From the Chief Medical Officer
Professor Sir Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

HSS(MD) 43/2026

FOR ACTION

Chief Executives, Public Health Agency/HSC Trusts/NIAS
Chief Operating Officer, SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums *(for onward distribution to practice staff)* and Community Pharmacies
OOH Medical Managers *(for onward distribution to staff)*

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Your Ref:
Our Ref: HSS(MD) 43/2026
Date: 9 November 2026

Dear Colleague

MHRA DRUG SAFETY UPDATE: Duvyzat®▼(givinostat): interim advice on risk mitigation measures following reports of deaths in patients while taking givinostat

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued the below Drug Safety Update.

Healthcare Professionals are asked to note and action the advice for healthcare professionals and advice for healthcare professionals to provide to patients, contained within the Drug Safety Update.

Please find the link to the complete **MHRA Drug Safety Update** included below:

Duvyzat®▼(givinostat): interim advice on risk mitigation measures following reports of deaths in patients while taking givinostat

There have been several reports internationally of deaths in patients with Duchenne muscular dystrophy (DMD) while being treated with Duvyzat® (givinostat). Following a review of these cases and associated evidence, the MHRA has proposed updates to the product information. Interim monitoring advice is being provided by the MHRA based on these proposals, pending independent review and finalisation of the MHRA's position.

Reporting advice

Duvyzat®▼ (givinostat) is subject to additional monitoring. Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals

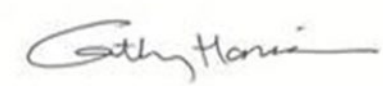
When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

For queries or more information, please contact info@mhra.gov.uk.

You can subscribe to the MHRA new Safety Roundup bulletin here. The latest MHRA Safety Roundup is available at the following link: **MHRA Safety Roundup**.

Yours sincerely





Prof Sir Michael McBride
Chief Medical Officer

Prof Cathy Harrison
Chief Pharmaceutical Officer

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