Reasons for Drug Market Access Failure in Portugal: A Retrospective Analysis of Public Reimbursement Reports

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OBJECTIVES

- This study investigates the reasons for failures in drug market access in Portugal, particularly due to negative reimbursement recommendations within the National Health Technology Assessment (HTA) System.
- The main objective is to determine the reasons of these failures.

METHODS

- The INFARMED website was searched for Reimbursement Evaluation Reports published between Jul-2020 and Feb-2024. Data was extracted from these reports to record whether each HTA process was approved, rejected or archived regarding reimbursement decisions, and the reasons for these verdicts.
- Sources of evidence and results of studies considered in each process were analysed versus the assessment matrix defined by the HTA Committee (CATS) (i.e., PICO criteria).
- For each drug with a positive pharmacotherapeutic evaluation (e.g., added therapeutic value [ATV] versus comparators), the results of the pharmacoeconomic evaluation (e.g., Incremental Cost-Effectiveness Ratios [ICERs]) and the negotiation stage were examined to elucidate potential causes of reimbursement rejection.
- Descriptive statistics were used (Microsoft Excel®).

RESULTS

- Out of 223 processes, 192 (86%) were recommended for reimbursement, and 21 (9%) received a negative recommendation.
- Ten (5%) processes were archived. Most negative reimbursement recommendations (n=16; 76%) was supported by failures in pharmacotherapeutic evaluation, namely inability to show ATV versus comparators.
- The reasons were lack of adequate evidence for comparisons (n=11; 69%), negative/ non-robust results to demonstrate clinical value in the evidence supporting comparisons (n=3; 19%) or both reasons (n=2; 12%).
- The remaining negative recommendations (n=5; 24%) were supported by high acquisition costs of the drugs, considered unsustainable for the National Health System.

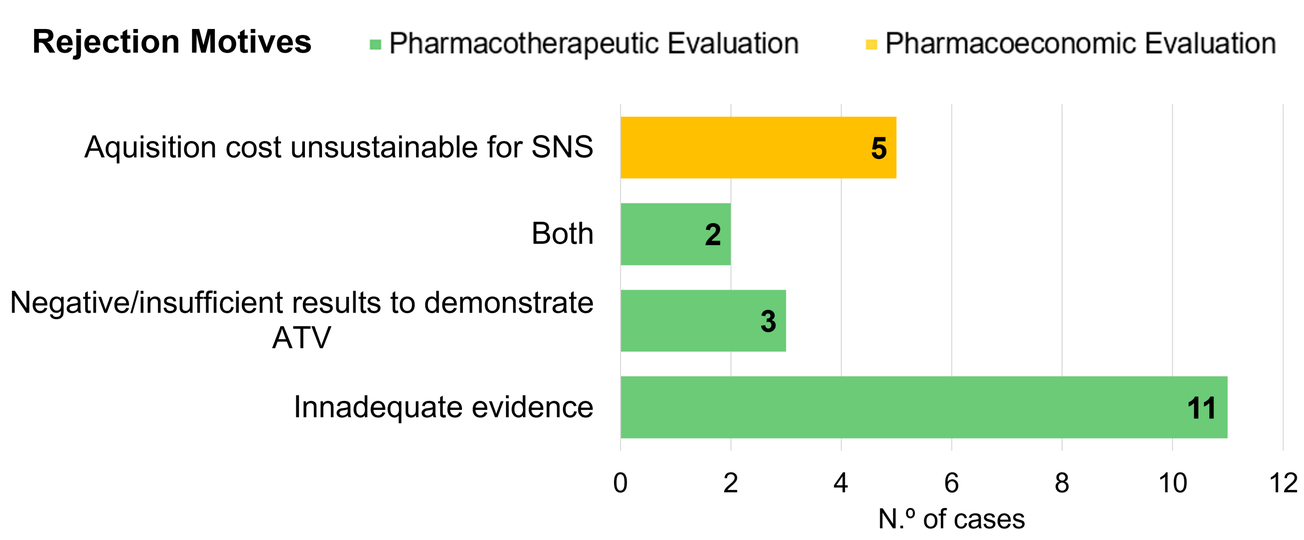

Fig. 1 – Results analysed from the Public Reimbursement Assessment Reports (14/07/2020 – 29/02/2024).

CONCLUSIONS

- The present findings suggest that pharmacotherapeutic evaluation is the stage of the HTA process that most impacts the outcome of a reimbursement recommendation.
- The mismatch between the requirements of the evaluation matrices (PICO) and the clinical evidence available on the medicines under evaluation and their comparators limits market access of therapeutic innovation.

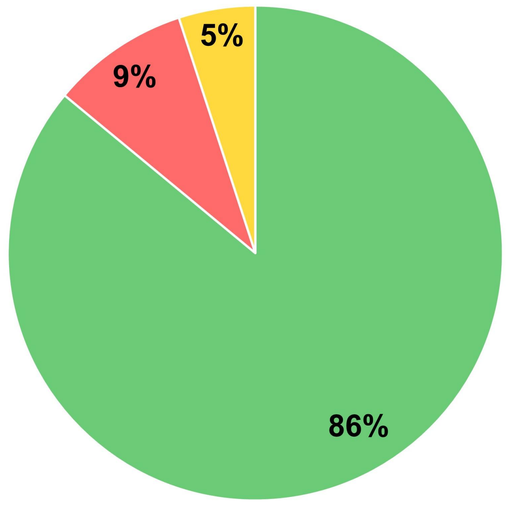

Fig. 2 – Main reasons for a negative recommendation for Public Reimbursement (14/07/2020 – 29/02/2024).