

Pharmaceutical Market Monthly Report - November 2025

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Summary

November Highlights

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Several updates were registered in November, including the addition of new reimbursed medicines and expansions of indications for existing therapies, updated therapeutic protocols, and the National Catalog of medicine prices was updated, while the Ministry of Health and the National Health Insurance Fund received significant budget increases to ensure continuity of medical services, personnel payments, and insurance benefits. Looking ahead to December, new and updated therapeutic protocols are expected, new and updated prices in the Public Catalog of medicine prices, as well as prices for infusion medicines included in CANAMED, and a Government decision establishing national cancer screening registries for breast, cervical, and colorectal cancers could be adopted and published.

November Highlights

List of reimbursed and free medicines updated: Approximately 40 new molecules were included in the reimbursement system for the first time, while for others, the therapeutic area for which they can be prescribed and reimbursed was expanded starting December 1. The medicines include new therapies and as well as indication extensions for serious chronic diseases, neurological, endocrine, metabolic, rheumatological, pulmonary diseases, oncological conditions, and rare diseases, which will be available to patients reimbursed.

Therapeutic protocols amended: Almost 20 therapeutic protocols for prescribing and monitoring the treatment with medicines that are given to the insured on the basis of a medical prescription were updated in November, for medicines that are used to treat conditions such as type-2 diabetes, acute leukemia, chronic lymphocytic leukemia, renal cell carcinoma, breast cancer, or venous thromboembolism.

National Catalog of medicine prices updated: The National Catalog of medicine prices authorized for marketing in Romania which can be marketed by entities that are in contractual relations with health insurance houses, county public health departments or with the Ministry of Health, was updated, with prices for 8 medicines authorized for special needs that required inclusion in CANAMED on an emergency basis, which entered into force on November 25, and 42 other new prices for medicines, along with price updates and prices removed starting with December 1.

Second budget correction: The budget of the Ministry of Health was supplemented in the second budget revision of this year, by RON 1.51 billion compared to the level established in the first budget revision, while the budget of the National Single Fund for Social Health Insurance was increased by RON 1.596 billion, on the revenue side, and by RON 2.233 billion, on expenses for ensuring continuity in the provision of medical materials and services, for the payment of salary influences for personnel employed in public health units and for the granting and settlement of sick leave and social health insurance benefits.

What to expect in December

New therapeutic protocols: After several protocols for prescribing and monitoring the treatment with medicines that are given to the insured based on a medical prescription were updated last month, approximately 14 new protocols should be introduced in December, and more than 10 other protocols updated. The list of conditions includes chronic primary immune thrombocytopenia, chronic obstructive pulmonary disease, renal carcinoma, spinal muscular atrophy, severe asthma, or metastatic breast cancer.

Public Catalog of medicines updates: The National Catalog containing the maximum prices of medicines which can be marketed by pharmacies or other entities that are not in contractual relations with health insurance houses, county public health departments or the Ministry of Health, will be updated with approximately 40 new prices to be included and over 20 amended, and other removed.

Prices for infusion medicines could be approved: The maximum prices of infusion medicines intended for healthcare units, valid in Romania, which can be used/marketed by marketing authorization holders or their representatives and wholesale distributors, in accordance with the new grid of manufacturer price ranges and mark-up rates, could be approved this month, as a draft order is in consultation since November. Thus, a new annex will be included in CANAMED, containing the respective prices.

Q3 2025 clawback classification: The list relating to the third quarter of 2025, which contains the classification of human medicines authorized for marketing in Romania and reported by medical service and medicine providers, supported from the National Health Insurance Fund and the budget of the Ministry of Health, into type I and type II medicines, for which marketing authorization holders owe a quarterly contribution calculated differentially, should be published in December.

Breast, cervical and colorectal cancer registries: A Government decision that proposes the establishment of the National Breast Cancer Screening Registry, the National Cervical Cancer Screening Registry and the National Colorectal Cancer Screening Registry, as well as regulating the modalities for carrying out activities for the establishment of databases resulting from the collection, registration, storage and classification of data and information on persons eligible to benefit from screening services, for monitoring participation in screening, the incidence of precancerous and cancerous lesions, assessing the quality of screening medical services and the impact of these medical services, could be adopted and published in the Official Gazette in December.