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Colm Burke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

13th October 2022

PQ: 47132/22

**To ask the Minister for Health the total medicines budget over the period 2019 to date in 2022, by year; if he will provide details of the specific amount of expenditure which was allocated to rare diseases; and if he will make a statement on the matter. -Colm Burke**

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 47132/22), which you submitted to the Minister for Health for response.

The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, using the resources available (provided) to it and the HSE considers a range of proposals from Industry when assessing pricing and reimbursement applications. The 2013 Act enables the HSE to consider the terms of any framework agreement in place when it is making decisions in relation to pricing. The HSE robustly assesses applications to ensure available resources can be stretched as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds and are in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is required to consider the following criteria prior to making any decision on funding / reimbursement:

(1) The health needs of the public,
(2) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings

and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and
(9) The resources available to the HSE

The majority of HSE medicine related expenditure is covered by Primary Care Reimbursement Service (PCRS). In addition to making payments in relation to medicines under the General Medical Services Scheme, the Drugs Payment Scheme and the Long Term Illness Scheme, the HSE PCRS also makes payments to suppliers and manufacturers of High Tech drugs as part of the High Tech Arrangements. High Tech drugs are specialised medicines initiated in secondary care and are appropriate to be dispensed in the community setting. High Tech medicines include expensive and innovative pharmaceuticals. PCRS also facilitates direct payments to public hospitals involved in the provision of national treatment programmes such as the National Cancer Control Programme, the National Hepatitis C Treatment Programme and Multiple Sclerosis Services. This ensures that there is a single funding strategy for the use of such high cost medicines in public hospitals and that there is no variation in access to funding for these medicines across the country.

The HSE PCRS related expenditure on medicines is detailed in the Annual Reports https://www.sspcrs.ie/portal/annual-reporting/report/annual. For ease of reference the pertinent information requested is summarised in the table below:

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Pharmacist Drugs and Medicines | €950.56m | €985.28m | €1,015.64m |
| Pharmacist Fees and Stock Order Mark-Up | €375.31m | €382.10m | €407.50m |
| Pharmacist High Tech Patient Care Fees | €25.84m | €28.26m | €31.00m |
| Manufacturers / Wholesalers High Tech Drugs and Medicines | €849.22m | €916.13m | €988.99m |
| Hospital - Oncology Drugs and Medicines | €68.82m | €82.87m | €114.13m |
| Hospital - Hepatitis C Drugs and Medicines | €46.73m | €21.94m | €21.84m |
| Hospital - Multiple Sclerosis Medicines (MS) | €0m | €12.33m | €19.37m |
| Outpatient Parenteral Antimicrobial Therapy (OPAT) - Drugs, Medicines and Appliances | €8.24m | €8.14m | €10.35m |

The HSE PCRS also provide the gross amounts reimbursed in relation to the top 100 medicines reimbursed under the community drug scheme and hospital reimbursement arrangements. The HSE historically published this information in its annual reports. The HSE maintains this information on the open data section of the PCRS website. https://www.sspcrs.ie/analytics/saw.dll?PortalPages.

The HSE PCRS does not collate data on orphan status of any medicinal product reimbursable on Schemes within the HSE PCRS remit. The Committee for Orphan Medicinal Products (COMP) is the European Medicines Agency's (EMA) committee responsible for recommending orphan designation of medicines for rare diseases. This designation is for medicines to be developed for the diagnosis, prevention or treatment of rare diseases that are life-threatening or very serious. In the European Union (EU), a disease is defined as rare

if it affects fewer than 5 in 10,000 people across the EU. The European Commission decides whether to grant an orphan designation for the medicine based on the COMP's opinion. The orphan status for a medicine is subject to change (i.e. may be removed from the Community Register of designated Orphan Medicinal Products). To check/clarify the current orphan status of a medicine, the appropriate repository for this information is the EMA website (https://www.ema.europa.eu/en)'

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service