Ireland

Recent and planned developments in pharmaceutical policies 2025

CHANGES IN PRICING

Pricing Framework Agreements with Pharmaceutical Industry:
1st October 2024: Rebate payable on all patent protected, exclusive medicines increased to 9% as per current Framework Agreement (2021- 2025).
Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI) Framework Agreements due for re-negotiation at the end of 2025. Currently considering factors for inclusion in the revised agreements.

Framework Agreement price reductions 2024: The IPHA Agreement allows for an annual, downwards only, pricing realignment exercise. In 2024, 812 products were subject to price reductions generating savings of €271m. The IPHA Agreement also allows for price reductions of medicines that become Patent-Expired Non-Exclusive Medicine. In 2024, 50 products were subject to price reductions generating savings of €160m.

Reference pricing: The Health (Pricing and Supply of Medical Goods) Act 2013 provides for a system of generic substitution and reference pricing for lists of interchangeable medicines. In 2024 a total of 56 interchangeable groups were reviewed. 21 interchangeable groups were subject to the setting of a new reference price e.g. lenalidomide price reductions estimated to achieve €13 million efficiencies in one year.

CHANGES IN REIMBURSEMENT

Free Contraception Scheme introduced in September 2022 for persons aged 17-35 years ordinarily resident in Ireland. The scheme includes: consultations, prescriptions, emergency contraception, fitting and removal of long-acting reversible contraception. Types of contraception include contraceptive injections, implants, IUDs (coils), patches, rings and oral contraceptive pills.

Prescription Charges for medical card holders is currently €1.50 per item for people <70 years to a maximum of €15 per month per family an€1 per item for people >70 years to a maximum of €10 per month per family. Drug Payments Scheme is currently €80 per calendar month per family.

Managed Access Protocols (MAPs): Increased volume of applications for subpopulations of the licensed indication. Reimbursement approval is based on managing this restricted reimbursement approval, leading to an increase in number of Managed Access Protocols (MAPs) overseen by the HSE Medicines Management Programme (MMP). MAPs support access to high-cost medicines, while providing oversight, governance and budgetary certainty to the payer e.g. liraglutide and dupilumab.

OTHER CHANGES

Pricing and Reimbursement (P&R) Application Tracker: The P&R Application Tracker was launched in December 2024. This is a publically accessible database, The purpose of the tracker is to increase information accessibility and transparency of the pricing and reimbursement process of medicines in Ireland. The tracker captures the current status of medicines as they navigate through the standard HSE pricing and reimbursement application process, to provide a complete timeline for each medicine. There are currently 38 medicine applications available on the tracker which is available at:
https://www.sspcrs.ie/portal/rdt/pub/application/home

HSE Health App for smartphone: Launched by the Department of Health in Feb 2025. Educational and informative source for Irish patients offering a secure way to access HSE information, find health services, keep and find personal health information.

Electronic Prescribing and the National Medicinal Product Catalogue (NMPC): Underway and in procurement phase. Roll out phase likely in 2026.

Health Service budget considerations: €30 million allocated to new medicines in 2025 – arising from savings generated from efficiencies of other medicines.

Price Increase Requests: Requests for price increases have increased significantly over the past 3 years. 2 received in 2021, 10 (2022), 32 (2023), 31 (2024).

SPECIAL TOPIC:
Current advances in HTA
(for EU Member States: Implications from EU-HTA Regulation)

Description of the HTA system in Ireland: The HSE commissions the NCPE (National Centre for Pharmacoeconomics) to assess new medicines following receipt of an application for reimbursement. The NCPE employs a two-step process to make recommendations. All medicines are subjected to a preliminary Rapid Review. Medicines where there is a query in relation to the comparative clinical efficacy and/or value for money will also be selected for a full health technology assessment (HTA). The outcome of the Rapid Review and/or full HTA is a recommendation to the HSE on reimbursement.
The HSE considers a number of factors along with the NCPE recommendation when deciding whether to reimburse a medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013 and include unmet need, clinical evidence, cost effectiveness and budget impact.

Implications of the EU Regulations: The NCPE in Ireland will work with other individual EU States participating in joint assessments of new medicines in 2025. The first products are due to be assessed in the coming months. The NCPE will also actively contribute to the Joint Scientific Consultations, providing early scientific advice on proposed clinical trials to pharmaceutical companies thereby enhancing the quality of future clinical evidence.