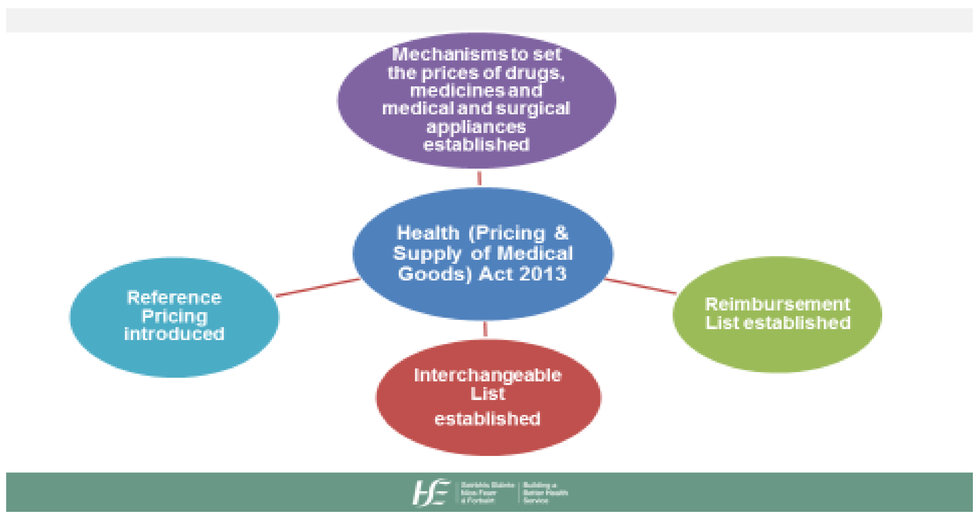
PHARMACEUTICAL SYSTEM IN IRELAND

Pricing and Reimbursement of Medicines

Health (Pricing and Supply of Medical Goods) Act 2013

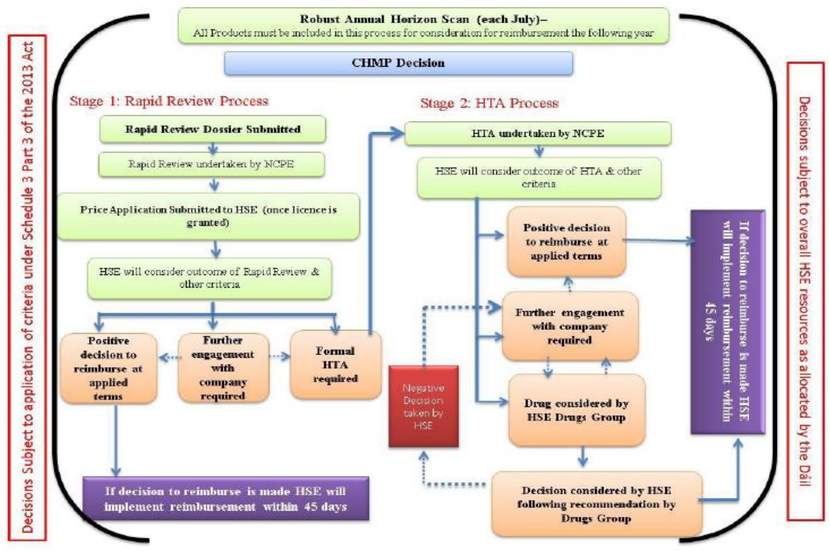


IPHA (Irish Pharmaceutical Healthcare Association) Agreement 2016

- Applies to medicines reimbursed via the Community Drug Schemes (including High Tech Arrangements) and Public Hospitals
- Revised basket of countries since previous agreement agreed: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK
- Ceiling Price set by reference to the average of same basket of 14 countries
- Prices realigned annually (downwards only)
- Rebates on sales to be paid annually (currently 5.5%)

Principles and Processes for the Assessment of New Medicines in Ireland (IPHA Agreement 2016 Schedule 1)

- Companies to submit annual Horizon Scan
- Rapid Review Dossier +/- Full Health Technology Assessment Dossier
- At all stages of the decision-making process the Health Service Executive (HSE) will subject each medicine to an assessment of affordability in accordance with the 2013 Act

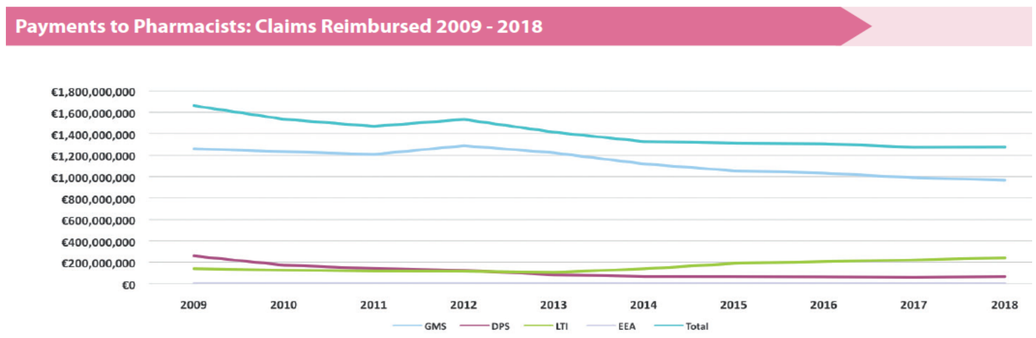


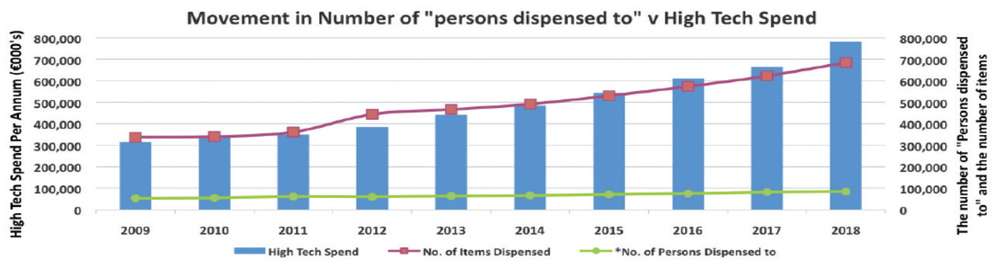
Medicines Management Programme

Aims to promote safe, effective and cost effective prescribing via a number of activities:

- The Preferred Drugs initiative, which identifies a single 'preferred drug' within a therapeutic drug class, offers prescribers useful guidance on selecting, prescribing and monitoring a drug for a particular condition.
- Prescribing Tips and Tools, which offer clear, concise guidance on the prescribing and monitoring of these drugs for their licensed therapeutic indications.
- Prescribing and Cost Guidance focus primarily on the associated costs of particular treatments, as well as providing useful information for prescribers and other healthcare professionals regarding prescribing, monitoring and reimbursement.
- Managed access processes for some reimbursable medicines.

Spend on Medicines 2009-2018





Recent Changes in Pricing and Reimbursement

Changes in Pricing

- Between June and August 2019, the HSE completed a review of reference prices previously set for interchangeable medicinal products as per the criteria listed in Section 24 of the Health (Pricing and Supply of Medical Goods) Act 2013. A total of 60 interchangeable groups were reviewed during this period. In addition, 6 interchangeable groups were subject to the setting of a new reference price.
- Between May and July 2019, the HSE engaged with suppliers of medicines to conduct a Price Realignment exercise (downwards only) in accordance with Sub-Clause 5.2 of the 2016 IPHA Agreement. Realigned prices were published on the HSE website and came into effect on 1st July 2019.

Changes in Reimbursement

- The requirement for prior reimbursement approval for non first-line standard oral nutritional supplements (ONS) came into effect on 1st July 2019.
- Rheumatology, Dermatology and Gastroenterology medicines were added to the the High Tech Hub from 1st June 2019. The High Tech Hub Ordering and Management System, which was rolled out nationally in March 2018, was developed to streamline administration of the High Tech scheme for pharmacists and to provide enhanced visibility of stock management and spending on this scheme to the HSE.

Other Developments

- In May 2019, the Medicines Management Programme completed the evaluation process for the identification of the best-value biological (BVB) medicines for TNF-α inhibitors on the High Tech Drug Scheme.
- A Pilot project is ongoing to expand the treatment of Hepatitis C from hospital-based to community-based services.
- Preparing for Brexit - The Department of Health, the Health Products Regulatory Authority (HPRA) and the HSE are implementing a comprehensive and coordinated set of preparations to ensure continuity of health services and continued supply of medicines and medical devices in the event of a 'no deal' Brexit.
- The prescription charge for medical card holders will be reduced by 50 cent (to €1.50 per item for people under the age of 70 and to €1 per item for people over the age of 70) from July 2020.
- The monthly threshold for the Drugs Payment Scheme will be reduced by €10 (to €114) from September 2020.
- The medical card weekly income threshold for people over the age of 70 will be increased by €50 for a single person (to €550) and by €150 for a couple (to €1,050) from September 2020.
- The Government intends to expand free GP care to children under the age of 8 and free dental care for children under the age of 6 from September 2020.
- From 1st June 2019, HSE Primary Care Eligibility and Reimbursement Service (PCERS) assumed governance for the processing of all new and review Long-Term Illness (LTI) applications.
- The HSE Technology Review Committee for Rare Diseases, appointed in June 2018, is continuing activities in 2019. This Committee reviews proposals received from industry or expert groups in Ireland for funding of new products for rare diseases, or expanded indications for existing products or related predictive laboratory tests for rare diseases. It is also responsible for providing contributions to the development of clinical guidelines for relevant Orphan Medicinal Products (OMPs).

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