

# How Health Policy Influences HTA Outcomes: Comparative Insights from Ukraine, Moldova, and Bulgaria

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## Background and Objective

- This study examines the influence of national health policy frameworks on health technology assessment (HTA) outcomes in three Central and Eastern European countries—Ukraine, Moldova, and Bulgaria.
- It aims to explore how political, regulatory, and institutional contexts shape HTA effectiveness and reimbursement decisions.

## Methods

- A comparative, descriptive analysis was conducted using legislative documents, HTA guidelines, and peer-reviewed literature from each country.
- Stakeholder interviews (where available) and institutional reports were reviewed to assess how policy priorities, regulatory maturity, and system constraints affect HTA implementation and decision-making.

## Conclusions

- Health policy plays a central role in shaping HTA processes across the region.
- While Bulgaria benefits from greater policy stability, Ukraine and Moldova face institutional and/or contextual barriers.
- In Ukraine, the ongoing crisis resulting from the conflict has strained institutional capacity and created a need for more flexible and responsive HTA processes.
- Strengthening policy-HTA alignment and regional collaboration could support more transparent and equitable access to innovative therapies.

## Results

- In Ukraine, HTA has evolved since the adoption of national legislation in 2016 and continues to align with international practices. Since 2022, conflict-related disruptions have strained the healthcare system, highlighting the need for technical capacity and agile, responsive HTA processes.
- In Moldova, HTA elements have been applied to outpatient medicine reimbursement since 2015, with price negotiations and device coverage added in 2021. In 2024, EU-aligned HTA arrangements were prepared and are being reviewed to introduce a system-wide mechanism that ensures transparent processes and shared benefits for all health-system stakeholders.
- Bulgaria operates a structured HTA process, but implementation is often influenced by shifting policy priorities and cost-containment goals within the National Health Insurance Fund.
- Across all three countries, strategic priorities, budget constraints, and institutional coordination significantly influence HTA outcomes and access timelines.

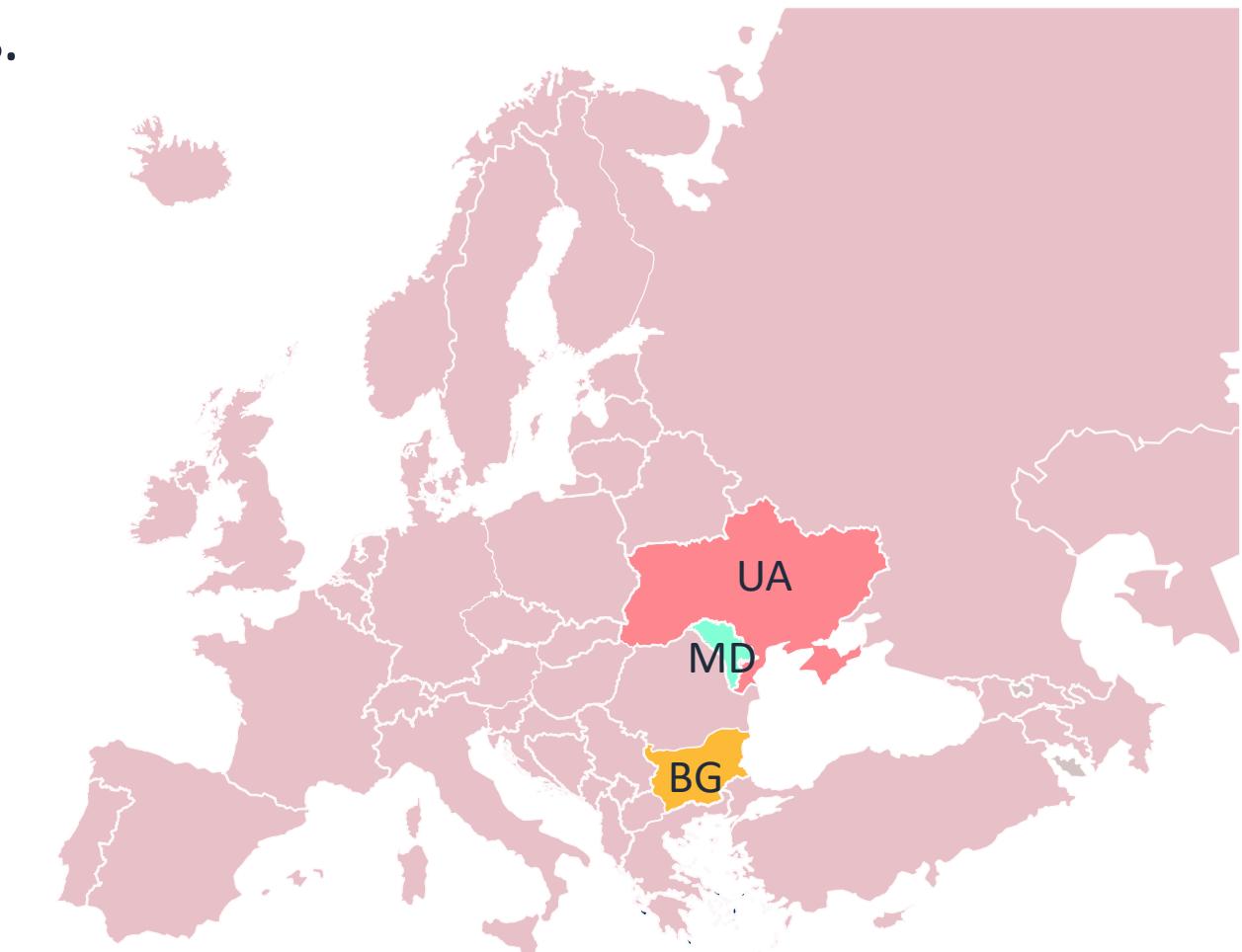


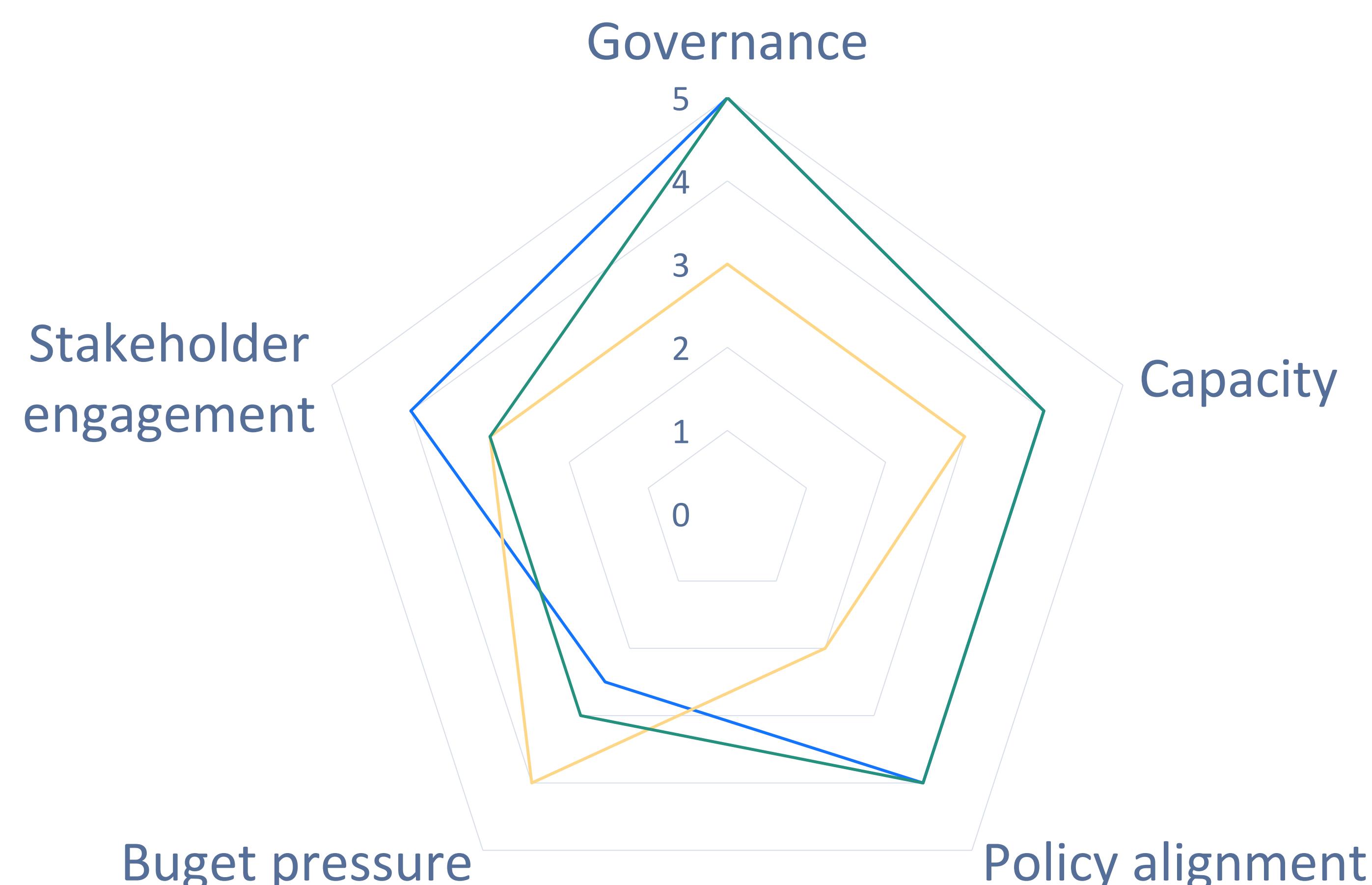
Table 1: Overview of answers to the HTA Policy questionnaire

Dimension	Ukraine	Moldova	Bulgaria
System evolution	2020 HTA law, >140 assessments	Emerging 2015, limited framework	Since 2003 PDL, structured process
Policy influence	Driven by priorities	Priorities and policy settings	Policy > CEA threshold
Challenges	Capacity expansion	Limited expertise, data & commitment	JCA workload + data
Budget	Budget constraints	National Health Insurance Company (CNAM) limits	National Health Insurance Fund (NHIF) discounts
Flexibility	Abbreviated HTA	Simplified for essential drugs	Shorter timelines w/JCA
Stakeholders	Defined roles	Consultative, method-driven, development of partners support	EU network engagement
Key policy factor	Reliable data use	Budget sustainability and political priority	Cost control
Collaboration	Joint training + research	Method alignment + price talks	Joint price negotiations

**Across CEE, policy shapes evidence into access.**

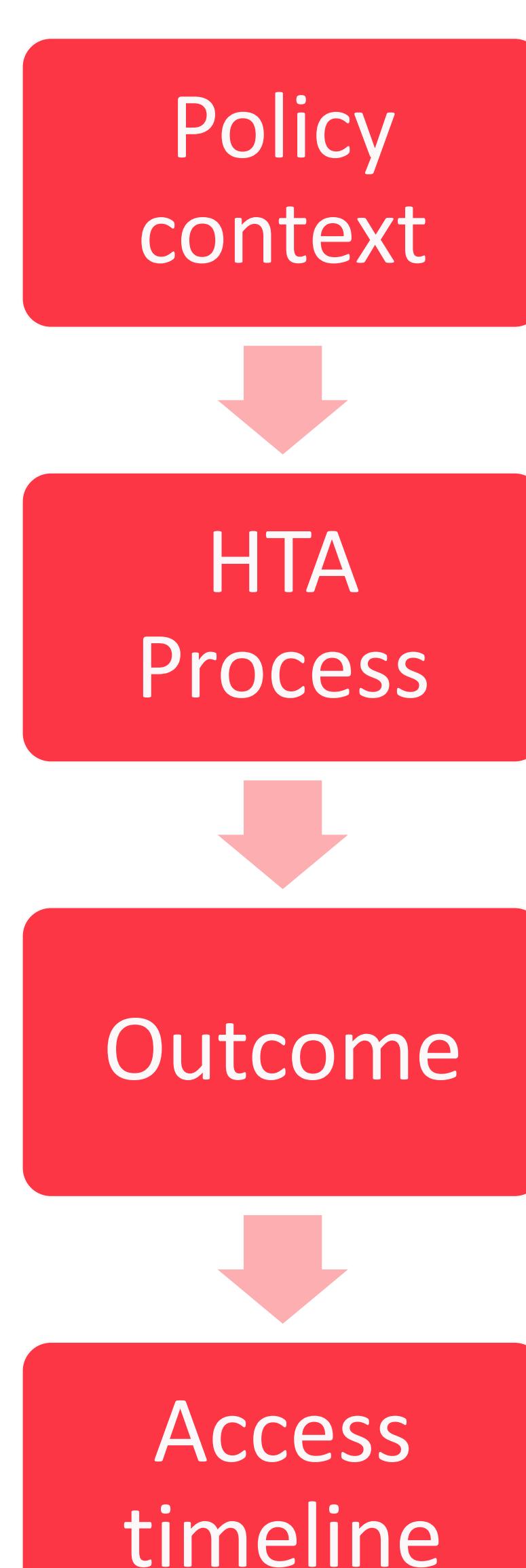
## Horizontal Radar Chart comparing HTA maturity dimensions

—Ukraine —Moldova —Bulgaria



Dimensions:

- Governance & Legal Framework – presence of HTA law, formal body, transparent procedures.
- Institutional Capacity – size and expertise of HTA staff, use of guidelines, data systems.
- Policy Alignment – how well HTA recommendations translate into real reimbursement policy.
- Budget Pressure – how strongly fiscal limits constrain HTA outcomes.
- Stakeholder Engagement – inclusion of patients, academia, and industry in HTA processes.



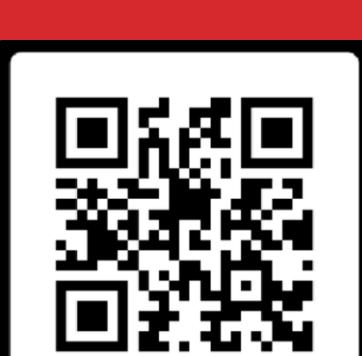
UA: RAPID BUILD-UP VS CAPACITY GAP

MD: BUDGET-LED DECISION-MAKING

BG: MATURE SYSTEM, POLICY-DRIVEN

References:

- Surgey G, et al. The development of a roadmap for Health Technology Assessment implementation in Moldova. *Front Public Health*. 2024;12:1470061. doi:10.3389/fpubh.2024.1470061.
- World Health Organization (UHC Partnership). *Republic of Moldova country profile*. WHO; 2024. Available at: <https://extranet.who.int/uhcpartnership/>
- Compania Națională de Asigurări în Medicina (CNAM). *Annual Report 2024 and Budget Law Implementation*. Chisinau: CNAM; 2025.
- LOZAN O, CHITAN E, ANTON A, CHITAN E, OBRZUT G. Health technology assessment: management of the National Health System. State University of Medicine and Pharmacy. 2024; 240 pages. ISBN 978-9975-36119-3. <https://elmau.org/uploads/2023/10/Abstract-Book-2024.pdf>
- CHITAN E, VOLOIEI I, TIMOFI A, LOZAN O. Determinants of health technology assessment implementation in Republic of Moldova: Shaping and managing innovative health ecosystems. *The European Health Management Conference* 2024, 5–7 June 2024, Bucharest Romania. Abstract Book pp. 213. <https://elmau.org/app/uploads/2023/10/Abstract-Book-2024.pdf>
- Ministry of Health of Ukraine. Cabinet of Ministers Decree No 1300 (23 Dec 2020) and Order No. 593 (29 Mar 2021); National HTA Legislation and Guidelines. Kyiv: MoH; 2021.
- Surgey G, Pniashko O, et al. Introduction of HTA for Medical Devices in Ukraine. *Value Health*. 2022;25(S1):S79–S80.
- Surgey G, Pniashko O, et al. HTA for Medical Devices in Ukraine. *Value Health Res Issues*. 2024;7:100198.
- <https://elmau.gov.ua/dokumenta-china-otveta-na-voprosy-tekhnologii-zayavly-ta-dosye/role=ua>
- National Council on Prices and Reimbursement of Medicinal Products (NCPRMP). *Ordinance on the Conditions, Rules and Procedure for Regulating and Registering Prices of Medicinal Products*. Sofia; 2024.
- Iskrov G, et al. Prospects of Risk-Sharing Agreements for Innovative Therapies in Bulgaria. *Front Pharmacol*. 2023;14:1150179. doi:10.3389/fphar.2023.1150179.
- European Commission. Regulation (EU) 2021/2282 on Health Technology Assessment and amending Directive 2011/24/EU. *Off J Eur Union*. 2021 Dec 22; L 458/1–70.



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