Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
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Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
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Tel: (01) 864 7100 Fax: (01) 834 3589

Pádraig O'Sullivan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

14th May 2025

PQ: 20312/25
To ask the Minister for Health if the drug duvyzat for the treatment of muscular dystrophy (givinostat) is available for reimbursement; and if she will make a statement on the matter. -Pádraig O'Sullivan

Dear Deputy O'Sullivan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 20312/25), 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.
On 25th April 2025, the EMA's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for givinostat

(Duvyzat®) for the treatment of Duchenne muscular dystrophy (DMD) in ambulant patients, aged 6 years and older, and with concomitant corticosteroid treatment. The European Commission is the authorising body for all centrally authorised medicines, who makes a legally binding decision based on the EMA's recommendation. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States. The marketing authorisation for givinostat (Duvyzat®) is awaited from the European Commission.

To date neither the EMA nor the HPRA have granted marketing authorisation for givinostat 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