

# SPS Medication Safety Update August 2023

## Recent critical patient safety alerts, reports, and publications

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# Patient Safety Alerts



- [Potent synthetic opioids implicated in heroin overdoses and deaths \(NatPSA/2023/009/OHID\)](#)

Nitrazenes found in drug testing. Potency and toxicity are uncertain but perhaps similar to, or more than fentanyl, which is about 100x morphine.

Deadline for action- 4/8/23

Related guidance on [potent synthetic opioids: preparing for a future threat](#) has been updated

# Recent regulator and statutory body activity



Medicines & Healthcare products  
Regulatory Agency

- [Hyoscine hydrobromide patches: risk of anticholinergic side effects, including hyperthermia](#)

Reports of serious and life-threatening side effects received particularly when used outside of the licence.

- [Codeine linctus: public consultation on the proposal to reclassify to a prescription-only medicine](#)

Reports of use of codeine recreationally for its opioid effects rather than use as a cough suppressant.

- [MHRA reinforces anaphylaxis emergency guidance as hospital admissions rise](#)

MHRA has reinforced its safety guidance to highlight importance of knowing how to use an adrenaline auto-injector & what to do after, following new admissions data.

- [Safety of valproate – new study on risks in children of men taking valproate](#)

Awaiting revised study analysis before final conclusions can be drawn and further guidance regarding risks in children of men taking valproate can be provided.

- [Ethypharm Aurum pre-filled syringes are incompatible with some manufactured needle-free connectors: risk of delay in administering potentially lifesaving medication, DSI/2023/008](#)

Ensure compatible needle free connectors (NFCs) are used with the Ethypharm Aurum pre-filled syringes

# Recent regulator and statutory body activity



Medicines & Healthcare products  
Regulatory Agency

- [Class 2 Medicines Recall: medac GmbH, Sodiofolin 50 mg/ml solution for injection/infusion \(400mg/8ml vial\), EL \(23\)A/26](#)

Recalled due to particles detected during long-term stability tests.

- [Quantum Pharmaceutical, Diltiazem HCl 2% Cream \[unlicensed medicine\], CLMR \(23\)A/05](#)

Company led medicines recall as a precautionary measure due to viscosity.

- [Class 2 Medicines Recall: B. Braun Medical Ltd, Various Products, EL\(23\)A/27](#)

Recalled as a precautionary measure after traces of midazolam were detected in batches.

- [Class 2 Medicines Recall: medac GmbH, Sodiofolin 50 mg/ml solution for injection/infusion, \(100mg/2ml vial\), EL \(23\)A/28](#)

Further batches are recalled due to particles detected during long-term stability tests.

- [Class 4 Medicines Notification: Accord, Olmesartan 10mg film coated tablets, EL \(23\)A/29](#)

Error with the Patient Information Leaflets.

- [Class 4 Medicines Notification, Accord, Irinotecan 20 mg/ml Concentrate for Solution for Infusion, EL \(23\)A/30](#)

Error with the Patient Information Leaflets.

# Pharmacovigilance Risk Assessment Committee (PRAC)



- [EMA review of data on paternal exposure to valproate](#)

PRAC is reviewing data on potential risk of neurodevelopmental disorders in children conceived by fathers taking valproate medicines. Review focuses on data from a retrospective observational study conducted by companies as an obligation following previous review in pregnancy.

# Direct HCP communication

In June 2023, the following letters were sent or provided to relevant healthcare professionals:

- Tresiba FlexTouch 100 units/mL solution for injection (insulin degludec): [Supply shortage in the UK](#)
- Gavreto (pralsetinib): [Increased risk for tuberculosis and measures to minimise this risk](#)
- Menopur powder and solvent for solution for injection (menotropin) Interim supply of Irish packs to mitigate supply disruptions in UK (letters for [75 IU dose](#), [600 IU dose](#), [1200 IU dose](#))

In July 2023, the following letters were sent or provided to relevant healthcare professionals:

- Rapifen Intensive Care 5mg/ml solution for injection (10 x 2ml ampoules): [difficulty opening ampoules](#)
- Systemic and inhaled fluoroquinolone antibiotics – [reminder on restrictions of use](#)
- [Co-amoxiclav powder for oral suspension \(amoxicillin, clavulanic acid\), Amoxicillin Suspension \(amoxicillin\): wrong 'sugar free' label on outer package](#)

In August 2023, the following letter was sent or provided to relevant healthcare professionals:

- Simponi (golimumab) 50 mg and 100 mg: [Important changes to the injection instructions for the SmartJect Pre-filled Pen](#)

More to follow once full list is published.

# SPC changes or Manufacturer RMM

- [Simbrinza 10 mg/mL + 2 mg/mL eye drops, suspension](#)

SPC updated to provide information about Stevens-Johnson syndrome/toxic epidermal necrolysis. Patients should be advised of and monitored for skin reactions.

- [Risk minimisation materials for Tibsovo \(ivosidenib\)](#)

Patient alert card issued advising symptoms which warrant urgent medical attention.

- [Risk management materials for Vaxchora \(cholera vaccine\)](#)

Information about reconstitution and administration published.

- [Risk minimisation materials for Olumiant \(baricitinib\)](#)

A patient held card and separate guidance for healthcare professionals involved in prescribing this product for atopic dermatitis or alopecia areata or for rheumatoid arthritis.

- [Targinact 20 mg/10 mg prolonged-release tablets](#)

SPC updated to include warnings that oxycodone can increase intrabiliary pressure and spasm because of its effects on the sphincter of Oddi.

# Drug shortages and discontinuations

- Recent medicine shortages and discontinuations are available via: the [SPS Medicines Supply Tool](#) (registration required to access)
- [Permethrin 5% cream](#)
- [Paracetamol 100mg/10ml solution for infusion](#)
- [Tegretol \(carbamazepine\) 100mg tablets](#)
- [Rasburicase \(Fasturtec\) 7.5mg powder and solvent for solution for infusion](#)
- [Disulfiram 200mg tablets](#)
- [Phenytoin 100mg capsules \(Accord\)](#)

This is not a comprehensive list. Only critical safety medication shortages have been highlighted.



# Specialist Pharmacy Service



- [Giving intermittent intravenous infusions by gravity in adults](#)

This resource covers infusing by gravity, associated risks, factors affecting suitability for this mode of administration, and governance considerations.

- PGD updates- [tranexamic acid](#), [aciclovir](#), [clotrimazole cream](#), [clotrimazole pessary](#), [doxycycline](#), [fluconazole](#), [imiquimod](#), [podophyllotoxin](#)
- Update- [Legal mechanisms to supply and administer medicines to individuals](#)
- Breastfeeding guidance- [antiplatelet](#), [oral or parenteral corticosteroids](#), [using inhaled or topical corticosteroids during breastfeeding](#), [treating opioid dependence](#)
- Unlicensed medicines guidance- [understanding unlicensed medicines](#), [explaining the licensed status of medicines](#), [using unlicensed medicines](#)

# National guidance, publications and resources

- [Women's health hubs](#)

Guidance to support improving access to and experiences of care, improve health outcomes for women and reduce health inequalities.

- [Pregnancy Loss review](#)

Review looks at options to improve practice and provides recommendations to create a forward-looking approach.

- [Government acts to boost the quality of care for mothers and babies](#)

Measures to be taken on a national level to further improve safety standards in maternity care.

- [All Wales protocol for the appropriate prescribing of antipsychotics for people living with dementia \(Consultation\)](#)

Protocol aims to guide best practice in the use of antipsychotics in people living with dementia, to reduce the risk of harm, and where possible to reduce unnecessary psychotropic prescribing.

- [New NHS campaign to help spot early signs of life-threatening constipation in people with a learning disability](#)

A series of resources developed to support conversations about constipation to help ensure people with a learning disability receive treatment at the earliest opportunity.

# National guidance, publications and resources

- [Joint statement on meeting regulatory standards during periods of global or national shortage of medicines](#)

Healthcare professionals should advise on, prescribe, supply, dispense or administer medicines within the limits of their training, competence and scope of practice, regulatory standards and guidance and the law.

- [Getting the fundamentals right: how to better prepare for discharge pressures next winter](#)

Author highlights possible solutions to help better prepare services for discharge pressures next winter.

- [Health Service Investigation Bureau: Annual Review 2022/23](#)

Review summarises the 16 investigation reports & 36 safety recommendations published in 2022/23.

- [Are patients told about medication side effects?](#)

Data from national patient experience surveys shows that only 25% of patients discharged from hospital in 2021 received information about possible side effects of their medicines prior to discharge and 13% report they were given no information about their medicines.

- [Technologies offering monitoring from home in virtual wards recommended for people with an acute respiratory infection](#)

In DRAFT guidance NICE has suggested virtual ward platform technologies and a digital platform have a role in allowing people with acute respiratory infection to be treated in their own homes.

# National guidance, publications and resources

- [Rapid Literature Review: The characteristics of safety cultures](#)

This review sets out to address the key characteristics of good safety culture, key enablers and barriers, evidence of good practice and the gaps in the evidence.

- [The practice of collaborative leadership: Across health and care services](#)

Report shares insights and evidence about how to collaborate well across health and care services.

- [Policy guidance on recording patient safety events and levels of harm](#)

This guidance is for users of the new Learn from Patient Safety Events service, providing context & guidance on selection of appropriate categories when recording incidents.

- [National medicines optimisation opportunities 2023/24](#)

This guidance describes the 16 national medicines optimisation opportunities for the NHS in 2023/24.

- [Opioids in Palliative Care- Patient Information Guide](#)

This guide aims to be a useful take-home supplement to consultations.

# Prevention of Future Death Reports (Regulation 28)



## Courts and Tribunals Judiciary

None relevant this month

# Primary research- Medication Safety

- [Is polypharmacy associated with difficulty taking medicines in people aged  \$\geq 85\$  living at home? Findings from the Newcastle 85+ Study](#)

Authors conclude patients 85 years and older have difficulty taking their medications, regardless of how many they are prescribed.

- [Polypharmacy and Deprescribing](#)

This article described polypharmacy and its consequences, and how deprescribing can reduce polypharmacy.

- [Provision of Digital Health Technologies for Opioid Use Disorder Treatment by US Health Care Organizations](#)

Survey of US healthcare organisations showed that 34% used at least one type of digital health technology to support management of opioid use disorder.

- [Understanding complexity in a safety critical setting: A systems approach to medication administration](#)

This study applied the Event Analysis of Systemic Teamwork (EAST) model to evaluate the hospital medication administration system to identify opportunities to optimise performance and patient safety.

- [The Growing Role of Technology in the Care of Older Adults With Diabetes](#)

Review describes current knowledge on impact of technology in this population, identifies major barriers to their use, describes areas of care that could be optimised by technology, and discusses areas for future research.

# Primary research- Medication Safety

- [England State of Maternity Services 2023](#)

Report highlights the issues in maternity services.

- [Global access and patient safety in the transition to environmentally friendly respiratory inhalers: the Global Initiative for Asthma perspective](#)

Viewpoint cautions that providing access to asthma relievers at affordable prices for patients in all countries, whether through pMDI or DPI devices, is arguably both important and urgent, and should be pursued in parallel with safer alternative propellants in asthma inhalers.

- [Missed nursing care in emergency departments: A scoping review](#)

This review identified 20 themes around missed nursing care.

- [Medication errors in children visiting paediatric emergency departments](#)

This multicentre prospective observational study discusses medication errors detected in paediatric patients visiting emergency departments in 8 Spanish hospitals.

- [Identifying a list of healthcare 'never events' to effect system change: a systematic review and narrative synthesis](#)

This Canadian systematic review aims to identify the most serious and preventable events for targeted improvement efforts.