



Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

Paul McAuliffe, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd September 2024

PQ: 33913/24

To ask the Minister for Health the accelerated processes the HSE operates for the pricing and reimbursement of medicines that can deliver immediate savings to the health service; and if he will make a statement on the matter. -Paul McAuliffe

Dear Deputy McAuliffe,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 33913/24), 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 medicine (BVM) initiatives, and pricing framework agreements 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 market dynamics. The HSE regularly reviews reference prices (at least annually) in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

- In 2021, reference pricing resulted in additional efficiencies for the Primary Care Reimbursement Service (PCRS) of €13.4m.
- In 2022, reference pricing resulted in annual savings for PCRS of €19.3m.
- In 2023, reference pricing resulted in additional efficiencies for PCRS of €25.01m.

Best-Value Medicine (BVM) Initiatives

Best-value medicines (BVM) initiatives including best-value biological medicines (BVB) initiatives are a cost saving measure utilised by the HSE. Best-value medicines represent the best value medicine to the HSE and are strongly encouraged by the HSE. They provide 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 are available at: <https://www.hse.ie/eng/about/who/cspd/medicines-management/best-value-medicines/>

Framework Agreements between the State and the Pharmaceutical Industry

The State has 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 deliver additional savings to the State. These savings are 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.

Framework Agreement on the Supply and Pricing of Medicines (i.e., the 2021 IPHA Agreement)

This incorporated a number of new cost saving measures, as outlined in the 2021 IPHA Agreement which are briefly outlined below:

- **Clause 5.2:** this is an annual, downwards only, pricing realignment exercise conducted by the Irish State in accordance with the provisions outlined in the 2021 IPHA Agreement.
- **Clause 7.2.1:** On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Medicine shall be reduced to 40% of the Original Ex-Factory Price.
- **Clause 7.2.2:** The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after 1st of January 2022 shall, in accordance with Sub-Clause 7.3, reduce to 40% of the Ex-Factory Price of that Medicine as of 1st October 2021.
- **Clause 8.2.1:** On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Biologic Medicine shall be reduced to 62.86% of the 31st of July 2016 Ex-Factory Price.
- **Clause 8.2.2:** The Price of a Biologic Medicine that becomes a Patent-Expired Non-Exclusive Biologic Medicine after 1st January 2022 shall, in accordance with Sub-Clause 8.3, reduce to 62.86% of the ex-factory price of that Biologic Medicine as of 1st October 2021.
- **Clause 8.2.3:** In addition to the applicable price reduction in respect of any Patent-Expired Non-Exclusive Biologic Medicine pursuant to Sub-Clauses 8.2.1 or 8.2.2, the Supplier shall pay to the HSE or the Relevant Agency a rebate of a sum equal to 12.5% of the value, at the price reduced in accordance with this Sub-Clause 8.2, of such Patent-Expired Non-Exclusive Biologic Medicine reimbursed by the HSE in the Relevant Schemes and of any such Patent-Expired Non-Exclusive Biologic Medicine supplied to the HSE or a Relevant Agency.
- **Clause 9.2.1:** On 1st of January 2022, the Price of each existing Patent-Expired Non-Exclusive Medicine in respect of which a Hybrid Medicine is available for Supply shall be reduced to 50% of the original ex-factory price.
- **Clause 9.2.2:** The Price of a Medicine that becomes a Patent-Expired Non-Exclusive Medicine after 1st of January 2022 shall, in accordance with Sub-Clause 9.3, reduce to 50% of the Ex-Factory Price of that Medicine as of 1st October 2021.
- **Clause 10:** The existing standard rebate on exclusive supply medicines increased to 7.75% of the ex-factory price from 1st January 2022 for 12 months. Over the course of the agreement, the rebate incrementally increases to 8.25% (for 9 months), 8.5% (for 12 months) and 9% (for 12 months).

The following table details the savings arising in PCRS from BVM initiatives and the 2021 IPHA Agreement:

IPHA Agreement Clause	Clause Description	2021	2022	2023
		€m	€m	€m
Clause 5	Price Realignments	€ 134.12	€ 155.00	€ 187.86
Clause 7	Pricing of Patent Expired Medicines on loss of exclusive supply	€ 52.69	€ 34.48	€ 77.53
Clause 8	Pricing of Patent Expired Non-Exclusive Medicines	€ 18.12	€ 24.64	€ 21.48
Clause 9	Pricing of Patent Expired Medicines in respect of which a hybrid medicine is available for supply	€ -	€ -	€ 3.00
Clause 10	Standard Rebate	€ 59.14	€ 83.69	€ 95.31
		€ 264.07	€ 297.81	€ 385.18
Best Value Biosimilars				
BvB		€ 80.35	€ 99.14	€ 113.80

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

Yours sincerely,



Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie