic regime of social security. The regulation of the right to health protection is reflected in the General Health Law (1986), the NHS Cohesion and Quality Law (2003), the Law on Guarantees and Rational Use of Medicines (2006), the General Public Health Law (2011) as well as Royal Decree-Law 16/2012, along with those that regulate specific healthcare matters included in the Health Code and in the rest of the norms and regulations that implement these.

10 Which is provided within the NHS's common supplementary portfolio.

In this context, the aim is to offer proposals to incorporate improvements in the governance of the system and in the management of the budget allocated to pharmacy, impacting prices, funding decisions, underfunding, assessment and selection of medicines, as well as prescription and other aspects related to the management of the Regions.

This study's analysis is built around the following components:

- Systematic review of the information available at different levels of public administration on consumption and/or expenditure on medicines in Spain, in order to identify possible improvements in its collection and use that enable its management to be improved and the assessment of initiatives and decisions with impact on prices and/or quantities consumed to be systematically introduced.

- Current situation and expected evolution of pharmacy consumption and expenditure in Spain, considering the different elements that determine this, its regional distribution and its composition. This analysis is contextualised, taking the situation of other countries into account. Relevant factors are identified in order to prepare the pharmacy expenditure projections (2018-2022).

- Identification of alternatives to ensure access to prescription and to control the growth of public pharmaceutical expenditure (price control policies, product control policies and expenditure control policies).

- Detailed analysis of the list of medicines funded and dispensed at the pharmacy. Study of authorisation, setting proces and reimbursinf procedures, evaluation of new medicines and the re-evaluation of those that are already funded. The analysis is contextualised by considering the situation of other countries (Germany, Canada, France, Italy, Portugal and the United Kingdom).

- Study of the national/regional legal framework for the procurement of medicines in which the different centralised purchase and contracting models have been introduced. More specifically, the Andalusian medicine selection system is analysed.

- Identification and analysis of the various regional policies on the prescription of medicines, in order to develop a taxonomy of rationalisation policies for medicine consumption and study their effect on expenditure and consumption.

- Simulation of changes in the model of contribution to the price of medicines determined by the current co-payment system in Spain.

Findings

Comisión Interministerial de Precios del Medicamentos y Productos Sanitarios (Interministerial Commission on Medicine and Healthcare Product Prices - CIPM) functioning

I. Low joint responsibility of Regions in decision-making related to funding, underfunding and prices. The structure of the CIPM is not balanced with the budgetary responsibilities of the agents that take part in it. The Regions have a low influence on decision-making (3 out of 11 votes), even though they bear 95% of the expenditure.

II. Inadequate supply of human and technological resources to support decision-making on funding. Lack of integration of information and an absence of tools to monitor expenditure. The lack of resources leads experts to solely concentrate on the introduction of medicines.

III. Lack of a system for some processes that should be recurring and almost automatic. The systematic review of reimbursement conditions and prices is not common practice. Price revisions are made if significant, but non-recurrent, increases in expenditure are detected without prioritisation guidelines or strategic budgetary planning.

Pricing

IV. Absence of a systematic cost-benefit analysis process of medicines that is binding for pricing and funding.

V. Prices are not systematically reassessed when therapeutic innovations are introduced, meaning these can coexist in the portfolio of alternative funded medicines in which prices do not adequately reflect position in the available therapeutic arsenal. These differences in prices, which do not reflect differences in therapeutic value, have significant implications on expenditure and distort the prescription.

VI. The RPS does not offer a comprehensive view by therapeutic indication of funded medicines' prices, so, similarly to the previous point, there are discrepancies in prices that do not reflect differences in therapeutic value.

VII. Absence of regulated procedures when considering the introduction of new medicines in budget planning. The MSCBS and the AEMPS monitor and analyse perspectives of the pipeline (medicines in the approval process), but with no reflection in expenditure planning.

VIII. Spain is a country widely used as an international reference for prices, a fact that makes negotiations with pharmaceutical companies more difficult.

IX. The RPS could have consequences on access to certain medicines. The downward pressure generated by the RPS on price compromises the economic viability of some of these prices and their commercialisation in Spain.

Improvements to the system

X. Overlapping of the Regions' medicine assessment actions and heterogeneity in their clinical value criteria, which means the current system functions inefficiently.

XI. Intersecting price cutting policies (Royal Decree 08/2010) no longer have the desired effect as they have lost their exceptional component and have been internalised by pharmaceutical companies.

XII. The current co-payment model can be improved in terms of equity (it penalises active low-income workers that heavily use the health system) and efficiency (monthly contribution limits can encourage strategic behaviour that comes at a cost to the NHS).

XIII. Andalusia's medicine selection system has been successful in achieving savings without compromising citizens' health.

Prescription of medicines

XIV. Great heterogeneity among the Regions in their prescription patterns. The lack of contrast and consolidation in prescriptions can facilitate inadequate treatments (abuse or shortage of medicines) or problems in their administration (inadequate means and dose).

XV. Citizens have insufficient knowledge about the importance of the rational use of medicines.

XVI. The work of pharmacies is largely limited to dispensing medicines, with not much importance given to other tasks of greater value.

1.3. Conclusions on findings and lessons learned

Based on the analysis performed and the findings obtained, AIReF puts forward the following proposals ordered according to the administration to which they are addressed.

Proposals

Those that affect the management of the MSCBS

1. Replacement of the CIPM with an independent authority that improves decision-making on prices, funding and underfunding. It is necessary to solve problems related to the lack of resources, the lack of a price revision system, improvements in technical documentation to be provided, coordination of regional assessment agencies, and to introduce mechanisms that take into account information about the pipeline of innovators and loss of patent protection in budgetary planning. This organisation's investigative body would be responsible for documenting and presenting proposals to the committee that makes pricing and funding decisions. It could be funded by charging fees to laboratories linked to any administrative procedure they initiate.

2. Updating and integrating information systems for the monitoring and systematic review of funding and reimbursement conditions, evolution of international prices, consistency between observed prescription practice and the indication for which the medicine was funded, provision for the authorisation of new medicines and consideration of budgetary impacts.

3. Systematic review of funding conditions. Inclusion of automatic clauses to review funding conditions when the price falls in reference countries, approved conditions are breached or new therapeutic equivalents are agreed.

4. Integration of evaluation agencies' efforts to avoid duplication and lack of coherence. Encouraging greater coordination between the AEMPS and regional agencies when analysing the contribution of innovative medicines.

5. Definition of a new RPS considering therapeutic indication (ATC 4) and active ingredient (ATC 5) simultaneously.

6. Review of the RPS and its application. Implementing a system of reported prices and clearly defining the selection criteria for the basket of comparable countries.

7. Apply binding cost-effectiveness criteria when setting the price of innovative medicines.

8. Review of cross-cutting price reduction policies, introduced in Royal Decree 08/2010. Elimination of the compulsory deduction of 7.5% and an increase in the deduction of 15% by 5 points.

9. Increase in the price of medicines with supply problems due to low prices (patented, generic and biosimilar).

10. Implementation of an avoidable co-payment system, whereby the patient would pay the difference between the price of the active ingredient up to the amount of funding and the retail price of the medicine that they collect at the pharmacy (in case the medicine has a higher retail price).

11. Introduction of a national, transparent medicine selection system, with only one bid per laboratory, at a uniform price and starting with groups of medicines with less impact on the national industry and for minor pathologies, batching, and that is licensed for 2 years.

Those that affect the Regions' management

12. Implementation of a practice improvement protocol in the supervision of prescriptions.

13. Pharmacotherapeutic review and monitoring of prescription medicines.

14. Introduction of a periodic control system to mitigate significant deviations in the consumption of medicines.

15. Implementation of education plans on healthcare and the rational use of medicines, aimed at the general population.

Those that affect the work of pharmacies

16. Modification of pharmacies' reimbursement model for the margin on sales of medicines to reimburse for services provided to users to improve the rational use of prescribed medicines (pharmacotherapeutic monitoring and promotion of adhesion).

Those that affect patients

17. Redefinition of a new co-payment model in Spain. Substitution of monthly contribution limits for annual contribution limits for pensioners. Redefinition of price instalments for medicines to make them more gradual, considering the elimination of the distinction between active workers taking multiple medicines and pensioners, to make the system more equitable.

Cross-cutting measures

18. Improvement of the information available in the different databases considered, promoting their connection for the monitoring of expenditure and transparency between different administrations, in order to improve the management of pharmaceutical provision.

Impact

The proposals made have different completion terms, are defined to different degrees of detail, require greater or lesser consensus among administrations and their economic quantification may be more or less precise according to the available information. For this reason, they have been grouped into three general frameworks in line with these factors.

The three groups of proposals, of which only those whose estimate is reasonably objective have been quantified, are as follows:

- **Proposals for technical consensus** with high feasibility and rapid implementation capacity, which require a boost from the MSCBS. **This will allow up to 1,500 million euros to be saved in 2022**.

- This group of proposals includes numbers 5, 8, 11, 13 and 14

Measures	Introduction Year	2022 Savings
1. Introduction of purchase model of auctioning medicines on a national scale.	2020	Up to €1,000 million
2. Definition of a new reference price system based on ATC4 and ATC5.	2020	€270 million
3. Pharmacotherapeutic review and monitoring of prescriptions made.	2020	€213 million
4. Implement periodic control systems to mitigate significant deviations in medicine consumption.	2019	€202 million
5. Cross-sectional pricing cuts.	2019	€83 million

– **Proposals for political consensus** require the concurrence of all administrations with health competencies. **It would mean optimising the current system and providing it with greater levels of co-responsibility and homogeneity while also generating efficiencies**.

– This group of proposals includes numbers 1, 2, 3, 4, 6 and 7 (all of these are included in the proposal to create an independent authority), as well as 9, 10, 12 and 17.

Improvements in terms of efficiency	
1	**New shared governance model for funding and pricing decision-making** Greater co-responsibility in decision-making Reinforcement of resources and decision-making processes for funding and pricing
2	**Implementation of best-practice protocols regarding prescriptions**

Improvements in terms of equity	
3	**New co-payment model with greater equity**

– **Proposals for social consensus**, with long-term implementation and high social and budgetary impact. They require the involvement of other key NHS agents whose activity is not carried out in the PA, such as prescribers, pharmacists and patients, so it is difficult to determine the time frame in which they could be fully operational. **They involve a transformation of the current system**.

This group of proposals include numbers 15, 16 and 18.

Improvements in terms of efficiency		
1	**Healthcare education** for the promotion of the **rational use of medications**	
2	**Change in pharmacies' remuneration model**	▶ **From margins to value-added services**
3	**Optimisation through the intelligent use of information (Big data)**	▶ **Aggregation and use of databases that are currently widely spread**

Throughout the document, the budgetary impact of the proposed measures will be explained in detail. Some impact similar areas and it is possible that, with their joint application, savings may amount to less than the sum of the estimates for each of the individual measures.