SPS Medication Safety Update November 2025

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

26/11/2025

Patient Safety Alerts

Harm from incorrect recording of a penicillin allergy as a penicillamine allergy

Issued: 20/11/2025 NatPSA/2025/006/NHSPS

Background - Reports of healthcare staff recording a patient's penicillin allergy as a penicillamine allergy in electronic prescribing systems. A 3-year review of national incident data identified the death of a patient because of an anaphylactic reaction to a penicillin-based antibiotic. They were inadvertently prescribed this antibiotic because their known penicillin allergy had been recorded as penicillamine allergy on their GP record.

For action by acute, community and mental health providers, health and justice services, primary care including nursing and care homes, general practice and community pharmacy

1. Primary and secondary care organisations should form a working group across an appropriate geographical area, chaired by an appropriate chief clinical information officer, to co-ordinate implementation of the following actions:
    a. Identify patients recorded as having a penicillamine allergy by running a report in relevant digital systems in primary and secondary care.
    b. Clinically review the accuracy of the allergy status and amend accordingly.
    c. Ensure allergy records in electronic prescribing and related digital systems that record allergy status are updated.

Recent regulator and statutory body activity

MHRA Safety Roundup: October 2025

Isotretinoin – updates to prescribing guidance and survey of services

British Association of Dermatologists

- Updated guidance for follow-up appointments during isotretinoin treatment (October 2025)
- Updated guidance for remote pregnancy testing during isotretinoin treatment (October 2025)
- Updated guidance for monitoring sexual function during isotretinoin treatment (October 2025)

Survey

- Clinical Service Leads for any service or clinic (NHS or private) that prescribes isotretinoin for the treatment of acne had to complete a baseline survey for their service by 16 November 2025

Recent regulator and statutory body activity

Class 3 Medicines Recall: Zambon SpA, Emylif (riluzole) 50mg orodispersible film, EL(25)A/47

Precautionary measure before batch reaches 24 months since the date of manufacture, as **ongoing stability testing identified out of specification results for unknown impurities**. Recall of one batch (C24QA104) .

Class 3 Medicines Recall: Sun Pharmaceutical Industries Limited, Atorvastatin 20mg and 80mg Film-coated Tablets, EL(25)A/48

Three batches (PTF6133A, PTF5991D & PTF5991F) recalled (precautionary measure) due to **failing dissolution test results** reported during **ongoing stability studies.**

Class 3 Medicines Recall: Sun Pharmaceutical Industries Limited, Fingolimod SUN 0.5mg hard capsules, EL(25)A/49

Reports of **capsule breakage on removing from the blister**. Precautionary recall of one batch – quarantine remaining stock

Recent regulator and statutory body activity

Influenza season 2025/26: early season activity and implications for clinical practice

- CEM/CMO/2025/002, 05-Nov-2025
- Briefing note

UKHSA surveillance data indicates that influenza is circulating in the community earlier than usual this season with a drifted strain of Influenza A(H3N2) predominating.

Clinicians should continue to promote and deliver influenza vaccination for eligible patients and for healthcare workers.

Clinicians are also reminded that early antiviral treatment reduces the risk of complications and improves clinical outcomes.

The state of health care and adult social care in England 2024/25

CQC report looking at trends, sharing examples of good and outstanding care, and highlighting where care needs to improve.

Recent regulator and statutory body activity

Dr Alison Cave: Pharmacists are on the frontline of medicines safety – and your reports make all the difference

As part of #MedSafetyWeek, the MHRA's Chief Safety Officer reflects in The Pharmacist on the vital role pharmacists play in keeping medicines and medical devices safe.

Putting Patient Safety at the Heart of Regulatory Innovation (Professor Henrietta Hughes)

England's Patient Safety Commissioner reflects on how the most powerful insights into safety come from the lived experiences of patients themselves and how harm can be prevented by listening to them and valuing their perspectives from the outset. MHRA

Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC 27 - 30 October 2025

Injectable tranexamic acid: serious adverse reactions when inadvertently given intrathecally

Following a review of medication errors, the European PRAC has agreed on a direct healthcare professional communication advising extreme caution when handling and giving injectable tranexamic acid, to ensure it is only given intravenously.

Healthcare professionals should take measures to prevent potential mix-ups between injectable tranexamic acid and other injectable medicines, especially those given intrathecally, that may be used during the same procedure, such as local anaesthetics.

The product information of injectable tranexamic acid medicines, including the outer packaging, will be updated to strengthen the warnings that these medicines must only be given intravenously.

Direct HCP communication

Valproate - containing medicines▼: new measures regarding the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception

Risk minimisation materials for valproate containing medicines now include new safety measures outlining the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception

Discontinuation of Levemir® Penfill® and Levemir® FlexPen®

Direct Healthcare Professional Communication advises of the discontinuation of these products (supply expected until Dec 2026). Patients should be advised of this and safely switched to alternative insulins/insulin delivery systems.

SPC changes

Mounjaro (tirzepatide) solution for injection in pre-filled pens (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg)

Additional warnings of pancreatitis added as fatal outcomes have been reported. Patients should seek immediate medical attention if persistent & severe abdominal pain arise. Discontinue if pancreatitis is suspected, and do not reinitiate if pancreatitis diagnosis is confirmed.

ProQuad (MMR vaccine, live) powder and solvent for suspension for injection in a pre-filled syringe

Priorix Tetra (Measles virus live attenuated , Mumps virus live attenuated , Rubella virus live attenuated , Varicella-Zoster virus live attenuated [Oka strain]) powder and solvent for solution for injection in pre-filled syringe

Encephalitis (seen during post-marketing use of live vaccines especially in patients who were immunocompromised) added as ADR. Prompt medical attention should be sought if reduced consciousness, convulsions or ataxia with fever and headache

SPC changes

Solu-Cortef (hydrocortisone sodium succinate) 100 mg and

Methylprednisolone sodium succinate injection (all strengths)

Panniculitis, unknown frequency, may occur following dose reduction or discontinuation and has been more frequently reported in the paediatric population.

Besremi (ropeginterferon alfa-2b) 250 micrograms/0.5 mL solution for injection in pre-filled pen

Updated with dosing in different ethnic groups, and its inclusion of polysorbate 80, which may cause allergic reactions.

Rifater 50mg/120mg/300mg Tablets (isoniazid, rifampicin, pyrazinamide)

Concurrent treatment with cabotegravir, fostemsavir and lenacapavir is contra-indicated, as rifampicin 600mg daily reduced exposure by 59%, 82% and 84%, respectively.

SPC changes

Eltam (levetiracetam) 100mg/ml oral solution

DRESS added as ADR (Drug Reaction with Eosinophilia and Systemic Symptoms). Presents with fever, rash, facial oedema, lymphadenopathies and blood abnormalities and occurs 2-8 weeks post initiation. Discontinue if DRESS suspected.

Doravirine products (Pifeltro 100 mg film-coated tablets, Delstrigo 100mg/300mg/245mg film-coated tablets)

Risk of severe cutaneous adverse reactions, including SJS /toxic epidermal necrolysis, identified during postmarketing use. Advise patients on signs and symptoms, stop treatment if these appear.

Manufacturer RMM

Gobivaz (golimumab) Patient Reminder Card

Card contains important safety information for patients to be aware of before and during treatment with golimumab, such as infections, and pregnancy and vaccinations.

Extraneal (icodextrin 7.5%) Solution for peritoneal dialysis

A letter sent in 2024 advising of the possibility of incorrect blood glucose results when using particular blood glucose monitors and test strips has now been added to the risk minimisation materials for this product.

Drug shortages and discontinuations

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

MSN: Discontinuation of Mivacurium chloride 10mg/5ml and 20mg/10ml solution for injection ampoules

Mivacurium chloride 10mg/5ml and 20mg/10ml solution for injection ampoules are being discontinued from late May 2026. There will be limited supply of both presentations until the discontinuation date.

Trust pharmacy procurement teams in ALL regions should take immediate action and work with clinical leads in anaesthetics and the local MSO to review use of mivacurium injection and consider switching to an alternative NMBA before supplies are exhausted.

Drug shortages and discontinuations

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MSN: Propranolol 80mg and 160mg modified release capsules

Propranolol 80mg M/R capsules are out of stock until early March 2026 & 160mg M/R capsules are out of stock until mid-late Jan 2026. I/R 40mg & 80mg tabs are available & can support increase in demand. Oral solution is available but cannot support increase in demand

MSN: Ibandronic acid 150mg tablets

Ibandronic acid 150mg tablets (the only licensed monthly bisphosphonate) are in limited supply until March 2026. Alendronic acid 70mg tablets and risedronate sodium 35mg tablets (once weekly bisphosphonate presentations) remain available and can support increased demand. Note that ibandronic acid 50mg tablets cannot support an increase in demand.

Drug shortages and discontinuations

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Vivaire (formoterol/beclometasone) inhaler to be discontinued

Zentiva has confirmed that the long-acting β2 agonist/corticosteroid inhaler is being discontinued, with stock of both the 100/6 and 200/6 strengths expected to be exhausted in 2026.

Discontinuation of Tresiba (insulin degludec) FlexTouch 100units/ml solution for injection 3ml pre-filled pens

Tresiba (insulin degludec) FlexTouch 100units/ml solution for injection 3ml pre-filled pens have been out of stock since 31 July 2023 and have subsequently been discontinued.

Specialist Pharmacy Service

[Considerations and interactions with GLP-1 receptor agonists]

Signposting for key risks and interactions of GLP-1 receptor agonists in diabetes, obesity, and weight management

[Spotlight, October 2025]

The October digest of NHS Specialist Pharmacy Service support for professionals working in all areas of the healthcare system covers events, new and updated guidance, publications, PGDs and shortages.

[New Medicines News – October 2025]

Newsletter produced by SPS Horizon Scanning highlights recent new product launches and medicines regulatory changes. More detailed information on medicines estimated to become available for use in next 2 financial years and on major new indications is in Prescribing Outlook.

[Polypharmacy and structured medication review explainer videos]

As part of a series on understanding polypharmacy, overprescribing and deprescribing, these animated videos explain the 7 steps of structured medication review, using a person-centred approach to managing polypharmacy.

Specialist Pharmacy Service

[Ex-Vivo Non-GMO Gene Therapy Medicinal Products – Pharmacy Institutional Readiness Guidance]

Document outlines key areas for focus of pharmacy expertise prior to an organisation implementing ex-vivo non-genetically modified organism gene therapies. Pharmacy oversight is required even when they are handled by another department or a third party.

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[Deriving and assessing stability data for medicines]

The NHS Pharmaceutical QA Committee has published five standard protocols to advise on designing, undertaking and evaluating stability studies.

[The licence and supporting evidence for denosumab 60mg biosimilars]

Denosumab 60mg biosimilars are licensed. Learn about indications, formulations, supporting evidence and differences.

Specialist Pharmacy Service

PGD template updates

- Buccal midazolam for seizures or symptomatic cocaine toxicity management
- Diazepam injection for seizures or symptomatic cocaine toxicity management
- Rectal diazepam for managing seizures
- Azithromycin (oral) for use within sexual health services
- Doxycycline for use within sexual health services
- Emtricitabine and tenofovir disoproxil tablets as PrEP
- Ulipristal acetate 30mg tablets for emergency contraception
- Combined oral hormonal contraceptive (COC) in reproductive health
- Ceftriaxone intramuscular injection for Neisseria gonorrhoeae
- Folic acid 5mg tablets for use during pregnancy

Specialist Pharmacy Service

Updated reproductive health protocols

- Lidocaine 10mg/ml spray for IUC insertion or removal
- Lidocaine plus prilocaine cream for IUC insertion or removal
- Omeprazole for use within antenatal and maternity services

Specialist Pharmacy Service

Intrathecal Medicines Considerations, updated

- Methotrexate: informing intrathecal risk assessment
- Etoposide: informing intrathecal risk assessment
- Rituximab: informing intrathecal risk assessment
- Gentamicin: informing intrathecal risk assessment
- Thiotepa: informing intrathecal risk assessment
- Diamorphine hydrochloride: informing intrathecal risk assessment

National guidance, publications and resources

2025 Resuscitation Guidelines

Adult life support

Call 999 for any unresponsive person before assessing breathing, ambulance service call handlers supporting recognition and CPR instructions

Adult advanced life support

Greater emphasis on effective ventilation and correct pad placement. Hospitals should strengthen early warning scores, critical care outreach, and patient and family escalation systems. Out-of-hospital prevention focuses on identifying and managing cardiovascular risk factors, inherited conditions, and early warning symptoms, especially in younger patients.

Update to post resuscitation care

Emphasises immediate, structured management using an ABC approach with airway protection, controlled oxygenation, normocapnia, and blood pressure targets above 100 mmHg systolic or mean arterial pressure of 60-65 mmHg.

National guidance, publications and resources

Influenza: treatment and prophylaxis using anti-viral agents (update)

Major changes include advice on use of new antiviral baloxavir marboxil, updated treatment recommendation tables, and amended recommendations to reflect the ability to prescribe antivirals out-of-season in primary care is no longer dependent on DHSC notification.(**UKHSA**)

UKHSA highlight vaccination is crucial as meningitis cases increase

UKHSA data have revealed there were 378 cases of invasive meningococcal disease confirmed in 2024-25, a rise on the previous year. Parents asked to get infants and toddlers are up to date with the MenB vaccine (**UKHSA**)

Consent: the green book, chapter 2 (update)

Now includes the CQC position on consent to treatment, clarification on who may seek consent to vaccination and information on consent in under 16-year-olds, disagreement between parents and vaccination in schools.(**UKHSA**)

UKHSA national surveillance data show total number of antibiotic-resistant infections in 2024 equates to average of nearly 400 newly reported cases per week

Cases of bacteraemia due to antibiotic-resistance increased by 9.3% since 2023 to 20,484 in 2024 & estimated deaths due to resistant infection increased to 2,379 in 2024, an increase of 338 deaths in 1-year. 65% of cases in last 6 years caused by E. coli (**UKHSA**)

National guidance, publications and resources

Royal Pharmaceutical Society calls for stronger safeguards in private prescribing

Responding to the Government's call for evidence on private prescribing, the RPS is urging a series of reforms to improve patient safety, transparency and accountability, particularly in online and non-NHS settings, for example joined-up identity checks (**Royal Pharmaceutical Society**)

Polypharmacy Programme: Getting the Balance Right

The report outlines the impact, economic analysis and learning from the programme, demonstrating changes in clinician and patient behaviour related to stopping inappropriate medicines. **Health Innovation Network**

Prevention of Future Death Reports (Regulation 28)

Paolino Amico: 2025-0585

Multiple morphine doses administered in error, due to prescription error, leading to overdose and respiratory failure which were not managed as per local guidelines

Events

- Discharged from hospital with oxygen
- Readmitted via A&E with pneumonia, given antibiotics, fluids and nebuliser
- In A&E regular morphine not prescribed or administered correctly - family administered patients own supply with nurses knowledge, not recorded, then morphine prescribed and administered
- F1 doctor prescribed, as directed by nurse, patient not reviewed
- MST dose increased from BD to QDS in error, not questioned when moved to ward, administered (6 doses in 24 hours taken)
- Although deterioration recorded (patient unresponsive) no emergency call made nor was on-call doctor informed
- Naloxone reversal was administered but dose was incorrect
- Patient suffered acute withdrawal

Prevention of Future Death Reports (Regulation 28)

Paolino Amico: 2025-0585

Coroner concerns

- Multiple nurses were involved in morphine administration and all had completed their original training outside of the UK and had undertaken a Trust medicines administration training that should have recognised that the prescription of MST 4 times a day was not appropriate. Mr Amico received 6 doses of MST in less than 24 hours instead of 2.
- Medicines administration refresher training for nurses is not mandatory and the Trust in reviewing this case has not followed a local recommendation from senior nurses for this to be included.

Prevention of Future Death Reports (Regulation 28)

Margaret Crooks: 2025-0581

Events

- Diagnosed as having a stroke she was given intravenous thrombolysis
- Developed complications from the thrombolysis medicines
- CT scan confirmed a large bleed caused by the thrombolysis medication, advice sought from another hospital stroke team as per protocol
- Doctors were not advised to give medication to try and prevent further bleeding.

Concerns

- Confusion amongst some of the stroke clinicians who support the work as to the level of support that was to be provided (to remote site) even though advice is time critical
- Advice provided by registrar with no input from consultant

Prevention of Future Death Reports (Regulation 28)

Ronald Perry: 2025-0580

Events

- Frail patient discharged from hospital, on an anticoagulant, to care home where he had a series of falls
- His family raised concerns about his falls risk.
- He had a fall that was not escalated for medical advice and no additional fall risk assessments were carried out
- Final fall led to admission where a bleed to the brain and fractures, including one to the neck of femur were diagnosed.
- An operation to manage the problems was followed by deterioration then death

Concerns

- Poor documentation of care
- Falls risk assessment documentation was incomplete and not updated after falls had occurred
- Falls policy on the need for medical advice for residents on anticoagulation who had an unwitnessed fall were not widely understood by staff or adhered to on all occasions.