SPS Medication Safety Update August 2026

Recent critical patient safety alerts, reports, and publications

Yuet Wan - Medicines Advice Pharmacist

The first stop for professional medicines advice

26/08/26

Patient Safety Alerts

Nil in August

Prevention of Future Death Reports (Regulation 28)

Time critical medicines/follow-up

Barbara Cope: Prevention of future deaths report

Unintentional staggered paracetamol overdose. Although blood sample collected and tested in timely manner, showing paracetamol high level, there was no evidence of communication and/or follow up of the abnormal result, therefore time critical medication was not commenced until 19 hours later., delaying the administration of N-Acetylcysteine. Paracetamol overdose requires time critical management to prevent further and irreversible damage to the liver.

This case highlights challenges of ensuring urgent results are flagged to clinician? What systems in place? How to ensure trail of communication is documented?

Resource: SPS pages: Understanding time critical medicines to support improvement

Mary Forlin: Prevention of future deaths report

Admitted to hospital following fall at home; respiratory failure, likely driven by an infection; source never identified and antibiotics did not resolve infection over extended period; guidance recommended review at 48-72 hours, but not followed, despite blood tests showing continuing signs of infection whilst on broad spectrum antibiotics, nor were microbiology tests ordered early on when antibiotics had had no immediate effect; a missed opportunity for targeted antibiotics.

This case highlights need to review systems which do not proactively flag, up, drive or require active consideration of tests, including whether and when results have been obtained, or whether further specialist tests should then be required. One to flag to infectious diseases team?

Supply of medicines on FP10 outside of working hours in prison

George Haldenby: Prevention of future deaths report

Patient with severe heart failure on pre-existing background of IHD died from heart failure as had not been prescribed furosemide by prison healthcare for 16 days. There is lack of local policy or process to ensure prison and healthcare staff have understanding of how to deal with FP10 issued outside of hours when a prescribing health professional is not available in prison to ensure prisoner receives necessary medications without delay. Furosemide not part of stock of critical medications held at the prison.

For awareness: review of 'Out-of-Hours' SOPs and training sessions for prison staff

Prevention of Future Death Reports (Regulation 28)

Clozapine

[Jack Burton- Prevention of future deaths report - Courts and Tribunals Judiciary]

Heavy smoker on clozapine 525mg, Stopping smoking tobacco likely led to fatal increase in clozapine levels. He was counselled on risk but did not inform psychiatrist so dose could be decreased. Psychiatrists noted lack of guidance on relevance of reduction in smoking, rather than cessation of smoking, and lack of standardised practice relating to asking questions and recording answers given when discussing possible symptoms of side effects of the medication.

This case highlights risk of stopping smoking without input of specialist to adjust dose and provides opportunity to remind non-specialists HCPs and patients/carers about this interaction.

Signpost to SPS page: managing-specific-interactions-with-smoking/ SLAM guidance

[Abbigail Smith (1): Prevention of future death reports]

Report into suicide of a patient (history autism, learning disability) who became non-compliant with clozapine; this was reported to community mental health services. The directions of psychiatrist were not followed up and conditions required to facilitate a safe discharge had not been met. Short-term prescription of diazepam to permit to permit clozapine to be re-titrated was incorrectly continued as permanent prescription in absence of a medical review and dose increased further with as she deteriorated from continued non-compliance.

This case highlights challenges of counselling and supporting an neurodivergent individual with LD on importance of adherence and accurate recording of pt status in notes and communication between the teams .

Signpost to SPS pages on clinical considerations for patients prescribed clozapine

Prevention of Future Death Reports (Regulation 28)

Penicillin de-labelling

Jennifer Birch: Prevention of future deaths report
Death due to hypoxic brain injury from anaphylactic reaction to teicoplanin in peri-operative period of an elective procedure; medical records reported allergy to penicillin (rash as a baby) so flucloxacillin, not prescribed. Teicoplanin used as an alternative in penicillin allergy, but risk of serious complications is greater; linked to rare but recognised risk of severe anaphylaxis, occurring in ~0.1-1% of cases. Some Trusts have rolled out inpatient initiative to de-label penicillin allergy from patient medical records where risk stratification determines that the patient does not have a true allergy.

This case illustrates what is action to be taken on allergy status based on history of rash as baby, and provides a reminder of penicillin de-labelling policies – is it embedded into practice? Is this a metric for infectious disease teams in trusts?

Useful resources:
BSACI guideline for the set-up of penicillin allergy de-labelling services by non-allergists working in a hospital setting
All Wales guidance for penicillin allergy de-labelling in adults in secondary care

Anticoagulation

Lacey Heath: Prevention of future death reports
A medically complex patient who struggled to achieve therapeutic anticoagulation died from a complete stenosis of her prosthetic aortic valve with thrombosis leading to a cardiac arrest, due to sub-therapeutic anti-coagulation. Concerns regarding her management are highlighted (including prohibitive cost of Coaguchek for the patient, no advocate, query learning disabilities, “clinicians not concerned about non-compliance”).

This case provides a reminder of need for robust counselling on anticoagulation as part of mechanical valve surgery consent- link in with anticoag and cardiology teams

Manufacturer risk minimisation materials (RMM)

Parenteral iron products
HCP and patient educational material providing important safety information and risk minimisation guidance to support safe and effective use of following products in accordance with the approved Risk Management Plan:

Ferinject (ferric carboxymaltose)
Molcava (ferric carboxymaltose) 50 mg iron/ml dispersion for injection/infusion
Venofer (iron sucrose)

Resource: SPS pages-minimising risks associated with administration of injectable iron

Inhaler dose counter

Ventolin Evohaler (salbutamol) 100 micrograms
Risk awareness dialogue aid covers counselling points for the new inhaler, which contains 200 puffs of salbutamol and does not have a dose counter. Patients should keep a record of puffs used and consider keeping a spare inhaler at places they spend their time.

Useful resource: Right Breathe search for inhalers with dose counter

MHRA Drug Safety Update

Finasteride and dutasteride – updated safety warnings for psychiatric side effects and sexual dysfunction

Following MHRA review, product information for finasteride and dutasteride containing medicines being updated to provide more information on risk of suicidal thoughts, sexual dysfunction and depression. Yellow Card data since 1994 to 31 May 2025 include 170 reports of suicidal ideation and related terms for finasteride (1mg and 5mg) and 5 reports for dutasteride 0.5mg. There were 19 fatal reports of suicide for finasteride and no fatal reports of suicide for dutasteride.

Increased liver monitoring for sotorasib (Lumykras▼) patients with recent immunotherapy

Hepatotoxicity is a common side effect and may lead to drug-induced liver injury. Following an update to SmPC, healthcare professionals should conduct more frequent LFTs for patients who received immunotherapy recently (within 3 months) before starting sotorasib. Review of clinical data, showed higher incidence of hepatotoxicity in this patient group vs. those who started sotorasib >3 months after last dose of immunotherapy, or who never received immunotherapy. Recent immunotherapy prior to starting sotorasib may also be a risk factor for ILD). Sotorasib should be withheld in patients with severe hepatotoxicity, or if ILD suspected.

Elranatamab (Elrexfio): risk of progressive multifocal leukoencephalopathy (PML)

A recognised adverse reaction; MHRA has received 10 reports as of 6 August 2026, including fatalities. Patients should be monitored for any new onset of or changes in pre-existing neurological signs or symptoms. If PML is suspected, treatment should be withheld and appropriate diagnostic testing initiated. If PML is confirmed, elranatamab must be discontinued

Updated MHRA guidance on point of care testing (POCT)

Updated incident reporting section (4.12) provides clearer information on when incidents involving POCT devices should be reported to MHRA, reporting routes available across UK, and records that should be retained to support investigations and Yellow Card submissions.

Reminder for those establishing or managing POCT services to review revised guidance, particularly sections on incident reporting and accreditation to ensure local reporting procedures align with this guidance.

Direct HCP communications

The complete MHRA Safety Roundup is available here.

Monitoring LFTs

Avacopan Vifor, previously known as Tavneos (avacopan)▼: Updated requirements for liver monitoring and stopping rules to mitigate risk of drug-induced liver injury and vanishing bile duct syndrome

Letter from CSL Vifor advises on updated requirements for liver monitoring (at least every 2 weeks for first 3 months) and for permanent treatment discontinuation, to include when ALP ≥2 times ULN (when source is the liver) and when clinical symptoms of vanishing bile duct syndrome are present.

Ontozry (cenobamate): new requirements for liver monitoring due to reports of severe liver injury

Letter from Angelini Pharma UK advises that cases of severe liver injury with hepatic failure have been reported, mainly when cenobamate is used with other antiseizure medications. LFTs should be evaluated before initiation and during treatment as clinically indicated.

Medicine Supply Notifications

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

Medicine Supply Notification: Nifedipine 10mg, 20mg, 30mg and 60mg modified-release tablets

Various brands and strengths of nifedipine modified-release tablets are experiencing supply issues (Tensipine® MR; Dexipress® MR; Adalat® LA; Neozipine® XL); Adanif® XL hs been discontinued. Alternative brands remain available and can support increased demand.

Medicine supply notification: Voltarol® Ophtha and Voltarol® Ophtha Multidose eye drops

Voltarol® Ophtha unit dose preservative-free out of stock until mid-Jan 2027. Voltarol® Ophtha Multidose eye drops will be discontinued by end of Oct 2026 and cannot support increased demand. Ketorolac, bromfenac and nepafenac eye drops (all contain preservative) remain available

Medicine supply disruption statistics, UK: data to June 2026

From January to June 2026, there were around 700 supply issue notifications and around 200 discontinuation notifications. In total in 2025, there were ~1400 supply issue notifications, lower than in 2024, and ~480 discontinuation notifications, higher than in 2024, 2023 and 2022.

Medicine Supply Notifications

Avalglucosidase alfa (Nexviadyme®) 100mg powder for concentrate for solution for infusion

Avalglucosidase alfa (Nexviadyme®) 100mg infusion is out of stock until 10th September 2026 and then may experience delayed deliveries until December 2026. Limited emergency stock of Nexviadyme® is available and is being allocated by order of national clinical urgency guidance.

Agalsidase beta (Fabrazyme®) 5mg and 35mg powder for concentrate for solution for infusion

Agalsidase beta (Fabrazyme®) 35mg infusion is out of stock until 4th September 2026 and then may experience delayed deliveries until December 2026. Agalsidase beta (Fabrazyme®) 5mg infusion remains available but cannot support increased demand; there may be delayed deliveries until December 2026. Process outlined for co-ordinating allocation between Specialised Commissioning services, Regional Pharmacy Procurement Specialists and homecare.

National guidance, publications & resources

MHRA

[Bladder Anticholinergics: review of risk of dementia]

Following recommendation from the CHM, MHRA review found overall, the available evidence is insufficient to confirm that bladder anticholinergic medicines directly increase dementia risk. However, study limitations mean a small increase in risk cannot be completely excluded.

All Wales Medicines Strategy Group

[Gabapentinoid resources for chronic pain]

Prescribing of gabapentinoids has continued to increase, as have concerns about their safety and harm. This resource pack provides guidance on appropriate use and encouraging a holistic approach to pain management to support safe and effective prescribing.

[History-based penicillin allergy de-labelling in adults]

Intended for use by all healthcare professionals to support identification of people who have a very low risk of having a true penicillin allergy, for whom it is safe to remove the penicillin allergy label based on history alone.

National guidance, publications & resources

Health Services Safety Investigation Body

Investigation report - Insulin: supporting safe self-administration for patients in the community with a learning disability

Third report in a series considering the self-administration of insulin by people with diabetes in community settings. Harm identified in people with learning disabilities and insulin-treated diabetes who were not adequately supported to administer insulin safely.

Consider how your organisation enables access to insulin self-management support, monitors and responds to issues that may impact on ability of person with learning disability to safely self-administer their insulin?

Related resource: SPS pages- Embedding the safer use of insulin

Electronic patient record systems – electronic referrals for ongoing care: advice and guidance

Interim report identified patient safety risks linked to how advice and guidance (A&G) services have been implemented across England. Report recommends that NHSE/DHSC undertakes a rapid evaluation of A&G processes to address the varying risks to patient safety.

MHRA

MHRA reaffirms the safety of childhood vaccination

Vaccination remains one of the safest and most effective ways to prevent serious infectious diseases. Large international studies, including national registry and sibling-controlled studies, have found no evidence linking vaccines to autism in children.

One to flag to Imm Vacc & Paed colleagues for dealing with "vaccine hesitant" patients and parents

No Summer Shortcut for Safe Weight Loss

With prescription weight loss medicines being advertised illegally on social media alongside quick-fix slimming claims, the MHRA is reminding people how to use GLP-1 medicines safely, spot illegal sellers and avoid diet changes that could interfere with their medicines.

Specialist Pharmacy Service

Responding to medication safety alerts and notifications

Fully reviewed and updated page covering how alerts are received, how safety alerts and notifications should be acted upon, and how to sustain compliance, with scope widened to include MHRA and HSSIB notifications.