



MHRA SAFETY ROUNDUP

June 2026

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

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Healthcare professionals should be aware of the potential for delayed onset of angioedema and the distinction between bradykinin- and histamine-mediated cases, as treatment strategies differ significantly and bradykinin-mediated angioedema does not respond to standard treatment.



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ACE-inhibitors: Be aware of the distinction between bradykinin- and histamine-mediated angioedema, as treatment strategies differ significantly



[Access the full article](#)

Specialisms: *Cardiovascular disease, General Practice, Emergency medicine, Pharmacy and Nephrology*

Summary

The product information for all ACE inhibitors is being updated to strengthen the warnings on the risk of delayed-onset angioedema, which may still occur after weeks to years of use. Healthcare professionals, particularly in emergency departments, should be aware of the potential for delayed onset of angioedema and the distinction between bradykinin- and histamine-mediated cases, as treatment strategies differ significantly and bradykinin-mediated angioedema does not respond to standard treatment.

Key Advice for Healthcare Professionals:

- angioedema is a known uncommon or rare side-effect of ACE inhibitor treatment. This can either be allergic (histamine-mediated) or less commonly non-allergic (bradykinin-mediated). Healthcare professionals should consider bradykinin-mediated mechanisms as a cause when standard anaphylaxis treatment is ineffective
- angioedema can occur at any time during treatment, including after weeks to years of use
- swelling of the tongue, lip, face, or larynx which may cause difficulty in breathing or swallowing may progress and can lead to airway compromise. Other symptoms can include gastrointestinal pain and cramps
- bradykinin-mediated angioedema is unlikely to respond to standard anaphylaxis treatments including adrenaline (epinephrine)
- lack of response to standard anaphylaxis treatments should prompt consideration of bradykinin-mediated angioedema, with treatment informed by clinical protocols
- if angioedema is suspected in a patient taking an ACE inhibitor, discontinue the ACE inhibitor immediately and do not restart



Key Advice for Healthcare Professionals to Provide to Patients:

- although uncommon or rare, angioedema (swelling of the face, lips, tongue, or throat) can occur at any time while taking an ACE inhibitor, even if you have been taking it for a long period without problems
- seek urgent medical attention if you develop swelling of the face, lips, tongue, or throat, or experience difficulty breathing or swallowing whilst taking ACE inhibitors
- do not take further doses of your ACE inhibitor if angioedema is suspected and inform a healthcare professional immediately
- inform healthcare professionals if you have ever experienced angioedema, including while taking an ACE inhibitor. Please be aware that angioedema can occur for other reasons, and a healthcare professional may still recommend an ACE inhibitor for you in these instances

Letters, medicines recalls and device notifications sent to healthcare professionals in June 2026

Direct Healthcare Professional Communications

We received notification that the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals in June 2026:

- [Ontozry ▼ \(cenobamate\): new requirements for liver monitoring due to reports of severe liver injury](#)
- [Tyenne 20 mg/mL concentrate for solution for infusion \(tocilizumab\): Interim Supply of Swedish/Finnish Stock to Mitigate Supply Disruption](#)
- [Isturisa 1 mg film-coated tablets \(osilodrostat\) \[PLGB 15266/0029\]: Interim Supply of Czech Republic, Slovakian and Slovenian Language Stock to Mitigate Supply Disruption](#). Sent to relevant stakeholders in May 2026.

Medicine Recalls and Notifications

In June 2026, recalls and notifications for medicines were issued on:



Class 2 Medicines Recall: Becton Dickinson UK Ltd, ChloroPrep 2% 1mL and ChloroPrep Frepp 2% 1.5mL applicators, EL(26)A/26. Issued 02 June 2026.

Becton Dickinson UK Ltd are recalling batches of ChloroPrep 2% 1mL applicators and ChloroPrep Frepp 2% 1.5 mL applicators due to a potential breach of sterility in the packaging process.

Class 3 Medicines Recall: Orbit Pharma Limited, Cyclizine Lactate 50 mg/ml Solution for injection, EL(26)A/29. Issued 16 June 2026.

Orbit Pharma Limited is recalling a specific batch of Cyclizine Lactate 50 mg/ml Solution for injection as a precautionary measure due to Good Manufacturing Practice (GMP) deficiencies identified at the manufacturing site.

Class 3 Medicines Recall: Flamingo Pharma UK Ltd, Flucloxacillin Capsules BP 500mg, EL(26)A/32. Issued 30 June 2026.

Flamingo Pharma UK Ltd have informed the MHRA that certain packs of Flucloxacillin Capsules BP 500mg contain the incorrect PIL. The affected packs contain the PIL for Amoxicillin 500mg Capsules instead of the PIL for Flucloxacillin BP 500mg Capsules.

Class 4 Medicines Defect Notification: Cadila Pharmaceuticals Limited, Mirtazapine 30mg Tablets, EL(26)A/28. Issued 8 June 2026.

Cadila Pharmaceuticals Limited has informed the MHRA of an error with the European Article Number (EAN) barcode on the cartons of a batch of Mirtazapine 30mg Film-Coated Tablets distributed in Crescent Pharma Limited livery.

Class 4 Medicines Defect Notification: Teva UK Ltd, Ponlimsi (Denosumab) 60mg Solution for Injection in Pre-filled Syringe, EL(26)A/27. Issued 04 June 2026

Teva UK Limited is reporting a labelling error on the carton for Ponlimsi (Denosumab) 60mg Solution for injection in Pre-filled Syringe. The carton states "For application to the skin" when the product is licensed for subcutaneous use.

Class 4 Medicines Defect Notification: Brancaster Pharma Limited, Benzylpenicillin benzathine 1.2 Million I.U. and 2.4 Million I.U. powder for suspension for injection, EL(26)A/31. Issued 29 June 2026.

Brancaster Pharma Limited has informed the MHRA that the Patient Information Leaflet (PIL) in the cartons for the batches listed in the notification were released with an outdated PIL.



Class 4 Medicines Defect Notification: Relonchem Limited, Gabapentin Relonchem 50mg/ml Oral Solution, EL(26)A/31. Issued 30 June 2026.

Relonchem Limited have informed the MHRA that particles have been observed inside some bottles of Gabapentin Relonchem Oral Solution, identified through a customer complaint.

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, SystemOne, 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 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 AI sandbox to accelerate medicines development and improve safety

The UK will launch a first-of-its-kind initiative to test how artificial intelligence (AI) can help make medicines safer for patients. Announced during London Tech Week on 9 June 2026, the programme will explore how AI could improve the assessment of accuracy and safety, better predict risks, and detect effects that existing approaches may not capture.

The Medicines and Healthcare products Regulatory Agency (MHRA) will establish a new regulatory sandbox, giving companies and researchers a controlled testing environment to work with regulators to explore how AI tools could be used to better understand medicines safety and predict potential side effects.

Adverse drug reactions send around 250,000 people to hospital in the UK every year, while around 90% of drugs fail during development, in part because existing methods cannot not always predict how medicines would behave in people.

The sandbox will allow innovators to test AI tools that have the potential to predict how medicines behave in the body, including how they are absorbed, processed and whether they might cause harm.

The programme will form part of a wider effort to modernise medicines development and support faster access to safe, effective and innovative treatments.

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

