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Bernard J Durkan, T.D.
Dáil Éireann,
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5th April 2022

PQ: 14961/22

To ask the Minister for Health the specific targets set out by his Department for increasing the use of generic medicines within the medicines market in Ireland; the extent to which Ireland compares to other European Union countries in the use of generic medicines; the estimated additional saving envisaged in 2022 by increased use of generic medicines; and if he will make a statement on the matter. -Bernard J. Durkan

Dear Deputy Durkan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14961/22), which you submitted to the Minister for Health for response.

The HSE is mandated to deliver the maximum savings possible and optimise the resources available to it. A suite of measures are available to the HSE for the management of current and future medicines expenditure. Two key measures anticipated to deliver savings to the State in 2022 include reference pricing and the implementation of the new framework agreements on the supply and pricing of medicines between the State and the Pharmaceutical Industry.

Reference Pricing
The pricing and reimbursement of all medicines in Ireland is set in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE in setting the price of any medicine is required to consider the criteria set out in Section 21 of the Health (Pricing and Supply of Medical Goods) Act 2013, which include:

(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 the statutory legislation that underpins the pricing and reimbursement of medicines in Ireland, the HSE is mandated to deliver the maximum savings possible and optimise the use of the limited resources available to it commensurate with maintaining supplies in the market place to meet patient needs. The Health (Pricing and Supply of Medical Goods) Act 2013 introduced a system of generic substitution and reference pricing in Ireland, which allows patients to opt for lower cost interchangeable (i.e. generic) medicines.

When medicines are off patent and designated as interchangeable by the Health Products Regulatory Authority, the HSE may set a reference price for such medicines utilising the powers set out in the Act. In doing so, the HSE is required to consider the following criteria as set out in Section 24 of the Act:

(a) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,
(b) the value for money afforded by the relevant listed items,
(c) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,
(d) the relevant prices of therapeutically similar listed items,
(e) the resources available to the Executive, and
(f) 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 medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.

The prices set for each medicine will vary based on the assessment of the criteria outlined in the Health Act 2013. The setting and revision of reference prices seeks to achieve optimal pricing for the HSE commensurate with maintaining continuity of supply. Decisions in relation to reference pricing must also be cognisant of potential supply challenges, such as Brexit and market dynamics.

In line with Section 24 of the Health (Pricing and Supply of Medical Goods) Act 2013, one of the criteria which the HSE must consider prior to setting a reference price for a medicine is the equivalent relevant price in all other Member States. The HSE reviews and considers European pricing and reimbursement data available to it to inform reference prices.

The HSE regularly reviews reference prices (at least annually) in line with the Health (Pricing and Supply of Medical Goods) Act 2013. The first reference prices were set on 1st November 2013 and to date, the HSE has set reference prices for hundreds of interchangeable groups. Prices of reference priced products are generally of the order of 70% - 90% lower than the prices paid when medicines were on patent. These significant price reductions for generic medicines have achieved savings of hundreds of millions to the State. The HSE will continue reference pricing activities in 2022 to deliver the maximum savings possible.

New Framework Agreements between the State and the Pharmaceutical Industry

Furthermore, in 2021, the State agreed two new 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 new framework agreements on the supply and pricing of medicines will contribute to the sustainable funding of new and existing medicines and are estimated to deliver additional savings to the State exceeding €600m than would otherwise have been realised. These savings will be achieved via a number of measures outlined in these agreements including enhanced price reductions for off-patent medicines including generic medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service