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Leo Varadkar, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

19th June 2024

PQ: 25144/24
To ask the Minister for Health to explain why melatonin when prescribed is not reimbursed on the DPS; and if he will make a statement on the matter.-Leo Varadkar

Dear Deputy Varadkar,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 25144/24), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for new 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 new medicines. The Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and considering pricing and reimbursement applications from the pharmaceutical industry.

Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the Reimbursement List.

Under the Health (Pricing and Supply of Medical Goods) Act 2013, products that are licensed will undergo a pricing and reimbursement approval process by the National Centre for Pharmacoeconomics (NCPE) on receipt of an application by the HSE from the Marketing Authorisation Holder. Melatonin (Circadin®) underwent a review in 2008 and reimbursement was not recommended by the NCPE as there is currently insufficient evidence to support the reimbursement of this product under the Community Drugs Schemes including the Drugs Payment Scheme (available at http://www.ncpe.ie/drugs/melatonin-circadin/).

The HSE Corporate Pharmaceutical Unit received an application for pricing and reimbursement of Melatonin (Slenyto® Prolonged-Release Tablets) on 3rd July 2019 from Flynn Pharma for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-

Magenis syndrome, where sleep hygiene measures have been insufficient. The first step in the process is the submission of a rapid review dossier (a clinical and economic dossier) to the National Centre for Phamacoeconomics (NCPE) for assessment. The rapid review was commissioned on 5th July 2022 and completed by the NCPE on 9th August 2022. The rapid review outcome recommends that a full Health Technology Assessment (HTA) is recommended to assess the clinical effectiveness and cost effectiveness of prolonged release melatonin (Slenyto®) compared to the current standard of care. However, to date the company have not made a HTA submission to the NCPE for assessment.

The position remains that a submission of a completed HTA dossier to the NCPE is required to progress this application, as per the formal processes governing the pricing and reimbursement of medicines.

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