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

David Cullinane, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

4th March 2025

PQ: 6305/25

To ask the Minister for Health to outline the breakdown of actual spending within the medicines budget from 2020 to 2024, distinguishing between off-patent medicines, including generic and biosimilar medicines and new/originator medicines; and to provide an estimate of the total savings generated for the State by the off-patent medicines industry during the same period, specifically those resulting from the launch of generic or biosimilar medicines following the expiration of originator patents. -David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 6305/25), which you submitted to the Minister for Health for response.

Breakdown of spending within the medicines budget:

The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, using the resources available (provided) to it and the HSE considers a range of proposals from Industry when assessing pricing and reimbursement applications. The 2013 Act enables the HSE to consider the terms of any framework agreement in place when it is making decisions in relation to pricing. The HSE robustly assesses applications to ensure available resources can be stretched as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds and are in line with the criteria set out under the Health (Pricing and Supply of Medical

Goods) Act 2013. The HSE is required to consider the following criteria prior to making any decision on funding / reimbursement:

(1) The health needs of the public,
(2) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,
(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and
(9) The resources available to the HSE

The HSE is unable to provide information on the net payments made to pharmaceutical suppliers and wholesalers as to do so would breach terms of commercial confidentiality which were placed on the HSE by suppliers when making commercial offerings. If the HSE were to release details at that level of detail it would breach confidentiality and would put at risk the ability of the HSE to get access to the best price options available for new medicines into the future. In the absence of significant international movement on transparency across pharmaceutical markets, currently the best pricing options are only available via non-transparent commercially confidential offerings and suppliers have made clear to the HSE that those offerings are absolutely contingent on the maintenance of commercial confidentiality.

Medicines are reimbursed and funded across a range of different systems e.g. in hospitals, in community services and under National Community Drug Schemes and centrally funded arrangements.

The majority of HSE medicine related expenditure is covered by Primary Care Reimbursement Service (PCRS). In addition to making payments in relation to medicines under the General Medical Services Scheme, the Drugs Payment Scheme and the Long Term Illness Scheme, the HSE PCRS also makes payments to suppliers and manufacturers of High Tech drugs as part of the High Tech Arrangements. High Tech drugs are specialised medicines initiated in secondary care and are appropriate to be dispensed in the community setting. High Tech medicines include expensive and innovative pharmaceuticals. PCRS also facilitates direct payments to public hospitals involved in the provision of national treatment programmes such as the National Cancer Control Programme, the National Hepatitis C Treatment Programme and Multiple Sclerosis Services. This ensures that there is a single funding strategy for the use of such high cost medicines in public hospitals and that there is no variation in access to funding for these medicines across the country.

The HSE has a limited budget to spend on new medicines. The HSE has negotiated a series of managed entry schemes or managed entry agreements (MEAs) for medicines it has approved in recent years. These agreements include innovative financial or pricing measures including confidential rebates or discounts, budget caps and / or other outcomes based innovative measures such as clinical outcomes monitoring or aspects of payment by results. The preference of the HSE would be that such pricing arrangements would be clear and transparent, but suppliers and manufacturers of these medicines will generally only agree to

such measures on the condition of commercial confidentiality. Notwithstanding the lack of transparency due to commercial confidentiality required by Industry these innovative measures do contribute significantly to reducing the cost of new therapies being reimbursed, thus improving both access and affordability of new medicines. In 2024, commercial negotiations in relation to medicines approved will deliver in excess of €371m in avoided additional costs over the next 5 years.

2021 New Drugs

Funding amounting to €50m was allocated to the HSE to support the approval of new drugs or for the approval of use for new licence indications, primarily in the Oncology and High Tech Arrangement space in NSP 2021.

A total of €91.5m was allocated in NSP 2022 in respect of the Full Year Cost of these drugs in 2022 of which €85m relates to PCRS and the remainder is in respect of Acutes.

The HSE approved a total of 52 drugs in 2021, of which 29 were new medicines, 21 were new uses of existing medicines, and 2 medicines were approved for expanded reimbursement.

Of the 52 drugs approved, 39 drugs were funded from the €50m New Drugs allocation and comprise of 15 ODMS, 17 High Tech, 4 Hospital & 3 CDS drugs.

The drugs listed above excludes the 5 new drugs approved on the basis that they assisted in the management of Covid-19 challenges and charged against Covid-19 funding in 2021.

2022 New Drugs

Funding amounting to €30m was allocated to the HSE to support the approval of new drugs or for the approval of use for new licence indications, primarily in the Oncology, High Tech Arrangement and Acute drugs space in NSP 2022.

A total of €40.7m was allocated in NSP 2023 in respect of the Full Year Cost of these drugs in 2023 of which €37.8m relates to PCRS and the remainder is in respect of Acutes.

During 2022, a total of 60 new medicines have been approved by the HSE, 30 of which are new medicines while 30 are licence extensions/new uses of existing medicines.

The new drug budget allocation of €30m had €1.1m allocated to Acute Drugs (reported external to PCRS), while from the remaining €28.9m budget element related to PCRS.

2023 New Drugs

Funding amounting to €18m was allocated in NSP 2023 to the HSE to support the approval of new drugs or for the approval of use for new licence indications of existing drugs. During 2023, a total of 36 new medicines were approved by the HSE, 15 of which are new medicines while 21 are licence extensions/new uses of existing medicines.

2024 New Drugs

Funding amounting to €20m was allocated in the April revised 2024 Letter of Determination to the HSE to support the approval of new drugs or for the approval of new uses of existing drugs and a further €10m was approved for use on new drugs or for the approval of new uses of existing drugs from HSE internally generated savings. The drugs are primarily in the Oncology, High Tech Arrangement and Acute drugs space. In 2024 the HSE approved 25 new medicines and 21 new uses of existing medicines for funding.

Total savings generated by the HSE:

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 the PCRS of €19.3m.
- In 2023, reference pricing resulted in additional efficiencies for the PCRS of €25.01m.
- In 2024, reference pricing resulted in efficiencies for the PCRS of €35.97m.

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 €m	2022 €m	2023 €m	2024 €m
Clause 5	Price Realignments	€ 134.12	€ 155.00	€ 187.86	€ 271.21
Clause 7	Pricing Of Patent-Expired Non-Exclusive Medicines	€ 52.69	€ 34.48	€ 77.53	€ 135.29
Clause 8	Pricing Of Patent-Expired Non-Exclusive Biologic Medicines	€ 18.12	€ 24.64	€ 21.48	€ 20.95
Clause 9	Pricing Of Patent-Expired Medicines In Respect Of Which A Hybrid Medicine Is Available For Supply	€ -	€ -	€ 3.0	€ 3.76
Clause 10	Standard Rebate	€ 59.14	€ 83.69	€ 95.31	€ 101.54
Total Savings:		€ 264.07	€ 297.81	€ 385.18	€ 532.74
Best Value Biosimilars (BvB)		€ 80.35	€ 99.14	€ 113.8	€134.23

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 and biosimilar medicines.

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