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Peadar Tóibín, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

24th June 2022

PQ: 29501/22

To ask the Minister for Health further to Parliamentary Question No. 639 of 29 March 2022, if a marketing company (details supplied) has submitted a pricing and reimbursement application; and if it will be made available to medical card holders if medically indicated by a doctor; and if he will make a statement on the matter. -Peadar Tóibín

Dear Deputy Tóibín,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 29501/22), 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, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources 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.

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

In terms of the specific details of the application for pricing and reimbursement of Semaglutide (Wegovy®):

The HSE Corporate Pharmaceutical Unit (CPU) received an application for pricing and reimbursement of Semaglutide 2.4mg (Wegovy®) on the 6th May 2022 from Novo Nordisk (the applicant) as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥30kg/m2 (obesity) or ≥27kg/m2 to <30kg/m2 (overweight) in the presence of at least one weight-related comorbidity e.g., dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.

- The first step in the process is the submission of a rapid review dossier (a clinical and economic dossier). The HSE commissioned the rapid review process with the National Centre for Pharmacoeconomics (NCPE) on the 9th May 2022. Following receipt of a rapid review dossier, the NCPE advised the HSE (9th June 2022) that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Semaglutide (Wegovy®) compared with the current standard of care, on the basis of the proposed price relative to currently available therapies. https://www.ncpe.ie/drugs/semaglutide-wegovy-hta-id-22029/

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

- The HSE CPU is currently reviewing the NCPE rapid review report and will arrange to meet with the applicant company to discuss issues arising from the report in due course.

- 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. Where additional budget impact arises, the HSE Drugs Group examines the product against the criteria set out in the Health (Pricing and Supply of Medical Goods) Act 2013 in advance of making a recommendation to the HSE Executive Management Team. The pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of any commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group will consider all of the evidence and make a recommendation to the HSE Executive Management Team.

- 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.

The application remains under consideration. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service