



Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

Barry Heneghan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

1st August 2025

PQ: 41240/25

To ask the Minister for Health the plans in place for the assessment and potential inclusion of the psychiatric medication lumateperone for the treatment of bipolar disorder under the drug payment scheme; and if she will make a statement on the matter. -Barry Heneghan

Dear Deputy Heneghan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 41240/25), which you submitted to the Minister for Health for response.

The HSE follows statutory processes around the addition of medicines to the formal Reimbursement List. Under those statutory processes, the HSE is legally required to consider a range of criteria which include unmet need, clinical evidence, economic evidence, budget impact and the resources available when making reimbursement decisions. The reimbursement decisions have to be in line with the relevant legislation, namely the Health (Pricing and Supply of Medical Goods) Act 2013.

In accordance with the legislation, a medicine must have a marketing authorisation (licence) to be included in the formal list of reimbursable items.

Lumateperone is not a licensed product in Ireland with the Health Products Regulatory Authority (HPRA).

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