Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

October 2026

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

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Drug Safety Update

IXCHIQ Chikungunya vaccine: UK marketing authorisation withdrawn following safety review Page 5

Following advice from the Commission on Human Medicines (CHM), the MHRA has concluded that the benefit-risk balance for the IXCHIQ chikungunya vaccine is no longer considered favourable and the UK marketing authorisation has been withdrawn.

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Continuous renal replacement therapy (CRRT) is used for managing severe acute kidney injury and fluid overload. Published evidence has shown that caspofungin can bind to polyacrylonitrile (PAN)-based membranes used in CRRT which may result in ineffective antifungal treatment.

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Nova Biomedical has identified quality issues affecting specified lots of StatStrip ketone test strips. The affected lots have been associated with quality-control (QC) failures and Nova Biomedical has initiated a recall, advising that these lots should not be used. Nova Biomedical has also paused distribution of the affected lots and advised that any further lots found to fail QC testing should also be withdrawn from use.

Drug Safety Update

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Antidepressants: new safety measures for all patients to improve communication of the risk of suicidal thoughts and behaviours and persistent sexual dysfunction

Access the full article

Specialisms: *Psychiatry, General Practice, Pain management, Pharmacy, Dispensing GP practice*

Summary

New safety measures are now being implemented for all patients taking antidepressant medications. This follows completion of a detailed review, involving patients and their families, into how the risks of suicidal thoughts and behaviours, and persistent sexual dysfunction are communicated in the patient information leaflets (PILs) that accompany antidepressant medications. These changes involve a new boxed warning in the PIL, a new patient card, and a supporting safety (ancillary) leaflet. The term post SSRI sexual dysfunction ("PSSD") is also being added to the PIL for some antidepressant medications.

Key Advice for Healthcare Professionals:

- discuss with patients when starting or changing the dose of an antidepressant or at their next review, the risk of suicidal thoughts and behaviours. Advise patients to seek urgent medical attention if they experience new or worsening feelings of suicidal intent in relation to starting an antidepressant, especially early in treatment or following dose changes
- discuss with patients when starting or changing the dose of an antidepressant, or at their next review, that there is evidence that some antidepressants are associated with a risk of sexual dysfunction and that symptoms may continue after stopping treatment with certain antidepressants. Some patients refer to this as “PSSD”
- follow the relevant NICE guidance and monitor your patients regularly after starting treatment with an antidepressant
- give your patient the safety (ancillary) leaflet when it becomes available in 2027 to support your risks and benefits discussions
- report suspected adverse reactions associated with antidepressants on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- if you have new or worsening suicidal thoughts, particularly when starting or changing dose of antidepressants, seek urgent medical attention. You can call NHS 111, or your local mental health crisis team, Samaritans on 116 123, or text “SHOUT” to 85258. You can find more information and support options on the NHS website
- there is the potential for you to experience sexual dysfunction with some antidepressants, which may continue even after you stop the medicine. Please contact your healthcare professional if you have any concerns
- these are not new risks for these medicines, but it is important to be aware of them
- do not stop taking your medicine without first speaking to your healthcare professional
- please also read the patient card and the Patient Information Leaflet which contains important information about your medicine
- when it becomes available in 2027, you will also receive a supporting safety (ancillary) leaflet explaining the benefits and risks of treatment options to help you have informed discussions with your healthcare professional about taking your medicine safely
- report suspected side effects via the Yellow Card scheme

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IXCHIQ Chikungunya vaccine: UK marketing authorisation withdrawn following safety review

Access the full article

Specialisms: *Infection prevention, Infectious disease, Immunology and vaccination*

Summary

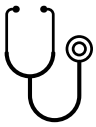
Following advice from the Commission on Human Medicines (CHM), the MHRA has concluded that the benefit-risk balance for the IXCHIQ chikungunya vaccine is no longer considered favourable and the UK marketing authorisation has been withdrawn. Healthcare professionals should no longer prescribe or administer the IXCHIQ vaccine and should instead consider alternative measures to reduce the risk of chikungunya infection in individuals travelling to affected areas.

Key Advice for Healthcare Professionals:

- the UK marketing authorisation for the IXCHIQ vaccine (chikungunya vaccine) has been withdrawn and the product is being removed from the UK market
- do not prescribe, supply or administer the IXCHIQ vaccine, and dispose of any remaining stock in accordance with local policies
- ensure that any materials, systems or communications referring to available UK vaccination options are updated to remove the IXCHIQ vaccine
- advise travellers of alternative measures to prevent chikungunya infection, including other available vaccines for chikungunya, avoidance of mosquito bites and adherence to current health-related travel advice
- patients who have previously received the IXCHIQ vaccine do not need to take any specific action as a result of this regulatory decision. However, they should seek medical advice if they have experienced a suspected adverse reaction following IXCHIQ vaccination
- continue to report suspected adverse reactions associated with the IXCHIQ vaccine on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- following a review of all available evidence the MHRA has withdrawn the UK marketing authorisation for the IXCHIQ vaccine because the benefits of this vaccine are no longer considered to outweigh its risks
- individuals who have already received the IXCHIQ vaccine do not need another vaccination or any other specific medical treatment because of this decision
- anyone who experiences a suspected side effect following vaccination should seek medical advice and report it on a Yellow Card



Continuous renal replacement therapy (CRRT): Consider delayed administration of concurrent echinocandins, such as caspofungin, to reduce the risk of adsorption onto new polyacrylonitrile (PAN)-based filter membranes

Access the full article

Specialisms: *Anaesthetics and intensive care, Cancer, Critical Care, Infection prevention, Infectious disease, Renal medicine, Urology and nephrology, Paediatrics and neonatology*

Device Details:

All continuous renal replacement therapy devices

Summary

Continuous renal replacement therapy (CRRT) is used for managing severe acute kidney injury and fluid overload. Published evidence has shown that caspofungin can bind to polyacrylonitrile (PAN)-based membranes used in CRRT which may result in ineffective antifungal treatment with potentially life-threatening consequences in critically ill patients. It is considered that the potential risk is greatest when a new membrane or filter circuit has commenced. This is because adsorption reduces over time as the membrane becomes saturated. The same risk cannot be excluded for other membrane types used in CRRT or other drugs with similar properties. Where possible, it is recommended that

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echinocandins such as caspofungin, and similar drugs, are administered at least six hours after initiation of PAN-based filter use, and after filter circuit set changes.

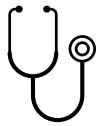
Key Advice for Healthcare Professionals:

- echinocandins, such as caspofungin, may adsorb onto PAN-based membranes used in CRRT which may result in ineffective antifungal treatment
- adsorption risk reduces over time as the membrane becomes saturated
- where possible, administration of antifungal treatments, including with echinocandins and similar drugs, should be at least 6 hours after CRRT has been initiated or following routine filter circuit set changes. CRRT should proceed as clinically indicated and should not be delayed or paused solely to facilitate drug administration, unless otherwise deemed necessary by the responsible clinician
- all healthcare professionals involved in the CRRT process and set up, as well as the prescribing, dispensing and administration of caspofungin, should be made aware of this recommendation
- seek specialist pharmacist, infectious disease, medical microbiology or mycology input if you are concerned about potential loss of therapeutic efficacy
- filter adsorption should be considered as a potential reason for treatment non-responders, or sub-therapeutic responses, whilst patients are receiving any concurrent treatment during CRRT
- healthcare providers should review and update local protocols and standard operating procedures to reflect the potential for drug adsorption during CRRT, and to include recommendations for timing of medication administration in the context of this DSI

Key Advice for Healthcare Professionals to Provide to Patients:

- the advice in this DSI is aimed at healthcare professionals in charge of treating and managing patients receiving CRRT. If you have any concerns about this advice, contact your healthcare professional

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Nova Biomedical StatStrip ketone test strips: risk of disruption to blood ketone testing due to quality-control failures and supply interruption

Access the full article

Specialisms: *Pathology, Emergency medicine; Diabetes; Paediatrics and neonatology; Critical care; Ambulance services; Community healthcare; Point-of-care testing*

Device Details:

Nova Biomedical StatStrip Ketone Test Strips

Part Number: **46951,** Product Name: **TEST STRIP 50CT KET STRIP DUAL PACK**

Summary

Nova Biomedical has identified quality issues affecting specified lots of StatStrip ketone test strips. The affected lots have been associated with quality-control (QC) failures and Nova Biomedical has initiated a recall, advising that these lots should not be used. Nova Biomedical has also paused distribution of the affected lots and advised that any further lots found to fail QC testing should also be withdrawn from use.

The recall, paused distribution and potential withdrawal of additional lots may result in a progressive reduction in the availability of ketone test strips and disruption to blood ketone point-of-care testing. Nova Biomedical has advised that replacement stock is not expected to be available in the UK for approximately 4 weeks, which may increase the risk of supply constraints during this period.

Key Advice for Healthcare Professionals:

- if your organisation uses Nova Biomedical StatStrips, establish which lots are currently held and available for clinical use
- discontinue clinical use and dispose of all lots identified by Nova Biomedical as subject to recall
- for lots that are not subject to recall, ensure users follow the instructions for use. If a lot fails QC testing on two consecutive occasions, remove the lot from use, dispose of any remaining test strips in accordance with local procedures, and switch to an

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alternative lot number if available, or use an alternative method for blood ketone testing
- do not assume that the current quantity of strips represents the duration of available supply, as additional lots may become unavailable if there is QC failure
- assess current and anticipated blood ketone testing capacity, including the number and location of ketone testing devices, current usable strip stock and anticipated out-of-stock dates
- identify and validate alternative ketone testing methods where available, including alternative point-of-care devices and laboratory testing
- where supply is constrained, prioritise available blood ketone testing for patients at greatest clinical risk, including patients with suspected or established Diabetic Ketoacidosis (DKA), paediatric patients, acutely unwell patients with type 1 diabetes and patients requiring serial ketone measurements during DKA treatment
- ensure that appropriate escalation arrangements are in place where clinically indicated ketone testing is unavailable
- ensure that relevant clinical, point-of-care testing, procurement and governance teams are aware of the supply disruption and appropriate local contingency arrangements are implemented

Key Advice for Healthcare Professionals to Provide to Patients:

- the advice in this DSI is aimed at healthcare professionals who are managing your care. You can be reassured that your healthcare professional will take the necessary steps to ensure your care is not impacted. If you have any concerns, contact your healthcare professional
- if you experience vomiting, abdominal pain, deep/rapid breathing, fruity/pear-smelling breath, marked drowsiness or confusion, severe thirst or dehydration, or are becoming progressively unwell, please seek urgent medical care as you may have diabetic ketoacidosis (DKA)
- continue following your prescribed sick-day/insulin plan unless your healthcare professional tells you otherwise. Do not stop using your insulin unless your healthcare professional tells you to
- keep checking blood glucose frequently if you have a meter or continuous glucose monitor (CGM) and report persistent or worsening high blood glucose levels

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#MedSafetyWeek (2 to 8 November 2026): Don't ignore suspected side effects, report them! Updates to the Yellow Card website and app

Access the full article

Specialisms: *All specialisms*

Summary

The annual #MedSafetyWeek campaign is taking place from 2 to 8 November 2026 to promote the importance of reporting side effects from medicines and medical device incidents. This year's theme is 'Side effects: don't ignore them, report them!'

The Yellow Card scheme relies on both healthcare professionals and patients reporting any suspected side effects and adverse incidents, allowing the MHRA to identify and monitor potential safety concerns related to medicines, devices, vaccines, blood products and e-cigarettes.

#MedSafetyWeek raises awareness of the Yellow Card scheme and this year's theme encourages the reporting of side effects and adverse incidents. Yellow Card reporting plays a key role in keeping patients safe and ensures that healthcare products remain effective and safe by helping the MHRA identify new safety issues as early as possible.

Key Advice for Healthcare Professionals:

You can support the campaign to raise awareness of the Yellow Card scheme by:

- **using the new campaign materials** on the Yellow Card website, including posters, digital screens, waiting room materials and social media assets, to raise awareness and promote Yellow Card reporting, signposting patients to the Yellow Card website or Yellow Card app
- **following MHRA social media channels and sharing content using #MHRAYellowCard, #MedSafetyWeek, #ReportSideEffects and #patientsafety** to raise awareness of reporting
- referring to our suite of Yellow Card e-learning modules, including the recently CPD accredited free British Pharmacological Society Assessment (BPSA)

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

Direct Healthcare Professional Communications

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

- Antidepressants: New safety measures for all patients to improve communication of the risk of suicidal thoughts and behaviours and persistent sexual dysfunction
- Guanfacine prolonged-release tablets (PL 49718/0136-0142): Important safety information missing from the Summary of Product Characteristics regarding QT/QTc interval prolongation
- Important information regarding the use of the alternative name Estraseven Duo 50 micrograms/7 micrograms/24 hours, transdermal patches for FemSeven® Conti 50 micrograms/7 micrograms/24 hours, transdermal patch
- IKERVIS 1mg/ml ciclosporin eye drops, emulsion: Interim Supply of Australian Stock to Mitigate Supply Disruption
- Lacosamide Neuraxpharm 10 mg/ml syrup (PL 49718/0079): Important safety information missing from current approved Summary of Product Characteristics regarding myoclonic seizures, ataxia and reproductive health counselling
- BEROMUN® Img, Powder for solution for infusion (Tasonermin- EU license number: EU/1/99/097/001): Interim Supply of German Stock to Mitigate Supply Disruption
- Caspofungin: use of polyacrylonitrile membranes during continuous renal replacement therapy
- Direct Healthcare Professional Communication on the association of Patent Blue Violet (Patent Blue V) with serious allergic reactions. *Sent to relevant stakeholders in August 2026*

Medicine Recalls and Notifications

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

Class 2 Medicines Recall: Norgine Pharmaceuticals Limited, Pedmarqsi 80 mg/mL solution for infusion, EL(26)A/42. Issued 12 October 2026.

Norgine Pharmaceuticals Limited is recalling the batches listed in the notification due to risk of particulate matter being present in the product identified during routine stability investigations.

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Class 2 Medicines Recall: Xeal Pharma, Clopidogrel Oral Liquids (all strengths), EL(26)A/43. Issued 26 October 2026.

Xeal Pharma have informed MHRA that all strengths of their Clopidogrel Oral Suspension and Clopidogrel Oral Solution products contain less than the labelled amount of clopidogrel.

Class 3 Medicines Recall: Norgine Limited, MOVICOL Plain 13.7g powder for oral solution, EL(26)A/41. Issued 5 October 2026.

Norgine Limited is recalling specific batches of product as a precautionary measure due to some units containing the incorrect amounts of active ingredients.

Class 4 Medicines Defect Notification: Neuraxpharm UK Limited, Levetiracetam Neuraxpharm granules for oral solution in sachet, EL(26)A/40. Issued 1 October 2026.

Neuraxpharm UK Limited have informed the MHRA that a review of the approved Patient Information Leaflet (PIL) has identified discrepancies between the current Neuraxpharm product safety information and the corresponding reference product 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

Reporting for medical devices

Healthcare professionals should report incidents:

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- 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)
- 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

Osimertinib: skeletal muscle toxicity

Myositis and blood creatine phosphokinase (CPK) increased are recognised side effects of osimertinib (Tagrisso). Cases of rhabdomyolysis have also been reported post-marketing in other countries, however the MHRA has not received any UK Yellow Card reports to date. Before initiating treatment, patients should be advised to report any unexplained muscle pain, tenderness, weakness, trouble moving arms or legs, dark tea-coloured urine, or decreased urination. Signs and symptoms of increased CPK, myositis, or rhabdomyolysis should warrant an appropriate clinical evaluation and treatment as indicated. In the case of severe events, osimertinib treatment may need to be interrupted (physicians should consult section 4.2 of the Summary of Product Characteristics).

Ioflupane: venlafaxine and other SNRIs may affect DAT scan interpretation

Cases of false positive interpretation have been reported in patients taking venlafaxine who have been referred for DAT scans using ioflupane as a radiotracer, resulting in potential misdiagnosis of Parkinsons Disease.

The product information for ioflupane has been updated to include this interaction, as well as additional guidance on the interpretation of DAT scan images. This is available on the MHRA products website.

This product information update follows a review of emerging evidence in the literature and on-going pharmacovigilance reports. Although the current available evidence is strongest for venlafaxine and there is limited information on the effect of other serotonin

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noradrenaline reuptake inhibitors (SNRIs), caution should be exercised when interpreting DAT scan images.

The mechanism by which venlafaxine and other SNRIs affects ioflupane binding is not clear; however, this interaction may be more relevant in patients receiving higher doses, elderly patients and/or patients with renal impairment.

Clinicians and nuclear medicine experts should be aware of this potential interaction and consider the need for local procedures to manage patients who are taking venlafaxine and SNRIs. Temporary discontinuation (at least 5 biological half-lives) may be considered before administration of ioflupane. However, this should be considered on a case-by-case basis, and where clinically appropriate and safe for the patient. Patients should also be advised to inform their doctors that they are taking venlafaxine ahead of the DAT scan procedure.

Publication of pneumococcal vaccine factsheet

The MHRA has published a new pneumococcal vaccine factsheet, designed to provide information and guidance for patients, parents and carers on pneumococcal disease and pneumococcal vaccination.

The factsheet outlines the safety and effectiveness of pneumococcal vaccines, who is eligible for vaccination in the UK, and how vaccination helps protect against serious illness.

This resource is now available for healthcare professionals to use when discussing pneumococcal vaccination and to support patients, parents and carers in understanding the protection these vaccines provide. For further information, view the full Pneumococcal Vaccine Factsheet – Information for Patients, Parents and Carers.

Ivacaftor, tezacaftor, elexacaftor (Kaftrio) in combination with ivacaftor (Kalydeco): reminder that information on the risk of serious liver injury was updated in 2025

Warnings on the risk of liver injury in the product information for Kaftrio-Kalydeco combination therapy were updated in 2022 (and published in a Drug Safety Update) to include a case of serious liver injury in a patient with pre-existing cirrhosis and portal hypertension which resulted in liver failure requiring liver transplantation.

Following an MHRA review in 2025, the product information warnings were further strengthened. The product information states that cases of liver failure leading to transplantation have been reported within the first 6 months of treatment in patients with and without pre-existing liver disease.

Current clinical advice to measure alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin levels before starting treatment, every 3 months during the first year of treatment, and annually thereafter remains appropriate to detect liver injury.

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