

Poland

Recent and planned developments in pharmaceutical policies 2025/2026

CHANGES IN PRICING

Refining the Effective Price Definition

Granting the Economic Commission authority to negotiate Minimum Drug Supply Declaration - Supply volumes to be negotiated with the Economic Commission - final approval by the Minister of Health.

Market authorisation holders (MAHs) submitting reimbursement applications upon request from the Minister of Health eligible for procedural incentives, e.g. no verification analysis fee and no full HTA submission for generics (only BIA required), and 50% fee for verification analysis by the Agency for Health Technology Assessment and Tariff System (AOTMIT) for innovative drugs.

Change in the threshold price calculation method for: new drugs applying for reimbursement in complex molecule groups and new presentations of drugs from the same manufacturer already listed for Reimbursement.

Amendments to the statutory 25% price reduction mechanism for innovative drugs introduction of a 'gradual' price reduction mechanism.

CHANGES IN REIMBURSEMENT

New Paradigm in Rare Disease Reimbursement - applying MCDA in Orphan Drug Assessment.

Phasing Out the Minimum Drug Supply Declaration Algorithm. Algorithm led to multiple interpretative issues: vague definition of the algorithm's variables, rigid proportionality misaligned with actual market shares, no reference to historical data, no consideration of the MAH's logistics capacity. Complete removal of the algorithm. Descriptive, non-numerical guidelines.

Minister of Health empowered to request a reimbursement application from a MAH. Minister of Health empowered to request a reimbursement application from a MAH. Statutory tool to set reimbursement priorities, with no penalties for opting not to apply.

Introduction of reimbursement for drug wastage in individually dosed therapies (intravenous dosing). Currently, reimbursement is based solely on administered doses (quantities), with hospitals bearing costs of dose-related wastage.

Possibility to submit a reimbursement application without proof of physical availability of the product at the time of application

OTHER CHANGES

- **The above section outlines proposed and likely—though not exhaustive—changes included in the ongoing amendment of the Reimbursement Act.** Key changes affecting therapy availability, efficiency of decision-making processes and transparency. Reforms cover areas such as rare diseases, named-patient import, the Economic Commission, compounded substances and pharmacy compounding, digitalization, and data collection.
- **Automation of Reimbursement** - The Ministry of Health, in cooperation with the e-Health Centre and MAHs, has launched work on a system that will automatically determine reimbursement levels for prescribed medicines, foods for special medical purposes, and medical devices. The system will link reimbursement indications with International Statistical Classification of Diseases and Related Health Problems codes (ICD codes). Prescribers will select an ICD code or, if insufficient, answer system-generated questions about the patient's clinical condition.

SPECIAL TOPIC:

Regulation, pricing and reimbursement of pharmaceutical combination products

Definition of a Fixed-Dose Combination (FDC)

- No single statutory/legal definition of a "combination product" in Polish pharmaceutical or reimbursement law
 - In practice, interpretation relies on guidance from the European Medicines Agency (EMA), including: *Guideline on Clinical Development of Fixed Combination Medicinal Products*
 - According to EMA: A fixed-dose combination (FDC) is a medicinal product containing ≥ 2 active substances presented in a single pharmaceutical form with fixed doses
 - Additional EMA criteria: Components must have a justified therapeutic rationale for combined use and the combination should provide at least one of the following - improved efficacy, or improved safety, or Improved patient convenience/adherence (compliance)
- Therefore, in Poland, the concept of a "combination product" is defined functionally (via EMA guidance), not legislatively

No dedicated pricing or reimbursement guidelines specifically addressing FDCs as a separate category. Combination products are assessed under general reimbursement framework (same rules as single-ingredient products), including: HTA evaluation, clinical and economic assessment, reference pricing / limit groups (where applicable)

In the absence of specific legal provisions, the only **consistent methodological approach to combination products derives from HTA practice, as applied by the Agency for Health Technology Assessment and Tariff System**, whereby each new technology is assessed in comparison to the relevant standard of care, and for FDCs, this typically entails a comparison between the fixed-dose combination (single product), and the same active substances administered concomitantly as separate products (free combination).

Amendment to the Reimbursement Act:

Combination drugs do not differ in effectiveness, application and safety of use from their single-component counterparts, while ensuring better adherence in the therapeutic process. The reimbursement system lacks complex drugs that are highly positioned in the current clinical recommendations for population diseases.

- The amendment proposes to abolish the requirement to submit a **complete set of analyses and the fee for preparing a verification analysis** in the case of applications for compounded drugs reimbursed in a pharmacy, provided that the indications of their single-component equivalents are financed to the same extent → this will simplify the reimbursement procedure for this group of drugs, contributing to their greater share in systemic reimbursement, which from the payer's perspective may result in generating additional savings due to the significantly lower costs of complex drugs compared to their single-component equivalents.