Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

August 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 August 2025

Direct Healthcare Professional Communications

In July and August 2025, the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals:

- Carbimazole or thiamazole (synonym: methimazole)-containing products: Risk of acute pancreatitis and strengthened advice on contraception
- Rapamune Oral Solution Product Quality Defect Notification, restricted use of medicinal product beyond the expiration date of syringe adapter
- Ceptava (mycophenolic acid) 360 mg Gastro-resistant Tablets Interim Supply of Italy and Spain Stock

Medicine Recalls and Notifications

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

Class 2 Medicines Recall: Fucidin 250 mg Tablets, LEO Laboratories Ltd trading as LEO Pharma, EL(25)A/38. Issued 4 August 2025
LEO Pharma is recalling the affected batch as a precautionary measure due to out of specification results for impurities during routine stability testing.

Class 4 Medicines Defect Notification: Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution, Zydus Pharmaceuticals UK Ltd, EL(25)A/39. Issued 7 August 2025
Zydus Pharmaceuticals UK LTD has informed the MHRA that there is an error on the artwork for the outer carton and Patient Information Leaflet (PIL) of Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution (pack size 150ml and 280ml bottles).

Class 4 Medicines Defect Notification: Levetiracetam Accord 100mg/ml oral solution, Accord Healthcare Limited, UK, EL(25)A/40. Issued 14 August 2025
Accord Healthcare Limited, UK has informed the MHRA that the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SPC) do not contain all the required safety information.

Class 4 Medicines Defect Notification: Fexofenadine Hydrochloride 120mg film-coated tablets, Chanelle Medical Unlimited Company, EL(25)A/41. Issued 21 August 2025

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Chanelle Medical Unlimited Company has informed the MHRA of an error with the European Article Number (EAN) / Global Trade Item Number (GTIN) barcode on certain batches of Fexofenadine Hydrochloride 120mg film-coated tablets, distributed by Healthcare Pharma Limited.

Class 4 Medicines Defect Notification: Ipca Laboratories UK Limited, Various Products, EL(25)A/42. Issued 26 August 2025
Ipca Laboratories UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in the products listed in this notification do not contain all the required 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

MHRA launches a Cosmetic Breast Augmentation Risk Awareness Tool

The MHRA is launching a Cosmetic Breast Augmentation Risk Awareness Tool. This follows an MHRA research study which found there were opportunities to improve risk communication for breast implant surgery.

The aim of the tool, which is arranged as a checklist, is to empower the patient to understand the current known risks associated with breast implants and cosmetic augmentation surgery and as an aid for discussion with their surgeon. The Cosmetic Breast Augmentation Risk Awareness Tool should be provided to patients at their first consultation. Patients are also encouraged to make use of the tool and may wish to bring a copy to their first consultation with their surgeon. Further information can be found on our guidance page.

Specific brand of children's magnesium gummies found to contain undeclared melatonin

The MHRA issued a press release advising parents and caregivers who have purchased Nutrition Ignition Kids Magnesium Glycinate Gummies to stop giving them to children and dispose of any remaining product safely, by taking it to a pharmacy. Testing of two batches by the MHRA identified melatonin, which is a prescription-only medicine, within the product. It is recommended that advice be sought from a healthcare professional if a child has any side effects that are of concern. Read the full press release

Health Institution Exemption for medical devices – Stakeholder survey

The MHRA invites any clinicians or health institutions using medical devices in Great Britain to share their experience of using the health institution exemption (sometimes referred to as an in-house manufacturing exemption) by completing this survey **by 11:59pm on Monday 15 September 2025**.

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We aim to refine the health institution exemption policy within the medical devices regulatory framework to help health institutions deliver safe, effective, and innovative devices to patients - closer to home.

Self-sampling at the point-of-care – enhancing access, improving care

As the UK regulator for medical devices, the MHRA ensures that self-sampling devices are safe, effective, and properly registered before they can be used. This article, which the MHRA have co-authored with the Royal College of Pathologists, sets out clear guidance on regulation, including device marking (UKCA/CE), transport requirements, and the importance of a system-wide approach to implementation. Read the full article

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For any enquiries, please contact info@mhra.gov.uk

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