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# Reform of economic evaluation of medicines in Spain: proposals from the Advisory Committee for Pharmaceutical Financing

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ABSTRACT

This paper describes the reforms recommended by the Advisory Committee on the Financing of Pharmaceuticals (CAPF) for the National Health System (NHS) of Spain from 2019 to 2024 for the drug pricing and reimbursement process, to integrate economic evaluations and improve efficiency and sustainability. The CAPF has proposed a three-phase reform of the economic evaluation (EE) and budget impact analysis (BIA) processes. The first phase involves the mandatory submission of EE and BIA by applicants for new drugs. The second phase involves the assessment of these submissions, coordinated by the Directorate-General for Pharmaceuticals. The third phase focuses on the application of these assessments to decision-making on drug positioning, pricing and financing. The CAPF's recommendations emphasise improved regulation, transparency and the development of methodological guidelines for economic evaluations. These proposals include a dynamic appraisal system and the creation of official NHS guidance on EE and BIA. The process is designed to ensure compliance with established criteria and to incorporate efficiency into decision-making. The initiatives of the CAPF aim to make progress towards the integration of efficiency in Spanish pharmaceutical policy seeking to improve the methodological quality and transparency of economic evaluations, ultimately contributing to more informed decision-making and sustainable healthcare practices.



## Reforma de la evaluación económica de medicamentos en España: propuestas del Comité Asesor para la Financiación de la Prestación Farmacéutica

*Palabras clave:*
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RESUMEN

Este artículo describe las reformas recomendadas por el Comité Asesor para la Financiación de la Prestación Farmacéutica (CAPF) del Sistema Nacional de Salud (SNS) de España entre 2019 y 2024 en el proceso de fijación de precios y reembolso de medicamentos, con el fin de integrar evaluaciones económicas y mejorar la eficiencia y la sostenibilidad. El CAPF ha propuesto una reforma en tres fases de los procesos de evaluación económica (EE) y análisis de impacto presupuestario (AIP). La primera fase implica la presentación obligatoria de EE y AIP por parte de los solicitantes de nuevos medicamentos. La segunda fase implica la evaluación de estas presentaciones, coordinada por la Dirección General de Farmacia. La tercera fase se centra en la aplicación de estas evaluaciones en la toma de decisiones sobre el posicionamiento, la fijación de precios y la financiación de los medicamentos. Las recomendaciones del CAPF destacan la mejora de la regulación, la transparencia y el desarrollo de directrices metodológicas para las EE. Estas propuestas incluyen un sistema de evaluación dinámico y la creación de una guía oficial del SNS sobre EE y AIP. El proceso está diseñado para garantizar el cumplimiento de los criterios establecidos e incorporar la eficiencia en la toma de decisiones. Las propuestas del CAPF tienen como objetivo avanzar hacia la integración de la eficiencia en la política farmacéutica española y buscan mejorar la calidad metodológica y la transparencia de las EE, contribuyendo en última instancia a una toma de decisiones más informada y a prácticas de atención sanitaria sostenibles.



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## Introduction

One of the main areas in need of review in health management and policy in Spain is the evaluation of the efficiency of medicines. As of now, the failure to systematically integrate the analysis of efficiency into decision-making processes for pricing and reimbursement leads to a significant opportunity cost in the use of public resources.

The Royal Decree-Law 16/2012, of April 20, on urgent measures to ensure the sustainability of the National Health System (NHS) and improve the quality and safety of its services, already established an Advisory Committee in Article 90 bis, although this committee was not created or formalized with explicit components until April 2019.[1] The responsibilities of the Spanish Medicines Law has included an Advisory Committee on the Financing of Pharmaceuticals (CAPF) for the NHS include advising the Department of Health on measures to improve: 1) the establishment of criteria and procedures for setting drug prices; 2) the incorporation and assessment of the economic evaluation of drugs; 3) the evaluation of the impact of drug financing policies; and 4) sustainability and efficiency of drug financing.

In advising the Ministry of Health, the CAPF responds to the Ministry's requests and actively works on a number of strategic lines to develop recommendations. The CAPF's agenda has been set to reorganise, transform and increase the transparency of the pharmaceutical pricing and reimbursement process in Spain. Its priority areas include: 1) criteria and procedures for the pricing and financing of new drugs and indications through a comprehensive evaluation and positioning process; 2) supporting tools (guidelines and procedures) for the evaluation and positioning of drugs to integrate efficiency into pharmaceutical policy; and 3) recommendations for the development of a dynamic evaluation system.[2]

The CAPF's agenda for reforming the drug pricing and financing process is in line with recommendations made to the Ministry of Health by other bodies.[3–6] The recommendations of the CAPF are advisory in nature and not legally binding. However, they allegedly play a significant role in the decision-making process by providing technical criteria and assessments that authorities consider when determining pharmaceutical benefits within the NHS.

## CAPF proposals for reforming the management of the pharmaceutical pricing and reimbursement

In 2022, the CAPF made a number of recommendations on criteria for financing medicines,[7] including improving regulation and transparency, developing guidelines, accountability, ex-post evaluation of measures, using a combination of methods for setting prices, considering relevant added clinical value, efficiency, uncertainty and budget impact in financing decisions, give key importance to efficiency measures, etc. The CAPF also recommended that the pharmaceutical industry should provide an economic evaluation when applying for pricing and reimbursement. Additionally, the CAPF emphasized that the drug evaluation process should be dynamic, encompassing both ex-ante and ex-post evaluations, with the latter incorporating the most recent available evidence updates.

The Therapeutic Positioning Reports were led by the General Directorate of Pharmacy (DGF) of the Ministry of Health and the Spanish Agency for Medicines and Medical Devices, with participation of technics and clinicians from the health services of the Autonomous Communities (a collaborative system called REvalMed). They were prepared to assist the Interministerial Committee on prices (CIPM) make decisions on pricing and reimbursement, with the involvement of multidisciplinary groups by types of pathologies, in order to describe a comparative clinical setting for the therapeutic positioning of new medicines.[8] The CAPF recommended, within the context of the REvalMed organization, that the economic evaluation and the comparative clinical evaluation[9] conducted by the technical teams for this process should be incorporated. This would involve the expansion and organization of qualified human resources. Until now, there has been little transparency and accountability regarding how economic evaluation has been used as a criterion for pricing and reimbursement.

As the reform of the entire drug evaluation, pricing and financing process may take time, in the first quarter of 2023, the CAPF proposed to start with a reform of the study of economic evaluation (EE) and budget impact analysis (BIA) in the medication evaluation procedure in Spain in three steps.[10] The first phase entails the mandatory submission of the EE and BIA by the applicant for pricing and financing, for new active substances, combinations, and new indications. The second phase entails the assessment of both, the EE and BIA, which is coordinated by the DGF. The third phase concerns to their application in the decision-making process regarding positioning, pricing, and financing. An economic evaluation should be conducted for medicines that provide a substantial additional clinical benefit, in accordance with a guide for relevant additional clinical benefits that should be developed.

With regard to the initial stage, it is proposed that the applicant for funding and pricing submit an EE and a BIA in conjunction with the so-called drug information dossier and economic offer.[10] Both economic analyses must adhere to the content and form criteria established by official guidelines of the NHS for EE and BIA, which will be established at the regulatory level. Furthermore, should such circumstances arise, both economic analyses must adhere to specific criteria established by the DGF regarding the particular case, including aspects such as the comparator(s) to be used in the EE, the trial results to be considered in the EE, alternatives to be included in the BIA (particularly in light of horizon scanning, as many new drugs could potentially be introduced within the next 2-3 years), or any other specific aspect of the case deemed appropriate. In conclusion, the terms of reference for the applicant to prepare the EE and BIA reports comprise two levels. The first level comprises general guidelines that are applicable to all cases. The second level comprises specific instructions that are dependent on the treatment and the therapeutic setting described by the previous pharmacoclinical evaluation.

During the second stage, the quality of the EE and BIA submitted by the applicant must be evaluated and managed. For this purpose, a list of criteria for assessing the quality and compliance with standards and recommendations of the EE and BIA, as well as the format in which the reviewers of these reports must present their assessment, should be established.

The third and final stage should include the criteria for assessing the results of economic evaluation and budget impact, as well as their application for decision-making regarding positioning, pricing, and financing. In particular, it should address how to use the results derived from the EE and BIA for decision-making, in conjunction with other relevant criteria.

## The CAPF economic evaluation guide in the context of these reforms

The proposed reform process by the CAPF necessitates the creation of an official NHS guide on EE and BIA. This is to ensure that funding applicants adhere to established criteria, both in content and format, as mandated by legislation. Furthermore, it is intended that this guide will set out an explicit process for assessing

the quality of these analyses. In fact, the reform proposal stipulated that the DGF could urgently commission the CAPF to oversee the development and coordination of guidelines for conducting EE and BIA studies by applicants, including the format for submission, and the assessment criteria. This would be done in collaboration with expert groups.

Last year, the DGF directly requested that the CAPF develop guidelines for economic evaluations. This was with a view to providing a methodological framework to guide the development and critical analysis of economic evaluations submitted to the DGF.[11]

The CAPF subsequently conducted an EE guide proposal in collaboration with an expert group and with external consultation to professionals representing a range of profiles. However, the responsibility for the latest version of the guide rests with the CAPF members. Subsequently, the Spanish Ministry of Health published the CAPF guide on the economic evaluation of medicines as proposed by the CAPF.

It is important to note that a guide on BIA and supplementary guidance that delves into specific methodological aspects related to economic evaluation are essential. In particular, guides on relevant added clinical benefit, efficiency thresholds, and clinical and economic uncertainty analysis are required. Economic evaluation and BIA are crucial for decision-making regarding the positioning, financing, pricing, and subsequent reassessments of drugs. The detailed articulation of all procedures constitutes the essential framework required to establish a comprehensive pharmaceutical policy.

## Current state of pharmaceutical policy and the suitability of the economic evaluation guide

In recent years, Spanish pharmaceutical policy has undergone significant changes, with initiatives by the Ministry of Health's to introduce the evaluation of the efficiency of medicines in the decision making process.[12,13] An illustrative example was the consolidation of Therapeutic Positioning Reports, as a reference tool for the positioning and evaluating the cost-effectiveness of medications in the NHS. However, this initiative, was overturned by the National High Court, for lack of appropriate legal support.[14] The Department of Health has now begun the process of approving the necessary regulations to allow the initiative to be re-launched.

Furthermore, the advent of contemporary innovations such as personalised medicine, digital health, regenerative medicine, nanotechnology in medicine, and virtual and augmented reality in healthcare will present challenges to the sustainability of the NHS. Consequently, the role of efficiency will become increasingly important as a criterion for healthcare decision-making.

The request by the DGF for an EE guide may be an initial step towards the formal incorporation of efficiency into the evaluation process, as previously recommended by the CAPF.

The current regulatory and normative context is of interest at both national and international levels. To our knowledge, there are three priority legislative reforms in Spain that can and should establish efficiency as one of the decision criteria in pharmaceutical policy: the Law on Guarantees and Rational Use of Medicines, the Royal Decree on the evaluation of healthcare technologies, and the Royal Decree on pricing and financing of healthcare products (other than medicines) funded by the NHS for out-patients. Furthermore, at the European level, the regulation on the evaluation of healthcare technologies is being developed, which will also play a significant role in Spanish pharmaceutical policy. This legislative reform presents an opportunity to increase and regulate efficiency considerations in healthcare decision-making and to establish procedures and increase transparency.

Consequently, it is imperative that the NHS be equipped with an efficient organizational structure and adequate budgetary resources in pharmaceutical policy processes and facilitate its adaptation to current circumstances.

## Conclusions

In conclusion, an economic evaluation guide represents a crucial component of the ongoing pharmaceutical policy reforms in Spain, which are expected to continue in the coming years. Such reforms are essential for health systems aiming to optimise resource allocation, promote efficiency, enhance the quality of care, and ensure the long-term sustainability of the system.

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## Transparency declaration

The corresponding author, on behalf of the other authors guarantee the accuracy, transparency and honesty of the data and information contained in the article, that no relevant information has been omitted and that all discrepancies between authors have been adequately resolved and described.

## Authorship contributions

Contributions to this research article were shared among all participating authors. The conceptualization and design of this article were carried out by all authors. The first draft of the paper was written by M. Trapero-Bertran and A. Ortega, but all authors contributed substantially equally to the final version of the manuscript.

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## Conflicts of interest

All authors are current or former members of CAPF.

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