SPS Medication Safety Update October 2025

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

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Patient Safety Alerts

Harm from delayed administration of rasburicase for tumour lysis syndrome

Issued: 9/09/2025

Deadline**:** 9/03/2026

Organisations providing emergency departments and cancer services should take steps to reduce the risk of harm from delayed administration of rasburicase for tumour lysis syndrome (TLS).

This National Patient Safety Alert requires action to prevent delays in the administration of rasburicase for tumour lysis syndrome (TLS). TLS is a life-threatening emergency that can develop when cancer cells break down rapidly, releasing harmful substances into the bloodstream. It requires urgent treatment with rasburicase in high-risk cases.

The alert requires NHS organisations providing emergency departments and cancer services to complete specific actions within 6 months, including updating risk assessment protocols, ensuring medication availability, and addressing operational barriers to timely treatment.

Recent regulator and statutory body activity

MHRA Drug Safety Updates

Paracetamol and pregnancy - reminder that taking paracetamol during pregnancy remains safe

Patients should be reminded and reassured that there is no evidence that taking paracetamol during pregnancy causes autism in children. Paracetamol is recommended as the first-choice pain reliever for pregnant women, used at the lowest dose and for the shortest duration. It also acts as an antipyretic and is therefore used to treat fever.

Isotretinoin – updates to prescribing guidance and survey of services

The Commission on Human Medicines (CHM) has endorsed changes to isotretinoin prescribing guidance. In addition, CHM is seeking further information from dermatology services who prescribe isotretinoin to inform any future changes to current risk minimisation measures.

All dermatology services that prescribes isotretinoin for the treatment of acne need to complete a baseline survey for their service by 16 November 2025.

Recent regulator and statutory body activity

Class 3 Medicines Recall: Accord Healthcare Ltd, Ipratropium Bromide 500 microgram / 2ml Nebuliser Solution, EL(25)A/45

Accord Healthcare Ltd is recalling a batch of Ipratropium Bromide 500 microgram/2ml Nebuliser Solution after a foil pouch was found to contain ampoules with incorrect labels intended for the Korean market. The incorrectly labelled ampoules are the same product and contain the same active ingredient but have Korean language labels and different batch details.

Class 4 Medicines Defect Notification: Relonchem Ltd, Various Products, EL(25)A/44

Relonchem Ltd has informed the MHRA that duplicate GTIN numbers have been assigned to certain Losartan potassium/Hydrochlorothiazide coated tablets in error and a duplicate EAN number has been assigned to certain Risperidone tablets in error.

Class 2 Medicines Recall: Baxter Healthcare Limited, Compound Sodium Lactate Solution for Infusion BP (Hartmann's Solution for infusion) in Viaflo 1000ml, EL(25)A/46

Baxter Healthcare is recalling one batch of Compound Sodium Lactate (Hartmann’s Solution) 1000mL. This is due to a packaging error where some cartons labelled as Hartmann’s Solution may contain Ringer’s Solution 1000mL

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting held on 1st-4th September 2025

Remsima (infliximab): new intravenous formulation contraindicated in patients with hereditary fructose intolerance

Before starting treatment with the new Remsima concentrate for solution for infusion, healthcare professionals must confirm that the patient does not have hereditary fructose intolerance. The product information and patient reminder card for Remsima will be updated to reflect this new information.

Tegretol (carbamazepine): use restricted in neonates as concentration of one excipient, propylene glycol, exceeds recommended threshold

Tegretol 100 mg/5 mL oral suspension should not be used in neonates below 4 weeks of age for term babies, or 44 weeks post-menstrual age for pre-term babies, unless there is no other treatment option available and the expected benefit outweighs the risks. This is because this formulation of Tegretol contains 25 mg of the excipient (ingredient) propylene glycol per 1 mL, which exceeds the recommended threshold for neonates of 1 mg/kg/day[1]. At doses of 1 mg/kg/day or higher, propylene glycol accumulates in neonates as their liver and kidneys are not mature enough to fully process and remove it from the body.

Pharmacovigilance Risk Assessment Committee (PRAC)

Risk of leukoencephalopathy

PRAC has started a review of medicines containing levamisole, to treat infections caused by parasitic worms in adults and children. The review follows concerns about a risk of leukoencephalopathy, a potentially serious condition that damages the white matter of the brain.

The committee will also assess the impact of the risk of leukoencephalopathy and demyelination on the benefit-risk balance of these medicines and issue a recommendation on whether their marketing authorisations should be maintained, varied, suspended or withdrawn across the EU.

Direct HCP communication

#MedSafetyWeek (3-9 November 2025): A call to action to improve patient safety

The annual #MedSafetyWeek campaign takes place from 3 to 9 November 2025. This year's campaign theme is 'we can all help make medicines safer.

SPC changes

Revised SPC: Dutasteride/Tamsulosin hydrochloride 0.5 mg/0.4 mg hard capsules

SPC updated to include reports of mood alterations (depressed mood, depression and, less frequently suicidal ideation) in patients treated with another oral 5-alpha reductase inhibitor. Patients should be advised to seek medical advice if any of these symptoms occur.

Revised SPC: Symbicort Turbohaler (budesonide, formoterol fumarate dihydrate) 100/6, Inhalation powder

SPC notes licence extension for use as Maintenance and Reliever Therapy (MART) in children 6-11yrs. Maintenance is 1 puff once or twice a day, with additional doses for breathlessness, up to max of 4 doses on any one occasion, and 8 doses (including maintenance doses) per day.

Manufacturer RMM

Risk Minimisation Materials: Breyanzi (lisocabtagene maraleucel) Product Handling and Administration Quick Reference Guide UK

Quick Reference Guide provides a summary of considerations and requirements prior to thawing the vials, required materials for preparing and administering, options for thawing, dose preparation, and administration.

Risk Minimisation Materials: Checklist for Healthcare Professionals for Glycopyrronium Bromide 2 mg/5 ml Oral Solution– Risk minimisation of anticholinergic side effects

This document has been produced to assist healthcare professionals in making thorough assessment of potential risk of anticholinergic adverse effects (e.g. urinary retention, cardiovascular & central nervous system effects) in a patient prior to starting & whilst taking treatment

Risk Minimisation Materials: Healthcare professional's guide to Fabhalta (iptacopan) for C3 glomerulopathy

The aim of this brochure is to help mitigate possible risks associated with iptacopan treatment by providing a guide focusing on safety areas of concern; predominantly risk of infection, and that patients have received appropriate vaccinations.

Drug shortages

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

Medicine Supply Notification for: Amiodarone 100mg and 200mg tablets

Anticipated re-supply

Date 21 November 2025. Amiodarone suspension remains available (Specials) in various strengths (including 100mg/5ml and 200mg/5ml) and pack sizes. Unlicensed imports of amiodarone 100mg and 200mg tablets have been sourced (lead times vary).

Medicine Supply Notification for: Shortage of Dalivit Oral Drops

Anticipated re-supply 14th November 2025. Abidec Multivitamin Drops remain available and can support increased demand

Medicine Supply Notification for: Shortage of Liothyronine 20microgram powder for solution for injection vials

Shortage start 31 October 2025. Anticipated re-supply date 30 April 2026. Alternatives such as unlicensed liothyronine 10microgram/ml solution for injection (XGen) remain, and Levothyroxine 200 micrograms/ml ampoules.

Drug shortages

Medicine Supply Tool: Shortage of Repaglinide 500microgram,1mg and 2mg tablets

Anticipated re-supply date 5 December 2025. Alternative glucose lowering medication remains available.

Medicine Supply Tool: Shortage of Dinoprostone (Prostin E2 vaginal tablets) 3mg pessaries

Shortage start 7 November 2025. Anticipated re-supply date. Alternative classes of treatment remain available as per NICE guideline [NG207] on inducing labour.

Medicine Supply Notification: Shortage of Anti – Tuberculosis (TB) Medicines

Anticipated re-supply 14th November 2025. A National Patient Safety Alert was issued on 29 July 2025. This Medicines Supply Notification supersedes the National Patient Safety Alert issued on 29 July 2025. Actions including an import ordering table can be found on the SPS Medicines Supply Tool.

Drug Discontinuation

Medicine Supply Notification: Discontinuation of Mometasone (Asmanex Twisthaler®) 200micrograms/dose dry powder and 400micrograms/dose dry powder inhalers.

Discontinuation date is 31 October 2025. For alternative treatments see NICE asthma guidelines

Medicine Supply Notification: Discontinuation of Admelog (insulin lispro) 100units/ml solution for injection cartridges, pre-filled pens and vials

Discontinuation until 14 March 2026. Review existing patients and consider switching to the originator insulin product, Humalog 100units/ml solution for injection, which can fully support the increased demand.

Medicine Supply Notification: Discontinuation of Exenatide (Bydureon BCise) 2mg/0.85ml prolonged-release suspension for injection pre-filled pen

Discontinuation date is 30 September 2025. Alternative GLP-1 RAs and dual GIP/GLP-1 RA remain available and can support increased demand.

Specialist Pharmacy Service

Preparing to use golimumab biosimilar

Phase 2 and 3 implementation checklists added.
Information updated with EU progress towards licensing; brand name added for Advanz product.

Trimethoprim for Urinary Tract Infection

Version 2.0 of PGD templates, valid from January 2026, have been published to allow organisations to undertake local governance processes in a timely manner.

Nitrofurantoin for Urinary Tract Infection

Version 2.0 of PGD templates, valid from January 2026, have been published to allow organisations to undertake local governance processes in a timely manner.

Vancomycin: informing intrathecal risk assessment

Full review of products, their licensed status and other characteristics which affect their suitability for intrathecal administration

Specialist Pharmacy Service

Colistimethate sodium: informing intrathecal risk assessment

Full review of products, their licensed status and other characteristics which affect their suitability for intrathecal administration

National guidance, publications and resources

Investigating under the Patient Safety Incident Response Framework (PSIRF): sharing HSSIB learning for future development

Report to share learning gained from our investigation activities and education programme about patient safety incident investigations under the Patient Safety Incident Response Framework (PSIRF).

Workforce and patient safety

Investigations consider how working conditions can be optimised to support patient safety, while maintaining and improving NHS staff wellbeing.

Prevention of Future Death Reports (Regulation 28)

James Rownsley 2025-0430

James died from severe burns at his home after his clothing ignited following contact with a gas. The presence of emollient cream on his clothing was a significant factor in his death. Whilst the report does not list actions for healthcare professionals, it raised concerns that there is still a lack of awareness with both healthcare professionals and the public regarding the extent of the risk.

- Do you have processes set up to ensure that any patients dispensed emollients from your dispensaries are counselled on the risks?

Emollients: new information about risk of severe and fatal burns with paraffin-containing and paraffin-free emollients - GOV.UK

Emollients A5 leaflet 290720

Prevention of Future Death Reports (Regulation 28)

Thompson Elliott 2025-0515

Thompson was a care home resident. Following a brief hospital admission, he was discharged back to his care home with new analgesia. Shortly after his return there was confusion over which analgesia he was on as his discharge letter could not be located. This resulted in him being administered both morphine and oxycodone in error leading to him being readmitted to hospital due to opioid overdose. He subsequently died of influenza A after being successfully treated for the overdose, but he did not have the physiological reserves to fight the virus due to his frailty and underlying malignancy.

Matter of concern raised

- The discharge letter could not be located which led to confusion over what medicines had been started in hospital and which were to be discontinued.
- Staff were not aware of processes to follow when they can't access relevant medicines information which ultimately resulted in an overdose.

Are you assured that all relevant medicines information is available when needed for all healthcare professionals who may need it?

Prevention of Future Death Reports (Regulation 28)

Amber Walker 2025-0528

Amber suffered from epilepsy. Following multiple episodes of cluster seizures she was recommended to increase her topiramate dose. She declined. At this consultation there was no discussion about SUDEP or Amber's increased risk. A month later Amber unfortunately died of SUDEP.

The concerns raised by the coroner were regarding training for medics and the lack of discussion with the patient, but they also highlighted useful tools that healthcare professionals may find useful including the SUDEP action "SUDEP checklist".

- This checklist may be useful for pharmacy staff counselling on epilepsy medicines
    - Evidence based tool to help clinicians in their discussions with people about epilepsy risks.

Primary research - Medication Safety

Guideline adherence for controlling incidence of medication errors: a systematic mixed-method review.

The article reviews the factors that affect healthcare professionals' adherence to safe medication therapy guidelines, which are important for patient safety and quality of care. The findings highlight the important role of hospital pharmacists in building multifaceted and multidisciplinary programs to address guideline adherence issues, as well as identified interventions that can improve guideline adherence.

Medication errors in Intensive Care Unit: Assessment of Knowledge among Critical Care Nurses and implementation of a simple strategy to reduce errors.

A quantitative cross-sectional study, collecting data on Knowledge, Perception & Behaviour of nurses on medication errors and patient safety. There was a significant difference in nurses' knowledge after education intervention in the use of computerized physician order entry system reducing medication errors (p 0.00) and alarm noises and ward emergencies increase error risk (p 0.001). Significant differences were noted in perception of the effects of protocols/ guidelines on ensuring proper management of therapeutic processes (p 0.014).

Primary research - Medication Safety

Parental involvement in paediatric patient safety incidents in general practice: a cross-sectional study.
A cross-sectional analysis was conducted of paediatric patient safety incidents occurring in general practice, with explicit evidence of parental involvement, between September 2014 and February 2023. This study identified several positive mitigatory actions taken by parents to keep their children safe. Primary care teams working to improve and design safer systems of care delivery for children in general practice should embrace the opportunity to learn with and from parents.

The crucial role of language interpretation services in patient safety and healthcare delivery
This article argues that interpretation services should be a core element of the NHS patient safety agenda, rather than being limited to an equality, diversity and inclusion consideration. Policy recommendations and supporting evidence are provided, calling for urgent action to protect vulnerable patients from avoidable harm.