Medicines & Healthcare products Regulatory Agency

MHRA SAFETY ROUNDUP

February 2026

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

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Falsified Mounjaro KwikPen 15mg pre-filled pens

Access the full article

Specialisms: *Dispensing GP practices, Emergency medicine, Endocrinology, diabetology and metabolism, General practice, Nutrition and dietetics, Pharmacy*

Summary

A falsified version of Mounjaro (tirzepatide) KwikPen 15mg solution for injection has been found supplied through one online pharmacy in the UK. The falsified product is labelled with batch D873576 and applies to Mounjaro KwikPen 15mg solution for injection in pre-filled pen only.

The issue was identified due to faults with the pens, where in all but one case the dose knob came off while in use. We have provided advice for healthcare professionals and patients as a precautionary measure who may be in possession of a 15mg pen with this batch number.

Key Advice for Healthcare Professionals:

- falsified Mounjaro (tirzepatide) KwikPen 15mg solution for injection in pre-filled pens have been identified. They have been supplied in the UK through one online pharmacy - The Private Pharmacy Clinic, located in Birmingham. To date 5 affected pens have been identified
- do not supply Mounjaro KwikPen 15mg solution for injection in pre-filled pens with batch number D873576, all 15mg pens with this batch number are falsified (see pictures of product in the linked article)
- this is a legitimate batch number for genuine Mounjaro KwikPen 7.5mg, and pens at this strength are not impacted
- quarantine all remaining stock that has the affected dose and batch number and return it to your supplier
- it is likely that the substance in the pens is tirzepatide, however the pens are not of the quality and safety standards of legitimate pens and are not safe to use
- all pens identified to date have had a faulty mechanism

- if a patient reports a faulty 15mg pen, ask them to check the batch number and instruct them to discontinue use of the pen if it matches the above-mentioned batch number and contact the MHRA. Patients should always be advised not to try and extract doses from any defective pen
- the MHRA has not received any reports of patient harm that required treatment after taking this falsified medicine
- patients should be advised on signs and symptoms of allergic reactions, infection or sepsis to look out for and any treatment should be provided accordingly
- patients may require replacement medication in order to continue their course of treatment
- The General Pharmaceutical Council have served a 'notice of conditions' on the pharmacy involved. The MHRA is continuing with their ongoing investigations
- report suspected adverse drug reactions to tirzepatide, or suspected defective pens to the Yellow Card Scheme

Key Advice for Healthcare Professionals to Provide to Patients:

- a falsified version of Mounjaro (tirzepatide) KwikPen 15mg solution for injection in pre-filled pen has been identified supplied by one UK online pharmacy - The Private Pharmacy Clinic, located in Birmingham
- this pharmacy is unable to provide more of this medication at this time
- check the batch number on any Mounjaro KwikPen 15mg pre-filled pens you have been dispensed
- if you have a 15mg pen with batch number D873576, do not use the pen. Pictures of the product are provided in the linked article
- patients who have this pen should report the case to the MHRA via info@mhra.gov.uk, please include "Mounjaro Pens" in the subject line. Patients should keep the pen in a safe place, the MHRA will arrange a collection
- if you are unsure of how to identify the pen, or are unsure on whether you have administered an affected batch and have any questions please speak to a healthcare professional
- if you have administered injections using the pen already, please be reassured that, on the basis of the cases reviewed to date, the risk to you is low
- if you have administered injections, and you are experiencing any unusual symptoms that you are concerned about, seek immediate medical attention

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- if you suspect that you've had a side effect to these affected pens, or suspect it's not a genuine product, or have a defective pen you can report it to our Yellow Card scheme. It is important patients do not try to extract any dosage if a pen is defective in any way
- patients should be reminded on the guidance on safe use of GLP-1's GLP-1 medicines for weight loss and diabetes: what you need to know - GOV.UK

Semaglutide (Wegovy, Ozempic and Rybelsus): risk of Non-arteritic Anterior Ischemic Optic Neuropathy (NAION)

Access the full article

Specialisms: *Emergency medicine, Endocrinology, diabetology and metabolism, General practice, Nutrition and dietetics, Ophthalmology and Pharmacy*

Summary

Non-arteritic anterior ischemic optic neuropathy (NAION), a condition that can cause sudden deterioration in vision, usually in one eye at a time, has been very rarely reported in association with semaglutide in the treatment of type 2 diabetes, weight management and cardiovascular risk reduction. Patients reporting a sudden loss of vision (including partial loss) while on semaglutide treatment should be urgently referred for ophthalmological examination.

Key Advice for Healthcare Professionals:

- semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist used to treat type 2 diabetes mellitus and for weight management and cardiovascular risk reduction
- semaglutide treatment may be very rarely associated with NAION, a condition which can cause vision loss, typically in one eye
- NAION typically causes sudden, painless vision loss in one eye that is often described as a blurring or cloudiness of vision
- privately prescribed semaglutide may not appear on the patient's medical history so if a patient presents with these symptoms, enquire about semaglutide use

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- patients reporting a sudden loss of vision (including partial loss) should be urgently referred for specialist examination by an ophthalmologist
- discontinue semaglutide treatment if NAION is confirmed
- advise new patients, or existing patients during medication reviews, to urgently attend eye casualty or A&E if they experience a sudden loss of vision or rapidly worsening eyesight
- report suspected adverse drug reactions associated with semaglutide, including NAION, on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- semaglutide treatment has, in extremely rare cases, been linked to a serious eye condition called NAION, which can affect your vision
- NAION usually affects one eye at a time
- if you notice a change in your eyesight, such as sudden blindness or your eyesight gets worse very quickly in one or both of your eyes during treatment with semaglutide, urgently attend eye casualty (if available in your area) or A&E
- you may be referred for an eye examination by an ophthalmologist

IXCHIQ Chikungunya vaccine: updates to restrictions of use following safety review

Access the full article

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

Summary

Following the completion of a safety review and the recommendations of the Commission on Human Medicines (CHM), the IXCHIQ Chikungunya vaccine is no longer indicated for adults over the age of 60 years, and is contraindicated in all individuals with hypertension, cardiovascular disease, diabetes mellitus, and/or chronic kidney disease. This action follows very rare fatal reactions, and other serious adverse reactions reported globally last year. In addition, the CHM have advised that the IXCHIQ vaccine should be given no later than 30 days prior to travel.

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Key Advice for Healthcare Professionals:

- Chikungunya vaccine (IXCHIQ) is a vaccine to protect against severe Chikungunya virus infection; strict adherence to contraindications and precautions is essential to reduce the risk of very rare but potentially fatal adverse reactions
- a live attenuated Chikungunya vaccine, IXCHIQ, first became available on the UK market on 18 June 2025
- IXCHIQ vaccine is already contraindicated in all individuals with immunodeficiency or immunosuppression as a result of disease or medical therapy, this includes IgA deficiency, history of thymus disorder or thymectomy
- following a review of the benefits and risks of the vaccine, the CHM has the following further recommendations:
    - do not use this vaccine in adults aged 60 years or over, or in individuals with hypertension, cardiovascular disease, diabetes mellitus, and/or chronic kidney disease
    - the vaccine should be given no later than 30 days prior to travel
    - in addition, a comprehensive benefit risk assessment must be conducted prior to vaccination by a healthcare professional trained in the benefit risk assessment of live vaccines
    - precaution is advised when considering vaccination in individuals with two or more underlying health conditions
- the product information for the vaccine will be updated to reflect these changes, and a letter for healthcare professionals will be circulated from the company in addition to this Drug Safety Update, to advise of the above-mentioned restrictions
- patients who have received the vaccine should be advised to seek emergency medical attention if they develop signs or symptoms associated with viraemia, including arthralgia, or neurological symptoms which may indicate encephalitis
- all patients who have received the vaccine should receive the manufacturer's Patient Information Leaflet as part of the travel consultation
- report suspected adverse reactions associated with the IXCHIQ vaccine on a Yellow Card

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Key Advice for Healthcare Professionals to Provide to Patients:

- the Chikungunya vaccine is for adults who plan to travel abroad to regions where Chikungunya virus is present. Chikungunya virus is a potentially life-threatening viral infection
- a live attenuated Chikungunya vaccine, IXCHIQ, first became available on the UK market on 18 June 2025
- you will not be given this vaccine if you are aged 60 years or over, or if you have hypertension, cardiovascular disease, diabetes mellitus, and/or chronic kidney disease, or if you are immunosuppressed or immunodeficient. This is because there have been rare reports of serious side effects in individuals aged 60 and above, and/or in individuals with the chronic conditions specified above. An alternative vaccine is available if IXCHIQ vaccination is unsuitable for you
- during your vaccine consultation you will be assessed by a healthcare professional for vaccine suitability, and the risks and benefits of having the vaccine will also be discussed with you
- if you have received a Chikungunya vaccine, you should seek urgent medical attention if you start to experience signs or symptoms associated with serious reactions resembling chikungunya infection, including arthralgia (severe joint pain), or neurological symptoms including encephalopathy (stiff neck, fever, confusion, memory loss, personality changes or loss of consciousness)

GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists: strengthened warnings on acute pancreatitis, including necrotising and fatal cases

Access the full article

Specialisms: *Endocrinology, diabetology and metabolism; GI, hepatology and pancreatic disorders; Nutrition and dietetics; Emergency medicine; General practice; Pharmacy*

Summary

The product information for all Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonists (dulaglutide, exenatide, liraglutide, semaglutide and tirzepatide) has been further updated

to highlight the potential risk of severe acute pancreatitis with these products, including rare reports of necrotising and fatal pancreatitis. Healthcare professionals should remain vigilant for signs and symptoms of acute pancreatitis in patients treated with GLP-1 and GLP-1/GIP receptor agonists.

Key Advice for Healthcare Professionals:

- be alert to the risk of acute pancreatitis in patients receiving Glucagon-Like Peptide-1 (GLP-1) receptor agonists and dual GLP-1/ glucose-dependent insulinotropic polypeptide (GIP) receptor agonists. There have been rare reports of necrotising and fatal pancreatitis associated with GLP-1 and GLP-1/GIP receptor agonists
- advise patients to seek urgent medical attention if they develop severe and persistent abdominal pain that may radiate to the back and may be accompanied by nausea and vomiting
- privately prescribed GLP-1s and GLP-1/GIPs may not appear on the patient's medical history so if a patient presents with these symptoms, enquire about GLP-1 or GLP-1/GIP use
- if pancreatitis is suspected, discontinue treatment with the GLP-1 or GLP-1/GIP receptor agonist immediately;
- do not restart therapy if the diagnosis of pancreatitis is confirmed
- GLP-1 and GLP-1/GIP receptor agonists should be used with caution in patients with a history of pancreatitis
- report suspected adverse drug reactions associated with this group of medications, including serious or fatal cases of pancreatitis, via the Yellow Card scheme

Key Advice for Healthcare Professionals to Provide to Patients:

- pancreatitis (inflammation of the pancreas) is a possible side effect with GLP-1 receptor agonists and dual GLP-1/ GIP receptor agonists. In rare cases this can have serious or fatal outcomes
- seek urgent medical attention if you experience severe, persistent abdominal pain, that may radiate to your back and may be accompanied by nausea and vomiting, as this may be a sign of pancreatitis
- do not restart GLP-1 receptor agonist or GLP-1/GIP receptor agonist treatment if pancreatitis is confirmed
- report suspected side effects through the Yellow Card scheme

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

Direct Healthcare Professional Communications

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

- Zentiva Thalidomide 50mg Capsules, hard (PL 17780/1266)
- IXCHIQ Chikungunya vaccine: updates to restrictions of use following safety review
- NATPAR (parathyroid hormone) ▼ 25; 50; 75; 100 micrograms/dose powder and solvent for solution for injection: Update on stock availability and marketing authorisation withdrawal. *Sent to relevant stakeholders in January 2026*

Medicine Recalls and Notifications

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

National Patient Safety Alert: Class 1 Medicines Recall Notification: Recall of Quetiapine Oral Suspension (unlicensed medicine), manufactured by Eaststone Limited due to a potential for overdosing, NatPSA/2026/002/MHRA. Issued 29 January 2026.

Eaststone Limited is initiating a recall of all batches of quetiapine oral suspension products due to a potential risk of overdose, which could have consequences for the safety of patients. The formula they have used to manufacture all batches of quetiapine oral suspension products is incorrect. The active content is twice the amount that it should be which could lead to overdosing. Any patients who have taken batches, including both expired and non-expired should be reviewed. Patients should be advised not to stop any treatments without consulting their relevant healthcare professional and a treatment review should be initiated as soon as possible.

Class 2 Medicines Recall: Sterling Pharmaceuticals Ltd (specials manufacturer MS 32515), KidNaps (Melatonin) 1mg in 1ml Oral Solution, EL(26)A/09. Issued 23 February 2026.

Sterling Pharmaceuticals Ltd and Veriton Pharma Ltd are recalling all batches of KidNaps (Melatonin) 1mg in 1ml Oral Solution due to out of specification stability results.

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Class 2 Medicines Recall: Syri Limited, T/A SyriMed, Baclofen 10mg/5ml Oral Solution, EL(26)A/06. Issued 3 February 2026.

Syri Limited, T/A SyriMed is recalling batches of product as a precautionary measure due to crystallisation observed over time in the oral solution.

Class 2 Medicines Recall: Accord Healthcare Ltd, Carmustine 100 mg Powder and Solvent for Concentrate for Solution for Infusion (1 vial 100mg powder, 1 vial of 3 mL solvent), EL(26)A/05. Issued 2 February 2026.

Accord Healthcare limited is recalling a single batch due to an out of specification test result.

Class 3 Medicines Recall: Norgine Limited, MOVICOL Ease Citrus Powder for oral solution 13.7 g, EL(26)A/08. Issued 17 February 2026.

Norgine Limited is recalling one batch of product as a precautionary measure due to some units containing low amounts of active ingredients.

Class 3 Medicines Recall: Aspar Pharmaceuticals Ltd, Ibuprofen 200mg Tablets, Ibucalm 200mg tablets, EL(26)A/07. Issued 4 February 2026.

Aspar Pharmaceuticals Ltd is recalling specific batches distributed in Aspar, Almus and Numark livery. The batches are being recalled as a precautionary measure following findings of foil perforations in some blisters.

Class 4 Medicines Defect Notification: Rayner Pharmaceuticals Limited, Dropodex 0.1% w/v Eye Drops, solution, EL(26)A/10. Issued 24 February 2026.

Rayner Pharmaceuticals limited have informed the MHRA that the batches listed in this notification do not include the concentration of phosphates in the product information.

Class 4 Medicines Defect Notification: Viatris Products Ltd, Arixtra solution for injection, pre-filled syringes, EL(26)A/04. Issued 28 January 2026.

Viatris has received reports of brown discolouration and blockage in the needle of pre-filled syringes of Arixtra. This quality defect is related to oxidation of the syringe needle.

Medical Device Field Safety Notices

Find recently published Field Safety Notices

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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 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

UKHSA and MHRA issue reminder to healthcare professionals regarding use of non-sterile alcohol-free wipes

The UK Health Security Agency (UKHSA) and Medicines and Healthcare products Regulatory Agency (MHRA) have issued a news story to remind the public not to use 4 specified non-sterile alcohol-free wipe products under any circumstances due to an ongoing risk of infection associated with their use.

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Additionally, UKHSA have released an urgent public health message to remind healthcare professionals of the recommendations as issued in the National Patient Safety Alert from 26 June 2025. Non-sterile alcohol-free wipes, of any type or brand, should not be used for first aid, applied on broken or damaged skin and should never be used for cleaning intravenous lines.

There have been 59 confirmed cases of Burkholderia stabilis associated with some non-sterile alcohol-free wipe products - identified in an outbreak in the United Kingdom from January 2018 to 3 February 2026. A small number of cases continue to be detected. These have included some serious infections which have required hospital treatment and 1 death has been attributed to Burkholderia stabilis infection.

Updates to instructions for use (IFUs) of Cardinal Health Chest Drainage Units & accessories

MHRA received reports that the Cardinal Health Aqua-Seal Chest Drain Units were being used in the paediatric and neonatal populations. This led to inconsistent tidaling and bubbling within the drain and lack of pneumothorax resolution leading to more serious consequences.

As outlined within the Instructions for use, the Aqua-Seal, Sentinel Seal, Altitude and Thora-Seal chest drain units are intended for use in the adult population, over 18 years only.

Healthcare professionals must ensure that the correct Chest Drain Units are selected for their patient, to avoid any further incidents.

For full details see the manufacturer's Field Safety Notice.

Respiratory tube connector: risk of patient harm due to manufacturing defect

Armstrong Medical notified MHRA of reports of tears between the ventilator circuit tubing and purple connector cuff. Following their investigation, a manufacturing defect was identified that may affect the junction between the tubing and the purple connector cuff. This can interrupt respiratory support and subsequent replacement of the circuit could lead to treatment delays. There is a risk of patient harm due to respiratory distress and hypoxia.

Armstrong Medical has produced a Field Safety Notice (FSN) and a formal recall is underway. Healthcare providers are advised to check the model numbers against the FSN and return or dispose of all affected units. Where healthcare providers are unable to source an alternative product, ensure the risks of continued use are assessed whilst remaining vigilant.

The manufacturer's Field Safety Notice provides detailed instructions for the Users of these products.

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Medical devices regulations: targeted consultation on the indefinite recognition of CE marked devices

The Medicines and Healthcare products Regulatory Agency (MHRA) has launched a public consultation, inviting members of the public to provide their views on proposals for the approach to recognising CE marked medical devices in Great Britain.

The consultation, which closes on 10 April 2026, invites responses from anyone who will be impacted by the proposals, including medical device manufacturers, distributors, approved bodies, healthcare professionals including clinicians, procurement teams, devolved administrations, and patient representative organisations. This consultation applies to medical devices in Great Britain. For guidance on the regulation of devices in Northern Ireland, see Regulation of devices in Northern Ireland.

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