An overview of pricing and reimbursement frameworks for medicinal products in Central Eastern European countries: mechanisms, rules, and Managed Entry Agreements.

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SUMMARY

OBJECTIVES

- Central Eastern European (CEE) countries encounter significant challenges related to pricing and reimbursement of medicinal products.
- Consequently, these countries are positioned in the lower quartile of medicine availability rates in Europe.
- This study aims to clarify the pricing and reimbursement frameworks across the CEE region.

METHODS

- Desk-based research was conducted from 1st December to 24th December 2024, using targeted searches on Health Technology Assessment (HTA) body websites and PubMed.
- Screening was performed by an independent reviewer and verified by a team of experienced market access professionals.

FINDINGS

- With the exception of Czechia and Bulgaria, all CEE countries fall below the European average in availability rates of medicinal products.
- CEE countries employ a mix of external and internal reference pricing, manufacturer-set pricing, or pricing based on the lowest manufacturer price from reference countries.

RECOMMENDATIONS

- There is significant variation in pricing models, from internal and external reference pricing, to direct manufacturer negotiations. By encouraging collaboration across CEE countries, especially in the context of the upcoming Joint Clinical Assessment (JCA), processes can be streamlined.
- It is important for manufacturers to understand how pricing and reimbursement decision-making will be conducted in individual CEE countries. This is especially crucial when exploring potential launch sequences.
- Most CEE countries experience longer-than-average delays. Therefore, simplifying and accelerating decisions by leveraging early dialogue between manufacturers and decision-makers could accelerate patient access.

BACKGROUND & AIMS

- CEE countries frequently encounter challenges with pricing and reimbursement frameworks, which can substantially affect the accessibility of medicinal products and lead to disparities across countries.
- According to a 2024 Waiting to Access Innovative Therapies (WAIT) study, CEE countries account for 78% of the lowest quartile of medicine availability rates in Europe[1].
- Excluding Czechia and Bulgaria, all CEE countries fall below the EU average in medicine availability rates, and all but Czechia experience longer-than-average times from central approval to availability.
- Understanding CEE reimbursement frameworks is crucial for improving access to essential treatments and ensuring that patients receive timely and effective care.
- This study aims to provide a comprehensive overview of the pricing and reimbursement frameworks for medicinal products across CEE countries.

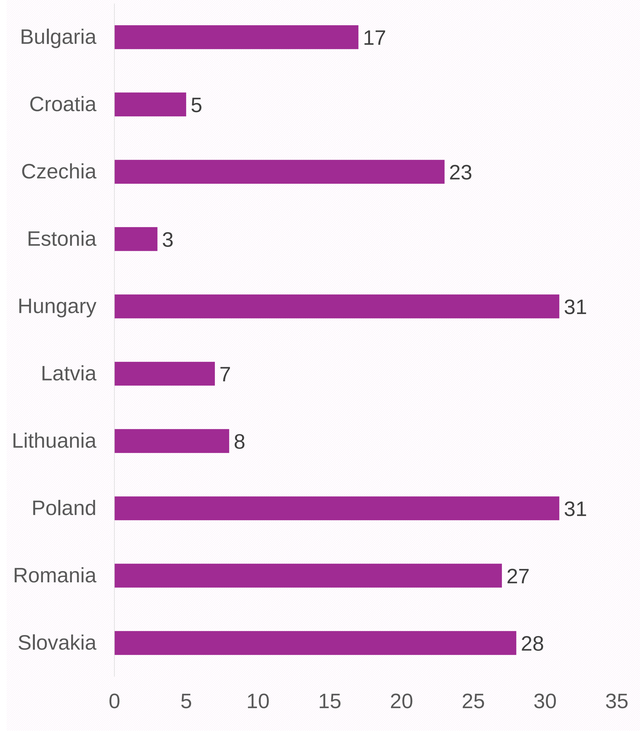
METHODS

- Targeted searches of HTA body websites and PubMed were conducted from the 1st of December to 24th of December 2024.
- The aim of the desk-based research was to extract detailed information on pricing regulations, key steps in the pricing and reimbursement procedures, special considerations for various categories of products (including orphan, non-orphan, and innovative medicines), and information on managed access agreements (MEAs) across CEE countries.
- CEE countries included: Bulgaria, Croatia, Czechia, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, and Slovakia.
- A single independent reviewer performed screening to ensure the relevance and quality of the gathered data.
- Following this, a team of experienced market access professionals verified the findings to ensure accuracy and relevance.

RESULTS

- The pricing of medicinal products varies across CEE countries due to an array of factors such as pricing regulations, economic conditions, market dynamic, and others.
- CEE countries have varying levels of reimbursement that is given to the manufacturer (Table 1).
- This reimbursement level varies depending on the type of disease, the type of treatment (essential, symptomatic, palliative, etc.), clinical significance, and budget resources allocated for procurement of the medicine.
- Seven of the ten countries, including Austria and Czechia, employ external reference pricing, benchmarking the prices of medicinal products against other countries (Figure 1).
- A minority of countries, specifically Poland and Lithuania, use internal reference pricing. A pricing system where prices are determined based on domestic market dynamics.
- Other CEE countries combine the lowest manufacturer price from reference countries with therapeutic value assessments.
- Three countries, including Bulgaria, Hungary, and Croatia, set prices through wholesalers or manufactures.
- MEAs play a crucial role in the pricing and reimbursement frameworks for medicinal products in CEE countries. These agreements are designed to facilitate access to innovative treatments while managing the financial risk associated with high-cost medicines.
- Policies on MEAs differ from country to country.
- Some CEE countries require mandatory agreements, while others adopt flexible approaches like financial risk-sharing agreements for uncertain clinical outcomes.
- The European Union (EU) JCA is expected to standardise clinical evidence assessments across countries. This standardisation will likely influence the design and negotiation of MEAs, promoting greater consistency and transparency in the pricing and reimbursement processes.

Figure 1. Number of reference countries considered while external reference pricing.



CONCLUSIONS

- Pricing and reimbursement policies in CEE countries are highly diverse, shaped by a combination of regulatory frameworks, economic conditions, and market dynamics.
- Pricing variations arise from differences in national pricing regulations, such as the use of external and internal reference pricing, as well as disparities in the economic capacity.
- Reimbursement levels differ based on the type of disease, the nature of the treatment, and the availability of healthcare budgets.
- These factors collectively contribute to significant challenges in ensuring equitable access to medicines across countries.
- As a result, many CEE countries struggle with the timely and consistent availability of medicinal products compared with other European countries.
- MEAs and other strategies aim to balance access to innovative treatments with cost containment, to mitigate the financial uncertainties whilst ensuring patients have access to necessary treatments.
- The introduction of the JCA is expected to standardise clinical evidence assessments, further influencing MEAs and pricing processes.

Table 1. Considered reimbursement levels in CEE countries

	Bulgaria	Croatia	Czechia	Estonia	Hungary	Latvia	Lithuania	Poland	Romania	Slovakia
Levels of reimbursement	25% 50% 75% 100%	85% 100%	There are no reimbursement levels or categories of co-payments	50% 75% 90% 100%	* 25% * 55% * 80% ** 50% ** 70% ** 90% ** 100%	50% 75% 100%	50% list A 50% list B 80% 90% 100% 100% list C	50% flat price co-payment 70% 100%	90% list A 90% list B 100% list C 20% list D	100% or partial (between 0 and 100%)

* Normative reimbursement
** Indication-linked reimbursement
Abbreviations: CEE, Central Eastern European; EU, European Union; HTA, health technology assessment; JCA, Joint Clinical Assessment; MEAs, Managed Entry Agreements; WAIT, Waiting to Access Innovative Therapies.

References

1. *EFPIA (2024), EFPIA Patients W.A.I.T. Indicator 2023 Survey. Retrieved from: https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf.*

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