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Paul Murphy, T.D.
Dáil Éireann,
Leinster House,
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Dublin 2.

30th January 2025

PQ: 46855/24

To ask the Minister for Health if he will instruct his Department to make melatonin available for children with autism diagnosis under the hardship scheme for medication, and not part of the DPS with a GP prescription; and if he will ensure that there is no requirement for a consultant script for access. -Paul Murphy

Dear Deputy Murphy,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 46855/24), which you submitted to the Minister for Health for response.

Melatonin has never been available through the formal Reimbursement List for reimbursement under Community Drug Schemes. 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.

Pharmaceutical companies are required to submit and pricing and reimbursement application should they wish for their product to be added to the Reimbursement List.

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 (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) in 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.

The HSE Corporate Pharmaceutical Unit received an application for pricing and reimbursement of Melatonin (Voquily® 1mg/ml Oral solution) in September 2024 from Caragen Ltd for sleep onset insomnia in children and adolescents aged 6-17 years with attention-deficit hyperactivity disorder (ADHD) where sleep hygiene measures have been inadequate. 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. However, to date the company have not made a Rapid Review submission to the NCPE for assessment.

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

Exceptional arrangements (Discretionary Hardship Arrangements) are considered for supply of items not on Reimbursement List for those with medical card eligibility. All applications for Melatonin under Discretionary Hardship Arrangements are reviewed on an individual patient basis. An individual reimbursement form is required to be completed and submitted by the prescribing consultant in all cases.

Sufficient clinical information, including therapies trialled to date should be submitted as part of the application to enable a positive recommendation. Applications are submitted by the dispensing pharmacy to the HSE local office for consideration.

Under Community Drug Schemes, Exempt Medicinal Products must be Consultant initiated. However, whilst the original prescriber is a Consultant and specialist in the relevant field, the HSE will accept a GP prescription further to the initial hospital prescription for approved patients

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