Relationship Between Cost-Effectiveness Threshold and Drug Reimbursement in Spain, Italy, and France

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OBJECTIVES: To assess whether incremental cost-effectiveness ratios (ICERs) and cost-effectiveness thresholds (CET) influence reimbursement decisions of medicines in Spain, Italy and France.
METHODS: Firstly, publications about the CET in Spain, Italy and France were reviewed. Secondly, we analyzed all the Therapeutic Positioning Reports (IPTs) published in Spain between 2021 and 2022 including an economic evaluation section, and we searched in them the specific ICER mentioned, when available. Lastly, we reviewed the corresponding evaluation reports from Italy (AIFA) and France (CEESP/HAS) looking for specific ICERs and extracted data from official websites on the reimbursement status in each of the countries for those drugs that had a reported ICER in Spain.
RESULTS: The CET range is unofficial in the three countries, typically laying between €25,000-60,000/QALY, with €30,000-40,000/QALY often cited, in Spain, €33,000/QALY in Italy and €50,000/QALY in France, where decisions are focused on therapeutic benefit (ASMR/SMR) and ICER inclusion is optional. Out of the 19 IPTs found in Spain including economic evaluation section, only 10 included ICER results, developed by Spanish Medicines Agency (AEMPS) or of external reference. Seven (70%) were reimbursed (some with restrictions) and three were denied with very high ICERs. In three cases (43%) the drugs were reimbursed exceeding the CETs. In Italy, all medicines were reimbursed under confidential discount agreements or expenditure caps, but reimbursement decisions did not reference an ICER. In France, nine were reimbursed (some with restrictions) and one was denied due to lack of therapeutic benefit. Only one included ICER, and this was exceeding the threshold but reimbursed in France.

CONCLUSIONS: Overall, CETs and ICERs play a limited and inconsistent role in drug reimbursement across Spain, Italy and France, overshadowed by clinical benefit, budget considerations and negotiation mechanisms. Strengthening transparency and integration of economic evaluation could enhance decision-making and equity in pharmaceutical access across these countries.

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