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UKRAINE

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Regulatory Advancements in the Ukrainian Pharmaceutical Market: Adoption of Law No. 4239

On February 12, 2025, the Verkhovna Rada of Ukraine approved Law No. 4239, introducing significant changes to the regulation of the pharmaceutical market. Key provisions include:

- Establishment of a National Price Catalog covering all medicines, both those financed by public funds and out-of-pocket expenditures. The first price declaration applies to medicines included in the National List of Essential Medicines.
- Implementation of external reference pricing (ERP) for medicines listed in the National Price Catalog. The ERP system is based on a reference basket of eight countries (Poland, Czech Republic, Hungary, Latvia, Slovakia, Romania, Moldova, and Bulgaria) and follows a standardized formula: exclusion of the lowest price and calculation of the average of the three lowest remaining prices
- Special pricing rules for originator medicines, which must undergo a separate price declaration procedure without ERP application.
- Price linkage for generics and biosimilars, establishing a structured pricing approach in relation to originator medicines.
- Limitation on maximum wholesale markup, restricting it to no more than 8%.

The law also mandates that pharmacies and pharmacy chains—regardless of ownership—must offer at least one of the three lowest-priced medicines available for purchase within the National Price Catalog when selling a drug with the same international non-proprietary name (INN), release form, and dosage.

Implementation Timeline for Price Declarations

Law No. 4239 specifies strict timelines for the initial price declaration of medicines registered in Ukraine:

- National List of Essential Medicines: within 60 days from the law's entry into force.
- All prescription medicines (excluding those in the National List): within 90 days.
- All other registered medicines: within 120 days.

Expansion of Managed-Entry Agreements (MEA)

The project of legislation outlines plans to expand managed-entry agreements (MEA) by introducing mixed financing models. This expansion will allow MEAs to be funded not only from the state budget but also from local budgets allocated for healthcare programs and initiatives.

CHANGES IN REIMBURSEMENT

By the Order of the Ministry of Health of Ukraine dated March 13, 2025, No. 440, the List of Medicines and the List of Medical Devices subject to reimbursement under the State Guarantees Program for Healthcare Services, as of February 26, 2025, have been approved. The order came into effect on March 31, 2025.

The List of Medicines includes:

- 502 medicines, which is 30 more positions than in the current List of Medicines.
- 61 insulin products, which is 2 fewer positions than in the current List of Medicines.
- 11 combined medications, which is 2 more positions than in the current List of Medicines.

The List of Medical Devices consists of 42 positions, which is 3 fewer than in the current List.

In 2024 was established the HTA Expert Committee - independent advisory committee for SEC MOH for appraisal process.

Law No. 123 establishes restrictions on conducting economic activities related to the sale of medicines. In particular, economic agreements that involve the provision—directly or indirectly—of marketing services, medicine promotion services, or other services related to the sale of medicines to end consumers at retail points of sale are permitted **only** between economic entities that manufacture or import medicines and a pharmacy or pharmacy network.
The procedure and conditions for providing such services will be separately approved by the Cabinet of Ministers of Ukraine.
Additionally, economic agreements involving the provision of advertising services for medicines **outside** retail points of sale are permitted **only** with economic entities that are neither under common control nor affiliated with licensees engaged in retail trade of medicines.

SPECIAL TOPIC: Current advances in HTA

Health Technology Assessment (HTA) in Ukraine

Health Technology Assessment (HTA) became mandatory in Ukraine in 2020 for any new medicine covered by public funds, in accordance with the Procedure for Conducting State HTA, approved by Resolution of the Cabinet of Ministers of Ukraine No. 1300, dated December 23, 2020.
The HTA Department of the State Enterprise "State Expert Center of the Ministry of Health of Ukraine" (SECMOH) was established in January 2019 to develop recommendations and provide evidence-based insights to the Ministry of Health (MoH) for rational healthcare financing. Its key functions include assessing the comparative efficacy, safety, cost-effectiveness, and organizational impact of health technologies to support decisions on their inclusion or exclusion from regulatory lists. The HTA Department actively collaborates with patients, clinicians, industry representatives, and policymakers.

International Cooperation

The HTA Department of SEC MOH maintains partnerships with ISPOR, NICE, HTAi, INAHTA, and the Norwegian Institute of Public Health to align Ukraine's HTA practices with international standards.

HTA Implementation and Impact

Final decisions on reimbursement of medicines made by the Ministry of Health based on HTA recommendations. Between 2021 and 2025, SECMOH conducted 119 HTA evaluations. The HTA process includes: core procedure – full expertise of company submissions; abbreviated procedure – assessments conducted upon MOH request. Among the 119 HTA conclusions, over 40% included recommendations for considering a Managed Entry Agreement (MEA). 15 MEAs were conducted by MOH and SE MPU. Additionally, 32 new medicines (by INN) were included in the National Essential Medicines List in 2024, following HTA recommendations and alignment with the WHO Essential Medicines List (EML). Also in 2024 was introduced new service - scientific advice and public discussion of project of HTA conclusion.

Alignment with EU Legislation

To evaluate the compliance of Ukrainian HTA regulations with European Union law (EU acquis), SECMOH, in collaboration with the MoH, conducted a comprehensive legal analysis. This assessment focused on Regulation (EU) No. 2021/2282 of the European Parliament and of the Council, dated December 15, 2021, on HTA, which amends Directive 2011/24/EU. The findings and future implementation strategies were officially presented during the bilateral screening meeting held on February 12, 2025, in Brussels.

Proposed Legislative Amendments

Based on a detailed gap analysis, key proposals for legislative amendments have been developed, focusing on: recognition of HTA outcomes from EU Member States before accession – integrating Joint Clinical Assessments (JCA) at the EU level into national HTA conclusions based on company submission data; implementation of amendments as an EU Member State – ensuring the alignment of Ukraine's HTA system with EU regulations upon accession.