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Colm Burke, T.D.
Dáil Éireann,
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Kildare Street,
Dublin 2.

13th March 2024

PQ: 9307/24

To ask the Minister for Health the cost of medicines dispensed with a breakdown of those which are still under patent and those off patent for each of the years ending December 2019, 2020, 2021, 2022 and 2023, in tabular form; 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 9307/24), which you submitted to the Minister for Health for response.

Note on patent medicines:

When a pharmaceutical company develops a new original medicine, it takes out a patent. The patent is a legal agreement that prevents other companies from making or selling the same medicine for a number of years. The new medicine usually has a unique name or brand. It can also be called a 'proprietary', a 'reference' or an 'originator' medicine. When a patent's time period comes to an end, other pharmaceutical companies can make a similar version – a generic or biosimilar – of the original medicine.

However, other factors can also influence when a generic or biosimilar medicine can enter the market.

Data exclusivity applies for a period of eight years from the initial authorisation of a medicine during which the marketing-authorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine. After this period, the marketing authorisation holder is obliged to release this information to companies wishing to develop generic versions of the medicine.

Supplementary protection certificates (SPCs) are an intellectual property right that serve as an extension to a patent right. An SPC can extend a patent right for a maximum of five years. A six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a Paediatric Investigation Plan (PIP). PIPs are required to support the authorisation of medicines for children. (Information available @ https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en#:~:text=Supplementary%20protection%20certificates%20(SPCs)%20are,extension%20to%20a%20patent%20right .)

Because of the legal complexities in relation to market exclusivity, it is not possible for the HSE to maintain a register of patented medicines nor does it collate data on the patent status of any medicinal product reimbursable on Schemes within the HSE PCRS remit.

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.

A Clause 7 notification is issued to a supplier upon confirmation of launch of a generic version of that supplier's originator medicine. The HSE notifies the supplier of the availability for supply of a generic version of their medicine. This results in the originator medicine being subject to a price reduction in accordance with Sub-Clause 7.2.2 of the IPHA Framework Agreement on the Supply and Pricing of Medicines 2021. The supplier is also notified that they may make representations within 28 days of receiving the notice.

A Clause 8 notification is issued to a supplier upon confirmation of launch of a biosimilar version of that supplier's originator biologic medicine. The HSE notifies the supplier of the availability for supply of a biosimilar version of their biologic medicine. This results in the originator biologic medicine being subject to a price reduction in accordance with Sub-Clause 8.2.2 of the IPHA Framework Agreement on the Supply and Pricing of Medicines 2021. The supplier is also notified that they may make representations within 28 days of receiving the notice.

A Clause 9 notification is issued to a supplier upon confirmation of launch of a hybrid version of that supplier's originator medicine. The HSE notifies the supplier of the availability for supply of a hybrid version of their medicine. This results in the originator medicine being subject to a price reduction in accordance with Sub-Clause 9.2.2 of the IPHA Framework

Agreement on the Supply and Pricing of Medicines 2021. The supplier is also notified that they may make representations within 28 days of receiving the notice.

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

- Relevant patent-expired non-exclusive medicines (in respect of which a generic medicine is available for supply) 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/health-act-2013-ipha-and-mfi-agreement-2021-2025.html)
- The price of each medicine that becomes a patent-expired non-exclusive medicine (in respect of which a generic medicine is available for supply) 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)
- Relevant patent-expired non-exclusive biologic medicines to be reduced to 62.86% of their original ex-factory price (Clause 8.2.1. IPHA Agreement) (https://www.hse.ie/eng/about/who/cpu/health-act-2013-ipha-and-mfi-agreement-2021-2025.html)
- The price of each biologic medicine that becomes a patent-expired non-exclusive biologic medicine after 1st January 2022 shall reduce to 62.86% of the ex-factory price of that biologic medicine as of 1st October 2021 (Clause 8.2.2 of the IPHA Agreement)
- The price of each existing biosimilar medicine to be reduced to 55% of the 31st July 2016 price of the reference originator (Clause 8.2.1 of the MFI Agreement)
- A new biosimilar medicine for which an application is made to be priced at no greater than 55% of the 1st October 2021 price of the equivalent branded original medicine (Clause 8.2.2 of the MFI Agreement)
- Relevant patent-expired non-exclusive medicines (in respect of which a hybrid medicine is available for supply) to be reduced to 50% of their original ex-factory price (Clause 9.2.1. 2021 IPHA Agreement) (https://www.hse.ie/eng/about/who/cpu/health-act-2013-ipha-and-mfi-agreement-2021-2025.html)
- The price of each medicine that becomes a patent-expired non-exclusive medicine (in respect of which a hybrid medicine is available for supply) after 1st January 2022 shall reduce to 50% of the ex-factory price of that medicine as of the 1st October 2021 (Clause 9.2.2 of the IPHA Agreement)
- A new hybrid medicine for which an application is made to be priced at no greater than 50% of the 1st October 2021 price of the equivalent reference originator (Clause 9.2.2 of the MFI Agreement)

In 2021 Clause 7 price reductions generated savings of €52.7 million. Clause 8 price reductions generated savings of €18.1 million.

In 2022 Clause 7 price reductions generated savings of €34.5 million. Clause 8 price reductions generated savings of €5.25 million.

In 2023 Clause 7 price reductions generated savings of €77.5 million. Clause 8 price reductions generated savings of €21.5 million. Clause 9 price reductions generated savings of €3 million.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service