

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
(9.9.2025)

Based on the scientific opinion adopted on 25 April 2025 by the European Medicine Agency's Committee for Human Medicinal Products (CHMP), on 6 June 2025¹ the Commission granted a conditional marketing authorisation for Duvyzat (active substance givinostat), intended for the treatment of Duchenne muscular dystrophy. The authorisation was granted within the timelines laid down in the legislation² following the consultation of the Member States in line with the comitology rules (examination procedure)³.

Duvyzat is indicated for patients from the age of six who are able to walk, to be taken at the same time as corticosteroid treatment. The benefit of Duvyzat was shown in a clinical study where, patients aged six years and older receiving Duvyzat on top of corticosteroids, maintained mobility longer compared to patients receiving placebo and corticosteroids. The benefit was measured by a reduction in the time needed to complete the four-stair climb test after 18 months of treatment.

To confirm the efficacy of Duvyzat, the company is requested to conduct two post-authorisation studies, a placebo-controlled study and an efficacy- safety study based on data from a patient registry of children with Duchenne muscular dystrophy⁴.

¹ Union Register of medicinal products <https://ec.europa.eu/health/documents/community-register/html/h1930.htm>.

² <https://eur-lex.europa.eu/eli/reg/2004/726/oj/eng>.

³ <http://data.europa.eu/eli/reg/2011/182/oj>.

⁴ Duvyzat <https://www.ema.europa.eu/en/medicines/human/EPAR/duvyzat>.