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Eoghan Kenny, T.D.  
Dáil Éireann,  
Leinster House,  
Kildare Street,  
Dublin 2.

26<sup>th</sup> February 2025

PQ: 4937/25

**To ask the Minister for Health the status of the reimbursement application for a medication (Fenfluramine); when she expects the medication to be available to patients in Ireland; and if she will make a statement on the matter. -Eoghan Kenny**

Dear Deputy Kenny,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 4937/25), 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 fenfluramine (Fintepla®):**

From the 1<sup>st</sup> March 2025, fenfluramine (Fintepla®) is approved to be added to the list of reimbursable items under the High Tech Drug Arrangements for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older, and for the treatment of seizures associated with Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older.

The HSE is aware that UCB are working to finalise a number of outstanding regulatory and commercial requirements to enable commercial launch of fenfluramine (Fintepla®) in Ireland. Following HSE Senior Leadership Team's approval of fenfluramine (Fintepla®), the HSE has proactively and readily engaged with UCB to facilitate and expedite patient access to fenfluramine (Fintepla®). The HSE awaits confirmation of launch from UCB to enable addition of fenfluramine (Fintepla®) under High Tech arrangements. The HSE remains committed to working with UCB to enable patient access to fenfluramine (Fintepla®).

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](mailto:Oireachtas.pcrs@hse.ie)**