SPS Medication Safety Update March 2026

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

29/10/25

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Class 2 Medicines Recall: Crescent Pharma Limited, Ramipril 5mg capsules, EL(26)A/11

Crescent Pharma is recalling one batch of Ramipril 5mg Capsules as a precautionary measure due to a potential error at the manufacturing site. There has been one complaint to date, where a pack of Ramipril 5mg Capsules (Batch Number GR164099) contains blister strips of Amlodipine 5mg Tablets inside the sealed carton. Stop supplying the impacted batch of Ramipril 5mg Capsules immediately; quarantine all remaining stock and return it to your supplier.

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

All batches are being recalled (at wholesaler and pharmacy level) within expiry due to confirmed out of specification results from annual stability testing relating to product appearance and total impurities. No ADRs have been reported.

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Class 2 Medicines Recall: Rokshaw Limited Trading as Curaleaf Laboratories, Curaleaf Oil [FS] 10mg/ml THC, 10mg/ml CBD (30ml), EL(26)A/13

Curaleaf Laboratories have reported a confirmed stability study failure where the THC content is below the acceptable level in Curaleaf Oil [FS] 10mg/ml THC 10mg/ml CBD (30ml). Affected batches are being recalled out of an ‘abundance of caution’.

Class 2 Medicines Recall: Regent Medical Limited / Mölnlycke Health Care, Hibiwash 500ml, EL(26)A/15

Mölnlycke Health Care are recalling specific batches of Hibiwash due to microbial contamination, identified as Burkholderia cepacia, at the manufacturing facility, following routine weekly microbiological monitoring. Stop using and supplying the specific batches of Hibiwash immediately. Quarantine all remaining stock and return it to your supplier using the approved process. HCP responsible for the management of patients with cystic fibrosis or awaiting lung transplant who have been supplied with Hibiwash since 10/2/26 should contact patients directly; if they have the affected batch, advise them to return it to the place of supply or sale, or a pharmacy for disposal and reassure them this is precautionary and the risk is low. Advise them that should they develop symptoms consistent with infection, to contact their clinical team for advice and seek medical attention. Please provide an alternative product following local procedures. There is no need to contact other patients.

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Class 3 Medicines Recall: Bayer Plc, Various Products, EL(26)A/12 (Gastrografin gastroenteral solution, Urografin 150 Infusion, Urografin 150 Injection)

Bayer Plc is recalling all stock of the above products ‘out of an abundance of caution’ due to the identification of an impurity above the acceptable limit. There have been no reports of patient harm. Affected batches should be quarantined and returned to supplier.

Class 4 Medicines Defect Notification: Baxter Healthcare Corporation, Onkotrone Injection 2 mg/ml concentrate for solution for infusion, EL(26)A/14

Baxter have informed the MHRA that the PIL packed in specified batches of mitoxantrone does not contain up to date information relating to the duration of contraception required for females after stopping taking this medication.

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

PIL and SmPC for affected batches were not updated in accordance with the ‘Annex to European Commission guideline on excipients in the labelling and package leaflet of medicinal products for human use’, which require the concentration of phosphates to be included.

Recent regulator and statutory body activity

MHRA Safety Roundup: February 2026

Falsified Mounjaro KwikPen 15mg pre-filled pens

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; to date 5 affected pens have been identified. They have been supplied in the UK through one online pharmacy - The Private Pharmacy Clinic, located in Birmingham. Advice is provided for HCP, as is advice on what to tell patients.

Recent regulator and statutory body activity

MHRA Inspectorate Blog: The importance of accurate GTIN & 2D barcode data

- Pharmacy automation depends on medicines having an accurate Global Trade Item Number (GTIN) & the 2D GSI DataMatrix barcode, which encodes the GTIN, batch number & expiry date.
- Incorrect/inconsistent barcode data causes these systems to fail. Examples of recent issues reported by HCPs include:
    - GTINs that scan as a different medicinal product, compared to the physical medicinal product name and details.
    - Incorrect data formats that cause robotic systems to reject valid stock.
    - Unreadable or missing 2D barcodes, rendering products unscannable and unusable.
    - Uncontrolled GTIN reuse across different products, leading to dangerous product confusion in existing systems.

- The Defective Medicines Report Centre (DMRC) have seen an increase in these artwork errors, which have a real-world consequence on patient safety; the potential for administration of incorrect medicines and missed doses due to stock rejection or delays have led to preventable harms, which should be avoidable.
- The Marketing Authorisation Holder is responsible for ensuring that the artwork and encoded data on a medicine pack is accurate, compliant, and aligned with regulatory and operational standards.
- A guide to defective medicinal products that includes how to report suspected issues to the DMRC can be found here.

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting held on 9th to 12th March 2026

PRAC warns about known risk of aseptic meningitis with chikungunya vaccine (Ixchiq)

Following its review of a safety signal, the PRAC has recommended updating the product information for the vaccine to reflect that serious side effects, such as aseptic meningitis, have also been observed in healthy young adults.

Previously, most reported cases had occurred in older people (over 65 years of age) or people with multiple long-term medical conditions.

Manufacturer RMM

Hympazvi (marstacimab) Patient Alert Card

The Patient Alert Card is designed to increase awareness about the thromboembolic event risk, highlight the key signs and symptoms of thromboembolism, when to seek urgent or emergency medical help, and to provide the prescribing physician's contact details.

Drug shortages

Recent medicine shortages and discontinuations are available via: the SPS Medicines Supply Tool (registration required to access)

Medicine Supply Notification: Shortage of Gastrografin oral solution and Urografin 150 solution for injection/infusion ampoules and bottles

Gastrografin oral solution and Urografin 150 solution for injection/infusion ampoules and bottles are out of stock until June 2027; Bayer has recalled all stock as a precautionary measure due to identification of an impurity above the acceptable limit. Omnipaque and Visipaque remain available and can support partial increased demand. Unlicensed supplies may be sourced; lead times vary.

MSO immediate actions (see MSN for full details):

- Work with procurement & appropriate clinical leads, in consultation with radiology leads, to review licensed and off-label uses and consider:
- switching to alternative products, ensuring:
    - clinical areas using Gastrografin or Urografin, including for small bowel obstruction are made aware of this shortage and the local mitigations;
    - contact is made with their regional GE Healthcare account manager to discuss monthly requirements of Omnipaque and/or Visipaque. Orders must be placed conservatively and in accordance with current requirements; and
    - prescribing systems and local guidance are reviewed and updated as required.
- using unlicensed products only where licensed alternatives are not appropriate (e.g. for small bowel obstruction), ensuring orders are placed within appropriate time frames as lead times may vary.

Drug shortages

Recent medicine shortages and discontinuations are available via: the SPS Medicines Supply Tool (registration required to access)

Medicine Supply Notification: Polyfusor Phosphates (50mmol phosphate in 500ml infusion)

There are intermittent supplies of Polyfusor Phosphates until mid-April 2026 followed by a full out of stock period with the next resupply date to be confirmed. Allocations have been put in place at a Trust level stocks currently available & outstanding incoming deliveries. Available stock has been ringfenced for homecare patients who are unaffected by this supply issue.

Sodium glycerophosphate 4.32g in 20mL (21.6%) solution for infusion ampoules remain available (each ampoule contains 20mmol of phosphate in 20ml) and can support increased demand.

NHS provider Trust pharmacy procurement teams and their local MSO should:

- consider centralising remaining Polyfusor Phosphates stock at pharmacy level;
- work with clinical colleagues to:
    - agree priority indications for which remaining Polyfusor Phosphates should be reserved, where possible; and
    - consider using sodium glycerophosphate 21.6% solution for infusion ampoules for phosphate replacement (see Supporting information in the full MSN and Medusa monograph for instructions on making up the infusion)
- order Polyfusor Phosphates in line with their allocation which can be obtained from the appropriate Specialist Pharmacy Service Regional Pharmacy Procurement Team.

Drug shortages

Recent medicine shortages and discontinuations are available via: the SPS Medicines Supply Tool (registration required to access)

Medicine Supply Notification: Co-trimoxazole 40mg/200mg/5ml oral suspension sugar free and 80mg/400mg/5ml oral suspension

Co-trimoxazole 40mg/200mg/5ml oral suspension SF will be out of stock from mid-March to June 2026. The 80mg/400mg/5ml suspension is also unavailable (resupply TBC). The 80mg/400mg and 160mg/800mg tablets remain available. Unlicensed suspension may be sourced, lead times vary.

Medicine Supply Notification: Shortage of Prochlorperazine (Stemetil) 12.5mg/1ml solution for injection amps

Prochlorperazine (Stemetil) 12.5mg/ml solution for injection ampoules are out of stock until early April 2026; buccal tablets remain available and can support increased demand. Alternative parenteral anti-emetics remain available and can support an increased demand.

Drug Discontinuation

Recent medicine shortages and discontinuations are available via: the SPS Medicines Supply Tool (registration required to access)

Discontinuation of Reslizumab (Cinqaero) 25mg/2.5ml and 100mg/10ml concentrate for solution for infusion vials

Reslizumab is licensed for severe eosinophilic asthma. All presentations (100mg/10ml and 25mg/2.5ml concentrate for solution for infusion vials) will be discontinued from early June 2026 and late December 2026, respectively. Trusts should inform/review patients and consider prescribing alternative human monoclonal antibody agents ahead of the discontinuation, in line with relevant NICE TA recommendations. Local protocols should be updated and amended. Note that Cinqaero is given IV; alternatives are administered subcutaneously.

Specialist Pharmacy Service – MSO content

The Medication Safety Officer (MSO) role (update)

Updated page, discussing the role and responsibilities of an MSO.

Practice support for the Medication Safety Officer (MSO)

Reviewed & updated page discusses the infrastructure of support opportunities that MSOs should utilise to deliver their role most effectively.

Reporting and management of medication safety events (update)

Updated page, covering reporting management systems, managing medication incident reports, promoting event reporting, supporting staff, and the MHRA yellow card scheme.

Learning from medication safety events (update)

Updated page, containing practical guidance to ensure learning from local safety events is translated into shared local and national learning.

Collaboration opportunities to improve medication safety (update)

Reviewed & updated page provides practical guidance on effective collaboration opportunities to promote medication safety improvements.

Specialist Pharmacy Service

Prescribing co-codamol and switching analgesics for pain relief

Supply of co-codamol 30mg/500mg tablets is limited until early June 2025. All formulations have been added to the MHRA export ban list. A serious shortage protocol (SSP) is not appropriate due to very high prescribing volumes. Further advice can be found on the SPS supply tool (registration required to access).

National guidance, publications and resources

BNF/BNFC Cautionary and advisory labels

Clarification that label 23 ‘Take this medicine when your stomach is empty’ means patients should be advised that food must be avoided for 2 hours before and an hour after taking each dose.

National guidance, publications and resources

Insulin: supporting safe self-administration for patients in the community with a mental health problem

This report from the Health Services Safety Investigations Body (HSSIB) focusses on adults who live with diabetes mellitus who require insulin, and who have not self-administered it as intended secondary to a mental health problem. While the findings of the report are around insulin and diabetes care, they may also be applicable to other physical long-term conditions that people experience.

HSSIB makes several safety recommendations/observations and advises on local learning & learning for ICBs; there is also local-level learning for organisations providing mental health and/or specialist diabetes services. E.g.

- How does your organisation ensure information about patients is available to other providers of care when required, for example to mental health teams about a patient's diabetes care?
- How does your organisation ensure patients with a mental health problem are not being discharged from clinics following a 'did not attend' without consideration of their circumstances and risks to their safety?
- How does your organisation identify patients who have had recurrent admissions with diabetic ketoacidosis or hypoglycaemia, and support staff to consider whether these patient require input from mental health services?
- How does your organisation keep staff up-to-date about the different types of insulin used in the NHS and their onset times to ensure this is considered as part of assessment of a patient's risk of self-harm?
- How does your organisation enable staff to work therapeutically with patients to support them to develop safety plans which include consideration of the risks associated with insulin?

Prevention of Future Death Reports (Regulation 28)

Alan Crabtree: 2026-0103

Mr Crabtree was admitted to hospital due to symptoms of pancytopenia ~2weeks after starting methotrexate for rheumatoid issues. Prior to admission, advice was sought from a community pharmacist for a sore throat, mouth ulcers & difficulty swallowing and he was treated under the Pharmacy First Scheme. Despite treatment, due to his weakened immune system, he developed pneumonia and died.

The coroner raised concerns regarding:

- The dose regime referred to in the "Shared Care Guideline for Oral Methotrexate in Rheumatological Conditions in Adults" (due for review in 2020, but still in use at the time it was prescribed to Mr Crabtree in 2025) doesn't reflect current practice and the initial dose recommended is sub-therapeutic; furthermore, no clear criteria are included for selecting an appropriate starting dose.
- The aforementioned Guideline was produced in September 2017. Since then, the "Pharmacy First" scheme has launched. The guidance therefore does not reflect the changes in responsibilities between secondary care, GPs & community pharmacists leading to ambiguity as to what type of healthcare professional a patient should consult and potentially fatal delay in ceasing methotrexate or commencing treatment for toxicity (an Arthritis UK PIL advises patients to inform their "doctor or nurse specialist" if they have signs of a sore throat and/or sores in the mouth).

Are the guidelines in your organisation (a) in date (b) reflective of current clinical practice and (c) clearly identify who patients should contact for urgent advice or monitoring concerns?

Prevention of Future Death Reports (Regulation 28)

Urmila Patel: 2026-0116

Mrs Patel was admitted to hospital with suspected sepsis on. Appropriate falls risk assessments were not undertaken, and no clear care plan was produced to address risks related to her mobility. A few weeks after admission, Mrs Patel sustained a fall whilst in the ward toilet, striking her head. At the time of the fall, she was not being adequately supported by ward staff. Despite Mrs Patel's son informing staff of the head injury, her warfarin was not discontinued, and no request was made for a head CT.

In the days that followed, Mrs Patel deteriorated and another medical review was triggered due to lowered consciousness and facial droop. At this stage, an urgent CT head showed a significant subdural haematoma, increasing brain pressure, causing a midline shift. At this stage, the warfarin was held. She was deemed not to be a safe candidate for neurosurgery and sadly died.

One of the coroner's concerns was the failure to review Mrs Patel's warfarin prescription after her initial fall.

Does your organisation have a system in place to review anticoagulation after a patient has had a fall?

Prevention of Future Death Reports (Regulation 28)

Clive Hyman: 2026-0034

Mr Hyman was prescribed apixaban for AF & post-CABG by his GP. He had an unwitnessed fall with head impact but didn't seek medical review; he and his wife were unaware of the increased risk of intracranial haemorrhage associated with anticoagulation.

He was asymptomatic for a few days, but then developed a sudden, severe headache and significant hypertension. An initial ambulance call was categorised as non-emergency. Later that afternoon, he became unresponsive with vomiting, prompting emergency service attendance and transfer to hospital, where a CT identified a left-sided subdural haemorrhage. He had medical treatment and then underwent an emergency decompressive craniectomy. Subsequent imaging showed bleeding within the pons and changes consistent with an ischaemic stroke. Despite withdrawal of sedation, he showed no neurological improvement and sadly died.

The coroner reviewed apixaban PILs and found none of them expressly addressed the steps to be taken by a patient if they sustain trauma to the head; furthermore, patients who have experienced head trauma may not realise that they could have an intracranial bleed.

Do you have assurance that if your organisation starts someone on anticoagulation, that the patient would be expressly told to seek medical attention if they suffer a head injury?

Prevention of Future Death Reports (Regulation 28)

Oriel Vasey: 2026-0124

Mrs Vasey was admitted to a Care Home. At one point during the transfer process, a nurse completed a form using a template containing information pertaining to a previous service user as the starting point. Unfortunately, this form had a penicillin allergy recorded; this erroneous information was added into her clinical record (even though the form was meant for financial decisions, not for clinical reasons) and as a result, when infection in a pressure area in her sacrum was identified, penicillin as the first-line antibiotic, was ruled out.

Family raised concerns that she had previously had penicillin, but the GP was unable to amend the record as this information had come from an official source and thus the risk of amending allergy information on family members word was greater than the risk of the allergy information being correct. Mrs Vasey subsequently died in hospital of sepsis, although the coroner found no evidence that use of a penicillin would have changed the outcome.

If your organisation uses templates for information recording, do you have assurance that any historical information present is removed?

How does your organisation confirm and verify the accuracy of patient allergy status?

Prevention of Future Death Reports (Regulation 28)

Wendy Boddington: 2026-0121

Ms Boddington was found deceased at home, where she was found to have two fentanyl patches on her body rather than the single patch prescribed by her GP. She had been prescribed fentanyl patches & codeine for chronic pain since 2011, following an accident and amputation of her arm. Post-mortem examination found that she had a toxic level of fentanyl in her system and codeine would have added to that toxicity.

At the time of initial prescription in 2011, GP awareness of the complications of fentanyl was more limited, but in 2014/15 GPs at the practice had attempted to address her level of opioid use, although she was not in agreement. However, she had at least annual medication reviews, where no clear plans to address her opioid use was found after 2015, meaning there were missed opportunities over a 9 to 10-year period.

There was also a missed opportunity for the hospital pain clinic to raise the fentanyl prescription with the practice in 2021. The court heard that oftentimes, opioid reduction/stoppage can be difficult, and Ms Boddington had expressed objections. There is no positive evidence that she had used two patches to deliberately harm herself; it was also noted that she had fallen and injured her ankle just days before her death and she was probably experiencing increased pain because of that.

This case highlights the significant challenges faced by the NHS to support patients reduce use of long-term opioids.

Prevention of Future Death Reports (Regulation 28)

Anna Burns: 2026-0127

Ms Burns had significant medical and mental health issues, including overdosing & suicidal ideation. She was prescribed medication both by her GP & local dependency services. She was found unresponsive; emergency services attended and found her deceased. Bottles of methadone were found at the scene, as were other packets of prescribed medication, including pregabalin and zopiclone - all of which had been dispensed that day.

Ms Burns had a previous Hospital admission with a suspected opioid overdose. Whilst a discharge summary for the opioid overdose was sent to her GP, but no such notification was sent to the local dependency service, who were the prescribing authority for her opiate replacement therapy.

The coroner's concern was the prescribing agency (for methadone) was unaware of the previous opiate overdose because they were not sent a discharge summary. Had they known, they would have reviewed her case and likely would have put in place restrictive prescribing practices (such as lower or single daily doses, possibly supervised).

Does your organisation have processes in place for notifying dependency services of admissions related to drug use or overdoses?

Prevention of Future Death Reports (Regulation 28)

Darren Dickson: 2026-0150

Mr Dickson experienced a period of mental ill health after witnessing an extremely traumatic incident at his place of work; he had started to take a benzodiazepine (BDZ) to help manage this. He subsequently sought help for his mental health and BDZ use, including from his GP and a local dependency service. He was found unresponsive and later pronounced dead despite treatment; he had BDZ and alcohol in his system at levels that, on the balance of probabilities, led to his death.

The coroner highlighted concerns that Mr Dickson had been seen by local dependency service for his BDZ use, but poor record keeping meant it wasn't clear what information or assistance was provided to him; they were also concerned at the poor level of communication the local dependency service had with his GP in relation to the issue of ongoing BDZ use and doses of drugs.

This case highlights the risks of BDZ and Z-drugs, and provides an opportunity to remind patients of these risks:
MHRA: Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression