Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

November 2025

Summary of the latest safety advice for medicines and medical device users

Contents

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Letters, medicines recalls and device notifications sent to healthcare professionals in November 2025

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in November 2025

- Information on Reported Cases of Patient Deaths Among Duchenne Muscular Dystrophy Patients Receiving Duvyzat®▼ (givinostat)
- Libtayo®▼(cemiplimab) 350 mg concentrate for solution for infusion: Batch / lot number and expiry date may become illegible following sanitisation and wiping of vial label
- DISCONTINUATION OF: Levemir® Penfill® and Levemir® FlexPen®

Medicine Recalls and Notifications

In November 2025, recalls and notifications for medicines were issued on:

Class 3 Medicines Recall: Sun Pharmaceutical Industries Limited, Fingolimod SUN 0.5mg hard capsules, EL(25)A/49. Issued 20 November 2025.

Sun Pharma UK Limited is conducting a precautionary recall of a single batch of Fingolimod SUN 0.5 mg hard capsules due to reports of capsule breakage on removing from the blister. No other batches of Fingolimod SUN 0.5mg hard capsules are impacted.

Class 3 Medicines Recall: Sun Pharmaceutical Industries Limited, Atorvastatin 20mg and 80mg Film-coated Tablets, EL(25)A/48. Issued 11 November 2025.

Sun Pharma UK Limited are recalling affected batches of tablets listed in the recall as a precautionary measure due to failing dissolution test results reported during ongoing stability studies.

Class 3 Medicines Recall: Zambon SpA, Emylif 50mg orodispersible film, EL(25)A/47. Issued 10 November 2025.

Zambon SpA is recalling an affected batch as a precautionary measure due to out of specification results for unknown impurities during ongoing stability testing.

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Class 4 Medicines Notification: Special Concept Development UK Limited, Baclofen 10mg Tablets, EL(25)A/51. Issued 27 November 2025.

Special Concept Development UK Limited has informed the MHRA that the Patient Information Leaflet (PIL) for the batches listed in the notification do not contain the correct safety information.

Class 4 Medicines Notification: Lexon UK Ltd, Moclobemide 150mg tablets, EL(25)A/50. Issued 25 November 2025.

Lexon UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the cartons for the batches listed in the notification is missing important updated safety information.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped.

Report a medicine

Healthcare professionals should report via a Yellow Card to:

- 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 (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

Reporting for medical devices

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your

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organisations medical device policies and procedures.

Reporting for Patients

Report a medicine or medical device

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

News Roundup

Reported Cases of Patient Deaths Among Duchenne Muscular Dystrophy Patients Receiving Duvyzat®▼ (givinostat) and reminder of risk mitigation measures

Please be aware of this Direct Healthcare Professional Communication which informs healthcare professionals that a number of deaths have been reported internationally in patients with Duchenne muscular dystrophy (DMD) who were treated with Duvyzat® (givinostat). No deaths have been reported in the UK.

The MHRA is currently reviewing these cases and will be seeking advice from the Commission on Human Medicines (CHM) at the earliest opportunity.

Healthcare professionals are reminded of the current monitoring requirements and warnings in the product information, see the DHPC for further information. Duvyzat can cause prolongation of QTc, so its use should be avoided in patients at increased risk for ventricular arrhythmias, such as those with congenital long QT syndrome, coronary artery disease, electrolyte disturbances, or those taking other medicines known to cause QT prolongation.

In patients with underlying cardiac disease or those on concomitant medications that cause QT prolongation, ECGs should be obtained prior to initiating treatment, during concomitant use, and as clinically indicated.

Duvyzat is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card scheme.

Tamoxifen: update to product information on QT Prolongation and monitoring recommendations for high-risk patients

Current clinical guidelines identify tamoxifen as a medicine with potential to prolong QT interval on an electrocardiogram (ECG), although the risk of Torsade de Pointes (TdP) is considered low. Tamoxifen is also known to cause QT prolongation in overdose.

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Following MHRA assessment of post-marketing safety data and clinical trial ECG results, new information has been added to the tamoxifen (Nolvadex) product information about QT interval prolongation observed on ECG.

Healthcare professionals are advised to monitor ECG and electrolytes before and during tamoxifen treatment in patients with risk factors for QT prolongation, including those with cardiac comorbidities or taking QT-prolonging medicines. Patients should be informed of this potential risk and advised to report symptoms such as palpitations, dizziness, or fainting.

For more information, the Summary of Product Characteristics and Patient Information Leaflets can be found on the MHRA website.

MHRA begins hosting Patient Safety Commissioner

Recently the MHRA welcomed Professor Henrietta Hughes, the Patient Safety Commissioner for England. MHRA begins hosting her office.

This marks an important step in strengthening patient safety. The Commissioner plays a vital role as an independent advocate for patients, ensuring their voices are heard and acted upon. While hosted by MHRA, the Commissioner remains fully independent, reporting directly to Parliament and setting her own priorities.

Welcoming Henrietta and her team to the MHRA's London office today, Chief Executive Lawrence Tallon said:

"Patient safety is the foundation of everything we do. By hosting the Commissioner, we're creating a stronger platform for collaboration while respecting independence. Together, we can amplify patient voices and drive innovation that delivers safer outcomes for all."

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