SPS Medication Safety Update May 2026

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

Patient Safety Alerts

Changes to the CAS website login process

Issued: 13/05/2026

From 17th May 2026 login to the CAS website will be via Multi-Factor Authentication (MFA) rather than the CAS website password you use at present.

What does this mean for me?

This change only impacts those who currently login to the CAS website (which is mainly those from NHS Trusts and Foundation Trusts who record responses for their organisation).

Generic / group / shared mailboxes can no longer be used as usernames to login to the CAS website however they can remain registered to receive email notifications when we issue alerts and safety messages.

They have contacted all organisations that are impacted and will register individual email addresses that will have the ability to login and record responses.

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Finasteride and Dutasteride – updated safety warnings for psychiatric side effects and sexual dysfunction

Finasteride is associated with depression, suicidal ideation and sexual dysfunction which may persist after treatment is stopped. Patients should be informed of the risks at the point of prescribing and advised to read the Finasteride patient cards and the patient leaflet for finasteride. When prescribing finasteride, medical records should be reviewed and the patient should be asked if they have a history of depression or suicidal ideation. Patients should be reviewed regularly for psychiatric and/or sexual side effects. Dutasteride works in a similar way to finasteride – therefore, as a precaution, a warning will be added to the dutasteride product information that mood alterations have been reported with the same class of medicine (finasteride).

Nasal decongestant sprays and drops containing xylometazoline hydrochloride / oxymetazoline hydrochloride: increased risk of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with overuse

There have been reports of worsening nasal congestion (rebound congestion) when the effects of nasal decongestant sprays or drops containing xylometazoline hydrochloride and oxymetazoline hydrochloride wear off. This typically occurs when these medicines are used for longer than recommended. Continued use can also lead to more serious and longer-lasting changes to the lining and structures of the nose (rhinitis medicamentosa). In addition, repeated use will result in a rapid and noticeable reduction in the medicine's effectiveness (tachyphylaxis). Patients and caregivers should be informed not to exceed the recommended dose and not to use for more than 5 consecutive days.

Recent regulator and statutory body activity

MHRA Safety Roundup: April 2026

Roundup covers the publication of a new RSV vaccine factsheet, and information about the EMA recommending withdrawal of marketing authorisations for levamisole medicines following safety review. It also includes letters, medicine recalls and device notifications sent to healthcare professionals.

MHRA invites views on proposed changes to medical device regulation

New pre-market regulatory requirements for medical devices and in vitro diagnostic devices entering the GB market have been published by the MHRA on the World Trade Organisation notification portal on Friday 8th May 2026.

Recent regulator and statutory body activity

Class 4 Medicines Defect Notification: Fresenius Medical Care Deutschland GmbH, balance 2.3% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, EL(26)A/24

Fresenius Medical Care Deutschland GmbH have identified an error in the Braille printed on the outer label.

Class 2 Medicines Recall: Amarox Limited, Sertraline 100mg film-coated tablets, EL(26)A/22

Amarox Limited is recalling one batch of Sertraline 100 mg film-coated tablets as a precautionary measure due to an error at the manufacturing site.

Class 4 Medicines Defect Notification: Milpharm Limited, Loperamide hydrochloride 2 mg Orodispersible Tablets, EL(26)A/23

In two batches, the patient information leaflet incorrectly instructs patients to swallow the tablets whole with a drink of water and omits the entry “Burning or prickling sensation of the tongue” as a rare but recognised local effect of the orodispersible formulation.

Direct HCP communication

Potential particulates in certain Visipaque (Iodixanol) and Omnipaque (Iohexol) 100 ml polymer bottles

Certain 100 ml bottles of Visipaque and Omnipaque may have particles adhered to the polymer bottles. The occurrence of these particulates is rare; these batches are not being recalled in the UK and may continue to be used as directed.

Enzalutamide Astellas 40mg film-coated tablet: enzalutamide laboratory test interference leading to falsely elevated digoxin plasma levels

Falsely elevated digoxin plasma level results with the chemiluminescent microparticle immunoassay (CMIA) have been identified in patients treated with enzalutamide, independently of being treated with digoxin. Results of digoxin plasma levels obtained by CMIA should be interpreted with caution.

SPC changes

Revised SPC: Leustat (cladribine) subcutaneous 2mg/ml solution for injection

Correction of timeframe given to not father a child after the last dose of Leustat subcutaneous from 3 to 6 months

Revised SPC: Loqtorzi (toripalimab) 240 mg/6 ml Concentrate for Solution for Infusion

SPC updated to state not to co-infuse other medicines via the same line. The risk of immune-mediated adverse reactions may be increased in people with pre-existing autoimmune disease (AID); flares of the underlying AID were frequent, but the majority were mild & manageable.

Revised SPC: Valcyte (valganciclovir) film-coated tablets and powder for oral solution

SPCs updated to state dosing of paediatric solid organ transplant patients is individualised based on renal function plus body surface area. Powder for oral solution updated with information on benzoate content; benzoates may increase jaundice in newborns (up to 4 weeks old).

Revised SPC: Mircera (methoxy polyethylene glycol-epoetin beta) solution for injection in pre-filled syringe, various strengths

SPC updated as Roche no longer offers free anti-erythropoietin antibody (AEAB) testing service. If pure red cell aplasia (PRCA) is suspected, clinicians should arrange AEAB testing via alternative diagnostic routes.

Manufacturer RMM

Risk Minimisation Materials for blinatumomab (Blincyto)

An interactive website version of the Nurse's Guide has been added to the available materials for this product, providing further information about how to minimise/prevent neurologic events including immune effector cell-associated neurotoxicity syndrome associated with its use.

Risk Minimisation materials for Alzakt (rivastigmine) 4.6 mg/24 h Transdermal Patch

A card providing instructions for use and a patient diary covers how and where to apply the patches, and instructions on how to complete the record sheet.

Drug shortages

MSN/2026/023 Midazolam (Epistatus®) 7.5mg/0.75ml oromucosal solution pre-filled oral syringes sugar free

Midazolam (Epistatus®) 7.5mg/**0.75ml** oromucosal solution pre-filled oral syringes are currently out of stock until late-May 2026. Midazolam (Buccolam® and generic) 7.5mg/**1.5ml** oromucosal solution pre-filled oral syringes remain available and can support increased demand

MSN/2026/024 Trurapi® (insulin aspart) 100units/ml solution for injection 3ml pre-filled Solostar pens

Trurapi® (insulin aspart) 100units/ml solution for injection 3ml pre-filled Solostar pens are in limited supply until late May 2026, followed by an out of stock period until mid-June 2026. Trurapi (insulin aspart) 100units/ml solution for injection 3ml cartridges to be used with AllStar PRO or JuniorSTAR pens. These are available and can support increased demand. NovoRapid Flexpen (insulin aspart) 100units/ml pre-filled pens. These are available and can support increased demand.

Drug Discontinuation

Discontinuation of Geloplasma 3% infusion 500ml Freeflex bags

Published 11 May 2026

Gelofusine 4% infusion 1litre Ecobags (B Braun) remain available and can support increased demand.

Specialist Pharmacy Service

Embedding the safer use of insulin, **Managing the risk of confusion between insulin products** & **Safety considerations when switching insulin products** (Published 6 May 2026)

In line with insulin safety week SPS have published three articles to focus on improving insulin safety. Implementing national standards to reduce preventable harm, reducing confusion between insulin products through clearer processes, and highlighting key safety principles for healthcare professionals when switching patients between insulin types.

Using transdermal patches safely in healthcare settings (Last updated 5 May 2026)

Clarity added for patients disposing of transdermal patches at home.

Embedding medication safety improvement within an organisation (Published 30 April 2026)

Webpage provides information on the Patient Safety Incident Response Framework (PSIRF), which can support effective prioritisation and delivery of medication safety improvements

Benztropine injection for acute dystonic reactions (Published 29 April 2026)

SPS has developed advice on use of unlicensed parenteral benztropine for treatment of acute dystonic reactions; this resource aims to support healthcare professionals in managing the discontinuation of procyclidine injection, the previous treatment of choice in the UK.

National guidance, publications and resources

Safety and quality in healthcare: why the distinction is important

Blog discusses a new paper by HSSIB and highlights that treating safety as the foundation of quality, rather than one dimension among many, is not a semantic preference, but the precondition for keeping patients safe.

Safe and effective dose management in electronic prescribing and medicines administration systems

This joint RCPCH and NPPG position statement calls for BNFC based dosing to be used across UK as basis for EPMA systems to calculate paediatric dosages and set safety dose limits; all of which should ideally account for child anthropometry and medical condition being treated.

Acne vulgaris: management – updated guidance (NG198)

Guidance updated to remove the need for 2 independent healthcare professionals to approve the use of isotretinoin in people under 18 years because this is no longer a regulatory requirement. Instead, the MHRA has introduced alternative risk minimisation measures. Source: National Institute for Health and Care Excellence

National dose banding table – zanidatamab 50mgmL

The national dose banding tables are to be used by hospital trust pharmacy teams to ensure a standard approach to dose banding of chemotherapy across all hospital trusts. Source: NHS England

National guidance, publications and resources

Investigation report — Insulin: supporting safe self-administration for patients in the community with a disability

Report warns disabled people with diabetes may lack adequate community support for safe insulin self-administration, creating life-threatening risks. Calls on NHSE & DHSC to strengthen support expectations and develop tools to assess patients', families' & carers' capability.

Prevention of Future Death Reports (Regulation 28)

No relevant information.

Primary research - Medication Safety

Exploring Medication Safety in Transitions From Prison to Community: A Qualitative Study

Health expectations : an international journal of public participation in health care and health policy 01 Jun 2026.

Members of staff were interviewed; five main factors impacting medication safety during transitions were identified: release practices, care coordination and communication issues, staffing shortages, IT system limitations, and patient-related factors. Suggested improvements included: electronic prescribing for timely access to medication, improved information transfer, dedicated discharge teams to ensure medication follow-up, early discharge planning to address medication needs, and multi-disciplinary meetings to coordinate complex care.

Educational Interventions Affecting Medication Error Reporting by Healthcare Professionals in Secondary and Tertiary Care: A Systematic Review and Narrative Synthesis.

Drug Safety 01 May 2026.

A systematic review. A better understanding of educational intervention methods, rationales, time frames, frequency, and effective co-interventions may improve medication error reporting. Combining education with other interventions had positive outcomes related to medication error reporting compared with education alone. Educational interventions improved the quantity and some quality measures of medication error reporting.

Primary research - Medication Safety

AI-Driven Approaches for Adverse Event Detection: A Systematic Review of Current Evidence.

Safety 01 Apr 2026

Artificial intelligence-powered methods are transforming adverse events detection from retrospective to predictive, proactive monitoring. There remain some challenges, however, including limited external validation, class imbalance, and interpretability of complex models. Future studies must address explainable artificial intelligence, multicenter trials, and high-quality well-annotated datasets to offer secure clinical integration.

When optimising the operating theatre compromises anaesthetic safety: ambient lighting, human performance, and medication error risk.

British Journal of Anaesthesia 01 May 2026.

Blue- or green-dominant ambient lighting is increasingly used in hybrid operating theatres to optimise surgical visualisation, but it can unintentionally compromise anaesthetic safety. Mitigation strategies should include localised white lighting at the anaesthetic workstation, enhanced label design, and lighting-independent technologies such as machine-readable drug labelling.

Primary research - Medication Safety

Root Cause Analysis, Action, and Audit (RCA3): A Novel Approach to Sustainably Reduce Medication Errors.

Journal of patient safety 01 May 2026.

A review looking at how RCA3, builds on RCA2 by adding routine audits assessing implementation, long-term effectiveness, and medication error recurrence within 12 months.

Creating a Drug Library for Zero Continuous Infusion Errors in a Paediatric Intensive Care Unit: A Quality Improvement Project.

Nursing in critical care 01 May 2026.

A scalable model is presented that demonstrates how smart pumps, EMR integration and multidisciplinary training can significantly reduce continuous infusion errors in PICUs, enhancing safety for vulnerable paediatric patients and providing a framework for adoption in other high-risk settings like emergency departments and subspecialty wards.

Primary research - Medication Safety

Exploring the applicability of the UK Prescribing Safety Assessment with early career pharmacists as preparation before formal prescribing training.

International Journal of Clinical Pharmacy June 2026

A study looking at the potential value in situating the PSA during the Foundation Training Year.

Medication errors involving parenteral nutrition preparations and concentrated electrolytes in a pediatric hospital: A qualitative analysis.

Journal of Parenteral & Enteral Nutrition April 2026.

Analysis of medication safety incidents at a paediatric university hospital, focusing on parenteral nutrition and concentrated electrolytes. Errors often occur during preparation and administration, primarily because of the complexity of individualised dosing. Contributing factors include high workload, limited resources, and employee-related factors. Hospitals should prioritise implementing systems-based, technology-driven defenses over person-focused strategies.