SPS Medication Safety Update April 2026

Recent critical patient safety alerts, reports, and publications

Jen Lynch - Medicines Advice Pharmacist

The first stop for professional medicines advice

29/04/2026

Patient Safety Alerts

Shortage of dinoprostone 3mg vaginal tablets and 1mg/2.5ml, 2mg/2.5ml vaginal gel

Issued: 8/4/2026 Deadline: 20/4/2026 NatPSA/2026/003/DHSC

There have been quality issues affecting the raw materials used in manufacturing of these dinoprostone products, which have resulted in supply interruptions.

This National Patient Safety Alert requires action to ensure that there is a co-ordinated Trust-wide approach to reserve available stock for specific patients and support safe product switches for others. Local guidelines or PGDs should be updated where necessary, and ensure staff are appropriately trained on any new procedures.

MSN/2025/049 has now been superseded by this NatPSA. This MSN related to previous stock issues with the dinoprostone 3mg pessaries only, and not the vaginal gel products.

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Class 2 Medicines Recall: Bio Products Laboratory Limited, Rabies, Human normal Immunoglobulin 500IU solution for Injection, EL(26)A/18

One batch of Human Rabies Immunoglobulin has been recalled following a stability failure for a reduction in potency. Quarantine affected batches and return to the supplier. No adverse events related to the defect have been reported. No action is required for patients who may have received this batch.

Class 2 Medicines Recall: Crescent Pharma Limited, Ramipril 10mg capsules, EL(26)A/19

Crescent Pharma Limited is recalling one batch of Ramipril 10mg Capsules as a precautionary measure due to a potential error at the manufacturing site. One complaint, to date, identified one blister pack of Ramipril 5 mg Capsules Batch No.: GR164094 inside a sealed carton of Ramipril 10 mg Capsules.

Class 3 Medicines Recall: Omega Pharma Ltd, Napralief 250mg Gastro-Resistant Tablets, EL(26)A/21

Omega Pharma Limited is recalling three specific batches of Napralief (naproxen) 250mg GR Tablets due to important safety and dosage information being missing from the PIL and outer carton. For example, the affected cartons do not include the instruction that patients must not take more than three tablets a day, which is a key dosage safety message intended to prevent overuse.

Recent regulator and statutory body activity

MHRA medicines alerts, recalls & safety information

Class 4 Medicines Defect Notification: Sandoz Limited, Apixaban 2.5mg and 5mg Tablets, EL(26)A/17

Sandoz Ltd. have informed the MHRA that the PIL in affected batches does not contain up to date information related to the newly authorised paediatric indication (children aged 28 days to <18 years), and updated guidance regarding use following spinal/epidural catheter removal.

Class 4 Medicines Defect Notification: Quadrant Pharmaceuticals Limited, Vesomni 6 mg/0.4 mg modified release tablets, EL(26)A/16

Quadrant Pharmaceuticals Limited have informed the MHRA that specified batches of their parallel imported packs of this product have been printed with the incorrect barcode/GTIN on the carton. Other product details on the carton, including name, strength and pharmaceutical form are correct.

Class 4 Medicines Defect Notification: Doncaster Pharma Limited, Hiprex 1g tablets, EL(26)A/20

Doncaster Pharma Limited has informed the MHRA of an error related to the Braille embossing stating the strength incorrectly as 1mg on the outer packaging of certain parallel imported batches of Hiprex 1 g tablets (POM). The printed text on the outer packaging, immediate packaging and PIL are correct.

Recent regulator and statutory body activity

MHRA Safety Roundup – March 2026

Roundup covers the publication of a meningitis patient factsheet, and a new MHRA and NICE aligned pathway alongside an improved advice service to help get new medicines to patients up to six months sooner. It also includes letters, medicine recalls and device notifications sent to healthcare professionals.

GPhC Position statement: The use of Artificial Intelligence (AI) in pharmacy

Statement sets out the GPhC's position on the use of AI in pharmacy practice, revalidation, and education and training. It also sets out the responsibilities of pharmacists, pharmacy technicians and pharmacy owners when using AI.

Weight management medicines and services: a review of GPhC inspections and concerns

Review highlights need for stronger governance, enhanced clinical safeguards and greater transparency in provision of weight management medicines and services, and sets out targeted actions for improvement, to strengthen practice and meet regulatory standards.

Pharmacovigilance Risk Assessment Committee (PRAC)

Meeting held on 7th – 10th April 2026

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

- PRAC agreed on a direct healthcare professional communication to inform that cases of severe liver injury with hepatic failure have been reported in patients treated with Ontozry
- Most cases occurred when the medication was used alongside other anti-seizure medications
- Prescribers are recommended to conduct LFTs before starting and throughout treatment with Ontozry
- Prescribers should carry out prompt clinical evaluation and LFTs in patients who have symptoms indicating liver injury
- Patients should be advised to immediately seek medical attention if they experience signs or symptoms indicative of liver injury
- If liver injury is suspected or detected, dose reduction or discontinuation of Ontozry should be considered, in line with the guidelines of the SPC

Direct HCP Communication

DHCP letter on behalf of all concerned Marketing Authorisation Holders: Tranexamic acid intravenous formulations–serious including fatal adverse reactions due to inadvertent intrathecal administration

Letter warns intrathecal (IT), epidural, intraventricular & intracerebral use is contraindicated. Fatalities after inadvertent IT administration have occurred due to mix-ups, mostly with injectable local anaesthetics.

Extreme caution advised with storage, handling & administration of intravenous formulations of tranexamic acid to ensure the correct route of administration.

Series of SPS Pages: Preventing errors on the medicine journey

Direct HCP Communication

Aurum range of prefilled syringes – how to mitigate risk of empty syringes being placed back into circulation

The labels on the twist box of the affected syringes at times appear to realign upon closure, which may result in twist boxes with empty syringes being placed back on the crash trolley instead of being discarded. Letter provides information on how to mitigate this risk.

Further information:

The letter applies to the Aurum range of prefilled syringes, which includes the following:

- Adrenaline (Epinephrine) Injection 1:10,000 glass prefilled syringe (PL 12064/0006)
- Adrenaline (Epinephrine) Injection 1:1000 prefilled syringe for Anaphylaxis (PL 12064/0058)
- Amiodarone 30mg/ml Solution for injection/infusion in pre-filled syringe (PL 12064/0047)
- Calcium Chloride Intravenous Infusion, 10% w/v pre-filled syringe (PL 12064/0020)
- Naloxone Hydrochloride 1mg/ml Solution for Injection in a pre-filled syringe (PL 12064/0060)

Direct HCP Communication

- Rabipur (Rabies vaccine, inactivated), powder and solvent for solution for injection in pre-filled syringe: Interim Supply of EU Stock to Mitigate Supply Disruption
- Uzpruvo 130mg concentrate for solution for infusion: Interim Supply of EU multi-lingual Stock to Mitigate Supply Disruption
- Direct Healthcare Professional Communication: Supply of Meflynate (methylphenidate) XL 10 mg, 20 mg &40 mg modified release hard capsules with blisters strips printed with Spanish labelling
- Signifor (pasireotide diaspartate) 0.6 mg solution for injection [PLGB 15266/0033]: Interim Supply of Australian Stock to Mitigate Supply Disruption
- Fucithalmic 1% w/w Viscous Eye Drops/ Fusidic acid 1% w/w Viscous Eye Drops: Interim supply of Spanish stock to Mitigate supply disruption
- Chlorhexidine updates to Patient Information Leaflet
- Ketorolac updates to Patient Information Leaflet

Manufacturer RMM

Risk Minimisation Materials for Feristark (ferric carboxymaltose)

The healthcare professional guide includes essential prescription and administration information to minimise the risk of serious hypersensitivity reactions. A patient guide discussing information on this risk, including when to seek immediate medical advice, is also available.

SPS Page: Minimising risks associated with administration of injectable iron.

Risk Minimisation materials to help reduce the risk associated with using caffeine citrate 20 mg/ml Solution for Infusion and Oral solution

An educational card is available, containing information on indication for use, loading & maintenance doses, key warnings and other risk information.

Toripalimab (Loqtorzi) Patient Alert Card

Card contains important safety information to lower the risk of immune-related side effects, including when to seek immediate medical attention. The card should be carried by the patient at all times and shown to any healthcare professional involved in their care.

Drug shortages

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

Shortage of Ramipril 1.25mg capsules

Anticipated resupply date: 29th May 2026. There are intermittent supply issues with ramipril 1.25mg capsules; ramipril 1.25mg & 2.5mg tablets and oral solution remain available but cannot support increased demand. Where supply is available, community pharmacists and dispensing doctors should consider limiting supply to one month of supply in accordance with SSP087 for eligible patients. Other low dose formulations of ACEIs & ARBs are available.

Shortage of Chlordiazepoxide 5mg and 10mg capsules

Discontinuation of one brand, shortage of another brand (anticipated resupply date: 17th July 2026). Crescent brand remain in stock although there are insufficient 5mg capsules to meet full demand. Alternative oral benzodiazepines remain available. Seek advice from specialist teams where necessary for individual patients or to review clinical protocols.

Shortage of Cefixime (Suprax) 200mg tablets

Anticipated re-supply date: 16th October 2026. Alternative broad-spectrum antibiotics remain available. Reserve residual stock for specific indications listed, or if unavailable consider the use of unlicensed tablets. Seek advice from specialists if needed.

Drug shortages

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

Shortage of Aspirin 300mg suppositories

Anticipated re-supply date: 29th May 2026. Consider prescribing aspirin 150mg suppositories to make up to the required dose where needed. Note: remaining stocks of aspirin 150mg suppositories are short dated with an expiry date of 31st May 2026.

Shortage of Capimune 25mg and 50mg capsules

No anticipated re-supply date. Do not initiate new patients on Capimune (ciclosporin) oral capsules. Refer to specialist teams to facilitate switching existing patients to an alternative brand.

Shortage of Adrenaline (base) 1mg/ml (1 in 1,000) solution for injection pre-filled syringes

Anticipated re-supply date: 1st January 2027. Adrenaline 1mg/1ml ampoules are available.

Shortage of Aztreonam 2g powder for solution for injection vials

Anticipated re-supply date: 5th June 2026. Aztreonam 1g powder for injection vials remain available.

Drug Discontinuation

Discontinuation of Insulin detemir (Levemir FlexPen) 100units/ml solution for injection 3ml pre-filled pens and insulin detemir (Levemir Penfill) 100units/ml solution for injection 3ml cartridges

Update to communication (MSN/2025/036U) issued on 14th August 2025.

Levemir products are being discontinued and stock exhaustion is expected in December 2026. This notification has been re-issued, as a high number of patients remain on Levemir products. Healthcare professionals are reminded to switch patients on Levemir to a suitable alternative as soon as possible.

Specialist Pharmacy Service

Supporting lithium safety across the system

Healthcare professionals in all settings who interact with patients prescribed lithium should be aware of safety considerations related to its use. **(New page)**

Parkinson's disease medicines in swallowing difficulties

Provides information on administration of Parkinson's disease medicines, including crushing tablets, to reduce the risk of missed doses in swallowing difficulties.

Existing series of SPS pages: Time Critical Medicines

Amendments to HMR 2012 supporting vaccine supply and deployment

Video with expert speakers outlines the April 2026 amendments to the Human Medicines Regulations (HMR) 2012 to support the supply and deployment of vaccines across the UK. **(New page)**

Understanding Vaccine Group Directions (VGDs)

A VGD is a legal mechanism to support the administration of UK licensed vaccines within nationally commissioned vaccination programmes. Webpage covers who can develop and authorise them, and work under them, supervision, HCP training & authorisation, and records management. **(New page)**

National guidance, publications and resources

Safety management systems: NHS England position statement

Statement summarises NHSE's position on the potential for safety management systems to improve patient safety. It defines a safety management system, details key principles for organisations to consider and lists next steps, including an updated NHS patient safety strategy.

Persistent risks to safe insulin care in hospitals

Health Services Safety Investigation Body (HSSIB) report focuses on the safety of patients in hospital in England who have diabetes requiring treatment with insulin. Issues considered include management of diabetes care and the safe administration of insulin for inpatients. Safety learning is detailed for ICBs and NHS Trusts.

NHS overhauls clinical standards to reduce maternal deaths

Every maternity service in England will need to meet the new maternity standards, aimed at tackling the leading causes of maternal death, including blood clots, strokes, cardiac disease, suicide, sepsis, obstetric haemorrhage and pre-eclampsia.

National guidance, publications and resources

Medicine supply management

Guidance provides an overview of the systems and processes DHSC and NHS England use for responding to medicine shortages, including national management of medicines supply, notification of shortages, and communications in response to shortages.

Electronic patient record systems in England: what do NHS staff think?

Survey of 1,725 NHS staff members between July-October 2025 found that 83% used electronic patient record systems (EPRs), with only 49% receiving training on how to use the system for their role. Although 75% felt EPRs improved patient care, 37% felt they weren't working well.

National guidance, publications and resources

Neonatal & Paediatric Pharmacists Group (NPPG): Choosing an oral liquid medicine for children position statement

Version 2 includes the addition of a statement describing risks associated with sorbitol use in patients under 2 years old with undiagnosed hereditary fructose intolerance and an increase to the acceptable daily intake of saccharin in line with European Food Agency standards.

GIRFT Neonatology: Guide to safe insulin use

Document sets out guidance for safe access, storage, handling, prescription, administration and disposal of insulin in neonatal services.

Prevention of Future Death Reports (Regulation 28)

Paul Nash: 2026-0161

Paul Nash died following an epileptic seizure after running out of his epilepsy medication (carbamazepine) and missing three doses.

Paul requested his repeat prescription, but then had no supply left the following day. Despite a charity which supports patients with brain injuries contacting the GP surgery on Paul's behalf and requesting an urgent prescription, it was not ready for collection the next day. He was found deceased at his home the following morning.

The following concerns were raised:

- **Urgent request for a prescription of a critical medicine was not prioritised by the GP surgery**
- **Many epilepsy patients experience difficulties in obtaining sufficient quantities of medication to prevent missed doses and ensure optimum seizure control**

Do you have assurance that prescription requests for critical medicines are communicated effectively and prioritised appropriately in GP surgeries?

Do you have assurance that appropriate quantities of critical medications are dispensed?

Prevention of Future Death Reports (Regulation 28)

John Tarrant Ref: 2026-0199

John Tarrant had an unwitnessed fall whilst an inpatient and sustained a bleed to the brain. This bleed worsened later that evening and became unsurvivable.

He was on long term anticoagulation (warfarin), but his INR was raised on admission and during his inpatient stay, so his warfarin was held. After his fall, advice was given regarding a view to reversing the effects of the anticoagulation. However, no reversal agent was administered and John died approximately 9 hours after his fall.

With regards to medications, the following concerns were raised:

- **Under appreciation of the importance and urgency of considering the administration of anticoagulation reversal medication**
- **The post falls proforma did not provide a prompt to act on anticoagulation prescribed**

Could consideration of the need for reversal agents for warfarin be forgotten in your organisation? Are staff deskilled in the safe use of warfarin?

Does your falls proforma include a section to ensure anticoagulation is reviewed appropriately?

Prevention of Future Death Reports (Regulation 28)

Roman Barr 2026-0148

Roman Barr died as a result of an asthma attack where earlier intervention by an emergency ambulance would have prevented his death.

Evidence was also heard that Roman had been using his salbutamol inhaler more frequently than recommended which indicated poor asthma control. Neither he, nor his family, were aware of the clinical significance of this increased use. Following his death, the GP practice conducted a review and introduced measures to better identify and monitor patients with high salbutamol use.

With regards to medication, the following concern was raised:

- **Despite the Drug Safety Update (April 2025) which reminded healthcare professionals of the risks associated with increased salbutamol use, the evidence in this case indicates the importance of identifying excessive reliever inhaler use may still not be fully recognised by patients or primary care**

Does your organisation have appropriate systems in place to identify and manage poorly controlled asthma, and the overuse of SABAs for patients in line with the MHRA guidance?

Prevention of Future Death Reports (Regulation 28)

John Fisher Ref: 2026-0166

John Fisher died after being admitted to hospital suffering from persistent focal seizures that over the next few days developed into status epilepticus. His seizures could not be controlled and led to his death. Questions were raised regarding recent antiepileptic medication compliance prior to admission due to a new care agency administering his medication. In particular, it was queried whether he had missed doses of sodium valproate and whether phenobarbital was being given or not.

With regards to medication, the following concerns were raised:

- **On initial transfer of care services, medication was included on the MAR which had been discontinued by the GP, and documentation records were unclear as to whether medication had actually been administered or not**
- **On transfer to another care agency, there was lack of details provided on the current medication and the doses, routes, frequencies, timings or forms of the medication. There was lack of documentation and a mistake in transferring information to an electronic MAR.**

This case highlights again the importance of ensuring the safe and effective transfer of information across different care systems.

Prevention of Future Death Reports (Regulation 28)

Wayne Austin: 2026-0213

Wayne Austin became unwell at a probation office. The ambulance service attended promptly and began advanced life support, including the administration of naloxone. However, there were issues with the effective administration of naloxone for Wayne by paramedics. After transfer to ED, he died as a result of combined buprenorphine and alcohol toxicity.

With regards to medication, the following concerns were raised:

- **The effective administration of naloxone was impacted by paramedics finding it confusing and difficult to identify and access the correct guidance from the JRCALC app for the appropriate indication. The first available tab was opened for a different indication and used.**
- **The appropriate frequency of naloxone administration could not be complied with due to the demands of other competing tasks, including the administration of other medication, making them potentially unrealistic.**
- **Each ambulance at the Trust only carries a box of 10 naloxone 400 microgram vials. In a situation such as Wayne's this would mean that three ambulances are required to comply with cardiac arrest (where opioid toxicity is the likely cause).**

Primary research - Medication Safety

[Double-checking in the safe administration of medicines: Policy and practice in English hospitals]

Journal of Health Services Research and Policy, Feb 2026.

In England, double-checking of medication administrations happens despite there being no regulatory requirement except for intravenous drugs and medicines that require complex calculations. There is currently no national picture of the extent to which organisational policies stipulate double-checking, the variation or how closely double-checking is perceived to be conducted in accordance with policies.

The variation between policies identified by the present study might reflect a lack of robust evidence underpinning the practice of double-checking. Research is needed to understand if double-checking is effective at preventing medication errors and, if it is, the exact circumstances in which it is effective to facilitate the standardisation of double-checking policies.

SPS Page: Understanding when a check adds value to medication processes

Primary research - Medication Safety

Exploring the Accuracy of Near-miss Reporting: A Mixed-methods Study

Journal of patient safety, Jan 2026.

The study aimed to explore health care professionals' descriptions of near-miss events and assess the validity using the World Health Organization (WHO) patient safety classification framework. A total of 2805 near-miss reports were reviewed from a tertiary hospital from 2021 to 2024 using a retrospective, mixed-methods approach.

Eighty-four percent were validated as true near misses, mostly related to medication safety. However, significant misclassification was observed in patient care and workplace safety reports, where many events were incorrectly labelled as near misses despite involving patient harm or reaching the patient without causing harm.

Primary research - Medication Safety

The Role of Artificial Intelligence in Reducing Dispensing Errors for Patient Safety and Quality: A Systems Approach

Risk Management and Healthcare Policy, Feb 2026.

A systems approach was used to synthesize current AI-enabled strategies for reducing dispensing errors and to outline a roadmap for their safe and effective implementation. The focus in particular was on an AI-based natural language processing (NLP) decision-support application as an exemplar, examining how it can be integrated into dispensing workflows to flag high-risk prescriptions and labelling discrepancies before medications reach patients.

It concluded that AI can enhance safety, timeliness and efficiency in dispensing. However, its value depends on disciplined socio-technical integration (of people, systems, design and risk) and feedback within learning healthcare systems, rather than on standalone algorithmic performance.

Primary research - Medication Safety

Leveraging technology to improve care: a real-time electronic dashboard within an anticoagulation stewardship service to optimise anticoagulant safety

Journal of Thrombosis and Thrombolysis, April 2026.

Electronic medical records, laboratory results, and medication data can be combined into electronic "dashboards", providing a novel way to screen patients prescribed anticoagulants for potential errors.

Approximately 10,500 prescribing events were screened, 718 (6.9%) requiring a change to therapy in 611 patients. Of these patients, 292 (48%) were sub-classified as "high-risk", and the remainder were "standard-risk" (n = 319, 52%). This real-time dashboard enables rapid screening and identification of inpatients at risk of anticoagulant-related bleeding, allowing for timely intervention to reduce harm.