



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

6th October, 2020

PQ: 25761/20

To ask the Minister for Health if he will review the current procedures that exist for applicants under the hardship scheme; 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 25761/20), which you submitted to the Minister for Health for response.

The HSE is satisfied that all requirements can be ordinarily met through the Reimbursement List maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act, 2013. Exceptional arrangements are considered under Section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013 - Supply of items not on Reimbursement List. The HSE must be satisfied that:

- (a) The patient requires that 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.

Discretionary Hardship Arrangements fall under Section 23 of the Act. Consideration of an application for funding treatment for an individual is warranted where unmet clinical need arises and not meeting that clinical need would have an irreversible impact on the patient's health. However, Schedule 3 of the Health Pricing and Supply of Medical Goods Act 2013 still applies to the consideration of the application on a patient specific exceptional basis.

The HSE carried out a review of the administrative arrangements pertaining to Discretionary Hardship Arrangements in 2016 and introduced a National

Framework to ensure uniformity of administration across the country. Pharmacists were informed of those changes in Circular 014/16. These changes were effective from 1st April 2016. Training and information materials were provided to HSE Medical officers, HSE Pharmacists and administration staff within the Community Healthcare Organisations. This information was cascaded locally and also provided to pharmacy contractors in the form of Circulars.

The Local Office operate within the framework (see Circular 048/16 attached). Applications outside of this framework are sent to Primary Care Eligibility & Reimbursement Service (PCERS) for review and recommendation for reimbursement. On occasion, the PCERS may seek the advice of the HSE Medicines Management Programme.

It should be noted that those products which are undergoing formal Pricing and Reimbursement Assessment or remain 'Not recommended for reimbursement' by the National Centre for Pharmacoeconomics cannot be approved under any of the Community Drug Schemes including Discretionary Hardship arrangements.

There are no immediate plans to review these patient specific arrangements.



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service