GUIDELINES FOR HEALTH ECONOMIC EVALUATION OF MEDICINES: PROPOSAL BY THE ADVISORY COMMITTEE FOR FINANCIAN PHARMACEUTICAL BENEFITS (CAPF) IN THE SPANISH NATIONAL HEALTH SYSTEM

HPR27

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INTRODUCTION

- ✓ The General Directorate of Pharmacy of the Ministry of Health commissioned a guideline for evaluating the efficiency of medicines in the National Health System (NHS) (1).
- ✓ Published in 2024, the guideline provides a methodological framework for conducting health economic evaluations of medicines.
- ✓ These evaluations are crucial for decision-making regarding the positioning, public reimbursement, and pricing of medicines.

OBJECTIVE

To present the main methodological aspects of the new guideline for the health economic evaluation of medicines in Spain, which aims to standardize and improve the transparency, quality, and consistency of evaluations to support evidence-based decision-making in the National Health System.

METHOD

- ✓ The guideline defines 17 key dimensions that health economic evaluations must address.
- ✓ A "reference case" was designed to establish standardized criteria for evaluations.
- ✓ The guideline was developed by a multidisciplinary working group of five experts in health economic evaluation, coordinated by the Advisory Committee for the Financing of Pharmaceutical Benefits (CAPF).
- ✓ The draft guideline underwent rigorous review, incorporating feedback from 31 external experts, CAPF members, and representatives from the General Directorate of Pharmacy (DGF), ensuring alignment with national healthcare policies and practical applicability.

RESULTS

- ✓ The guideline defines 17 key dimensions for conducting health economic evaluations, including objective, perspective, comparators, and management of uncertainty.
- ✓ A standardized reference case is provided to ensure consistency and transparency in evaluations (*Table 1*).
- ✓ Prioritizes cost-utility analysis (CUA), using QALYs, while allowing for other methods when justified.
- ✓ The guideline introduces two uncommon dimensions: the validation of decision models, emphasizing both internal and external validation to ensure robustness, and the re-evaluation of decisions, which addresses the need to update assessments based on new evidence and evolving contexts.
- ✓ A comprehensive checklist was developed to assess the methodological quality and reporting of economic evaluations.

This reference case table has been summarized for space reasons. Further details can be found in the original guideline document in Spanish (1) or in a paper to be published in Gaceta Sanitaria in 2025 (2).

Table 1 Sections or dimensions and reference case for a health economic evaluation

SECTION OR DIMENSION	REFERENCE CASE
1. Objective and scope	Clearly define the evaluation's goal and whether it is an initial or re-evaluation.
2. Perspective	Focus on the healthcare payer perspective (National Health System).
3. Study population and subgroups	Define the eligible population and consider relevant subgroups for analysis.
4. Comparators	Include standard practice and other relevant alternatives for comparison.
5. Type of economic evaluation	Prioritize cost-utility analysis (CUA); justify alternatives if used.
6. Evidence of efficacy/effectiveness and safety	Base on high-quality clinical trials or adjusted comparisons.
7. Measurement and assessment of health outcomes	Use QALYs for CUA and clinically relevant outcomes for other analyses.
8. Identification, measurement and assessment of the use of resources and costs contemplated/consumed	Identify, measure, and value all relevant resources transparently.
9. Time horizon	Ensure it captures all significant differences in outcomes and costs.
10. Discount	Apply a 3% annual rate for costs and health outcomes beyond the first year.
11. Methods of analysis	Employ transparent modeling techniques for extrapolation and synthesis.
12. Validation of decision models	Conduct internal and external validation of decision models.
13. Management of uncertainty	Perform deterministic and probabilistic sensitivity analyses.
14. Presentation of results	Present incremental cost-utility/effectiveness ratios and uncertainty.
15. Summary of the main results, their interpretation, limitations, transferability, discussion and other relevant considerations	Highlight key findings, limitations, and transferabilityequity considerations relevant to the analysis will be clearly articulated.
16. Source of financing and conflicts of interest	Disclose funding sources and conflicts of interest.(authors, consulted experts, reviewers).
17. Re-evaluation	Address uncertainties and justify changes in re-evaluations.

CONCLUSIONS

- ✓ The guideline marks a significant step in reforming health technology assessment (HTA) processes in Spain.
- ✓ It aims to optimize resource allocation within the NHS by relying on robust clinical and economic evidence.
- ✓ Designed as a foundational document, it can be adapted to evaluate other health technologies beyond medicines

REFERENCES

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