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

Denise Mitchell, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

30th January 2025

PQ: 1872/25

To ask the Minister for Health his plans, if any, to make the medication lumateperone available via the drugs payment scheme; and if he will make a statement on the matter. -Denise Mitchell

Dear Deputy Mitchell,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 1872/25), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around medicines. The Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and processing pricing and reimbursement applications from the pharmaceutical industry. Pharmaceutical companies are required to submit formal applications to the HSE if they wish their medicines to be added to the list of reimbursable items covered under community drugs schemes and arrangements / funded via hospitals. In order to submit a formal application, the medicine must hold a marketing authorisation.

The European Medicines Agency (EMA) is a centralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. The EMA plays an integral role in the authorisation of medicines in the EU via the centralised procedure.

The Health Products Regulatory Authority (HPRA) is the competent authority responsible for the regulation of human medicines in Ireland. A company can submit an application for a marketing authorisation directly to the HPRA if the product in question is not required to be approved through the centralised procedure.

To date neither the EMA nor the HPRA have granted marketing authorisation for Lumateperone for any indication.

As outlined above, the national assessment and decision process cannot commence in the absence of a marketing authorisation.

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