SPS Medication Safety Update August 2025

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

Patient Safety Alerts

- Nil NPSA alerts

Recent regulator and statutory body activity

Class 2 Medicines Recall: Fucidin 250 mg Tablets, LEO Laboratories Ltd trading as LEO Pharma, EL(25)A/38

LEO Pharma is recalling the affected batch as a precautionary measure due to out of specification results for impurities during routine stability testing. Stock should be quarantined and returned to the supplier.

Class 2 Medicines Recall: ChloraPrep 1mL Clear Sterile Solution/Applicator, Becton Dickinson UK Ltd, EL(25)A/36

Becton Dickinson UK Ltd has informed the MHRA that some units exhibit an open seal on the packaging of the applicator. This is linked to the Class 2 Medicines Notification EL(25)A/22. This defect could increase the risk of the applicator device being contaminated with pathogens.

Class 4 Medicines Defect Notification: Levetiracetam Accord 100mg/ml oral solution, Accord Healthcare Limited, UK, EL(25)A/40

Accord Healthcare Limited, UK has informed the MHRA that the PIL and SPC do not contain all the required safety information. Missing Information is summarised in the Appendix of the document linked.

Recent regulator and statutory body activity

Class 4 Medicines Defect Notification: Topiramate Zydus Pharmaceuticals UK 20mg/ml Oral Solution, Zydus Pharmaceuticals UK Ltd, EL(25)A/39

Zydus Pharmaceuticals UK LTD has informed the MHRA that there is an error on the artwork for the outer carton and PIL of the 20mg/ml Oral Solution (pack size 150ml and 280ml bottles). The instruction for use is missing the step to **shake well prior to opening and before each use**.

Class 4 Medicines Defect Notification: Olmesartan medoxomil 10mg film-coated tablets, Jubilant Pharmaceuticals NV, EL(25)A/37

Jubilant Pharmaceuticals NV has informed the MHRA that the PIL in the cartons for the batches listed in this notification include an outdated PIL.

Pharmacovigilance Risk Assessment Committee (PRAC)

New treatment for Niemann-Pick type C disease

The committee (CHMP) recommended granting a marketing authorisatiom for Aqneursa – shown to significantly improve neurological signs, symptoms and functioning.

New injection for easier prevention of HIV infection in the EU and worldwide

Injectable lenacapavir, administered twice yearly, is highly effective at preventing HIV

First reformulation of an inhaled medicine with environmentally friendly gas propellant

The new propellant in Trixeo Aerosphere and Riltrava Aerosphere has lower global warming potential.

Direct HCP communication

Vipranop 5 micrograms/ml (Noradrenaline) Solution for Injection and Infusion: potential risk of medication errors

Letter summarises the differences between this and existing noradrenaline products and notes the potential risk of underdosing or overdosing, and risk of serious adverse drug reactions or lack of efficacy should the incorrect strength of noradrenaline be administered.

- Prescribers should always specify the dosage of noradrenaline on each prescription (quantities less than 1 mg should be written in micrograms and not abbreviated to mg).
- Healthcare professionals should check whether the product requires dilution before administration.

SPC changes or Manufacturer RMM

Revised SPC: Daktarin (miconazole) oral gel products

SPC now states product contains 23mg alcohol in each 2.5 ml dose corresponding to 7.5 mg/g; this amount equivalent to <1ml of beer or 1ml of wine, which will not have any noticeable effects. Also now warns that excipient benzyl benzoate & polysorbate can cause allergic reactions.

Revised SPC: Trileptal (oxcarbazepine) 600 mg Film-coated Tablets

SPC has been updated to note data from an observational study indicating an increased risk of children being born small for gestational age (defined as birth weight below the 10th percentile) following prenatal exposure to oxcarbazepine (15.2% vs 10.9% for no exposure).

Revised SPC: Ultramol (caffeine, codeine phosphate, paracetamol) Soluble

SPC updated to warn that concomitant administration of codeine with anticholinergics or medicines with anticholinergic activity (e.g. TCAs, antihistamines, antipsychotics, muscle relaxants, anti-Parkinson drugs) may result in increased anticholinergic adverse effects.

SPC changes or Manufacturer RMM

Revised SPC: Angitil (diltiazem) SR/XL Capsules

SPC updated to advise that, due to CYP3A4 and P-gp inhibition, caution should be exercised when diltiazem is co-administered with DOACs. Information about interactions between colchicine and diltiazem, and QT-prolonging medicines and diltiazem also added to SPC.

Revised SPC: Pentasa (mesalazine) prolonged release granules, slow release tablets, suppositories and enema preparations

Idiopathic intracranial hypertension (IIH) has been reported in patients receiving mesalazine. Patients should be warned for signs and symptoms including severe or recurrent headache, visual disturbances or tinnitus, and mesalazine should be discontinued if IIH occurs.

Revised SPC: AVAXIM Junior (hepatitis a vaccine) suspension for injection in pre-filled syringe

SPC updated to note that the booster dose should be given between 6 months and 15 (previously 10) years after the first dose.

Drug shortages and discontinuations

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

Medicine Supply Notification: Dinoprostone (Prostin E2 Vaginal Tablets) 3mg Pessaries

The pessaries will be out of stock until January 2026. Alternative dinoprostone products, Prostin E2® 1mg and 2mg vaginal gel and Propess® 10mg vaginal delivery system, are available and can support an uplift in demand.

Medicine Supply Notification: Estradiol (Progynova® TS) 50micrograms/24hours and 100micrograms/24hours transdermal patches

The patches will be **discontinued** from late December 2025. FemSeven® 50micrograms/24 hours and 100micrograms/24 hours transdermal patches (**once-weekly** estradiol patches) remain available and can support the increase in demand.

Drug shortages and discontinuations

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Updated Medicine Supply Notification: Levemir® (insulin detemir) FlexPen® 100units/ml solution for injection 3ml pre-filled pens and Levemir® Penfill 100units/ml solution for injection 3ml cartridges

Since the previous notification on the **discontinuation** of these products, supplies of which are anticipated to be exhausted by the end of 2026, joint guidance from the ABCD and PCDO Society has been produced to manage the transition of patients to other insulin products.

SSPs for Cefalexin oral suspensions sugar free further extended

The DHSC has further extended the existing SSPs for Cefalexin 125mg/5mL oral suspension sugar-free and Cefalexin 250mg/5mL oral suspension sugar free to Friday 26 September 2025.

Specialist Pharmacy Service

Switching brand and generic anti-seizure medicines for epilepsy
New page published regarding switching between different manufacturers' anti-seizure medicines requires individual assessments and careful consideration about whether it will be suitable.

Managing the risk of confusion between injectable iron products
New page published on minimising the risk of confusion between different injectable iron products may prevent inadvertent harm.

Minimising risks associated with administration of injectable iron
New page on mitigation strategies to help minimise harm.

Podcast
Understanding safe use of medicines challenges in palliative and end of life care
Discusses challenges in the safe use of medicines and understanding these issues to help implement safety initiatives to improve outcomes.

National guidance, publications and resources

UK Health Security Agency - Meningococcal B: vaccine information for healthcare professionals - updated

Resource updated to include guidance on incorrect intervals between doses.

UK HSA - Shingles vaccination: updated guidance for healthcare practitioners

This guidance has been updated to include immunosuppressed individuals aged 18 years and over, and its content has been reviewed, reorganised and updated to align with the revised Green Book chapter.

Dept of Health & Social care - Managing a robust and resilient supply of medicines

This policy paper outlines the Department of Health and Social Care and NHS England's ongoing work and future plans to improve shortage management and strengthen medicines supply chain resilience.

National guidance, publications and resources

HSSIB - Medication related harm

- HSSIB have completed three local investigations, and a national investigation is underway in relation to the safe use of ePMA, looking at medication related harm.
- These investigations explore the safety issues associated with medication not given. HSSIB was told of many instances where patients do not receive the medication they need whilst in hospital, at home or in a nursing home.

HSSIB - Online prescribing: challenges and opportunities to improve patient safety

This investigation explores risks to patient safety when patients use online prescribing services which are outside of their usual NHS care provision, including such as independent online pharmacies.
As well as investigating the challenges of sharing patient information between the NHS and independent online prescribing services.

Prevention of Future Death Reports (Regulation 28)

Margaret McNaughton: Prevention of Future Deaths Report

Ref: 20205-0397

The medical cause of the patient's death was found at inquest to be partly due to cardiac arrest due to Penicillin anaphylaxis.

The patient was admitted into hospital due to breathing difficulties and was diagnosed with a respiratory infection, she also has a background of COPD.

Hospital records stated that Mrs McNaughton had no known drug allergies (NKDA), but the source of this information was unclear. Both the paramedics and triage nurse reported that she denied any drug allergies, although it is uncertain whether the Electronic Patient Record (EPR) was available in the Emergency Department at the time.

Before the patient was seen by any clinician she was prescribed IV co- amoxiclav.

There was no evidence that the prescribing clinician checked the patient's allergy status, consulted her directly, or accessed the Clinical Web Portal, which clearly recorded a penicillin allergy in both hospital and GP records.

This gross failure led to the administration of co-amoxiclav, resulting in a fatal anaphylactic reaction and cardiac arrest within 25 minutes of the co-amoxiclav administration. She then later passed away.

Prevention of Future Death Reports (Regulation 28)

Margaret McNaughton: Prevention of Future Deaths Report

Ref: 20205-0397

The coroner highlighted the following concerns:

- Requirements to check a patient's allergy status and record the findings has not been included in any Trust Policy.
- They were unable to see any guidance within the Trust policies on HOW a patient's allergy status should be checked or recorded and by whom and where.
- They were also concerned that there was no apparent requirement for a prescriber to record that they have either checked the patient's allergy status themselves before prescribing OR checked the source of the information contained within the hospital records.

Prevention of Future Death Reports (Regulation 28)

Robert Simpson: Prevention of Future Deaths Report
Ref: 2025-0423

Regarding a patient who had colonic cancer, underwent a hemicolectomy in Hospital. Following surgery, whilst on the ward, he developed hospital acquired pneumonia and an anastomotic leak. Despite a raised CRP and knowledge of a collection requiring drainage he was discharged home.

- No antibiotics were provided on discharge and no appointment for drainage was booked.
- A few days later the patient was readmitted into hospital as their condition deteriorated at home – the patient then passed away at hospital despite receiving drainage and treatment.

Coroners Concerns:

- The pt had been discharged with medication (gabapentin) that did not belong to him and had missed two doses of antibiotics (fidaxomicin) due to the drug being out of stock, this was not communicated to the doctors and hence no alternative was prescribed.
- The Trust were unable to confirm if any systems were in place to ensure that patients were not left without necessary medication.

Prevention of Future Death Reports (Regulation 28)

Kenneth Edwards: Prevention of Future Deaths Report

Ref: 2025-0414

The patient died as a consequence of bleeding to the brain caused by two falls, which was contributed to by blood-thinning medication administered to him whilst in hospital.

The patient was awaiting results of a CT scan and was given enoxaparin and clopidogrel.

The patient passed away due to further bleeds and the scans showed subdural and subarachnoid haemorrhages.

Points of concern:

- Administering anticoagulants / antiplatelets whilst awaiting CT scan results of the head is not best practice and is **contraindicated.**

Prevention of Future Death Reports (Regulation 28)

Chloe Barber: Prevention of Future Deaths Report

Ref: 2025-0421

- Regarding 18 yr old girl who had a history and died from self-harm and of taking multiple overdoses of tablets
- She was making a transition between children's and adolescent mental health services (CAHMS) and adult services. She refused to engage with adult mental health services.
- Concerns identified that there is no defined pathway that assists young people making the transition between CAMHS and adult psychiatric services, to ensure continued of care and medicines safety.

Interesting for the mental health MSOs to consider their arrangements for transition to adult services and continuation of medicines.

Prevention of Future Death Reports (Regulation 28)

Resmije Ahmetaj: Prevention of Future Deaths Report
Ref: 2025-0424

- This is regarding another MH related death (clozapine)
- The lady died due to falling from a height in a car park whilst suffering from an exacerbation of psychosis due to subtherapeutic clozapine levels.
- Lack of communication and escalation within the Trust's mental health team – specifically regarding **subtherapeutic levels of clozapine – which were not acted upon**

Useful SPS pages for organisations which deal with clozapine:
Clinical considerations for patients prescribed clozapine
Managing the risks associated with patients prescribed clozapine
Managing constipation in people taking clozapine