

SPS Medication Safety Update September 2025

Recent critical patient safety alerts,
reports, and publications

Jen Smith - Pharmacist

The first stop for professional medicines advice

Patient Safety Alerts

- [National Patient Safety Alert: Harm from delayed administration of rasburicase for tumour lysis syndrome.](#)
- Alert for action by organisations providing and Emergency Department or/or cancer services.
- Actions required by 09/03/2026.
 - See SPS page [Ensuring time critical use of rasburicase](#)

Recent regulator and statutory body activity

Class 2 Defects

- [Fucidin](#) (Leo, EL(25)A/38): Out of specification results.

Class 4 Defects

- [Fexofenadine 120mg film-coated tablets](#) (Chanelle, EL(25)A/41). Error in bar code.
- [Gemcitabine 2g/52.5mL concentrate for solution for infusion](#) (Hikma, EL(25)A/43). Error in PIL.
- [Levetiracetam 100mg/mL oral solution](#) (Accord, EL(25)A/40). Missing information in PIL and SmPC.
- [Topiramate 20mg/mL oral solution](#) (Zydus, EL(25)A/39). Error in carton artwork and PIL.
- [Ipca Laboratories UK products, various](#). Errors in PILs.

Recent regulator and statutory body activity

Other

- [GLP-1 medicines for weight loss and diabetes: what you need to know](#) (Patient guidance from MHRA, updated 20/08/2025)
- [Decolonisation of individuals to prevent recurrence of Staphylococcus infection](#) (UKHSA rapid systematic review: conflicting evidence, most effective interventions could not be determined).
- [EMA warns about sharp rise in illegal medicines sold in the EU](#). Marketed as GLP-1 receptor agonists; may not contain labelled active substance, and may contain harmful levels of other substances.
- [Spike in hospital admissions due to botulism](#) from unlicensed botulinum toxin products; MHRA is investigating.
- [**MHRA Safety Roundup: August 2025**](#)

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting 1-4 September 2025

- **Burosumab (Crysvita).** New recommendations for monitoring due to risk of severe hypercalcaemia.
- **Carbamazepine (Tegretol).** Use restricted in neonates as concentration of propylene glycol exceeds recommended threshold. See also:
 - EMA: [Questions and answers on propylene glycol used as an excipient](#)
 - NPPG Position Statement: [Choosing an oral liquid medicine for children](#)
- **Caspofungin.** New warning against use of polyacrylonitrile-based membranes during continuous renal replacement therapy.
- **Infliximab (Remsima).** New intravenous formulation contraindicated in patients with hereditary fructose intolerance (due to sorbitol content).
- **Levamisole.** Review started regarding risk of leukoencephalopathy.

Other

- **Clozapine.** Revised recommendations for blood monitoring endorsed at [July PRAC](#) meeting. [DHCP letter with evidence](#) now published.

Direct HCP communication

- **Carbimazole or thiamazole/methimazole:** Risk of acute pancreatitis – discontinue and do not restart; strengthened advice on contraception – but may still be used during pregnancy if necessary (hyperthyroidism must be appropriately treated)
- **Ceptava (mycophenolic acid):** Interim supply of Italian or Spanish stock. Same formulation as UK product, and is considered licensed in the UK.
- **Rapamune (sirolimus):** do not use after the expiry date of the syringe adapter (which may be earlier than the medicine expiry date)
- **Rybelsus (oral semaglutide):** Risk of medication error due to introduction of new formulation with increased bioavailability.

SPC changes or Manufacturer RMM

Risk Management Materials

- [Jylamvo \(methotrexate\) 2mg/mL oral solution](#). Guide for healthcare professionals.
- [Rybelsus \(semaglutide\) tablets](#). Patient guide for transition to new formulations.
- [Zeposia \(ozanimod\) capsules](#). Letter regarding updates to RMM, regarding Immune Reconstitution Inflammatory Syndrome (IRIS).

SPC changes

- [Cyklokapron \(tranexamic acid\) injection](#). New warning to only use intravenously due to fatal events when inadvertently administered intrathecally. SPC recommends labelling syringes.

Drug shortages and discontinuations

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

Overview articles

- [Pancreatic enzyme replacement therapies](#) (Creon - updated 12/08/2025)
- [Prescribing available HRT products](#) (fully reviewed – updated 22/08/2025)
- [Prescribing available medicines to treat ADHD](#) (Elvanse Adult no longer marketed; adult indications are in Elvanse SmPC – updated 03/09/2025)

New shortages

- Co-trimoxazole 80/400/5mL suspension
- Dinoprostone (Prostin E2 vaginal tablets) 3mg pessaries
- Hydralazine 20mg powder for solution for injection ampoules
- Repaglinide tablets

Drug shortages and discontinuations

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

Discontinuations

- [Admelog \(insulin lispro\) 100 units/mL](#) injection cartridges, pre-filled pens and vials (exhaustion mid-March 2026 onwards)
- [Freestyle Libre 2 sensor](#) – will be deleted from Drug Tariff; prescriptions dispensed from 01/10/2025 will be disallowed by NHSBSA
- Glucagon 500 micrograms/0.1mL and 1mg/0.2mL solution for injection pen
- Hypurin porcine insulin – exhaustion dates brought forward
- Topotecan 0.25mg and 1mg capsules (new)
- Triamcinolone acetonide 10mg/mL (Adcortyl) and 40mg/mL Kenalog vials (new)

Specialist Pharmacy Service

Food Supplements

- [Understanding food supplements](#) – the regulatory & quality differences between food supplements and medicines
- [Using food supplements](#) – when to, and how manage the risks of, using food supplements for medical purposes

Palliative Care

- Podcast: [Understanding safe use of medicines challenges in palliative and end of life care](#) (14/08/2025)
- MSATS – [Safe use of medicines in palliative and end of life care](#) (event: 24/09/2025)

Other articles

- [Addressing medication safety inequalities across the system](#) – strategies and signposting to support actions to address medication safety inequalities

Specialist Pharmacy Service

Injectable iron

- Managing the [risk of confusion between injectable iron](#) products
- Minimising [risks associated with administration of injectable iron](#)

Other drug-specific articles

- [Switching brand and generic anti-seizure medicines](#) for epilepsy
- [Ensuring time critical use of rasburicase](#). Updated to add National Patient Safety Alert and updated British Society of Haematology guidance

National guidance, publications and resources

- [HSSIB exploratory review](#) of maternity and neonatal services, pending national review later this year.
- WHO calls for safe care for every newborn and child on World Patient Safety Day. [HSSIB](#) has a page linking to 23 reports aiming to improve care for patients (especially newborns and children).
- [2023 LeDeR report into avoidable and preventable deaths of people with learning disabilities](#) found that although the rate of avoidable deaths in people with learning difficulties or autistic people has fallen, it remains twice as high as in the general population.

Prevention of Future Death Reports (Regulation 28)

[Jacob Wooderson 2025-0426\)](#)

Events:

- Prescribed lisdexamfetamine for ADHD. Dose increased from 50mg to 70mg; patient reported adverse effects to friends but not psychiatrist. Died of sudden arrhythmic death syndrome. Dose increase of lisdexamfetamine may have contributed.
- Consultations by video; psychiatrist made handwritten notes which were copied up afterwards and the original destroyed.
- Baseline blood pressure and heart rate not recorded, and patient was not sent a follow-up letter after dosage increase

Concerns:

- Blood pressure and heart rate were not monitored sufficiently
- Patients may not recall verbal advice regarding adverse effects, especially if only given at start of treatment, or not followed up in writing
- Remote consultations may mean prescribers are more reliant on patients providing information (such as heart rate, blood pressure) outside the consultation

Prevention of Future Death Reports (Regulation 28)

[Venetia Pierce 2025-0427](#)

Events

- Patient was prescribed nitrofurantoin for UTI prophylaxis
- Reported a number of LRTIs and periods of coughing over the next few months
- Admitted to hospital with a chest infection, died despite treatment with antibiotics and steroids.
- Further testing and history indicated more likely than not that patient had developed nitrofurantoin-induced pneumonitis leading to her death

Concerns

- Although the [MHRA issued a drug safety alert regarding ADRs of nitrofurantoin](#) in 2023, this did not pop up on prescribing system (EMIS) unless the patient had a co-existing pulmonary condition (the patient did not).
- Awareness of this adverse effect is limited amongst GPs and hospital clinicians.

Prevention of Future Death Reports (Regulation 28)

[Audrey Newman 2025-0443](#)

Events

- Patient admitted to hospital with suspected encephalitis; started on antibiotics and aciclovir
- Lumbar puncture planned but not done due to shortage of trained staff; antibiotics and aciclovir continued
- LP finally completed a week later (negative); delay due to no single consultant taking ownership – escalation based on ‘goodwill’ rather than a firm procedure
- Patient developed severe renal failure and died; possibly contributed to by aciclovir that was continued unnecessarily

Concern

- Absence of formal pathway/procedure for requesting assistance, and formal responsibility for providing such assistance, resulted in significant delay in assistance with procedure being received.

Prevention of Future Death Reports (Regulation 28)

[Peter Thomas 2025/0450](#)

Events

- Elderly patient admitted to hospital with serious infection and delirium; gave (probably erroneous) account of drinking
- No collateral information sought from patient records or family
- Patient given 80mg diazepam according to CIWA protocol (which he did not need); patient became unconscious
- 2 doses of antidote given but patient did not regain consciousness

Concerns

- CIWA protocol does not take account of patient factors such as age and comorbidities, resulting in potential over-treatment/toxicity

Prevention of Future Death Reports (Regulation 28)

Other

- [Gemma Weeks \(2025-0428\):](#) Lack of understanding amongst the public of the significant adverse effects of chronic ketamine misuse

Primary research - Medication Safety

- [Ocular adverse events with semaglutide](#) (review & meta-analysis). JAMA Ophthalmol 2025.
 - Semaglutide is associated with nonarteritis anterior ischaemic optic neuropathy (NAION)
- [Maintaining appropriate stocks in an operating room pharmaceutical unit](#): mapping of the supply chain. Eur J Hosp Pharm 2025.
 - Risk map of where stock errors are most likely to occur.