



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

2nd March 2023

PQ: 7801/23

To ask the Minister for Health the drug reimbursement decisions made by the HSE drugs group and executive management team, respectively in each of its meetings from January 2019 to date 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 7801/23), which you submitted to the Minister for Health for response.

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. In doing so, 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. Were the HSE not to do so, the Irish taxpayer would be faced with funding demands of hundreds of millions in excess of current demands i.e. the assessment and decision making processes continue to deliver significantly improved offerings to the Irish State enabling the State to provide patient access to medicines.

There are formal processes which govern the pricing and reimbursement of medicines and the application process for new medicines to be funded and / or reimbursed.

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

The HSE considers a pricing application for indicated uses in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE considers 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 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 consider all of the evidence and make a recommendation to the HSE Executive Management 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 HSE Drugs Group recommendation for each medicine reviewed is also included in the published minutes.

The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management 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 uses 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. A list of the HSE Executive Management Team decisions for medicines from 2019 to date is provided.

Yours sincerely,



Suzanne Doyle
Primary Care Eligibility & Reimbursement Service