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Colm Burke, T.D.
Dáil Éireann,
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Kildare Street,
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28th July 2022

PQ: 38286/22

To ask the Minister for Health his views on whether a proposal by an organisation (the European Federation of Pharmaceutical Industries and Associations) on equity-based tiered pricing would help to broaden access to new medicines for all Europe's citizens; 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 38286/22), which you submitted to the Minister for Health for response.

The HSE is the national authority with responsibility for the pricing and reimbursement of new medicines or new uses of existing medicines. The legislation underpinning the National Application, Assessment & Decision Process for new medicines is 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.

The 2013 Act transparently sets out details of the criteria that the HSE must consider when making decisions in relation to pricing and reimbursement.

Prior to making any decision regarding funding / reimbursement of a medicine, the HSE must have regard to the following 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 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 2021 the HSE, the Department of Health, the Department of Public Expenditure & Reform and the Irish Pharmaceutical Healthcare Association engaged in negotiations that led to a new Medicines Supply Agreement i.e. the 2021 IPHA Agreement. As part of the negotiation of the Agreement significant effort was spent considering a range of options to improve the efficiency of pricing and reimbursement application processes. The Irish Pharmaceutical Healthcare Association, the representative organisation for many multi-national pharmaceutical companies, in its press release welcoming the 2021 Agreement flagged that the Agreement "*will improve patients' access to the latest innovative medicines"* and that *"the Agreement provides for adequate, sustained investment in innovative new medicines, with allocations decided annually based on horizon scanning and the budgetary process"* and *"has the potential to improve the operating environment for the adoption of innovative new medicines in the health services"* https://www.ipha.ie/new-medicines-supply-agreement-to-improve-patients-access-to-innovative-new-treatments/

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service