



Pádraig O'Sullivan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

13th June 2023

PQ: 26092/23

To ask the Minister for Health the number of patients who received medicines in 2022 under section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013, which refers to supply of a medicine outside of the reimbursement list; whether or not any of these medicines had an orphan designation; and if he will make a statement on the matter. -Pádraig O'Sullivan

Dear Deputy O'Sullivan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 26092/23), which you submitted to the Minister for Health for response.

Under section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013, the HSE may, at its discretion and subject to such conditions as it considers appropriate, make arrangements to supply an item, pursuant to section 59 of the Health Act 1970, to a patient notwithstanding that the item is not a listed item if the HSE is satisfied that -

- (a) the patient requires the item for clinical reasons, and
- (b) there is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

Supply of items under Discretionary Hardship Arrangements for those with full GMS eligibility falls under section 23 of the 2013 Act. However, these individual claims are processed via the Local Health Office, not the Primary Care Reimbursement Service. In 2022, 23,959 people accessed products under these arrangements.

The list of Exempt Medicinal Products assigned an administrative code under Community Drug Schemes was published in September 2016 (enclosed). This list was recently reviewed by the HSE Medicines Management Programme (MMP) and reimbursement support continues on the basis of the unmet clinical need in line with section 23 of Health (Pricing and Supply of Medical Goods Act) 2013. The revised list with 160 Exempt Medicinal

Products, which was effective from 1st March 2023 is enclosed. The number of patients with full GMS eligibility who accessed the EMP List of coded products in 2022 was 60,157.

Under the Drugs Payment Scheme (DPS), the number of patients who accessed products under section 23 of the Health (Pricing and Supply of Medical Goods) Act was 45,121. The DPS threshold reduced from €114 to €80 over this period. Since 1st March 2022 the DPS threshold has been €80. This data may not capture claims which are under the DPS monthly threshold amount.

Drugs, medicines and non-drug items reimbursable under LTI Scheme are intended for the treatment of the primary condition. Core Lists were developed following detailed consultation with Medical Officers, HSE Pharmacists and HSE Medicines Management Programme (MMP). The HSE is satisfied that all items that should be necessary for the treatment of each primary LTI condition are provided on these Core Lists which may include products under section 23 of 2013 Act. The Core Lists are published at <https://www2.hse.ie/services/schemes-allowances/lti/approved-medications/#:~:text=Lists%20of%20approved%20medicines%20%28March%202023%29%20Acute%20leukaemia,Diabetes%20insipidus%20Diabetes%20mellitus%20%28gestational%20diabetes%20not%20included%29>. Under the Long Term Illness (LTI) scheme, the number of patients who accessed products under section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013 was 6,035

The information provided is based on claim data which has been received by the Primary Care Reimbursement Service (PCRS) from Community Pharmacists and includes items reimbursed by PCRS only. PCRS data does not capture items dispensed outside of the Community Drug Schemes where the prescription has been paid for privately by the patient or patient representative. PCRS does not capture data in relation to diagnosis or indication for the medicines reimbursed including whether the item is of orphan designation.

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service