



Roisin Shortall, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

9th December 2021

PQ: 57841/21

To ask the Minister for Health if an application has been received by the HSE to register a product as an exempt medicinal product (details supplied); when a decision on reimbursement will be made on this process; and if he will make a statement on the matter. -Róisín Shortall

Details Supplied:

PCBD110 – cannabis-based product for treatment of epilepsy which HPRA has advised does not meet criteria for Medical Cannabis Access Programme. There is currently no product approved on the MCAP which meets the clinical guidelines for treatment in epilepsy. Approval of this product is supported by clinicians & Epilepsy Ireland

Dear Deputy Shortall,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 57841/21), which you submitted to the Minister for Health for response.

The HPRA are the responsible statutory authority in respect of Exempt Medicinal Products (EMP) and their importation into the country. There is a notification process for importation of EMPs.

There are national processes for pricing and reimbursement of licensed Medicinal Products. The HSE has recently approved reimbursement of Cannabidiol (Epidyolex®) 100 mg/ml oral solution (containing the same active ingredient as PCBD110) via the High Tech Drug Arrangements for the following indications:

- use as adjunctive therapy of seizures associated with Lennox-Gastaut Syndrome (LGS) in conjunction with Clobazam, for patients 2 years of age and older,
- use as adjunctive therapy of seizures associated with Dravet Syndrome (DS) in conjunction with Clobazam, for patients 2 years of age and older, and

- use as adjunctive therapy of seizures associated with tuberous sclerosis complex (TSC) for patients 2 years of age and older.

The manufacturer expects to have supply in Ireland in January 2022.

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.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service