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

2nd of June, 2022

PQ: 25084/22

To ask the Minister for Health the key performance indicators that he is applying to the pricing and reimbursement system for the supply of medicines outside of those criteria defined in the Health Act 2013; if the timelines for patient access from the application is measured by the HSE and National Centre for Pharmacoeconomics as a priority; 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 25084/22), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for new medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE considers pricing and reimbursement applications for new medicines and new uses of existing medicines in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013.

When considering the proposed relevant price by a supplier of a medicine, the HSE must have regard to the following criteria as set out in Section 21(2) of the 2013 Act:
(a) The equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,
(b) The relevant prices of therapeutically similar listed items,
(c) The potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,
(d) The potential budget impact of the item if it were to become a listed item,
(e) The ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
(f) The resources available to the Executive, and
(g) The terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.

Prior to making any decision regarding funding / reimbursement of a medicine, the HSE must have regard to the following general criteria as set out in Schedule 3 (Part 3) of the 2013 Act:

(a) The health needs of the public,

(b) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,

(c) The availability and suitability of items for supply or reimbursement,

(d) 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,

(e) The potential or actual budget impact of the item or listed item,

(f) The clinical need for the item or listed item,

(g) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,

(h) 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

(i) The resources available to the HSE.

The National Centre for Pharmacoeconomics (NCPE) publishes the timelines of pharmacoeconomic assessments on their website: https://www.ncpe.ie/pharmacoeconomic-evaluations/all-drug/ .

The HSE Executive Management Team (EMT) receives data on performance indicators in respect of new medicines.

The Health (Pricing and Supply of Medical Goods) Act 2013 under Clause 23 includes provision for the HSE to have discretion to make arrangements to supply an item not included on the reimbursement list to certain patients, subject to such conditions as it considers appropriate. The HSE must be satisfied that:

- The patient requires that items for clinical reasons, and
- There is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

However, products in the National Application, Assessment and Decision process for new medicines are precluded from those discretionary arrangements.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service