SPS Medication Safety Update November 2026

Recent critical patient safety alerts, reports, and publications

Yuet Wan - Medicines Advice Pharmacist

The first stop for professional medicines advice

25th November 2026

Patient Safety Alerts

None issued November

Prevention of Future Death Reports (Regulation 28)

Adverse drug reaction

Alexander Mulroney

Death by suicide soon after starting second line ofloxacin (behavioural change day 2, suicide day 3) ; no previous history emotional /mental ill-health, nor considered at risk of self-harm. **Ofloxacin did not cause death but induced a 'determination to end life'**. Established warning: "Fluoroquinolones can cause psychiatric side-effects, including depression and psychosis, even after first dose. In rare cases, these can lead to thoughts or attempts of suicide and have been associated with completed suicide of a patient without a history of psychiatric disorders." Current warnings provide insufficient safeguards and fails properly and adequately to inform prescribers and patients of danger. Software applications warnings expressed as **High Severity Warning** (non-specific referring to "very rare reports of disabling and potentially long-lasting or irreversible side effects" without mentioning suicide). **Medium Severity Warnings** (12 which begin with reference to MHRA warning of suicide or suicide attempts followed by 41 lines of dense and small print text, all relating to non-fatal outcomes, and 12th warning states, "Alert – MHRA advises quinolones can cause psychiatric side effects including depression and psychosis which can lead to thoughts or attempts of suicide.")

In a typical time constrained doctor/patient consultation, the placing of an under stated reference to the possibility of suicidal thoughts at the end of a relatively long and complex list of so-called medium severity alerts is missed, or is misleading, or is ineffective.

For consideration: include reminder of this adverse effect in local safety communication

Related resources/responses

Drug Safety Update (2023):Fluoroquinolone antibiotics: suicidal thoughts and behaviour

Healthcare professionals prescribing fluoroquinolone antibiotics are reminded to be alert to risk of psychiatric reactions, including depression and psychotic reactions, which may potentially lead to thoughts of suicide or suicide attempts and advise patients to be alert to these risks.

Drug Safety Update (2024): Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate

This follows review of effectiveness of current measures to reduce identified risk of disabling and potentially long-lasting or irreversible side effects. Reiterated to remain alert to risk of suicidal thoughts and behaviours with use of fluoroquinolone antibiotics.

MHRA and BNF response

- MHRA noted concerns about effectiveness of current risk communications and will consider whether current regulatory and risk-minimisation measures remain appropriate and if any further action is required to support safe use of these medicines.
- BNF said third-party system developers can use its content to create hierarchy of warnings, but this is not determined by *BNF*. They will reach out to MHRA to discuss ways of further highlighting warnings around use of ofloxacin and quinolones to prescribers and patients.

Prevention of Future Death Reports (Regulation 28)

Medication adherence in mental health setting

Benjamin Pesian

Death by suicide : stopped taking aripiprazole for schizoaffective and bipolar affective disorder and relapsed; detained under Mental Health Act; following psychiatric assessment, MDT decided cariprazine to be used, with PRN promethazine. Although he tolerated and reacted well to risperidone medication, this wasn't given on this occasion. Detention status removed and converted to informal patient status. At the time, displaying behaviours associated with psychotic episode.

Noted concerns about quality and timely preparation of risk assessments and Trusts organisational learning from these incidents and timely implementation of recommendations made by external investigation report author.

Jonathan Doughty

Death by suicide : mental state significantly deteriorated during 2024; was to be assessed under Mental Health Act with view to involuntary admission as refusing treatment and medication, harming himself, actively suicidal and showing signs of psychosis. Assessment could not take place as no acute bed available, and he had to be kept safe in community until bed found, with risk to be managed, often by family members or crisis team nurses who might only visit for a short time.

Consider linking in with mental health colleagues on how to improve uptake of depot /long-acting antipsychotics in patient non adherent to oral antipsychotics

NICE CG178- 1.5.6 Using depot/long-acting injectable antipsychotic medication

BMJ: Nottingham attacks inquiry: what we learnt, and what families want next (series of errors, omissions, and misjudgments resulted in Calocane's mental illness being poorly managed; wrong decision to discharge him, not given depot antipsychotic, as "disliked needles", leaving him unmedicated)

Note event: MSATS (02 December) Safe use of medicines in mental health: a whole-system approach

Prevention of Future Death Reports (Regulation 28)

Electrolyte disturbance secondary to PPI

Peter Leech

Seizure likely due to electrolyte disturbance secondary to PPI and recent history of diarrhoea. On admission found to have aspiration pneumonitis secondary to seizure, and despite treatment, condition deteriorated and passed away. Omeprazole had been started during a hospital admission and continued by GP practice on a long-term basis at time when history of epileptic seizures was well established. No guidance was given to the GP about duration of the prescription, who was also not aware of increased risk of seizure caused by electrolyte disturbance as a result PPI treatment.

Note:

- MHRA Drug Safety Update (2014): Proton pump inhibitors in long-term use: reports of hypomagnesaemia
- SPC (omeprazole)- severe hypomagnesaemia reported in patients treated with PPIs for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur, but they may begin insidiously and be overlooked.

Action:
Reminder in local comms / prescribing guidance about this adverse effect of PPIs
Encourage review of patients on long term PPIs
Ensure prescribing and discharge documentation for PPIs include duration of treatment

MHRA Drug Safety Update

MHRA safety roundup: October 2026

Osimertinib (Tagrisso): skeletal muscle toxicity

Myositis/blood creatine phosphokinase increases are recognised side effects. Cases of rhabdomyolysis reported post-marketing in other countries, however, no UK Yellow Card reports to date. Before initiating treatment, patients should be advised to report any unexplained muscle pain, tenderness, weakness, trouble moving arms or legs, dark tea-coloured urine, or decreased urination. In case of severe events, treatment may need to be interrupted.
For awareness

Ioflupane: venlafaxine and other SNRIs may affect DAT scan interpretation

Cases of false positive interpretation in patients on venlafaxine referred for DAT scans using ioflupane as radiotracer, resulting in potential misdiagnosis of Parkinsons Disease. Ioflupane product information updated to include interaction and guidance on interpretation of DAT scan images. Evidence strongest for venlafaxine and limited information on other SNRIs but caution still advised for others. Mechanism of effect on ioflupane binding not clear; may be more relevant in patients on higher doses, elderly and/or patients with renal impairment. Temporary discontinuation (at least 5 biological half-lives) may be considered before administration of ioflupane on a case-by-case basis, and where clinically appropriate and safe for patient. They should also be advised to inform doctors they are on venlafaxine ahead of DAT scan.
Ensure clinicians and nuclear medicine team aware of interaction

Ivacaftor, tezacaftor, elexacaftor (Kaftrio) in combination with ivacaftor (Kalydeco): reminder that information on the risk of serious liver injury was updated in 2025

Following MHRA review in 2025, product information warnings further strengthened to state that cases of liver failure leading to transplantation have been reported within first 6 months of treatment in patients with and without pre-existing liver disease. Current clinical advice to measure ALT, AST, and total bilirubin before starting treatment, every 3 months during the first year of treatment, and annually thereafter remains appropriate to detect liver injury.
Flag to CF teams

Manufacturer RMM

Sodiofolin@ (folinic acid) 50mg/mL solution for injection/infusion - requirement to use a PES or PVDF filter due to observation of partides and potential risk of thrombo-embolic event

Visible particles were found in this product, as part of ongoing stability programme. Until further notice, healthcare professionals are required to use only pump systems with particle filters, or syringe filters, made of PES or PVDF, with a pore size ≤5 µm, for administration.
Flag to oncology team

Guanfacine prolonged-release tablets (Neuraxpharm): Important safety information missing from the Summary of Product Characteristics regarding QT/QTc interval prolongation

Prolonged QT/QTc interval has been reported during post-marketing use of guanfacine (uncommon adverse reaction & also a potential manifestation of guanfacine overdose). In patients who develop QT prolongation, consider dose reduction or discontinuation of guanfacine.

Lacosamide Neuraxpharm 10 mg/ml syrup: Important safety information missing from current approved Summary of Product Characteristics

Current product information in SmPC for this product does not fully reflect available safety information regarding neurological adverse reaction profile & reproductive health counselling associated with lacosamide. Letter details further information for healthcare professionals.

Zynyz® (retifanlimab) Patient Card

The Patient Card, which should be carried by patients at all times, contains important safety information to minimise the risk of immune-related adverse reactions.

MHRA Drug Safety Update

Duvyzat®▼ (givinostat): interim advice on risk mitigation measures following reports of deaths in patients while taking givinostat

Following review of cases, interim monitoring advice from MHRA, include more frequent ECG and electrolyte measurements. Before any amendments to the product information are made, the MHRA will consider the findings of an ongoing independent review.

Direct HCP communications

The complete MHRA Safety Roundup is available here

European Medicines Agency

EMA's human medicines committee (CHMP) has adopted direct healthcare professional communication (DHPC) about potential effect of Mounjaro (tirzepatide) on the reliability of oral contraceptives

DHPC reminds healthcare professionals that contraception is recommended for women who can become pregnant; when using oral contraceptive, to either add barrier method for 4 weeks after tirzepatide & for 4 weeks after each dose increase, or switch to non-oral method. Limited information available on effect of tirzepatide on pharmacokinetics and efficacy of oral contraceptives in women with obesity, overweight or type 2 diabetes mellitus.

Comment: unclear if DHPC will be issued in UK as already listed in SPC (administration of combination oral contraceptive [0.035 mg ethinyl estradiol/0.25 mg norgestimaten] in presence of single dose of tirzepatide 5mg resulted in reduction of oral contraceptive Cmax and AUC) **but useful reminder of interaction.**

Medicines UK

Antidepressants: New safety measures for all patients to improve communication of the risk of suicidal thoughts and behaviours and persistent sexual dysfunction

Dear Healthcare Professional Letter details new safety measures being implemented for patients on antidepressants following review, involving patients and families, into how risks of suicidal thoughts and behaviours, and persistent sexual dysfunction are communicated in PILs (new boxed warning in PILs, new patient card, supporting safety (ancillary) leaflet, term post SSRI sexual dysfunction ("PSSD") being added to PIL for certain antidepressants)

Action: Advise prescribers of updated safety information and ensure patients are counselled

Medication Supply Notifications

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

Medicine Supply Notification: Phenytoin 100mg tablets (Teva)

Teva brand of tablets are out of stock until late November 2026. Phenytoin 100mg tablets from Aurobindo Pharma – Milpharm Ltd remain available and can support an uplift in demand.

Flag to colleagues: patient counselling/reassurance if dispensed Aurobindo- Milpharm product in light of MHRA advice on class 1 AED (to maintain on a specific manufacturer's product)

Medicine Supply Notification: Fixapost®, Vizilatan Duo®, Eysano® preservative free eye drops

MSN contains advice on available alternatives to Fixapost® and Vizilatan Duo® (latanoprost 50micrograms/ml/ timolol [0.5%] 5mg/ml) and timolol (Eysano® 0.5% & 0.25%) preservative-free eye drops, which are currently out of stock, and their anticipated resupply dates.

Flag to ophthalmology colleagues : review if all patients require PF formulation; if concentrations of timolol changed during shortage, dosing frequency may need to be adjusted and be aware of potential side effects if using a higher concentration)

PrescQIPP: Given their greater cost, local guidance should be agreed to target PF eyedrops to those groups of patients most likely to benefit

National guidance, publications & resources

Health Services Safety Investigation Body

The use of lithium for bipolar disorder

Investigation into why lithium may not always be considered or offered to people who could benefit from it, even though recognised as effective and recommended in national guidance. Report calls for development of position statement and protocol on its use.

Take note of HSSIB safety observation: organisations involved in caring for patients on lithium can improve patient safety by having clear pathways with physical health teams for timely follow-up if a person's physical health is affected by their medication, including shared discussions between specialities to ensure patient receives consistent message of balance of risks

Take note of HSSIB local-level learning prompts

Awareness of national guidance

1. Support staff to have balanced and accessible discussion of risk vs benefit
2. Signpost pt to others shared experiences
3. How are pts with bipolar disorder not Rx lithium reviewed
4. Identify health inequality related barriers to receiving lithium
5. Systems and processes to arrange appropriate monitoring, Act on out-of-range results and communicate follow-up actions
6. Work with other local services to co-ordinate care
7. Inspire confidence in infrastructure to support safe management of lithium
8. Can existing local infrastructure, such as clozapine clinics, be adapted to support safer and more consistent lithium monitoring
9. Monitor how many patients are taking lithium
10. Enable joined up working across sectors when pt's wellbeing affected by lithium
11. Assurance that responsibility for lithium monitoring remains clear when patients move between teams

Note event: MSATS (02 December) : Safe use of medicines in mental health: a whole-system approach (includes perspective of carer whose mother experienced lithium toxicity)

National guidance, publications & resources

Health Services Safety Investigation Body

Insulin: supporting safe self-administration for patients in the community – inequalities in technology and access to care

Final report focuses on availability and design of diabetes technologies and insulin pen devices. It highlights that people with learning disabilities/mental health problems potentially miss out on hybrid closed-loop systems that could support safer insulin self-administration. It also brings together shared learning from across the series and makes further safety recommendations.

Action: local-level learning from across the series and safety recommendations:

- ensure staff caring for patients who use diabetes technology have required knowledge and skills to support them to manage their technology safely
- support staff to explore how a disability or impairment may influence ability to use an insulin pen device or diabetes technologies
- ensure access to resources to support prescribers to know which insulin pen devices are suited to patients with different disabilities or impairments
- ensure staff are aware of responsibilities to report incidents associated with diabetes medication, devices and technology, including to manufacturers and MHRA

Note: SPS resource: Developing insulin safety across a system

Beyond insulin: seeing the whole person in diabetes care

In blog ahead of World Diabetes Day (14 Nov), safety investigator reflects on recent investigations into insulin self-administration in vulnerable groups which identified need to protect independence, and plan for changing needs to improve access to technology, and join up services

National guidance, publications & resources

Medicines and Healthcare products Regulatory Agency

#MedSafetyWeek (2 to 8 November 2026): Don't ignore suspected side effects, report them! Updates to the Yellow Card website and app

The annual #MedSafetyWeek campaign is raising awareness of the Yellow Card scheme, and this year's theme encourages the reporting of side effects and adverse incidents from medicines and medical device incidents.

Signpost to e-learning modules (three for pharmacists: ADR safety/Reporting ADRs/Patients and ADRs)
Share examples of work done for MedSafety Week; progress on uptake of the modules

MHRA Women's Health Programme 2026-2030
Programme supports work to improve the safety and effectiveness of medicines and medical devices used by women, and to ensure women's needs are better reflected in healthcare research and regulation.

For awareness: fewer than 1% of trials approved in the UK including pregnant and breastfeeding women resulting in significant evidence gaps and potential barriers to safe and effective treatment with medical products.

NHS England

National paediatric early warning system (PEWS)

NHSE is introducing a national standardised approach to tracking deterioration in children in hospital. The patient wellness question, a core component of Martha's Rule, is embedded in national PEWS. Before using observation and escalation charts for ED and inpatient settings, staff should complete the associated e-learning modules.

For information- relevant to paediatric MSOs

National guidance, publications & resources

MIMS

Fire-retardant emollient, Novamol Protect, now available in UK

Novamol Protect (10% urea) gel is indicated for dry, itchy skin conditions. Formulated with humectants and povidone, the manufacturer claims this gel, unlike typical emollients, does not increase the patient's ignition risk from fire exposure **For awareness, flag product to dermatology colleagues, does it have a place in therapy?**
Classed as cosmetic, : Product website
Note Prevention of future deaths report Aug 2025: James Rownsley – emollient on clothing and sofa throw; calor gas fire; (fire services data- 50 deaths in England involving emollient creams)

Related information:
- MHRA Drug Safety Update 2018, 2020
- SPS page: Managing fire risk with emollients **(will be amended to explicitly mention "oily component" in emollients potential fire risk once transferred to fabrics).**

Thomas Pocklington Trust
Accessible Healthcare in a Digital NHS

This parliamentary report sponsored by the national sight loss charity sets out evidence and practical recommendations needed to ensure a digitally enabled NHS is also an accessible and equitable one, so Government's ambitions for digital healthcare do not leave blind and partially sighted people behind.

For producers of digital content: **strengthen compliance with Accessible Information Standard**

Office for National Statistics
Deaths related to drug poisoning in England and Wales: 2025 registrations

Report notes 5519 deaths in 2025, equivalent of 92.4/million people, the first annual decrease since 2012.

For awareness: Graphs of age-standardised mortality rates for selected substances linked to drug-poisoning deaths, 1993 to 2025, relating to conventional medicines (any antidepressant, any antipsychotics, benzos, paracetamol, codeine, tramadol, Z drugs), drugs of misuse, and new psychoactive substances

National guidance, publications & resources

House of Lords Childhood Vaccination Committee

[No time to lose to reverse the decline in childhood vaccination rates]

Report notes rates have fallen for over a decade. UK has lost measles elimination status. By October, there had been more than 4,000 measles cases (3 fatalities). Parents are more likely to feel confident about vaccination if they have spoken to a trusted healthcare professional.

[Conversations With Vaccine-Hesitant Patients]
JAMA Insights notes vaccine hesitancy is one of top risks to public health identified by WHO. Practitioners who recognise why patients are concerned and tailor their interventions accordingly are better able to counter misinformation and support confident vaccination decisions.
Flag to Imm Vacc teams

Neonatal & Paediatric Pharmacy Group

[Using Standardised Strengths of Liquid Medicines in Children – 11th edition]

Latest update of this consensus statement, written to highlight that these standardised concentrations exist and to encourage all prescribers to prescribe these concentrations, includes 15 medicines (lisinopril and calcium carbonate added following a consensus-finding exercise).

British Heart Foundation

[Left Behind: A Policy Response to Cardiovascular Inequalities in Severe Mental Illness]

Report finds people with severe mental illness face a higher risk of cardiovascular disease, but are less likely to receive timely diagnosis, treatment and support. It makes 6 recommendations, including reducing smoking and strengthening NHS Annual Health Checks.

Note event: MSATS (02 December) [Safe use of medicines in mental health: a whole-system approach]

Specialist Pharmacy Service

5α-reductase inhibitors (benign prostate hyperplasia) monitoring

Drug monitoring monograph suggests men prescribed finasteride or dutasteride for benign prostatic hyperplasia should have their prostate specific antigen (PSA) monitored six months after starting treatment. Includes advice from MHRA Drug Safety Update on ADRs.

Reminder: MHRA Drug Safety Update (May 2026) advises patients to contact a healthcare professional if they experience suicidal thoughts, depression, or sexual dysfunction, ADRs that may persist after treatment has stopped.

Optimising medicines during fasting

Webpage covers clarifying fasting restrictions & shared decision making, identifying people at risk, reviewing medicines (time critical, dehydration, hypoglycaemia, administration with food), optimising medicines (timing, dosing, routes), and communicating the medicines plan.

Related resource- SPS: Understanding time critical medicines to support improvement

Flag to colleagues: assess medicine-related risks during fasting and adjust treatment to support safe and effective medicines use. Ramadan begins in February

Primary research - Medication Safety

N/A for November