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Denis Naughten, T.D.
Dáil Éireann,
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15th July 2022

PQ: 35122/22

To ask the Minister for Health the steps that are being taken to increase the volume of generic medicines used to fulfil prescriptions to achieve the European Union average of 70%; the estimated savings to the annual drug bill as a result; and if he will make a statement on the matter. -Denis Naughten

Dear Deputy Naughten,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 35122/22), which you submitted to the Minister for Health for response.

A suite of measures are available to the HSE for the management of current and future medicines expenditure. These measures include reference pricing, HSE Medicines Management Programme (HSE-MMP) led best-value medicines (BVM) initiatives, pricing framework agreements between the State and the pharmaceutical industry, and procurement of medicines in hospital settings supported by the HSE National Drugs Management Programme Dynamic Purchasing System.

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.

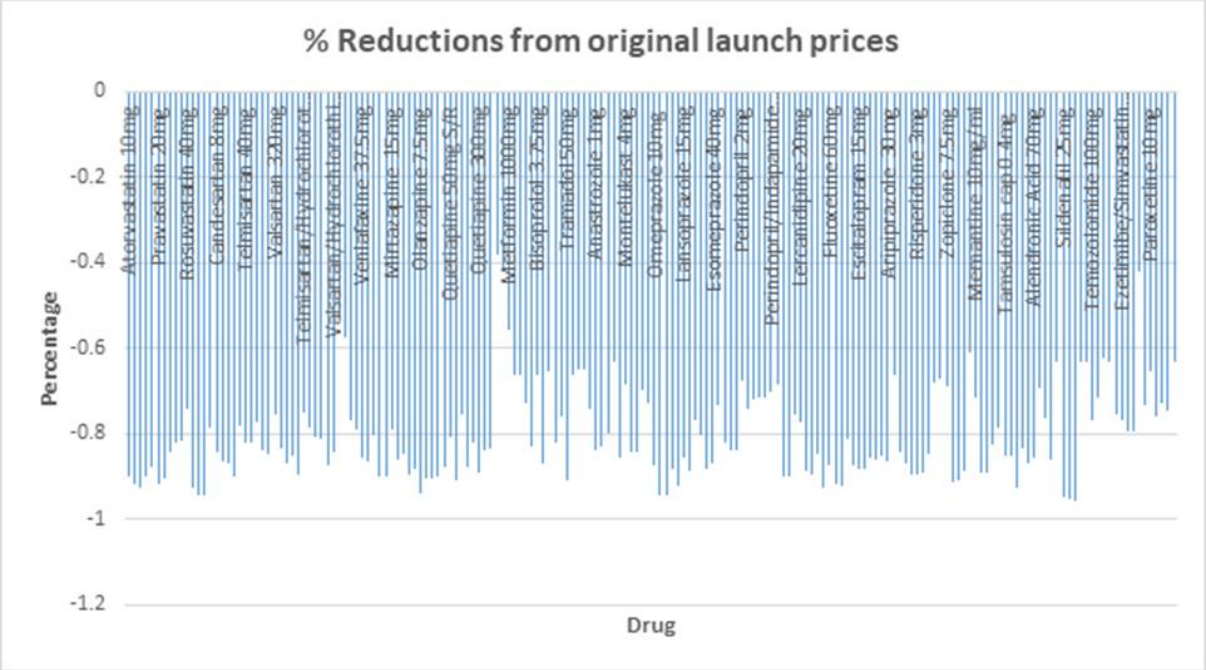
In accordance with the statutory legislation that underpins the pricing and reimbursement of medicines in Ireland, the HSE is mandated to deliver the maximum savings possible and optimise the use of the limited resources available to it commensurate with maintaining supplies in the market place to meet 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.

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.



Best-Value Medicine (BVM) Initiatives

Best-value medicines (BVM) initiatives are a cost saving measure utilised by the HSE. Best-value medicines are often provided to the HSE at a lower cost than the originator brands of medicines. This provides the HSE with an opportunity to reduce the cost of providing such medicines to patients. Further information in relation to potential best-value medicine initiatives for 2022 are available at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-value-medicines/mmp-bvb-and-bvm-processes-2022.pdf

New Framework Agreements between the State and the Pharmaceutical Industry

The State has 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. These savings will be achieved via a number of measures outlined in these agreements including enhanced price reductions for off-patent medicines and increased rebate contributions for on-patent medicines.

With specific regard to patent-expired non-exclusive medicines these framework agreements ensure:

- Relevant patent-expired non-exclusive medicines (other than biologic or hybrid medicines) to be reduced to 40% of their original ex-factory price (Clause 7.2.1. 2021 IPHA Agreement) (https://www.hse.ie/eng/about/who/cpu/ipha-price-reduction-2022/)
- The price of each medicine that becomes a patent-expired non-exclusive medicine after 1st January 2022 shall reduce to 40% of the ex-factory price of that medicine as of the 1st October 2021
- A new generic medicine for which an application is made to be priced at no greater than 40% of the 1st October 2021 price of the equivalent branded original medicine

The HSE National Drugs Management Programme Dynamic Purchasing System

The HSE Drugs Management Programme has developed a strategy for the Procurement of Medicines in Acute and non-Acute Hospitals available at: https://www.hse.ie/eng/about/who/national-drugs-management-programme/procurement-of-medicines-strategy-document.pdf

The strategy provides for the introduction of a National Dynamic Purchasing System (DPS) as the preferred model to facilitate compliant procurement of medicines by HSE and HSE-funded hospitals. Accordingly the National Dynamic Purchasing System has been used by hospitals for procurement of generic medicines.

Effective implementation of the above suite of measures has led to, and will continue to lead to, significant savings for the HSE and State, including increased utilisation of generic medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service