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

4th March 2025

PQ: 6304/25

To ask the Minister for Health to provide details of the total annual medicines budget for each year from 2020 to 2024. -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 6304/25), which you submitted to the Minister for Health for response.

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.

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