



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

15th July 2022

PQ: 35338/22

To ask the Minister for Health the role and composition of the HSE drugs group; and if he will make a statement on the matter. -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 35338/22), 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.

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. 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 is reviewed by the HSE Drugs Group along with the outputs of any commercial negotiations, and any patient group submission(s) received.

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 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.

Details of the HSE Drugs Group membership can be found in the below table. One post is to be filled due the retirement of Ms Joan Donegan in June 2022, who held the title of Director of Nursing (Office of Nursing & Midwifery Services).

Member	Title
Prof. Áine Carroll	Chair, Medical Consultant
Mr Shaun Flanagan	Primary Care Reimbursement Service (Assistant National Director)
Ms Aoife Kirwan	Public Interest Member
Dr David Hanlon	National Clinical Advisor and Group Lead Primary Care (General Practitioner)
Professor Risteárd Ó Laoide	National Director of the National Cancer Control Programme (Medical Consultant)
Dr Philip Crowley	National Director for Quality Improvement (Medical Doctor)
Dr Valerie Walshe	Office of the Chief Financial Officer (Economist, PhD)
Post Vacant	Office of Nursing & Midwifery Services (Director of Nursing)
Dr Roy Browne	Mental Health Division (Consultant Psychiatrist)
Dr Cliona McGovern	Public Interest Member / Ethicist
Mr Michael Power	Public Interest Member
Dr Anne Dee	Specialist in Public Health Medicine
Ms Helen Byrne	Acute Operations Division (Assistant National Director)
Prof Ellen Crushell	Consultant in Inherited Metabolic Disorders
Dr Lisa Cogan	Consultant in Medicine for the Elderly, Medical Director, Royal Hospital Donnybrook

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 included in the published minutes'.

Yours sincerely,

A handwritten signature in black ink that reads "Suzanne Doyle". The signature is written in a cursive style with a horizontal line underneath the name.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service