SPS Medication Safety Update February 2026

Recent critical patient safety alerts, reports, and publications

Christine Randall – Medicines Advice Pharmacist

The first stop for professional medicines advice

26/11/2025

Patient Safety Alerts

Recall of Quetiapine Oral Suspension (unlicensed medicine), manufactured by Eaststone

NatPSA/2026/002/MHRA

Class 1 Medicines Recall Notification

29-Jan-26

- A manufacturing error affecting all batches of quetiapine oral suspension made by Eaststone Limited resulted in twice as much quetiapine being present in the solution compared to the amount stated on the packaging
- Eaststone Limited clarified that a total of 166 units/bottles were manufactured between 26 October 2025 and 26 January 2026 and distributed to healthcare customers
- All patients dispensed this product since 26 October 2025 to 26 January 2026 should be contacted.

Recent regulator and statutory body activity

Class 2 Medicines Recall: Paliperidone Mercury Pharma prolonged-release suspension for injection in pre-filled syringes

Remaining stock recalled as precautionary measure due to Good Manufacturing Practice (GMP) deficiencies cited during a recent inspection at the manufacturing site. Due to the ongoing remedial actions at the site, there may be delays in the manufacture of future batches.

Class 2 Medicines Recall: Syri Limited, T/A SyriMed, Baclofen 10mg/5ml Oral Solution

Specific batches of product are being recalled as a precautionary measure due to crystallisation observed over time in the oral solution

Class 2 Medicines Recall: Accord Healthcare Ltd, Carmustine 100 mg Powder and Solvent for Concentrate for Solution for Infusion (1 vial 100mg powder, 1 vial of 3 mL solvent)

Onebatch of Carmustine 100 mg Powder and Solvent for Concentrate for Solution for Infusion (1 vial 100mg powder, 1 vial of 3 mL solvent) is being recelled due to an out of specification result for Non-Volatile Residue observed during Official Medicines Control Laboratory (OMCL) testing

Recent regulator and statutory body activity

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 3 Medicines Recall: Aspar Pharmaceuticals Ltd, Ibuprofen 200mg Tablets, Ibucalm 200mg tablets

Specific batches distributed in Aspar, Almus and Numark livery are being recalled as a precautionary measure following findings of foil perforations in some blisters.

Class 3 Medicines Recall: Norgine Limited, MOVICOL Ease Citrus Powder for oral solution 13.7 g

Norgine Limited is recalling one batch (454699) of product as a precautionary measure due to some units containing low amounts of active ingredients.

Class 4 Medicines Defect Notification: Viatris Products Ltd, Arixtra solution for injection, pre-filled syringes

Viatris has received reports of brown discolouration and blockage in the needle of pre-filled syringes of Arixtra. This quality defect is related to oxidation of the syringe needle. The defect occurrence is estimated to be very rare and as Arixta is considered critical to the continued supply of this medication, it is not being recalled

Recent regulator and statutory body activity

MHRA Safety Roundup: January 2026

- **Improving Information Supplied with Gabapentinoids (Pregabalin/Gabapentin), Benzodiazepines and Z-Drugs** - Strengthened warnings regarding addiction, dependence, withdrawal, and tolerance for gabapentin, pregabalin, benzodiazepines, and z-drugs
- **Statins: update to product information on the role of the nocebo effect in muscle-related events** - changes to product information have been recommended following publication of publication of a meta-analysis by the Cholesterol Treatment Trialists' (CTT) Collaboration on the effect of statin therapy on muscle symptoms which describes the role of the nocebo effect in muscle-related events
- **Epimax Ointment and Epimax Paraffin-Free Ointment: reports of ocular surface toxicity and ocular chemical injury** – reminder to healthcare professionals of the Drug Safety Update regarding Epimax Ointment and Epimax Paraffin-Free Ointment. Reports of ocular surface toxicity and ocular chemical injury where patients have been prescribed or advised to use these emollients on the face or around the eyes continue to be received.

Recent regulator and statutory body activity

MHRA

GLP-1 receptor agonists and dual GLP-1/GIP receptor agonists: strengthened warnings on acute pancreatitis, including necrotising and fatal cases - Product information updated to highlight potential risk of severe acute pancreatitis, including rare reports of necrotising & fatal pancreatitis. If pancreatitis is suspected, treatment should be discontinued immediately, and should not be restarted if the diagnosis is confirmed

Semaglutide (Wegovy, Ozempic and Rybelsus): risk of Non-arteritic Anterior Ischemic Optic Neuropathy (NAION) Semaglutide may be very rarely linked to NAION. Patients with sudden loss of vision should be urgently referred for specialist examination. New or existing patients during medication reviews with sudden loss of vision or rapidly worsening eyesight should be advised to attend A&E.

Isotretinoin – changes to prescribing guidance and additional risk minimisation measures Healthcare professionals can now prescribe isotretinoin to those under 18-years old without seeking the agreement of a second prescriber. Alternative risk minimisation measures have been introduced to ensure it continues to be prescribed and dispensed safely.

MHRA issues new guidance for people using mental health apps and technologies

New advice on using apps and other digital tools to support mental health is being published by MHRA as part of free online resources developed with NHSE for public, parents, carers and health, social care and education professionals who use or recommend these tools.

IXCHIQ Chikungunya vaccine: updates to restrictions of use following safety review

Following safety review and recommendations of the Commission on Human Medicines, the vaccine is no longer indicated for adults ≥60 years, and is contraindicated in anyone with hypertension, cardiovascular disease, diabetes mellitus, and/or chronic kidney disease.

Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC 9 - 12 February 2026

Leukoencephalopathy confirmed as a serious side effect of levamisole

- Withdrawal of marketing authorisations for levamisole medicines recommended
- (not licensed in the UK, listed in BNF as available as import)
- information reviewed showed that symptoms of leukoencephalopathy may occur after a single dose of levamisole and may develop within one day to several months after treatment
- review did not identify any measures to reduce the risk or any group of people who may be at higher risk of developing leukoencephalopathy
- considering that levamisole medicines are used to treat mild parasitic worm infections and that levamisole-induced leukoencephalopathy is a serious condition with an unpredictable onset, the benefit–risk balance of these medicines was considered negative

Direct HCP 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

Zentiva Thalidomide 50mg Capsules, hard (PL 17780/1266)

To ensure continuity of supply, Zentiva has obtained approval from MHRA to supply some batches with German details printed on the foils in UK cartons alongside current approved UK Patient leaflet. The product in the German blister has the same formulation as the UK product.

Manufacturer RMM

Risk minimisation materials: denosumab biosimilars (Bildyos 60 mg and Bilprevda 120 mg Solution for injection)

Dear Healthcare Professional letter advises prescribers to inform and/or remind patients of the risk of osteonecrosis of the jaw during treatment, and to provide them with a patient reminder card containing important safety information to be aware of before and during treatment.

Drug shortages and discontinuations

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

Shortage of Potassium canrenoate 200mg/10ml solution for injection ampoules (imported)

Anticipated re-supply date: 27 February 2026. 200mg/10ml preparation should be sourced as a direct substitute, if possible. Procurement teams should liaise with their medication safety officer if the 200mg/2ml preparation is purchased to agree risk reduction measures to prevent dosing errors.

Shortage of Phenobarbital 30mg and 60mg tablets

Anticipated re-supply date: 27 March 2026. Consider prescribing phenobarbital 30mg tablets (Accord or Bristol) or phenobarbital 15mg tablets (Teva) to make up the required dose. Phenobarbital is a category 1 anti-epileptic drug so ideally patients should be maintained on a specific manufacturer's product.

Shortage of Sodium valproate (Epilim Chronosphere) 100mg modified-release granules sachets sugar free

Anticipated re-supply date: 24 April 2026. Consider switching to Epilim crushable tablets or Epilim 200mg/5ml oral liquid to make up the required equivalent daily dosage.

Shortage of Propafenone (Arythmol) 150mg tablets

Anticipated re-supply date: 03 April 2026. Consider prescribing flecainide tablets or increasing the dose to 300mg BD is appropriate.

Specialist Pharmacy Service

This series of three articles aims to support NHS Trusts in assessing and mitigating risks of error and contamination when choosing the appropriate location for aseptic manipulation of injectable medicines.

Assessing risks when reconstituting injectable medicines

Assess risks of error and contamination when choosing the appropriate location for aseptic manipulation of injectable medicines.

Risk factors: manipulation of injectable medicines

Key factors to be considered when assessing potential patient-safety risks of aseptic manipulation of injections.

Mitigating the risks of manipulating injectable medicines

Identified patient-safety risks associated with manipulation must be mitigated as far as reasonably possible.

National guidance, publications and resources

Medicines security - a national priority

Report finds medicine supply shortages are not prioritised as the potential national security issue they represent, given significant risk to people's health when they cannot access medication. There is lack of oversight/coordination by government/NHS over medicine resilience.

House of Lords Public Services Committee

The costs of tackling drug harms in prisons

Report outlines how illicit drug use in prisons undermines rehabilitation, harms health and threatens safety. Effective action needs strong coordination between HMPPS and health services, yet staff report limited influence whilst funding pressures add to the challenge.

National Audit Office

National guidance, publications and resources

Global State of Patient Safety 2025

Report highlights persistent challenges and opportunities for patient safety improvement worldwide, setting out strategic "ambitions" to guide countries in improving safety governance, implementation, patient involvement, and data use to drive safer care.

Imperial College London

Labelling of Dispensed Oral Medicines for Children position statement

In version 2, recommendation to express dose for oral liquid medicines in terms of millilitres (mL) only is unchanged but updated to note it can also be expressed in terms of "spoonfuls", provided that volume of spoonful is also specified on the label e.g. "….5mL spoonful".

Neonatal & Paediatric Pharmacists Group

Statin prescribing information updated to highlight that most muscle symptoms are not caused by the drugs

Article highlights recent MHRA review which concluded majority of muscle symptoms reported by statin users may be due to the 'nocebo effect', where negative beliefs about treatment lead to people experiencing real symptoms. SPCs are being updated with the analysis findings.

Monthly Index of Medical Specialities

National guidance, publications and resources

ACMD announces decision on the classification of ketamine

The ACMD has advised the government ketamine should remain a class B controlled substance, but that police forces and health care professionals must receive greater support to better identify, prevent and respond to ketamine-related harms.

Advisory Council on the Misuse of Drugs

GLP-1 Receptor Agonists and Risk of Optic Nerve or Vision-Threatening Events in Patients With Type 2 Diabetes or Cardiometabolic Diseases: A Meta-analysis of Randomized Controlled Trials

Review (20 RCTs; n=83,288) found GLP1-RAs did not lead to increased risk of optic nerve and/or serious adverse events, e.g ischaemic optic neuropathy, ocular ischaemic syndrome, papilledema, blindness, blurred vision, visual impairment, & reduced acuity (OR 1.20, 95%CI 0.73–1.97)

Source: Diabetes Care

National guidance, publications and resources

Barcode Standards and Patient Safety: Position Statement from Royal Pharmaceutical Society

Royal Pharmaceutical Society (RPS) has joined the call from NHSE for regulatory changes to mandate 2D barcodes on UK medicines packaging and include GTIN information in the licensing process for medicines. Minimum data required is GTIN, batch number and expiry date.

MMRV programme: information for healthcare practitioners (updated)

Updated to note parents/carers should be advised to avoid using ibuprofen if a child develops a varicella-like rash 3-4 weeks after vaccination, because of theoretical potential risk it may increase the risk of secondary skin infection when used in natural chickenpox infection.

UK Health Security Agency

Prevention of Future Death Reports (Regulation 28)

Lyn Maher: 2026-0053

Lyn was prescribed clarithromycin for a chest infection while taking simvastatin for high cholesterol. She received two prescriptions and on neither occasion was she told to stop taking her statin by either her GP, nor by either of two community pharmacist dispensing . Lyn was admitted to hospital but was not asked about co-ingestion of simvastatin and clarithromycin. She deteriorated and a diagnosis of rhabdomyolysis was missed, she died from a cardiac arrest due to hyperkalaemia.

The Coroner's concerns:

- 2 community pharmacists did not tell Lyn, (nor pass a message via her family who collected the tablets), that she must stop taking simvastatin during the clarithromycin course for her chest infection. There is confusion and variety of opinion amongst pharmacists around the extent of expectation or duty to perform 'clinical checks' to enable safe prescribing and what that practically entails.
- There is confusion amongst community pharmacists around the conflict between the expectation of safe prescribing/dispensing and patient confidentiality (when someone other than the patient collects the medication).
- Community pharmacists have limited access to the Welsh Clinical Portal which would enable them to properly and safely counsel patients to stop contraindicated drugs (here simvastatin with clarithromycin) (information which is available routinely in English pharmacies)

Prevention of Future Death Reports (Regulation 28)

Roger Smith: 2026-0069

Mr Smith's care was complicated by the inappropriate administration of tinzaparin. His previous medical history included a diagnosis of cerebral amyloid angiopathy which increased his risk of stroke. Correspondence from a neurologist at another hospital advised against use of anticoagulation. This advice was not followed and although Mr Smith declined tinzaparin it was administered without discussion with Mr Smith or his family. Mr Smith suffered a stroke following 7 doses of tinzaparin and died 8 days later.

The Coroner's concerns :

- The trust EPMR system was ineffective and inaccurate - advice concerning the prescription of anti-coagulation therapy was not flagged to clinicians within the EPMR
- Communication between patients/families was ineffective – the concerns of the patient and his declining tinzaparin were not considered or investigated
- Effective procedures to enable the input of a specialist stroke team with multidisciplinary experience were not in place

Prevention of Future Death Reports (Regulation 28)

Mark Turner: 2026-0065

Mark suffered from paranoid schizophrenia for which he took clozapine. He also took citalopram. Citalopram was prescribed appropriately and it was taken as prescribed. He was found dead at his home and the postmortem found cause of death to be citalopram toxicity. It was concluded that this was a complication from the use of citalopram as prescribed

The Coroner's concerns:

- there is no guidance, locally or nationally, as to what steps should be taken when a high serum level is returned in patients being monitored as they are taking clozapine

Clinical considerations for patients prescribed clozapine

Managing the risks associated with patients prescribed clozapine

Prevention of Future Death Reports (Regulation 28)

Sidra Aliabase: 2026-0031

Sidra was born prematurely at 27 weeks, she had long QT syndrome and a patent ductus arteriosus. She was wrongly prescribed sodium acid phosphate rather than sodium chloride at approximately 5 times the recommended dose for a neonate of her size. This mis-prescription and overdose directly led to and caused hypocalcaemia and bradycardia, exacerbated by long QT syndrome. The phosphate was lowered rather than stopped, following contact from the pharmacy. The drug error was not communicated to the consultant in time. Hypocalcaemia was apparent on blood gas analysis but not recognised by clinicians immediately, although corrective treatment started and expert opinion was sought Sidra died 2 days after the initial prescription error.

Coroner's concerns:

- Poor communication between hospital teams
- Plans to diagnose long QT interval postnatally not in place for premature deliveries of at risk babies
- The drop-down prescribing menu is more likely to lead to errors in drug selection for drugs of similar names.

Prevention of Future Death Reports (Regulation 28)

Avery Hall: 2026-0048

Avery died having developed global hypoxia and diffuse alveolar damage with hyaline membranes in the lung following his birth as his development in pregnancy had been compromised by reduced amniotic fluid leading to poor lung development and impairment of urine production by the kidneys. During pregnancy Avery's mother had continued to take Candesartan, previously been prescribed for migraines. She had no definitive advice from clinicians to stop taking it. This medication is contraindicated in pregnancy due to risks including foetal renal failure and pulmonary hypoplasia.

Coroner's concerns:

- No advice was provided on the risks of this medication should she be considering having a child.
- Avery's mother sought advice from her GP about which of her prescribed medications were safe to use during pregnancy, she was given no specific advice to stop using Candesartan, other than it was best to stop all medicines in pregnancy
- The candesartan remained on repeat prescription
- There were a number of opportunities for a warning during her pregnancy