Ireland

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING	CHANGES IN REIMBURSEMENT
Drug cost rebate for proprietary medicines increased by 0.25% to 5.5% from 1st August 2018 Annual price realignment on 1st July 2018 to the average price (ex-factory or equivalent) in the 14 reference EU countries 41 medicinal products had reference price set/revised on 1st August 2018	Cystic fibrosis medicines added to High Tech hub

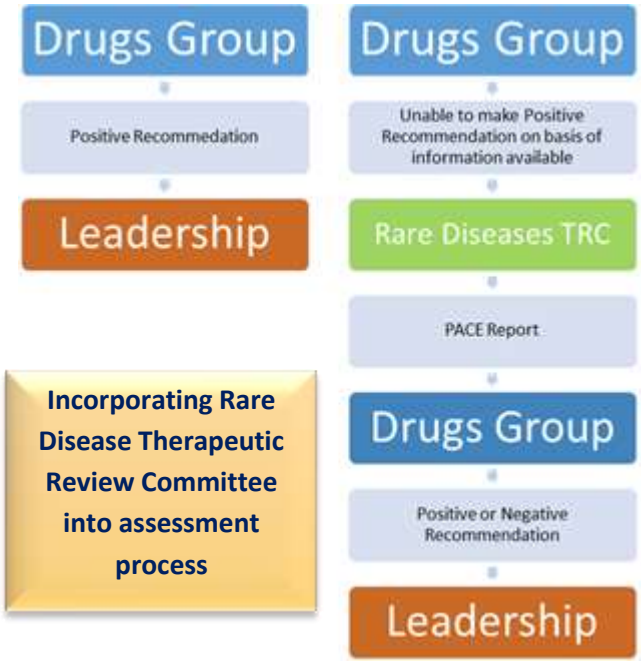
OTHERS CHANGES

- Oireachtas Joint Committee for Health (JCH) February 2018 Report on Evaluating Orphan Drugs
- HSE Medicines Management Programme (MMP) currently undertaking a period of consultation in relation to MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting
- HIQA Guidelines for the Economic Evaluation of Health Technologies in Ireland 2018 & Guidelines for the Budget Impact Analysis of Health Technologies in Ireland 2018

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

Recommendation 30 in the National Rare Diseases Plan for Ireland 2014-2018: The HSE develop a working group to bring forward appropriate decision criteria for the reimbursement of orphan medicines and technologies. The approach should include an assessment system similar to that for cancer therapies established under the national cancer control programme

July 2018: Prescribing Guidelines for the use of Sapropterin Hydrochloride (BH4) in the Testing of BH4 Responsiveness in Patients with Phenylketonuria (PKU) & in the Treatment of BH4 Responsive Patients with PKU



Please describe briefly if and what incentives are applied in your country in order to support the market entry of orphan medicines. It is not required to illustrate incentives set through EU legislation, i.e. Regulation (EC) No 141/2000 on orphan medicinal products.

- Countries outside the EU are invited to explain their regulatory framework on orphan medicines in brief.
- If an orphan medicine is authorised in your country, which special incentives are set to bring it to the market?

Please state, what incentives exist, who was responsible for the implementation (e.g. government, hospital, sickness fund, medicines agency) in your country and describe the incentives with regard to the following aspects (no need to cover all points):

- Research and development (e.g. specific promotion programmes of responsible institutions?)
- Market access prior to marketing authorisation (e.g. are compassionate-use programmes allowed in your country?)
- Availability (e.g. is the product available on the market for patients?)
- Place of treatment (e.g. out-patient and/or in-patient, Centre of Expertise)
- Pricing (e.g. do special arrangements for setting a price for orphan medicines exist in your country?)
- Funding (e.g. are there special funds to reimburse orphan medicines?)
- Reimbursement (e.g. do patients benefit from certain reimbursement schemes for orphan medicines in your country? Are reimbursement rates higher for orphan medicines?)
- Assessment of orphans (e.g. are dossier requirements different for orphan medicines?)

Similar questions have been responded in a study conducted by our institute, the Austrian Public Health Institute, in 2011. For more detailed information have a look at the PPRI Webpage:
http://whocc.goeg.at/Literaturliste/Dokumente/BooksReports/EMINet_Initial%20investigationOMP_updated2011.pdf and
https://ec.europa.eu/health//sites/health/files/files/orphanmp/doc/orphan_inv_report_20160126.pdf