

SPS Medication Safety Update March 2024

Recent critical patient safety alerts, reports, and publications

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Patient Safety Alerts



England

- Nil new alerts



**National
Patient
Safety Alert**

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

- [MHRA approves new formulation of denosumab](#)

Denosumab (Xgeva) 120mg solution for injection in a pre-filled syringe is authorised by the MHRA. This is a more convenient option vs current vial preparation.

- [MHRA investigates risks associated with montelukast after concerns over neuropsychiatric reactions](#)

Review will cover new data on risks, lack of awareness of side effects among patients, carers, & clinicians, and whether further regulatory action is needed.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

- [Class 4 Medicines Defect Information: Orifarm UK Ltd, Concerta XL 18mg & 36 mg prolonged release tablets, EL \(24\)A/07](#)

There is an error with the Patient Information Leaflet packaged within the parallel import packs of the listed batches.

- [Class 2 Medicines Recall: medac GmbH \(t/a medac Pharma LLP\), Sodiofolin 50 mg/ml, solution for injection/infusion \(folinic acid 400mg/8ml vial\), EL\(24\)A/08](#)

Batches recalled due to particles detected during long-term stability testing.

- [Class 3 Medicines Recall: Besins Healthcare \(UK\) Ltd, Oestrogel Pump-Pack 750 micrograms/actuation Gel \(estradiol\), EL \(24\)A/09](#)

Besins Healthcare (UK) Ltd has informed the MHRA that a defective pump system was detected in two batches of Oestrogel Pump-Pack 750 micrograms/actuation Gel.

- [Class 4 Medicines Notification: Fresenius Kabi Limited, Sodium Chloride Intravenous Infusion 0.9% Freeflex, EL \(24\)A/10](#)

Wrong quantity printed on infusion bag packaging for affected batches.

Pharmacovigilance Risk Assessment Committee (PRAC)



Nil relevant

Direct HCP communication

Awaiting publication of February letters sent

SPC changes or Manufacturer RMM

- [Diflucan \(fluconazole\) 150 Capsules](#)

SPC updated to consider contraception with long courses in women of childbearing potential throughout the treatment period and for 1 week after the final dose. Added data from a meta-analysis on cardiac malformations.

- [Tasmar \(tolcapone\) patient diary: Risk Minimisation Information for Patients](#)

Booklet contains information on risks of liver injury, neuroleptic malignant syndrome and the monitoring required.

- [Risk Minimisation Materials for Epysqli \(eculizumab biosimilar\)](#)

A healthcare professional's guide, patient/parent information guide, alert card and vaccination certificate.

- [Kevzara \(sarilumab\) Patient Alert card: Risk Minimisation Information for Patients](#)

Card contains important safety information that patients need to be aware of before, during & after treatment.

- [Risk Minimisation materials for Cerdelga \(eliglustat\)](#)

The prescriber guide contains a checklist of actions, CYP2D6 genotyping assessment information and alert card.

- [Risk Minimisation Materials for alglucosidase alfa \(Myozyme\): Safety information packet for healthcare professionals](#)

Guidance on risks associated with treatment, risk management, and immunological testing.

- [Risk Minimisation Materials for Tyruko \(natalizumab biosimilar\)](#)

Guide on risk and nature of PML, risk minimisation steps and management along with alert card.

SPC changes or Manufacturer RMM

- [Revised SPC: Trileptal \(oxcarbazepine\) 150 mg Film-coated tablets](#)

Section 4.6 -potential for congenital abnormalities in the offspring of women treated with combination therapies is greater than those receiving monotherapy.

- [Revised SPC: Oxypro \(oxycodone\) prolonged-release tablets \(all strengths\)](#)

“Sphincter of Oddi dysfunction” (SoO) added as an adverse effect (frequency not known). This can raise intrabiliary pressure & increase risk of pancreatitis; use with caution in patients with pancreatitis/ biliary tract disease.

- [Revised SPC: Scheriproct \(prednisolone/cinchocaine\) Ointment](#)

SPC notes epidemiological studies suggest possible increased risk of oral clefts in newborns of women treated with glucocorticoids (GCs) during 1st trimester.

- [Revised SPC: Xgeva \(denosumab\) 120 mg solution for injection](#)

SPC updated to highlight that this is a single use vial.

- [Revised SPC: Spravato \(esketamine hydrochloride\) 28mg nasal spray solution](#)

Respiratory depression listed as rare & transient adverse effect that may occur at high doses after rapid injection when used for anaesthesia. Spravato should only be used in patients with clinically significant cardiovascular or respiratory conditions if benefit outweighs risk.

- [Revised SPC: Truvada \(tenofovir disoproxil fumarate, emtricitabine\) film-coated tablets](#)

Decreased bone mineral density added as a common adverse reaction, and updated warning/precaution on bone effects.

Drug shortages and discontinuations

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

[Fiasp FlexTouch](#)

[Salbutamol 2.5mg/2.5ml nebulas](#)

[Discontinuation of Hydrogen Peroxide 3%, 6% and 9% solution](#)

[Pamidronate disodium 30mg/10ml and 90mg/10ml solution for infusion vials](#)

[Lamotrigine tablets \(Accord-UK Ltd\)](#)

[Medroxyprogesterone 200mg tablets](#)

[Semaglutide \(Ozempic\) solution for injections](#)

[Prochlorperazine 12.5mg/1ml solution for injection ampoules](#)

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

Specialist Pharmacy Service



Resources

- [Ensuring time critical use of rasburicase](#)
- Breastfeeding pages- [GI antispasmodics](#), [treating insomnia](#), [treating heartburn and dyspepsia](#), [treating rectal and anal disorders](#), [impetigo](#), [macrolides](#)
- Eculizumab biosimilar- [preparing to use](#), [good governance](#), [license and supporting evidence](#)
- Tocilizumab biosimilar- [preparing to use](#), [good governance](#), [license and supporting evidence](#)
- [Occupational health services \(OHS\) and medicines mechanisms](#)

Webinars

- [Supporting pharmacists with HRT decision making](#)
- [Primary care discussions: HRT use in clinical practice](#)

National guidance, publications and resources

- [Hypertension Case-Finding Service: publicity campaign launches 11th March](#)

DHSC launched a public campaign to encourage those aged ≥ 40 years to get a free blood pressure check at the nearest participating pharmacy.

- [The challenges and potential of intermediate care](#)

Article discusses what intermediate care is, different types, pathways, two key pressures & whether it can help acute services.

- [Fourteen nitazenes made Class A controlled drugs](#)

New synthetic opioids classified as Class A drugs to prevent drug related deaths in the UK.

- [NIHR Commentaries: Mental health support in schools is well-received but challenges remain](#)

Expert commentaries are provided on research evaluating the roll out of the first wave of the Children and Young People's Mental Health Implementation programme, and how it can be improved.

- [HSSIB Investigation report: Temporary staff – involvement in patient safety investigations](#)

During analysis of 30 serious incident investigation reports, there were 18 cases between May 2022 & May 2023 where locum, bank or agency staff involved in an incident were then not involved in subsequent investigation, which may 'undermine' its ability to improve patient safety.

National guidance, publications and resources

- [Marketing campaign launches to drive up childhood vaccinations](#)

UKHSA has launched a campaign across England to remind parents/ carers of risks of missing vaccines and an urgent call to action to catch up on missed vaccinations.

- [Whooping cough infections rise in England](#)

There has been a continued increase in pertussis cases at the start of this year, with 553 confirmed in Jan vs 858 cases for 2023.

- [How to reduce antibiotic use in primary care](#)

The research presented at the NIHR Evidence webinar provides evidence that antibiotic prescribing may be reduced safely. It also highlights groups of people who are at greater risk and for whom antibiotics may still be preferred.

- [UKHSA surveys healthcare workers about antibiotic use and resistance](#)

The aim of the survey is to gain a better understanding of knowledge and perceptions to provide a base to support future needs in terms of policy and education changes, and to fill in gaps in the evaluation of communication campaigns and resources for healthcare professionals.

- [The antimicrobial potential of bacteriophages report: government response](#)

The committee's report highlights the threat of antimicrobial resistance and proposes that phages have the potential to play a vital role in responding to it.

National guidance, publications and resources

- [What do virtual wards look like in England?](#)

Virtual wards have the potential to improve outcomes for patients & health care systems, but high quality data are needed to know if this is the case.

- [Mounjaro \(tirzepatide\) prescribing issues](#)

Community Pharmacy England had advised KwikPen (KP) cannot be dispensed against prescription for auto-injector pen (AIP); reports of scripts being handwritten.

- [Policy guidance: conditions for which over the counter items should not be routinely prescribed in primary care](#)

Provides recommendations for items available over the counter that should not be prescribed in primary care.

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

Guidance on best practice in initiation, monitoring, review, tapering and stopping of antipsychotics when prescribed for people with dementia who express distress.

Prevention of Future Death Reports (Regulation 28)



Courts and Tribunals Judiciary

- [Ref: 2024-0120](#) methadone and benzodiazepine intoxication (6th March)

Inaccurate Clinical Opiate Withdrawal Scale score assigned led to an increase in methadone prescription.

Encouraged to look for physical signs of withdrawal rather than relying only on patients to share symptoms.

- [Ref: 2024-0123](#) Fluoxetine, dihydrocodeine and cocaine ingestion (14th March)

Lack of clear communication including lack of restricted medicine discharge supply with support worker and between the medical team/primary care.

Use of abbreviations which were not well understood by the medical team.

- [Ref: 2024-0137](#) Pain relief given by paramedics (19th March)

Morphine given to a patient involved in a collision. Availability of analgesics for paramedics to give for immediate pain relief due to barriers such as legislation was raised.

Primary research- Medication Safety

- [Look-alike medications in the perioperative setting: scoping review of medication incidents and risk reduction interventions.](#)

This scoping review aimed to identify and explore the issues related to look-alike medication incidents in the perioperative setting and the reported risk reduction interventions.

International Journal of Clinical Pharmacy

- [Exploring the Role of Guidelines in Contributing to Medication Errors: A Descriptive Analysis of National Patient Safety Incident Data](#)

Difficulties finding and using information from clinical guidelines contribute to thousands of prescribing and medication administration incidents, some of which are associated with substantial patient harm.

Drug Safety

- [The Limits of Clinician Vigilance as an AI Safety Bulwark](#)

This Viewpoint examines the potential problems of clinician reliance on the use of artificial intelligence (AI) in health care and offers suggestions on how AI could be designed to promote clinician vigilance.

Journal of the American Medical Association

- [Special report: has the online pharmacy bubble burst?](#)

Distance-selling pharmacies are contractually obligated to provide services & deliver prescriptions anywhere in England, but investigation in 2023 found 72% were breaching their NHS contracts by only operating in small geographical areas, putting local contractors under pressure.

Pharmaceutical Journal

Primary research- Medication Safety

- [Establishing a research agenda for the study and assessment of opioid withdrawal](#)

Article summarises substantial gaps in understanding of opioid withdrawal that are likely to continue to limit major advancements in its treatment.

Lancet Psychiatry

- [Patient perspectives on primary care providers role in long-term opioid therapy](#)

Small Dutch study (n=25) highlights the need for risk counselling during initial opioid prescriptions, ongoing medication evaluations including tapering conversations, and more support from their healthcare professionals during a tapering attempt.

British Journal of General Practice

- [Identification of enteral nutrition errors in a single-center quality-improvement audit](#)

A 15.9% error rate in EN order execution/documentation and 14% compliance with documentation of 48-h hang time was found. Several areas of opportunity to improve current EN use process identified.

Nutrition in Clinical Practice

Primary research- Medication Safety

- [A medication reconciliation failure: A case report and incident analysis](#)

This case report discusses a therapeutic duplication in DOAC use for a 90 year old lady.

International Journal of Risk & Safety in Medicine

- [Dabigatran-related serious medication errors: an analysis using data from VigiBase](#)

Serious medication errors related to dabigatran mainly occurred during prescription and administration.

European Journal of Clinical Pharmacology

- [Standardised direct oral anticoagulants prescription for treatment of acute venous thromboembolism in the emergency department: A quality improvement initiative](#)

Implementation of standardised DOAC prescriptions improved medication appropriateness and reduced inappropriate prescriptions.

Thrombosis Research