

with a similar scope. For each eligible organization, information was extracted on the inclusion of economic factors during decision-making and the existence of predefined criteria for judging the results of economic evaluations.

Results: Sixty-nine organizations from 56 countries were identified, of which 66 (96%) considered economic factors for HTA. Fifty-two (79%) organizations conducted cost-effectiveness analyses, 42 (64%) assessed budget impact, and one focused solely on total technology costs. Thirty-four organizations (51%) declare not having criteria for economic evaluation, whereas 14 (21%) from 12 countries had explicit criteria. There were no data found for 18 organizations (27%). Among the organizations with explicit criteria, 11 (17%) applied willingness-to-pay thresholds in cost-effectiveness evaluations and five (8%) applied criteria related to budget impact for decision-making, such as a maximum percentage of budget impact.

Conclusions: Although most organizations consider economic factors for HTA, many do not have explicit, predefined criteria for decision-making. Among those that presented such criteria, willingness-to-pay thresholds for cost-effectiveness analyses were the most common. The findings of this study also help to identify complementary factors that can be considered to promote greater systematization and transparency in the decision-making process.

PD193 Submission Processes And Requirements For Health Technology Assessment In Australia, Canada, England, France, And Germany

Emily Gregg, Charlotte Graham,
Karina Watts (karina.watts@york.ac.uk) and
Stuart Mealing

Introduction: As health technology assessment (HTA) bodies introduce more rigorous requirements, the submission process is becoming increasingly diverse between countries. This study assessed the HTA submission processes and requirements in Australia, Canada, England, France, and Germany. This helps identify where efficiencies can be made in the global market access strategy, such as when to submit HTA dossiers.

Methods: A pragmatic review and desk-based research were conducted in November 2023. Published articles, HTA guidelines, process documents, conference abstracts, and white papers were reviewed to identify country-specific processes with implications for market access strategy. Where available, information was extracted about the general submission process and stakeholders involved (including regulatory, HTA, and pricing authorities), clinical evidence requirements, and pharmacoeconomic evidence requirements for HTA submission. Comparisons of the median time from marketing authorization to HTA decision within each country allowed the identification of efficiencies in individual HTA submission processes. The key findings and between-country differences were summarized narratively.

Results: The review identified several areas with implications for market access strategy. The median HTA review time was shortest in Australia (125 days) and longest in England (266 days). Australia and Canada have both sequential and parallel regulatory and HTA processes. The median time taken from regulatory approval to HTA recommendation was faster with the parallel process than with the sequential process in both countries. All countries required comparative clinical evidence within the indication. The weight placed on pharmacoeconomic evidence varied between countries. In Germany, economic evaluation has yet to play a real role. Requirements for additional information after HTA submission occurred within all HTA bodies.

Conclusions: HTA processes in Australia, Canada, England, France, and Germany differ from one another. This will likely affect the market access strategy for health technology developers. Similar requirements allow efficiencies in the preparation of submission documentation. Future research should investigate the impact of the European Union HTA regulation on market access and how this could affect strategic decision-making.

PD194 The Scenario Of Hospital-Based Health Technology Assessment In Brazil, Italy, And Poland

Rossella Di Bidino (rossella.dibidino@policlinicogemelli.it),
Iga Lipska, Monika Kukla and
Marilia Mastrocolla de Almeida Cardoso

Introduction: Hospital-based health technology assessment (HB-HTA) is evolving constantly. In 2023, a survey was conducted by the HB-HTA Interest Group of Health Technology Assessment International with the aim of collecting data on HB-HTA activities, including perceptions of the role of, potential for, and barriers to HB-HTA. Overall, 87 responses were collected: 41 from hospitals performing health technology assessment (HTA), 18 from hospitals not conducting HTA, and 28 from policymakers.

Methods: The survey collected data from 28 countries. Italy, Poland, Brazil provided the highest number of responses. We conducted a descriptive comparative analysis focusing on these three countries to investigate whether and how the policies for HB-HTA, the activities of HB-HTA, and the perceptions of HB-HTA differed among policymakers and hospitals not performing HTA.

Results: Overall, 19 responses were collected from Italy and 10 each were collected from Brazil and Poland. While Italy (n=10) and Brazil (n=8) had a high number of responses from hospitals performing HB-HTA, most of the responses from Poland (n=9) were from hospitals not performing HTA. There was a lack of policies for HB-HTA in all three countries. HTA was performed in big hospitals (≥ 500 beds) in Italy and Brazil. HB-HTA covered all kinds of technologies, including digital health. In Poland, hospitals not conducting HTA recognized the ability of HB-HTA to promote cost containment. Policymakers were open to including HB-HTA in their activities.