SPS Medication Safety Update December 2025

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

Patient Safety Alerts

Supply of Licensed and Unlicensed Epidural Infusion Bags

Issued: 2/12/2025 Deadline: 12/12/2025 NatPSA/2025/007/DHSC

There are supply issues affecting epidural bags from Sandoz and Fresenius Kabi containing: bupivacaine, bupivacaine and fentanyl, levobupivacaine and fentanyl. A range of alternative licensed and unlicensed bags are available to support demand.

This National Patient Safety Alert requires action to ensure there is a co-ordinated trust-wide approach to support safe product switches. This includes reviewing supplies and current practice and switching to appropriate alternatives in a safe manner.

Royal College of Anaesthetists issues advice in response to shortages of commercially prepared epidural infusions

Recent regulator and statutory body activity

MHRA Drug Safety Update: December 2025

Rybelsus ® (semaglutide tablets): transition to new formulation and risk of medication error.

There is a risk of patient harm arising through medication error during a transition period where the original and new formulation of Rybelsus ® tablets, which have different stated mg doses but are bioequivalent, will both be available on the market.

MHRA Drug Safety Update: November 2025

Mesalazine and idiopathic intracranial hypertension

Idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine. Patients using any form of mesalazine should be warned to look for signs and symptoms of IIH including severe or recurrent headache, visual disturbances or tinnitus. If symptoms of IIH occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately.

Festive foods and medicines: MHRA shares advice to help you stay safe this winter

Highlighted examples of some of the potential interactions include cranberry and leafy greens and brassica vegetables with warfarin, and tyramine-rich foods with monoamine oxidase inhibitors. People who use insulin are advised to enjoy sugary seasonal snacks in moderation.

Recent regulator and statutory body activity

MHRA Safety Roundup: November 2025

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Recent regulator and statutory body activity

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

This precautionary recall of a single batch of fingolimod is due to reports of capsule breakage on removing from the blister. No other batches are impacted. Remaining stock of affected batch to be quarantined.

Class 4 Medicines Defect Notification: Moclobemide 150mg tablets (Lexon UK Ltd), EL(25)A/50

Lexon UK Ltd has informed the MHRA that the Patient Information Leaflet (PIL) in cartons for certain batches is missing updated safety information. The information relates to use of buprenorphine with moclobemide, which can lead to serotonin syndrome.

Class 3 Medicines Recall: prednisolone 5mg soluble tablets (Activase pharmaceuticals limited)

This precautionary recall of two batches of prednisolone is due to a limited number of reports of blister pockets becoming swollen over time. The blister pocket swelling is due to carbon dioxide build up from gradual excipient reaction with trace amounts of moisture.

Field Safety Notice: FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors (Abbott Laboratories Ltd)

Certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors may provide incorrect low glucose readings which may lead to wrong treatment decisions for people living with diabetes. Anyone potentially affected can visit www.FreeStyleCheck.com to check if their sensor is affected.

Recent regulator and statutory body activity

Class 4 Medicines Defect Notification: Special Concept Development UK Limited, Baclofen 10mg Tablets, EL(25)A/51

Company has informed MHRA that the Patient Information Leaflet (PIL) for the batches listed in this notification do not contain the correct safety information. The safety information missing in the PIL and previous SPC is summarised in this notice.

Class 4 Medicines Defect Notification: Flamingo Pharma UK Ltd, Amitriptyline Hydrochloride 10mg, 25mg, 50mg Tablets, EL(25)A/52

Patient Information Leaflet in the products listed in this notification do not contain all the required safety information. The missing information relating to serotonin syndrome and dry eye is detailed in this notification.

National dose banding table – talquetamab 2mg/mL

NHS England: 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.

EMA booklet: Safety of medicines

The EMA now offer a booklet guiding readers through a medicine's lifecycle, showing how EMA helps ensure the safety of medicines from before authorisation, throughout the approval process and during pharmacovigilance processes.

NHS maternity signal system will spot and stop emerging safety concerns

NHS England: The new tool rapidly analyses data routinely recorded by maternity teams on wards to identify potential emerging safety issues. Once a signal is generated, the unit must carry out a critical safety check within 8 working days and share action taken with regional & national teams.

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting held on 24th-27th November 2025

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.

Direct HCP communication

Keppra OSL 150mL - dosing syringe change from 3 to 5mL

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

Tegretol® 100 mg/5ml Liquid (carbamazepine): Limitation of use in neonates. Sent to relevant stakeholder in November 2025

Information on Reported Cases of Patient Deaths Among Duchenne Muscular Dystrophy Patients Receiving Duvyzat®▼ (givinostat)

Libtayo®▼(cemiplimab) 350 mg concentrate for solution for infusion: Batch / lot number and expiry date may become illegible following sanitisation and wiping of vial label

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 outcome 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.

Revised SPC: Bunov (buprenorphine) 5 microgram/h & 20microgram/h transdermal patches

SPC updated in line with the MHRA guidance that prolonged release opioids, such as buprenorphine patches, should not be used in acute post-operative pain, owing to the increased risk of persistent post-operative opioid use and opioid-induced ventilatory impairment.

Revised SPC: Carvykti (ciltacabtagene autoleucel) 3.2 × 10^6 – 1 × 10^8 cells dispersion for infusion

Updated to include warning about reactivation of John Cunningham virus, leading to PML, which has been reported in patients treated with Carvykti who have also received prior treatment with other immunosuppressive medications. Cases with fatal outcome have been reported.

Revised SPC: Ozempic (semaglutide) solution for injection in pre-filled pens (various strengths)

Non-arteritic anterior ischaemic optic neuropathy (NAION) has been added as a very rare side effect. Patients reporting a sudden loss of vision or partial loss should be urgently referred for ophthalmological examination. Treatment to be discontinued if diagnosis confirmed.

SPC changes

Revised SPCs: Doravirine products (Pifeltro 100 mg film-coated tablets, Delstrigo 100mg/300mg/245mg film-coated tablets)
SPCs updated to highlight risk of severe cutaneous adverse reactions, including Steven-Johnson syndrome /toxic epidermal necrolysis, identified during postmarketing use. Patients should be advised on signs and symptoms, and treatment should be stopped if these appear.

Revised SPC: Lamictal (lamotrigine) products
SPC updated to include additional information on use with other oestrogen-containing products such as HRT, advising interaction not been studied, but it may similarly affect lamotrigine pharmacokinetics, therefore, close monitoring required to ensure effectiveness of lamotrigine.

Revised SPC: Rifater 50mg/120mg/300mg Tablets (isoniazid, rifampicin, pyrazinamide)
SPC updated to note concurrent treatment with cabotegravir, fostemsavir and lenacapavir is contra-indicated, as rifampicin 600mg daily reduced exposure by 59%, 82% and 84%, respectively.

Revised SPC: Tegretol (carbamazepine) 100 mg/5ml Liquid
SPC updated to note that it is no longer recommended for children below 4 weeks of age because of the potential adverse effects/toxicity from the excipient propylene glycol (25mg per mL). A Dear Healthcare Professional Communication regarding this will be distributed soon.

SPC changes

Revised SPC: Qarziba (dinutuximab beta) 4.5 mg/mL concentrate for solution for infusion

SPC updated to include warning that cases of atypical haemolytic uraemic syndrome (aHUS), including some fatalities, have been reported. Patients should be monitored for signs and symptoms of aHUS, and if diagnosed, treatment should be discontinued permanently.

Revised SPCs: Zovirax (acyclovir) preparations

SPCs updated with addition of warning on severe cutaneous adverse reactions (SCARs), including TEN, SJS, DRESS, AGEP and EM. Treatment should be discontinued if signs and symptoms of SCARs appear and no retreatment with aciclovir or valaciclovir if SCARs diagnosis confirmed.

Revised SPC: Rozex (metronidazole) 0.75% w/w Gel

SPC updated with contraindication in patients with Cockayne syndrome, as there have been reports of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation in these patients.

Revised SPC: Rybelsus (semaglutide) tablets (various strengths)

Non-arteritic anterior ischaemic optic neuropathy (NAION) has been added as a very rare side effect. Patients reporting a sudden loss of vision or partial loss should be urgently referred for ophthalmological examination. Treatment to be discontinued if diagnosis confirmed.

SPC changes

Revised SPC: Darzalex (daratumumab) 1800 mg solution for injection

Updated to advise that in order to reduce the incidence of stopper coring, the use of large diameter or blunt tip transfer needles or multiple stopper punctures, should be avoided.

Revised SPC: Metrogel (metronidazole) 0.75% w/w Gel

Cockayne syndrome, a rare genetic disorder, added as contraindication due to reports of severe hepatotoxicity/acute hepatic failure (including cases with a fatal outcome) with very rapid onset after treatment initiation with products containing metronidazole for systemic use.

Revised SPC: Ngenla (somatrogon) 24mg and 60mg solution for injection in pre filled pen

Updated following PRAC recommendation, to advise that the site of injection should be rotated at each administration, and if more than one injection is required to deliver a complete dose, each injection should be administered at a different injection site, to prevent lipoatrophy

Revised SPCs: Benzylpenicillin benzathine powder for suspension for injection

SPCs updated to note the potential for benzylpenicillin benzathine formulations to block the needle if intramuscular injection of the reconstituted product to the patient is not made at a slow, steady rate, and to introduce practical guidance regarding how to mitigate this issue.

Manufacturer RMM

Risk Minimisation materials (RMM) to help reduce the risk associated with using Afqlir (aflibercept) 40 mg/ml Solution for injection in pre-filled syringe

The following RMM are available: patient guides across all licensed indications, outlining the condition, contraindications and advice on side effects, and a HCP guide with detailed injection instructions, and advice on patient counselling, and side effects management.

Educational Risk Minimisation Materials to help reduce the risk associated with using Myrin (thalidomide) 100 mg tablets

Materials comprise information guide for healthcare professionals (HCPs) involved in prescribing & dispensing, guide for patients, adverse event form, risk awareness forms to assist HCPs in counselling patients, a patient card, and pregnancy outcome & pregnancy report forms.

Educational risk minimisation materials to help reduce the risk associated with using Eydenzelt (aflibercept) 40 mg/ml solution for injection in a vial

Materials comprise a patient guide to explain the use of this aflibercept biosimilar, a prescriber guide and a QR code leaflet to provide QR codes to the patient guide.

Manufacturer RMM

Risk Minimisation Materials for Mynzepli (aflibercept) 40 mg/mL solution for injection in a vial and pre-filled syringe

Materials include patient guides across all licensed indications, outlining the condition, contraindications and advice on side effects, and a healthcare professional guide containing detailed injection instructions and advice on patient counselling & management of side effects

Patient reminder card on the risk of osteonecrosis of the jaw associated with using denosumab biosimilars

The reminder card contains safety information relating to the risk of developing osteonecrosis of the jaw (may affect up to 1 in 10 people) and can also occur after stopping treatment. It recommends some precautions that patients should take to reduce this risk.

Drug shortages

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

Royal College of Anaesthetists issues advice in response to shortages of commercially prepared epidural infusions

SSPs for Creon® 10,000 and 25,000 gastro-resistant capsules further extended to Friday 16th January 2026

MSN/2025/063 NeoRecormon® (Epoetin beta) 6,000units/0.3ml solution for injection pre-filled syringes

MSN/2025/062 Rivastigmine 4.6mg/24hours and 9.5mg/24hours transdermal patches

MSN/2025/061 Mivacurium chloride 10mg/5ml and 20mg/10ml solution for injection

MSN/2025/060 Ibandronic acid 150mg tablets

MSN/2025/064 Nifedipine (Fortipine® LA) 40mg modified-release tablets

MSN/2025/066 Epoetin beta (NeoRecormon®) 20,000units/0.6ml solution for injection pre-filled syringes

MSN/2025/067 Sotrovimab (Xevudy®) 500mg/8ml solution for infusion vials

MSN/2025/065 0.3% citrate buffered sodium chloride 0.9% infusion bags 250ml and 1000ml (unlicensed)

Drug Discontinuation

Discontinuation of Levemir® Penfill® and Levemir® FlexPen®

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

Supplies were exhausted in March 2024.

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

Supplies were exhausted in July 2023.

Specialist Pharmacy Service

[Prescribing available epidural infusion bags]
Epidural infusion bags availability varies currently. Check for available licensed and unlicensed products to keep up to date.

[The licence and supporting evidence for denosumab 60mg biosimilars]
Webpage discusses the indications, formulations, supporting evidence and differences between all denosumab 60mg biosimilar products licensed in the UK in November 2025, which may be launched following loss of patent exclusivity anticipated November 2025.

[The licence and supporting evidence for denosumab 120mg biosimilars]
Webpage covers licensed indications, formulations, evidence supporting safety and efficacy, extrapolation of data from other indications, differences between brands (administration, sodium content, other excipients of interest, latex, needle characteristics, storage & stability).

[Ensuring the safe use of amphotericin B injection]
This article highlights the risks factors associated with the confusion and mis-selection of amphotericin B products (liposomal products and Fungizone), as well as the key measures that should be taken to prevent selection errors.

Specialist Pharmacy Service

[Advising on complementary products and conventional medicines]

This article forms part of a series providing guidance on decision making when advising on interactions with supplements and complementary, herbal and alternative products, including homeopathy, Chinese and Ayurvedic.

[Using solid oral dosage form antibiotics in children]

This article provides guidance on off-label crushing, dispersing or opening solid oral antibiotics that are commonly prescribed in children, when licensed suspension formulations are not available

[Medicines shortages leaflets and posters]

DHSC and NHS England have produced leaflets and posters for patients and healthcare professionals on impact and management of medicines supply issues, which can be printed to use in surgeries and pharmacies.

National guidance, publications and resources

[Suspected sepsis in people aged 16 or over: recognition, assessment and early management – guidance (NG253)]

Updated guidance recommends smaller amounts of IV fluid initially for those at risk of serious illness/death due to sepsis & individualised assessment after every infusion. This is 1 of 3 guidelines forming original sepsis guideline that has been split up.

[Patient safety commissioner for England warns barcode errors on medicine packs could be 'potentially fatal']

Warning comes as petition launched by pharmacists report growing problems with barcode data errors & missing 2D barcodes on UK medicine packs. The issue has been highlighted by several class 4 medicines defect notifications in 2025 that were linked to barcode/labelling problem.

[Patient safety issues associated with electronic patient record (EPR) systems – a thematic review]

This report, a thematic review of HSSIB's investigations associated with EPR systems, emphasises how EPR systems still contribute to patient care being missed, delayed or recorded incorrectly despite national recommendations and actions intended to reduce risks.
Source: Health Services Safety Investigation Body

National guidance, publications and resources

MMR: updated patient group direction (PGD) template

Recommendation for routine dose at 1-year of age and 3 years 4 months removed following changes to MMR childhood immunisation programme, commencing 1 Jan 2026. Dieticians, occupational therapists, pharmacy technicians & podiatrists added to section 3 (characteristics of staff).

MMRV: patient group direction (PGD) template

Template supports administration of measles, mumps, rubella & varicella vaccine from 1-year of age for routine immunisation or from age 9 months if early protection required against varicella, in accordance with UK immunisation programme & UKHSA guidelines on varicella outbreak.

Updated BNF monograph to reflect new formulation of Rybelsus® (oral semaglutide) replacing initial formulation

These 2 formulations will temporarily co-exist on market, which may cause confusion & increase risk of medication errors. To highlight change in formulation, updates were made to sections of semaglutide monograph in BNF, including indications, dose, & important safety information.

Prevention of Future Death Reports (Regulation 28)

Dominic Philip: 2025-0617

Dominic suffered a fatal anaphylactic reaction to contrast. He had a known allergy to lidocaine. Lidocaine was found in his blood but the source was unknown.
The coroner raised concerns regarding

- how the patient came into contact with lidocaine
- potential allergies being identified in advance and
- how supplies of lidocaine are managed

Philip Hogarth: 2025-0628

Following a total hip replacement, Philip died from a myocardial infarction and pulmonary oedema. He suffered from chronic iron-deficiency anaemia and received an iron transfusion 7 days prior to the operation which at inquest was thought to be too close to surgery to have the desired effect. The coroner raised the following concerns over the lack of consistent approach to pre-operative management of anaemia, including:

- Availability of clinical guidelines detailing pre-operative administration of iron therapy
- Funding arrangements for iron therapy

Prevention of Future Death Reports (Regulation 28)

Ashana Charles: 2025-0620

Ashana was being treated for CMW colitis with IV ganciclovir and parenteral nutrition. She suffered a cardiac arrest and died from acute obstruction of small pulmonary arteries by cellulose fibres, which had embolised from inadvertently contaminated intravenous infusions at some stage of product preparation or administration. The source of fibres could not be identified, but the sudden death from embolism would have been prevented had a 1.2 micron filter been used in IV infusion, which was not standard practice at the time.

The coroner raised the following concerns:

- The IV feed equipment was not retained for investigation following the death. They recommend that this should be retained for pathological investigation where there is an unexplained death within 24 hours of parenteral feeding
- The use of 1.2 micron filters was not standard practice at the time. BNPG guidance now recommends this.
- MHRA and NHSE are asked to consider whether the regulatory systems for production and administration of parenteral feeding need to be better integrated, with sharing of risk assessment data and consistent guidance.

Prevention of Future Death Reports (Regulation 28)

Valerie Gibson: 2025-0630

Valerie died on an inpatient psychiatric unit due to natural causes contributed by the use of olanzapine.

The coroner raised concerns regarding

- the lack of thorough check of patients' possessions to ensure no unauthorised items were available to them
- the uncertainty amongst staff as to the correct process for dispensing and administering medication via electronic medication cabinets
- A lack of understanding with regards to supervision requirements for preceptee nurses for medication administration
- The varied practices regarding disposal of unwanted liquid medication
- Poor documentation of medication doses administered
- Controlled drug practices and second checks

Primary research - Medication Safety

Republished case report: Ciprofloxacin-induced drug fever

Drug-induced fever is an uncommon adverse drug reaction often overlooked in clinical practice. Case highlights importance of considering it once other causes have been excluded, as early recognition can prevent unnecessary antibiotic escalation, and reduce hospital stay.

Republished case report: GLP-1 agonists-induced autoimmune pancreatitis

Article discusses 3 cases of type 1 autoimmune pancreatitis (T1AIP) occurring within a year of initiation of incretin therapy for type 2 diabetes. The authors suggest possible mechanisms and comment that insulin-based regimens may be preferred in patients also affected by T1AIP.

Republished case report: Progestin-induced liver injury in an asymptomatic patient

Article discusses the case of a female in her mid-40s diagnosed with norethisterone-induced liver injury (DILI). It covers the various aspects of evaluating suspected DILI, combining clinical assessment with the use of diagnostic tools to aid in identifying the offending agent.

Primary research - Medication Safety

Editorial: Paracetamol (acetaminophen) use in pregnancy and risk of autism and ADHD

Article discusses umbrella review of this topic, which supports global medical consensus, noting clinicians should weigh unsubstantiated risk of paracetamol for neurodevelopmental disorders against evidence-based risks of other analgesics & serious harms of not treating fever.

Benefits and harms of ADHD interventions: umbrella review and platform for shared decision making

Review (115 articles) found although some drug interventions offer medium to large benefits in the short term for management of ADHD symptoms, they can be poorly tolerated The online platform should facilitate implementation of shared decision making in daily practice.

Causality, severity and avoidability of adverse drug reactions in children: An 11-year review

In Australian study (n=599; median age 8.7 years), most ADRs (74%) were mild, 25% moderate & 1% severe. Commonly implicated drugs were antimicrobials (46%), analgesics (9%), antiepileptics (8%) & monoclonal antibodies (6%). One in six paediatric ADRs were potentially avoidable.