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Brendan Griffin, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd September 2024

PQ: 33824/24

To ask the Minister for Health the number of requests the HSE has made to pharmaceutical companies to submit an application for reimbursement based on the health needs of the public; and if he will make a statement on the matter. -Brendan Griffin

Dear Deputy Griffin,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 33824/24), which you submitted to the Minister for Health for response.

There is a national application, assessment and 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.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

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.

A pharmaceutical company can apply to the HSE for reimbursement for a specific indication (use) of a specific licensed medicine. Medicines can have more than one licensed (market authorised) indication and each indication represents a separate application.

The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to pricing and reimbursement applications for medicines. 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.

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 Senior Leadership Team.

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 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.

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. In order to submit a formal application the medicine must hold a marketing authorisation. The decision of pharmaceutical companies to market licensed medicines i.e. whether or not to submit a formal application, are outside the control of the HSE.

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