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Mary Lou McDonald, T.D.
Dáil Éireann,
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14th February 2023

PQ: 2190/23

To ask the Minister for Health if his attention has been drawn to reports that the Health Service Executive is not meeting is obligations as set out in section 18 of the Health (Pricing and Supply of Medical Goods) Act 2013 and that this failure is leading to shortages in supply of commonly-used generic pharmaceutical products; and if he will make a statement on the matter. -Mary Lou McDonald

Dear Deputy McDonald,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 2190/23), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources 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.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(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 December 2021 the State agreed two multiannual agreements with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI):

- Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)
- Framework Agreement on the Supply and Pricing of Generic, Biosimilar, and Hybrid medicines (i.e., the 2021 MFI Agreement)

These framework agreements on the supply and pricing of medicines contribute to the sustainable funding of new and existing medicines and are considered to deliver additional savings to the State. The savings achieved are via a number of measures outlined in the agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines.

In the interests of continuity of supply, where it becomes uneconomic for a Supplier to supply a particular medicine under the terms of the Agreements, direct representations may be made by the Supplier to the HSE for variation of any term of the Agreement, in relation to that medicine, including its price terms (Section 14.4 of the 2021 IPHA Agreement and Section 13.4 of the MFI Agreement outlines exceptional circumstances processes for the respective Industry members). Where representations are made to the HSE under these Clauses, the HSE shall have the final decision on whether to vary the terms of the Agreement in any case but will consult with the Supplier before reaching its decision. The HSE expects a robust submission of evidence to support any claim, from any Supplier, in the event that they wish to set out to the Executive an inability to meet pricing terms set out in said Agreements.

The HSE is duly taking into account its obligations when making decisions related to pricing and reimbursement applications, as set out in the Health (Pricing and Supply of Medical Goods) Act 2013. The timeframe permitted for assessment, as set out in the statutory legislation, permits so called 'stop-clocks', when further information can be requested by the HSE. Generally 'stop-clocks' are not required where an applicant company submits a pricing and reimbursement application to the HSE for commonly used generic medicines, when the application satisfies the Health (Pricing and Supply of Medical Goods) Act 2013 criteria as outlined, and the reimbursement price requested by the applicant meets the terms of the Industry Framework Agreements, which is the case for the majority of applications for commonly used generic medicines.

In 2020 and 2021 the HSE approved approximately half of all applications for pricing and reimbursement within 60 days of receipt of the application. This includes applications for generic medicines, biosimilar medicines, hybrid medicines and new chemical entities (orphan and non-orphan) and excludes applications for parallel imported medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service