The Role of Economic Evaluation in HTA in Spain

Top 5% Finalist for the ISPOR 2023 Research Presentation Awards

HPR132

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Introduction

- Since 2013, each drug approved under centralized procedure by the European Medicines Agency (EMA), and to be marketed in the Spanish National Health System (NHS), undergoes an assessment in a Therapeutic Positioning Report (TPR). TRPs aim to position each new drug within clinical practice[1].
- In 2020, Ministry of Health published a new TRP procedure, and economic evaluation was included[2]. There is no information on the impact of the measure to date.

Objective

The main objective was to analyze the characteristics of the economic evaluations included in the therapeutic positioning reports in Spain.

Methods

- Using R, we programmed a scraping tool to find all published TPRs with economic evaluation on the website of the Spanish Ministry of Health[1].
- The scraping tool found all the TRPs published, selected those from 2020 onwards, downloaded all their PDF documents and searched for the "economic evaluation" section. All those that contained an economic evaluation were flagged for manual review.
- Simultaneously, all TRPs in progress up to June 2023 were identified manually.
- An extraction form was developed to complete with the characteristics of the TRPs, including:
  - Publication status.
  - Commissioning and the publication year.
  - Status of the evaluated drug.
  - Type of compound.
  - Orphan designation.
  - Therapeutic area.
  - Reimbursement situation.
  - Type of economic evaluation.
  - Type of methodology.
  - Outcomes measures.
- A statistical descriptive analysis was carried out.

Results

- 31 TRPs with economic evaluation have been commissioned (16 published, 2 finished but not published, and 13 in progress).
- Among those published (n=16), 69% comprised new drugs (Table 2), 63% orphan medicines, and the most common area was oncology (31%) (Table 3). 63% of the drugs evaluated were chemical substances, 25% biological and 13% Advanced Therapy Medicinal Products (ATMP).
- Most TRPs (43.75%) concluded with a conditional reimbursement decision, one TRP (6.25%) proposed unconditional reimbursement (6.25%), and 12.50% concluded with no reimbursement decision. The remaining TRPs did not have a funding request (31.25%) or did not have safety approval from the Spanish Agency for Medicines and Health Products (AEMPS).
- All TRPs comprised ex-novo budget impact analysis. Some TRPs included additional (ex-novo and/or existing) cost-utility (31%), cost-minimization (31%) and cost-effectiveness (13%) analyses (Figure 1).
- As for the methods used, cost comparisons were used in 63% of TRPs when therapeutic equivalence was assumed, as well as partitional survival models (38%) and Markov models (31%) (Figure 2).
- In many cases, some of the basic characteristics of the models were not reported. The time horizon was not reported in 50% of the evaluations, sensitivity analyses were not mentioned in 56% of the cases, and the methodology was not clearly stated in 12%.

Table 1. Reimbursement situation

Reimbursed	6.25% (1)
Reimbursed for certain indications/conditions	43.75% (7)
Not reimbursed by resolution	12.50% (2)
AEMPS authorization pending	6.25% (1)
In process/ without request for reimbursement	31.25% (5)

AEMPS: Spanish Agency of Medicines and Medical Devices

Figure 1. Type of economic evaluation

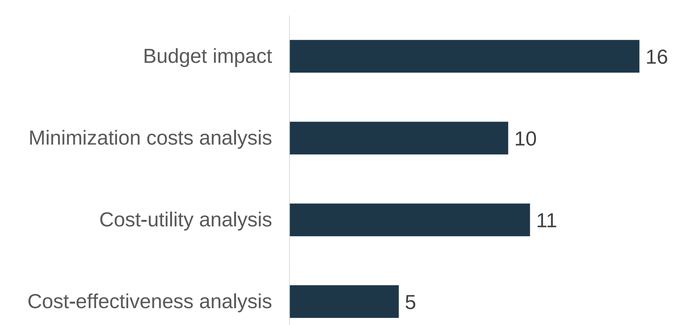

Table 2. Status

New indication	31.25% (5)
New drugs	68.75% (11)

Table 3. Therapeutic area

Circulatory	6.25% (1)
Dermatology	12.5% (2)
Digestive	6.25% (1)
Endocrinology	6.25% (1)
Hematology	12.5% (2)
Musculoskeletal	6.25% (1)
Neurology	12.5% (2)
Oncology/Hematology	6.25% (1)
Oncology/Solid	31.25% (5)

In some cases, TPRs comprised more than one economic evaluation

Figure 2. Methodology

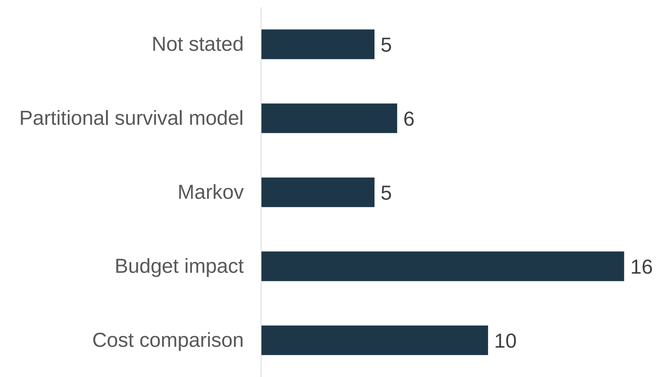

Table 4. Outcomes measures

ICUR	7,706 – 793,415 €/QALY	n = 11
ICER	2,077 – 7,453,607 €/outcome	n = 5
Budget impact	-102,686,155 – 130,211,815 €	n = 16

ICUR: Incremental cost-utility ratio; ICER: Incremental cost-effectiveness analysis; QALY: quality-adjusted life years

Conclusions

- Economic evaluation is increasingly important in the HTA of new drugs in Spain. The inclusion of economic evaluation in TPRs is still in progress, with a trend towards incorporating more sophisticated methods that should be sustained over time.
- However, TRPs with economic evaluation are not yet mandatory by law and their continuation depends on upcoming developments in the legal field.

References: 1. Spanish Agency of Medicines and Medical Devices (AEMPS) (2023). Therapeutic positioning reports (https://www.aemps.gob.es/) **2.** AEMPS (2020). *Plan de consolidación de los informes de posicionamiento terapéutico de los medicamentos en el Sistema Nacional de Salud* (https://www.aemps.gob.es/).

*Talzenna is missing from this chart due to its wide range (commissioned in May 2019, released in November 2021).