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David Cullinane, T.D.
Dáil Éireann,
Leinster House,
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12th August, 2022

PQ: 39603/22

To ask the Minister for Health the meaning of the term supplier of an item which is applied by the HSE with regard to section 18 (1) of the Health (Pricing and Supply of Medical Goods) Act 2013; if, with regard to the long-term illness scheme or any other scheme, the term is inclusive of the dispenser of relevant medicines and appliances or if it refers solely to the patent holder or manufacturer; and if he will make a statement on the matter.-David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 39603/22), 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 ('2013 Act'). 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. 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 HSE is required to consider the following criteria when it is making decisions in relation to pricing of Medicines:
(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.

In accordance with section 18 in the '2013 Act' the supplier of an item may make an application in the specified form, accompanied by the fee (if any) prescribed in regulations made under section 29 in respect of this section, to the Executive requesting the Executive to add the item to the Reimbursement List.

In accordance with section 29 in the '2013 Act' the Minister for Health may, with the consent of the Minister for Public Expenditure and Reform, prescribe by regulations the fees to be paid to the Executive by the suppliers of items, or a class of such suppliers, who make applications (or applications which fall within a class of applications) under section 18 (i) to the Executive requesting the Executive to add the items to the Reimbursement List, and (ii) in respect of the reasonable administrative costs of the Executive in performing its functions under section 18 in respect of such applications.

Statutory Instrument No: 576 of 2016, the Health (Reimbursement List) (Application fees) Regulations 2016 provide a statutory basis for fees charged by the HSE in respect of their reasonable administrative costs in assessing applications by manufacturers for the inclusion of their products (primarily drugs) on its Reimbursement List https://www.irishstatutebook.ie/eli/2016/si/576/made/en/print

A definition for 'Supplier' is provided for in both the 2021 Framework Agreement on the Supply and Pricing of Medicines (IPHA Agreement) and the 2021 Framework Agreement on the Supply and Pricing of Generic, Biosimilar and Hybrid Medicines (MFI Agreement) https://www.hse.ie/eng/about/who/cpu/health-act-2013-ipha-and-mfi-agreement-2021-2025.html

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service