SPS Medication Safety Update January 2026

Recent critical patient safety alerts, reports, and publications

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28/01/2026

Patient Safety Alerts

Steriflex No. 109 (1L) and No. 171 (2L): Potassium Chloride 0.15%, Sodium Chloride 0.45%, Glucose 2.5% Bags

Issued: 14/01/2026 Deadline: 6/02/2026 NatPSA/2026/001/DHSC

Fresenius Kabi are transitioning their Steriflex® range of licensed and unlicensed IV fluid bags to DEHP-free IV fluid bags in line with changes to reach regulations, and have experienced a shortage during this change due to increased demands and lack of availability of raw materials.

The following products will be continued within their portfolio however there will be a shortage during this transitional period:

- Steriflex® No. 109 (1L): potassium chloride 0.15%, sodium chloride 0.45%, glucose 2.5% containing potassium 20mmol in 1L is out of stock until September 2026.
- Steriflex® No. 171 (2L): potassium chloride 0.15%, sodium chloride 0.45%, glucose 2.5% containing potassium 40mmol in 2L will be out of stock from May until August 2026.

Fresenius Kabi have applied monthly allocations for Steriflex® No.171 (2L) bag. Contact your FK account manager if you require further information. A range of alternative IV fluid bags from other suppliers are available, but the use of these products will require review of protocols and prescriptions on electronic prescribing systems and some may require additions to pre-made bags.

Actions:

- Assess where the Steriflex® No. 109 (1L) and No.171 (2L) bags are used within their Trust including paediatric and adult oncology/ haematology.

Recent regulator and statutory body activity

MHRA Safety Roundup – December 2025

Roundup covers mesalazine and idiopathic intracranial hypertension, transition to new formulation of Rybelsus (semaglutide tablets) and risk of medication error, and letters, medicine recalls and device notifications sent to healthcare professionals.

MHRA and National Fire Chiefs Council issue winter emollient safety warning

The MHRA and the National Fire Chiefs Council are urging the public to be aware of fire risks linked to emollient skin creams, highlighting three simple precautions: 1) keep away from flames; 2) keep warm safely; 3) wash bedding and clothing regularly.

MHRA urges public to avoid illegal online weight-loss medicines this New Year

The MHRA continues to warn the public about serious risks linked to buying weight loss medicines from unregulated websites or through social media, stressing they are prescription-only & should only ever be supplied after a proper assessment by a qualified healthcare professional

Recent regulator and statutory body activity

MHRA Safety Roundup: January 2026

This covers the changes to prescribing guidance and additional risk minimisation measures for isotretinoin, improving information supplied with gabapentinoids benzodiazepines and Z-Drugs, letters, medicines recalls and device notifications, and a news roundup.

Recent regulator and statutory body activity

Class 2 Medicines Recall: Mercury Pharmaceuticals Ltd, Paliperidone Mercury Pharma prolonged-release suspension for injection in pre-filled syringes, EL(26)A/01

Mercury Pharmaceuticals Ltd is recalling remaining stock of paliperidone pre-filled syringes as a precautionary measure due to Good Manufacturing Practice (GMP) deficiencies cited during a recent inspection at the finished product manufacturing site.

Class 3 Medicines Recall: Fingolimod Glenmark 0.5 mg Hard Capsules (Glenmark Pharmaceuticals Europe Ltd)

One batch (1501919) is being recalled as a precautionary measure following stability test results that showed out-of-specification results (a delay in capsule dissolution). Recall is being undertaken at a Pharmacy and Wholesaler level.

Class 4 Medicines Defect Notification: Blumont Pharma Limited, Ocumont Eye Ointment 1% w/w, EL(26)A/03

Healthcare professionals are advised to be aware that the outer carton of the affected batch does not contain Braille. Appropriate support should be provided to patients with visual impairment when dispensing this product, in line with local procedures.

Recent regulator and statutory body activity

GPhC shares advice on safe prescribing and dispensing in response to emerging patient safety concerns

- Letter covers dispensing and supply of methotrexate,
- Checking interactions and contra-indications,
- Patient counselling,
- The risk of overdose from propranolol,
- Ensuring fluoroquinolone use is clinically justified,
- Using IT systems to support safe prescribing and dispensing.

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting held between 12-15th January 2026

The Committee did not start or conclude any referral procedures. Information on ongoing safety referrals is provided in the 'Ongoing referrals' table below.

Information on all topics discussed by the PRAC is available in the agenda.

Use of paracetamol during pregnancy unchanged in the EU

Update as of 20 January 2026

Recent publication confirms no increased risk of autism, ADHD or intellectual disability

A recent systematic review and meta-analysis published in The Lancet Obstetrics, Gynaecology, & Women's Health has found no evidence that using paracetamol at recommended doses during pregnancy increases the risk of autism spectrum disorder, ADHD or intellectual disability in children. This supports the existing evidence and advice that the EMA issued on the use of paracetamol during pregnancy.

Pharmacovigilance Risk Assessment Committee (PRAC)

EMA and FDA set common principles for AI in medicine development

EMA and the U.S. Food and Drug Administration (FDA) have jointly identified ten principles for good artificial intelligence (AI) practice in the medicines lifecycle.

The principles give broad guidance on AI use in evidence generation and monitoring across all phases of a medicine, from early research and clinical trials to manufacturing and safety monitoring.

The principles are relevant for those developing medicines, as well as for marketing authorisation applicants and holders. They will underpin future AI guidance in the different jurisdictions and support enhanced international collaboration among regulators, organisations setting technical standards and other stakeholders.

Direct HCP communication

Dear Healthcare Professional Communication: Mivacurium 2mg/ml, Cisatracurium 2mg/mL solution for injection, administration instructions for specified batches where glass particles may be present

Small, visible or subvisible glass particles may be present in listed batches due to issues identified during manufacture and/or through the ampoule opening process. Letter contains information on actions to be performed when preparing or administering units from these batches.

Direct Healthcare Professional Communication: Tegretol® 100 mg/5ml Liquid (carbamazepine) - Limitation of use in neonates

An assessment of the product's label in another country found that the propylene glycol content exceeds the recommended threshold for neonates (1 mg/kg/day). The SPC has therefore been updated to note that it is no longer recommended for use in this patient group.

Dear Healthcare Professional Communication-Levetiracetam (Keppra) oral solution: Risk of medication error due to change of dosing syringe

A new 5mL dosing syringe (delivering up to 500mg) will replace the 3mL syringe (up to 300mg). When dispending, caregivers should be informed about the change in volume, the correct dose and how to measure it using the 5mL syringe. Both sizes may be available at the same time

Direct HCP communication

Direct Healthcare Professional Communication: Tyenne 20 mg/mL concentrate for solution for infusion – PLGB 08828/0359-Temporary Supply of Finnish/ Swedish dual labelled stock

To ensure continuity of supply, Fresenius Kabi Limited has obtained approval from MHRA to supply stock (batch number 16UK05) that is Finnish/Swedish labelled. This product is the same quality, formulation and specifications as that approved in the UK.

Direct Healthcare Professional Communication- Xenpozyme 20mg powder for concentrate for solution for infusion (olipudase alfa): Interim Supply of European Union Packs to Ensure Supply Continuity

Sanofi has obtained approval from MHRA to supply EU authorised packs in Irish livery for batches EW1846 and EW2333. The product from the EU has the same formulation as the UK product. These packs are considered licensed in UK.

SPC changes or Manufacturer RMM

Revised SPC: Nipent (pentostatin) 10 mg powder for solution for injection, powder for solution for infusion

SPC updated to include information providing advice on adequate duration of contraception for female patients and advice to lactating women on the adequate duration to abstain from breastfeeding, and information on contraception for male patients.

Revised SPCs: Wegovy (semaglutide) formulations

SPC updated to note data from epidemiological studies may indicate an increased risk of non-arteritic anterior ischaemic optic neuropathy during treatment with semaglutide. Patients reporting a sudden loss of vision should be urgently referred for ophthalmological examination.

Revised SPC: Tecentriq (atezolizumab) – all formulations and strengths

SPC updated with warning of uveitis as an adverse drug reaction (ADR) of uncommon frequency for monotherapy and rare with combination therapy. In addition, cytomegalovirus infection, tenosynovitis, arthritis and sarcoidosis added as ADRs for monotherapy.

SPC changes or Manufacturer RMM

Revised SPC: Rezurock (belumosudil mesylate) 200mg film-coated tablets

SPC updated to advise caution when co-administering belumosudil with sensitive CYP1A2 substrates (for example theophylline, warfarin, tizaidine or pomalidomide), for which minimal concentration changes may lead to serious toxicities.

Revised SPC: VARIVAX (varicella-zoster virus, live) vaccine

Updated to warn of encephalitis (fatal in some cases e.g. immunocompromised patients) reported during post-marketing use & also a consequence of varicella infection itself. Medical attention needed if signs (reduced consciousness, convulsions, ataxia, fever or headache) appear.

Revised SPC: Augmentin Duo 400/57 (amoxicillin trihydrate, clavulanic acid) powder for oral suspension (mixed fruit flavour)

Addition of haemophagocytic lymphohistiocytosis/macrophage activation syndrome as an adverse event of unknown frequency. This syndrome of pathological immune activation can be life threatening. Treatment should be discontinued unless alternative aetiology can be established.

SPC changes or Manufacturer RMM

Risk Minimisation Materials for Exambol (argatroban)

DHPC letter contains detailed safety information on the ready-to-use solution for infusion (1 mg/mL) and highlights some key differences in the packaging from the existing single/multidose concentrate formulation (100 mg/mL).

Risk Minimisation Materials for Yesafili (aflibercept) 40 mg/ml Solution for injection in pre-filled syringe

Materials include a prescriber guide and patient guides covering use for each of the licensed indications.

Educational risk minimisation materials for Vgenfli (aflibercept)

Materials include a prescriber guide containing important safety information and advice on storage and handling, preparation, and administration, as well as a patient guide on its use for its licensed indications.

Isotretinoin – changes to prescribing guidance and additional risk minimisation measures

The Commission on Human Medicines (CHM) has endorsed changes to the risk minimisation measures for isotretinoin, following a review of the impact of the measures implemented in 2023. We ask healthcare professionals to review these new measures and supporting materials and integrate them into their clinical practice.

Drug shortages and discontinuations

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

Medicine supply notification: Diamorphine 5mg, 10mg and 100mg powder for solution for injection ampoules

The 5mg and 10mg ampoules are out of stock, the 100mg ampoules are expected to become unavailable from early Jan, and the 30mg ampoules are unable to support increased demand. Morphine sulfate injection has been identified by clinical experts as the first-line alternative opioid

Medicine Supply Notification: Co-codamol 30mg/500mg tablets

There will be limited supply from early February to early June 2026. Paracetamol 500mg tablets and codeine 30mg tablets remain available and can support a full uplift in demand. Other strengths and forms of co-codamol remain available but cannot support an uplift in demand.

Drug shortages and discontinuations

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

Discontinuation of Emerade 150micrograms/0.15ml (1 in 1000), 300micrograms/0.3ml (1 in 1,000) and 500micrograms/0.5ml (1 in 1,000) solution for injection auto-injector pens

Status of Emerade 150micrograms/0.15ml (1 in 1000), 300micrograms/0.3ml (1 in 1,000) and 500micrograms/0.5ml (1 in 1,000) solution for injection auto-injector pens has been changed from shortage to discontinuation.

Discontinuation of Nifedipine (Fortipine LA) 40mg modified-release tablets

Status of Fortipine LA 40 tablets has been changed from shortage to discontinuation. Status and Actions section has been updated to reflect this change.

Discontinuation of Buprenorphine/Naloxone (Suboxone) 2mg/500microgram and 8mg/2mg sublingual tablet

Specialist Pharmacy Service

[Switching between pyridostigmine and neostigmine]

Switching between pyridostigmine and neostigmine in myasthenia gravis requires care and application of a stepped process. Page discusses considerations before switching, provides step-by-step guides to dose conversion, and discusses monitoring after the switch.

[Understanding time critical medicines to support improvement]

This resource aims to increase awareness & understanding of medicines that are more likely to cause harm if they are not taken at their intended timepoint. It provides insights & actions to promote organisational engagement with improving the safer use of time critical medicines

[Avoid prescribing desiccated (natural) thyroid extract]

This web page highlights natural thyroid extracts (DTE) for hypothyroidism can only be initiated by an NHS endocrinologist on a case-by-case review. Risks of hyperthyroidism, long term effects and difficult dose adjustments are common concerns associated with DTE products.

[Switching between gabapentin and pregabalin for neuropathic pain (updated)]

Updates to this resource include addition of age, respiratory function and the risk of abuse to the considerations section.

National guidance, publications and resources

Expanding access to naloxone: supply and emergency use

DHSC consultation on proposals to allow hostels, day centres & outreach services for people experiencing homelessness to supply naloxone without prescription, to create publicly accessible emergency naloxone boxes, & to clarify rules for workplaces at risk of opioid contamination

Expansion of the NHS routine childhood vaccination programme to include chickenpox

Following a recommendation from the JCVI, children will now be offered protection against chickenpox with a combined MMRV vaccine at 12 and 18 months of age. This will replace the MMR vaccine, and protect against measles, mumps, rubella and chickenpox.

Royal Pharmaceutical Society (RPS) reminds public to limit nasal decongestant spray use to seven days

During the cold and flu season, the RPS is reminding the public that longer use can cause ‘rebound congestion’, when people become dependent on the sprays to breathe more easily. New data from RPS show nearly 60% of pharmacists questioned think patients are unaware of the risk.

National guidance, publications and resources

HSSIB – Patient care in temporary care environments

This investigation explores the management of patient safety risks associated with using temporary care environments, often referred to as ‘corridor care’ and ‘temporary escalation spaces’. The investigation recognised that pressures around patient flow are constant and that temporary care environments are year-round.
NHS regional and national organisations can improve patient safety by enhancing understanding of the use of temporary care environments across all hospital settings. This may include agreeing definitions of temporary care environments and enhanced information gathering on their use and impact on patient safety.

Medicines in community mental health services

This report was commissioned by CQC and carried out by Ipsos, and looks at how medicines are managed and used in community mental health settings. It shares key findings, challenges, and examples of good practice to help support safe, effective, and person-centred care. Whilst focusing on community mental health aspects will be transferable to other teams.

The state of health care and adult social care in England 2024/25 also highlights important themes around access to care with a focus on people who may experience health inequalities.

Prevention of Future Death Reports (Regulation 28)

Paula Doreen: 2025-0511

Paula was admitted to hospital after suffering from a fractured humerus after a fall. Her death was contributed to hepatic failure and paracetamol overdose after a medication error resulted in an unintended therapeutic excess of paracetamol being prescribed alongside co-codamol for multiple days without pharmacy picking up the error.

The coroner raised concerns regarding:

- EPR system duplicate checking feature not being adopted by hospital trust
- Lack of a robust process for ensuring consistent clinical response to the management of therapeutic excess and potential for toxicity.
- Medicine reconciliation during admission did not identify OTC paracetamol that Paula took after her fall.

- Does your organisation have a robust governance process for local EPMA decisions to be ratified and monitored via?
- Does your medicines reconciliation policy cover recent doses of OTC medicines taken?

Prevention of Future Death Reports (Regulation 28)

Edward Jones: 2025-0633

Edward died from streptococcal sepsis. He had been promptly assessed upon presentation but a diagnosis was not confirmed. Failure in communication meant that a venous lactate was not repeated and incorrectly presumed normal. Prescribing of antibiotics was considered several times, but on each occasion the threshold was not thought to be reached.

The coroner raised concerns regarding:

- The hospital trust's Sepsis Screening Tool (SST) was not used at any time. A single positive score mandates urgent assessment by a senior decision maker and if sepsis is confirmed to ensure prompt management, including giving IV antibiotics within 60 minutes. The SST tool is not designed to diagnose sepsis directly as this is the task of the senior decision maker but rather to prompt a targeted assessment, which will confirm sepsis or specifically eliminate it.

- Does your organisation have assurance that tools and checklists are used as intended in clinical practice?

Prevention of Future Death Reports (Regulation 28)

Urielle Kuyenga: 2025-0635

Urielle's death was caused by sepsis resulting from bacterial pneumonia. Urielle was predisposed to fatal consequences of respiratory infections as she suffered from sickle-cell disease.

The coroner raised concerns regarding:

- As a patient with Sickle Cell Disease, Urielle was prescribed prophylactic penicillin to mitigate the risk of her developing fatal symptoms arising from typical respiratory infections. Urielle's mother chose not to collect those prescriptions and administer penicillin to Urielle. Urielle's specialist doctors believed that her GP was monitoring the prescription and dispensation of the penicillin, whilst Urielle's GP was misled by Urielle's mother that the hospital were dispensing the medication directly. The breakdown of communication means that Urielle was left unprotected from opportunist infection which caused this avoidable death.

- Does your organisation have a process for monitoring prescriptions that are not collected?
  - Do you contact the patient?
  - Does the prescriber get informed?

Prevention of Future Death Reports (Regulation 28)

David Dugdale: 2026-0007

David fell as an inpatient in hospital and was diagnosed with bilateral NOFs, he was transferred to a secondary hospital and underwent multiple surgeries; however, he died 4 months after first admission due to pneumonia, fracture displacement and a sacral pressure sore.

The coroner raised the following concern regarding medicines:

- David's pain was not managed effectively despite carers repeatedly trying to advise nursing staff that he was in pain.

- Can your organisation demonstrate that they listen to carer's concerns regarding medicines?
- Do you utilise patient feedback regarding pain management to improve services?

Primary research - Medication Safety

Learning from end-of-life injectable medication patient safety incidents in the community: a mixed-methods analysis

British Journal of General Practice 12 January 2026

Analysis (2,150 incidents) highlighted delays or errors in assessment, prescribing, or administration. Contributing factors included poor continuity of care, equipment design, low staffing, and cognitive issues, highlighting the need for targeted system-wide interventions.

MSATS Webinar - https://www.sps.nhs.uk/articles/msats-safe-use-of-medicines-in-palliative-and-end-of-life-care/

When shortcuts fall short: The hidden danger of abbreviations in critical care

Journal of Critical Care Volume 91, February 2026, 155236
Effective critical care communication is vital for patient safety, yet the risks of ambiguous abbreviations and acronyms or initialisms in clinical communication remain understudied. This narrative review aims to identify potentially ambiguous abbreviations and acronyms in critical care and evaluate their potential implications for clinical safety and communication quality. From this, educational interventions and standardized protocols could be devised to optimize communication. Ambiguous abbreviations and acronyms pose a significant threat to safe and effective communication in critical care. Standardized terminology, education, and clear documentation practices are urgently needed to mitigate these risks and improve patient safety.

Primary research - Medication Safety

Contributing factors of paediatric medication errors involving high-alert medications: A qualitative content analysis of self-reported medication safety incidents

Research in Social and Administrative Pharmacy, Volume 22, Issue 1, January 2026, Pages 135-146,

High-alert medications can cause severe medication errors (MEs) in paediatrics. A comprehensive understanding of the factors contributing to errors is needed to establish risk management actions. The CF (contributing factors) of paediatric MEs involving high-alert medications are multifaceted and have a wide impact on the entire system design, from organizational strategies to individual tasks. Risk management actions and further studies addressing paediatric-specific challenges are required to ensure the most optimal systemic defences, enabling proactive monitoring error-provoking conditions in clinical practice.

Primary research - Medication Safety

Age-specific differences in patient safety incidents: focus on falls and medication using the Korean patient safety incident reporting and learning system (2016–2023)

Age-specific differences in patient safety incidents: focus on falls and medication using the Korean patient safety incident reporting and learning system (2016–2023). *BMC Health Serv Res* (2026).

This study aimed to analyse the characteristics and key risk factors of falls and medication incidents across different age groups using 8 years (2016–2023) data from the Korea Patient Safety Incident Reporting and Learning System (KOPS). The study identified distinct age-specific risk associations in PSIs, with medication incidents predominantly affecting CYAs, and fall incidents primarily impacting OAs. These findings underscore the necessity for healthcare systems to implement targeted, age-specific safety protocols and enhance monitoring strategies. Strengthening surveillance practices and delivering age-appropriate education programs are critical to preventing incidents among vulnerable populations.