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Short communication

The Nexus of drug pricing, pharmacoeconomics, and HTA: a comparative analysis of regulatory paths in EU Member States and Western Balkan Countries

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Introduction

Increasing pressure on healthcare budgets, driven by the market entry of high-cost innovative therapies, particularly in oncology, has intensified the transition toward Value-Based Healthcare (VBHC) frameworks across Europe (ISPOR, 2026). In parallel, the implementation of Regulation (EU) 2021/2282 on Health Technology Assessment introduces a centralized Joint Clinical Assessment (JCA) model intended to harmonize clinical evidence evaluation among EU Member States (European Parliament and Council, 2021). In contrast, most Western Balkan countries continue to rely predominantly on External Reference Pricing (ERP), while Health Technology Assessment (HTA) implementation remains heterogeneous and

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institutionally underdeveloped (EURIPID Collaboration, 2024; WHO, 2021).

Objectives

This study aimed to comparatively evaluate the interrelationship between regulatory pathways, pharmaceutical legislation, medicine pricing policies, reimbursement mechanisms, and HTA implementation in selected EU Member States and Western Balkan countries. Additionally, the study explored the evolving role of pharmacoeconomics, HTA, Joint Clinical Assessments (JCA), and Managed Entry Agreements (MEAs) in supporting market access, pricing negotiations, and fiscal sustainability for high-cost innovative medicines.

Materials and methods

A mixed-methods comparative policy analysis was conducted. Regulatory desk research reviewed legislation and institutional frameworks related to health insurance, medicinal products, pricing, reimbursement, and HTA in Bosnia and Herzegovina, Montenegro, North Macedonia, Serbia, and selected EU Member States. Additionally, a structured 40-item expert survey was distributed to stakeholders from regulatory institutions, healthcare systems, academia, patient organizations, and the pharmaceutical sector. Key domains included ERP, value-based pricing, HTA implementation, JCA integration, MEAs, governance, RWE utilization, and access to innovative medicines.

Results and discussion

Findings demonstrate substantial divergence between EU Member States and Western Balkan countries regarding the integration of HTA into pricing and reimbursement decision-making. In EU systems, HTA outcomes increasingly support value-based pricing and reimbursement negotiations, while MEAs are used to address clinical uncertainty and optimize access to innovative therapies (Callenbach et al., 2024; Grueger et al, 2026). Conversely, Western Balkan countries continue to rely predominantly on ERP, with HTA serving mainly as a supportive rather than decisive tool (WHO, 2021; EURIPID Collaboration, 2024). Key barriers include limited pharmacoeconomic expertise, institutional fragmentation, and insufficient local RWE. Nevertheless, the growing use of financially based MEAs indicates an emerging shift toward more sustainable access models for high-cost medicines. Alignment with the EU JCA framework may strengthen evidence-based reimbursement decision-making and improve regional HTA harmonization (European Parliament and Council, 2021).

Conclusion

To achieve sustainable market access and align with EU standards, Western Balkan countries must transition from purely price-centric models to value-based HTA frameworks where economic evidence and MEAs actively inform the price-setting process. Synchronizing regulatory paths with the EU's JCA framework and strengthening regional technical capacity are essential steps to ensure equitable access to life-saving innovative therapies.

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