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

Ken O'Flynn, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

15th October 2025

PQ: 52830/25

To ask the Minister for Health if she will publish in full the rationale, minutes, and assessments underpinning reimbursement decisions on oncology drugs since 2020; and if not, the reason for the continued confidentiality. -Ken O'Flynn

Dear Deputy O'Flynn,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 52830/25), which you submitted to the Minister for Health for response.

There is a national application, assessment & decision process for new medicines and new uses of existing medicines which is underpinned by primary legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around new medicines.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(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 CPU is the interface between the HSE and the Pharmaceutical Industry in relation to pricing and reimbursement applications for medicines. Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the list of reimbursable items / funded via hospitals. The role of the CPU is to manage the process around pricing and reimbursement applications for medicines received by the HSE from Industry and to lead on pricing negotiations with individual companies around specific medicines. Further information regarding the application process is available on the HSE website: https://www.hse.ie/eng/about/who/cpu/reimbursement-of-p-r-applications.pdf

In the event that an application for reimbursement is submitted to the HSE-CPU, the National Centre for Pharmacoeconomics (NCPE) plays a pivotal role in assisting the HSE with the assessment of all new medicines and new uses of existing medicine(s). Since September 2009, in collaboration with the HSE-CPU, the cost-effectiveness of all new medicines are considered prior to a decision being made by the HSE. The NCPE makes a recommendation in relation to reimbursement at the price submitted by the company in its rapid review or HTA dossier / application. The NCPE may recommend in favour of or may recommend against reimbursement.

The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. Pharmacoeconomic reports are reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. The minutes of the HSE Drugs Group meetings are published and publically available online: https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/.

The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

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