Is the paradigm shifting?

The REvalMED pilot program and subsequent integration of economic evaluations to influence pricing and reimbursement discussions in Spain

EE754

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Background

- The Therapeutic Positioning Reports ("*Informes de Posicionamiento Terapéutico*", IPTs) were introduced in Spain in 2013 to assess the value of new therapies at the central level, and to provide evidence that can guide the pricing and reimbursement decision-making at the regional level. In October 2020, a pilot program was launched to establish a network of HTA evaluators (REvalMED) aiming to improve the IPT process by integrating economic evaluations (EEs) into the assessments. In June 2023, the Spanish National Court annulled the program as the mechanisms followed for its approval were not in line with the Spanish Constitution. Since then, IPTs have been developed in the same manner as in 2013-2020. This study aimed to assess the progress made during the extent of the pilot program with regards to the integration of EEs into the IPTs in Spain.

2013: IPTs gets introduced in Spain

2020: REvalMED pilot program launches

2023: Spanish court annuls the pilot program

Methods

- REvalMED meeting minutes published between October 2020 and May 2023 were screened to identify products entering the pilot program and their corresponding IPTs were retrieved. Data on time for assessment (time between entering the pilot program and IPT publication), characteristics and methodology used in the EEs of IPTs were collected.

Results

- 30 products entered the pilot program, although only 17 had an IPT published at the time of search.
- The time to publish an IPT with an associated EE (16.5 months) was longer than before the pilot program implementation (6.7 months), where no EE were conducted.
- Most of the IPTs in the pilot program were for drugs in oncology (solid tumors) (n=14), followed by rare diseases (n=4) (**Figure 1**).
- While all IPTs published at the time of search included an EE, the cost-effectiveness was not possible to assess in 4/17 cases.
  - Type: Cost-utility (CUA), cost-effectiveness (CEA) and cost-minimization analyses (CMA) were similarly used (**Figure 2**).
  - Authorship: Most EEs were developed de-novo by REvalMED, while the rest consisted of adaptations from existing models (**Figure 2**).

Figure 1: Most common therapeutic areas in the pilot program

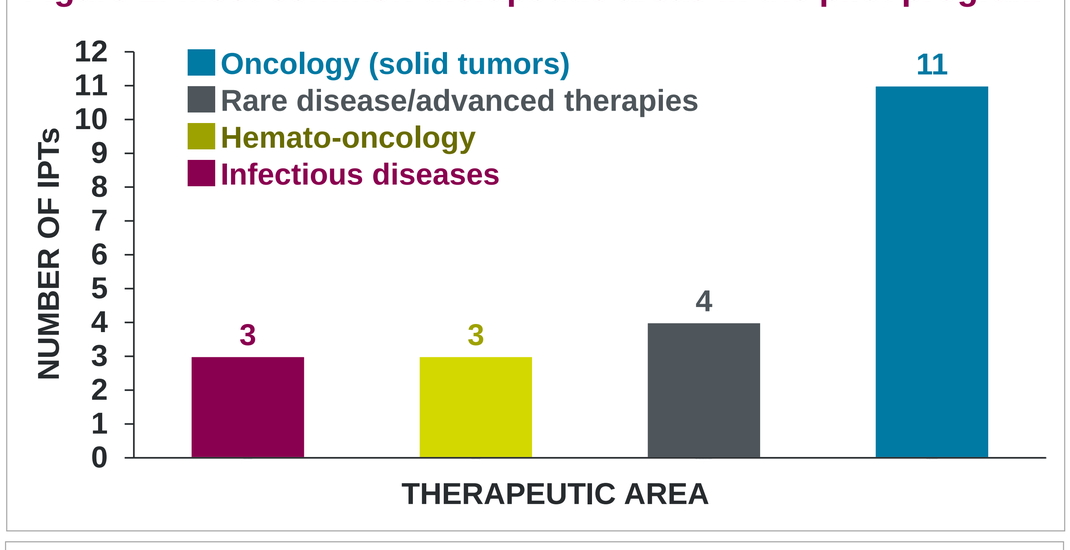
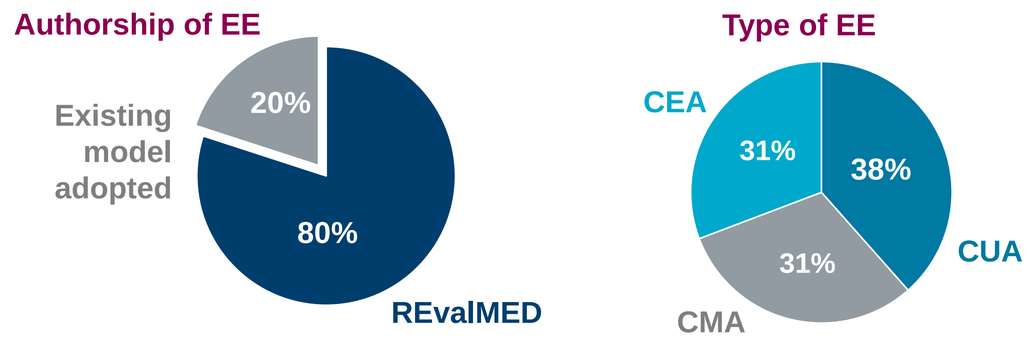


Figure 2: Characteristics of EEs included in the IPTs



Discussion and conclusions

- Although the REvalMED pilot program was annulled and the time needed for assessment was more than doubled (16.5 vs 6.7 months), it succeeded in setting a precedent for the inclusion of EEs into IPTs in Spain (17/17 IPTs published included an EE), demonstrating the willingness and ability to incorporate economic modelling into a process that has been historically clinically driven, despite the complexities and timelines associated with the development of the EEs. As the introduction of the EU Joint Clinical Assessment (JCA) in 2025 is likely to expedite or replace the IPTs in Spain, there will be a new opportunity to advance in the integration of EEs into pricing and reimbursement negotiations. Any future endeavors will require data generation activities at the national level to ensure the EEs inputs are representative of the Spanish landscape, and early payer engagement will be crucial to validate national EEs models before submission to the authorities.

REFERENCES: [1] Plan para la consolidación de los ITPs de los medicamentos en el sistema nacional de salud. *Comisión Permanente de Farmacia del Consejo Interterritorial del SNS. (*2020), page 8; [2] AEMPS. Meeting minutes from REvalMED 2020-2023 (2023). [3] AEMPS. Informes de Posicionamiento Terapeutico (2023).