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Duncan Smith, T.D.
Dáil Éireann,
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22nd December 2022

PQ: 61500/22

To ask the Minister for Health the reason that some branded medicines have not been required to be reduced in price following the approval of a generic equivalent, as required by the 2021 industry agreements; and if he will make a statement on the matter. -Duncan Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 61500/22), which you submitted to the Minister for Health for response.

The HSE is mandated to deliver the maximum savings possible when making decisions in relation to pricing of medicines and optimise the use of the limited resources available to it commensurate with maintaining continuity of supply in the market place to meet patient needs.

In accordance with the Health (Pricing and Supply of Medical Goods) Act 2013, 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)

The Framework Agreement on the Supply and Pricing of Medicines is an agreement between the State and Industry, and it is the responsibility of the HSE to manage the implementation of same, in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013. These framework agreements on the supply and pricing of medicines contribute to the sustainable funding of new and existing medicines and are estimated 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. The HSE works diligently to harvest the maximum possible value of the Industry Framework Agreements. The Industry Agreements also generally provide for clear direction to all parties in relation to the requirements of the State for the supply and pricing of medicines. In the vast majority of cases, the relevant processes work seamlessly and the relevant price reductions are transparently harvested in line with the terms of the Agreement and in compliance with the Health Act 2013. If and when suppliers / manufacturers are not in a position to provide the full value in accordance with the Industry Agreements then the HSE would be required to formally consider whether a product could remain reimbursable.

With specific regard to patent-expired non-exclusive medicines the 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 (Clause 7.2.2 of the IPHA Agreement)
- 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 (Clause 7.2.1 of the MFI Agreement).

If a company submits representations in relation to notifications of price reductions, as outlined in the various clauses of the Framework Agreements, then the HSE is required under both the 2013 Act and the Industry Agreements to give due consideration to any such representations. Part 3 of Schedule 1 of the Health (Pricing and Supply of Medical Goods) Act 2013 sets out clearly that the HSE is required to consider relevant representations from

suppliers when making pricing decisions. Section 14.4.1 of the 2021 IPHA Agreement specifically states that *"Where a Supplier considers itself to be disproportionately prejudiced by the terms of this Agreement, direct representations may be made to the HSE by that Supplier for variation of any term of this Agreement including its price terms"*. Section 14.4.3 of the 2021 IPHA Agreement provide additional details on the process that must be followed and the issues that may arise. Section 13.4 of the MFI Agreement outlines similar exceptional circumstances processes for MFI members.

One circumstance, which arises on occasion, is where a generic company may be of the legal view that there is no existing patent or data exclusivity which prevents them launching a generic product on the Irish market but the original branded company may be of the legal view that it has existing patents in place which are being breached. In such circumstances, when the HSE goes through the required process (set out in Section 7.3 of the IPHA Agreement) the branded company may make clear to the HSE its view that the circumstances do not fall within the relevant clauses of the Industry Agreements. In this specific circumstance, it is not possible for the HSE to unilaterally apply the terms of an "Agreement" as the HSE is not a court and it would be inappropriate of the HSE to make any legal determination in relation to the validity of either parties case.

Other circumstances can arise where a company may make representations that the terms of the 2021 Agreements disproportionally impact on its international business or alternatively may impact on its ability to supply the Irish market and Irish patients. The HSE carefully considers any such representations in line with the processes agreed. The general preference of the HSE would be that all pricing arrangements be clear and transparent, but on occasion an individual supplier and/or manufacturer of a medicine will only agree to measures that are intended to glean the full value of the Industry Agreements on the condition of commercial confidentiality. The HSE will carefully weigh up the implications of each decision if ultimately agreeing to such conditions, and will always take into account the aforementioned criteria, set out in the statutory legalisation, when making such decisions. Notwithstanding the lack of transparency due to commercial confidentiality required by companies in certain instances, measures agreed do ultimately contribute to reducing the cost of therapies being reimbursed, thus improving the affordability of medicines overall.

In summary, both the IPHA and MFI Agreements recognise that exceptional circumstances can arise and put in place specific processes to enable pharmaceutical companies to make representations in circumstances where a company considers itself to be disproportionally prejudiced by the terms of the Agreements and the HSE is required to consider same. The HSE cannot discuss any specific individual cases or any individual agreements or arrangements that it may have in place with third parties.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service