PP54 Towards Equitable Pricing: Unraveling The Complexities Of External Reference Pricing In Medical Devices

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Introduction: External reference pricing (ERP) serves as a widely adopted method for establishing authorization and reimbursement prices for pharmaceuticals in Europe. However, its application within the medical device (MD) industry remains shrouded in uncertainty. This study seeks to investigate the feasibility of integrating ERP into the realm of MDs, identify pertinent challenges and ambiguities, and propose solutions to bolster affordability and accessibility.
Methods: The methodology encompassed a systematic search across diverse databases (Google Scholar, Google, ResearchGate, PubMed), utilizing combinations of relevant keywords, like "medical device," "external reference pricing," "price," "reimbursement," "affordability," "challenge," and "implement." Articles were thoroughly evaluated by each researcher independently, followed by a consensus-based approach for final assessment. Rigorous scrutiny of relevance, potential insights, study design, and methodology ensured a comprehensive review, maintaining a high standard of research quality. This meticulous process guaranteed the inclusion of pertinent literature on ERP and MD pricing, enhancing the study's depth and breadth.
Results: Global ERP application in the MD sector exhibits significant variability in country selection, pricing methods, and adaptations to market changes. Pricing and reimbursement policies across international contexts contribute to this diversity, involving authorization procedures, regulatory oversight, technology appraisals, and state financing limitations. Challenges in establishing equitable pricing frameworks underscore the need for clear guidelines, regulatory empowerment, regular audits, and international collaborations. Transparent methodologies for reference price calculation are essential. Addressing observed shortcomings involves negotiating lower prices, implementing subsidies, promoting generic competition and local production, and tailoring reimbursement policies to treatment needs, enhancing affordability and accessibility on a global scale.
Conclusions: Ambiguities in implementing ERP for MDs underscore the necessity of equitable pricing frameworks. The highlighted multidimensional strategies and consideration of market dynamics are deemed essential for the feasibility of ERP in MDs. These insights emphasize the cruciality of a structured and transparent roadmap for optimizing ERP in the realm of MDs, holding significant potential for ensuring affordability and accessibility.

PP55 Health Technology Assessment Scoping Definition For Health Regulation

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Introduction: The first phase of a health technology assessment (HTA) is to define the scope of the assessment and choose the appropriate type of studies. The HTA in Regulation has been produced in cooperation with the Oswaldo Cruz Foundation (Brasilia) and the Brazilian Health Regulatory Agency (Anvisa). This work reports the Brazilian experience with HTA priority-setting within the time period 2022 to 2023.
Methods: Focusing on Anvisa's 2022 to 2030 research themes, a workgroup developed a priority-setting cycle addressing the following four steps: (i) survey application to define problems and topics (August to October 2022); (ii) data compilation and exploratory searches by topic; (iii) workshops with technical areas (March to June 2023), aiming to refine themes, define research questions, and determine what types of studies will be conducted); and (iv) presentation of prioritized themes.
Results: Forty-six topics at the intersection of HTA and health regulation were prioritized. Macro-agendas for medical devices and medicines were the most frequent. The studies (39 scoping reviews, nine rapid HTAs, and four technical reports) aimed at post-market surveillance, definition of regulatory problems, selection of the best regulatory options, and identification of the legal basis for the selected problem. These studies will be used to assess the impact of the proposed solutions on stakeholders and identify any potential risks associated with them. Lastly, the studies will provide recommendations for decision-making regarding health regulatory measures.
Conclusions: By establishing technical cooperation between stakeholders to gather the best available evidence for regulatory decision-making processes through HTA studies, scoping definition based on the real needs of decision-makers has taken place. In this collaboration, experts were mobilized to expand response capacity and technical-scientific knowledge to support decision-making in health regulation.

https://doi.org/10.1017/S0266462324002265