SPS Medication Safety Update
April 2024
Recent critical patient safety alerts, reports, and publications

Presented by

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Medicines & Healthcare products Regulatory Agency

Specialist Pharmacy Service

NHS England

Patient Safety Alerts

National Patient Safety Alert

National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload

- Transfusion-associated circulatory overload (TACO) is one of the **most common causes of transfusion-related deaths in the UK** and cases have increased substantially in recent years.

- This alert contains further information and action for providers to reduce risks for patients.

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Pharmacovigilance Risk Assessment Committee (PRAC)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRAC concludes available evidence does not support causal links between GLP-1RAs (dulaglutide, exenatide, liraglutide, lixisenatide and semaglutide) and suicidal and self-injurious thoughts and actions

After reviewing available evidence from non-clinical studies, clinical trials, post-marketing surveillance data and available studies, PRAC considers that no update to product information is warranted. Marketing authorisation holders will continue to monitor these events closely.

New safety information for healthcare professionals: advice to CHMP on new Rybelsus tablets (oral semaglutide)

In the context of an ongoing application (line extension) to introduce new strengths of Rybelsus tablets, PRAC agreed on content of proposed direct healthcare professional communication & communication plan explaining differences between current and newly proposed formulations.

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Direct HCP communication

Paxlovid DHCP_PSUSA-10984-202306

Paxlovid (nirmatrelvir; ritonavir): reminder of life-threatening and fatal drug-drug interactions with certain immunosuppressants, including tacrolimus

Refixia® ▼ 3000 IU powder and solvent for solution for injection (nonacog beta pegol): Carton printing error

There has been a printing error on the carton for Refixia 3000® IU powder and solvent for solution for injection (nonacog beta pegol) due to missing text.

Ebglyss ▼ 250 mg solution for injection in pre-filled pen and prefilled syringe (lebrikizumab): Interim Supply of Great Britain Stock to Mitigate Supply Disruption

Almirall Limited ensuring supply of Ebglyss 250 mg solution for injection in pre-filled pen and prefilled syringe (lebrikizumab) to Northern Ireland

Pseudoephedrine – Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Drug shortages and discontinuations

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

Isosorbide mononitrate (Monomil® XL) 60mg modified-release tablets

Pabrinex® (Vitamins B and C) Intravenous and Intramuscular High Potency solution for injection

Adoport (tacrolimus) 0.75mg hard capsules

Diazepam 10mg/2.5ml rectal solution tubes

Insulatard® InnoLet® (insulin isophane human) 100units/ml suspension for injection 3ml pre-filled disposable devices

Levemir InnoLet® (insulin detemir) 100units/ml solution for injection 3ml pre-filled disposable devices

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

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[Understanding complementary medicines]

This resource discusses points to consider when advising on the use of complementary medicines. It covers definition, NHS prescribing, safety, licensing and registration, food supplements, homeopathy, Chinese, Ayurvedic & herbal medicines, and their regulation.

[Calculating kidney function]

This resource explains the different methods for calculating renal function and their limitations. It has been updated to include information about which weight to use when calculating CrCl using the Cockcroft-Gault formula and how to convert from eGFR to actual GFR.

[How to perform preparation risk assessments for ATMPs]

Two preparation risk assessment templates have been developed for cell and tissue-based advanced therapy medicinal products (ATMPs) and in-vivo gene therapies.

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SPS Webinars:

- Temperature controlled storage of medicines
  An SPS Quality Assurance (QA) bite size learning event on controlling the temperature of medicines in storage.

- Primary care discussions: HRT use in clinical practice
  This ‘on the couch’ webinar, the second in a series of two, will be addressing questions around the challenges faced by pharmacists with HRT decision making.

- What’s new in PGDs and medicines mechanisms: an update
  An update session for those managing and using PGDs and other medicine mechanisms in practice

Visit the SPS website to watch back past webinar events

National guidance, publications and resources

Expert Panel: Evaluation of the Government's progress on meeting patient safety recommendations

This report warns that government action to improve patient safety 'requires improvement'. The report highlights shortcomings across three policy areas—maternity care and leadership, training of health & social care staff, and safety culture and whistleblowing.

Measles guidance for primary, community care, emergency departments and hospital

Guidance on diagnosis, assessment and management, includes in the appendices, a summary flow chart and details on prescribing and supply of immunoglobulin for measles post-exposure prophylaxis following risk assessment.

National measles guidelines - update to measles post exposure prophylaxis section

Guidance states it is reasonable to use available SC human normal immunoglobulins by IM route (off-label). Only Cuvitru has contraindication to IM use; if only this is available, SC may be suitable but action may be delayed, so if clinically urgent, IM may have to be considered.

Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management – guidance (NG240)

Guideline covers recognising, diagnosing and managing bacterial meningitis and meningococcal disease in babies, children, young people and adults. It aims to reduce death and disability by helping healthcare professionals recognise meningitis and treat it quickly and effectively.

NICE Guidance: Desflurane decommissioning and clinical use

This guidance describes the context of the national decommissioning of desflurane (due to higher global warming potential than alternatives). It provides clarity to the NHS regarding the limited, permitted use of desflurane from 1 April 2024 onwards

Prevention of Future Death Reports (Regulation 28)

Courts and Tribunals Judiciary

Ref: 2024-0161 – Safeguarding documentation (25th March)

- A safeguarding report submitted by NHS district nurses was insufficiently detailed to reflect the concerns that had developed regarding the deceased. The content of the safeguarding report did not trigger the threshold to investigate the matter further.

Ref: 2024-0185 – Inadequate handover (15th April)

- At times of high pressure and business, the staffing levels were insufficient. There are inexperienced nurses trying to manage a very high workload, without senior nurse support to try and increase staffing levels on a shift.
- Handovers and key conversations between staff, both nursing and medical staff, in ED and with Paediatric staff are not routinely documented, and outcomes from handovers and escalations do not result in clear action plans and allocated tasks.

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Primary research- Medication Safety

Differences in prescribing errors between electronic prescribing and traditional prescribing among medical students: A randomized pilot study

Study in Netherlands (n=84) found medical students assessed in an e-prescribing system were more likely to make errors related to the prescribed amount (71.4% v 19%), whereas those assessed using traditional prescribing were more likely to make administrative errors (19% v 2.4%).

Ombudsman partially upheld complaint against NHS Trust for not warning patient about potential extreme side effects of taking steroids

The 61 year old patient prescribed prednisolone after vision loss in one eye and infection in other eye soon began experiencing disrupted sleep and severe headaches which then developed into more serious side effects, including aggression and psychosis, lasting for weeks.

Recent regulator and statutory body activity

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- MHRA approves combined antibiotic cefepime/enmetazobactam (Exblifep 2g/0.5 g powder for concentrate for solution for infusion)

This 4th-generation cephalosporin+extended spectrum beta-lactamase inhibitor is licensed for treatment of complicated UTIs including pyelonephritis, hospital-acquired pneumonia, including ventilator associated pneumonia & treatment of bacteraemia associated with these conditions.

- MHRA approves clinical trial of camizestrant in early breast cancer patients on endocrine-based therapy

This phase III open-label study is aiming to enrol 5500 patients worldwide to assess if this oral selective oestrogen receptor degrader can improve survival outcomes compared to standard adjuvant endocrine-based therapy for patients who are ER-positive and HER2-negative.

- MHRA approves combined antibiotic cefepime/enmetazobactam (Exblifep 2g/0.5 g powder for concentrate for solution for infusion)

This 4th-generation cephalosporin+extended spectrum beta-lactamase inhibitor is licensed for treatment of complicated UTIs including pyelonephritis, hospital-acquired pneumonia, including ventilator associated pneumonia & treatment of bacteraemia associated with these conditions.

- MHRA approves two generic liraglutide formulations

Liraglutide Zentiva (Zegluxen), equivalent to Victoza, is indicated for the treatment of type II diabetes. Nevolat, equivalent to Saxenda, is indicated for weight management. Zentiva is waiting for the expiration of a patent in November 2024 before NHS launch.

Recent regulator and statutory body activity

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[Class 3 Medicines Recall: Accord-UK Ltd, Co-Codamol 8/500mg Effervescent Tablets (Key Pharmaceuticals Livery), EL (24)A/12]
Accord-UK Ltd is recalling a specific batch of Co-Codamol 8/500mg Effervescent Tablets (Key Pharmaceuticals Livery) as a precautionary measure due to the internal tablet blister strips being printed with an incorrect expiry date.

[Class 3 Medicines Recall: Bristol-Myers Squibb Pharmaceuticals Limited, OPDIVO 10 mg/mL concentrate for solution for infusion (nivolumab), EL(24)A/11]
Bristol-Myers Squibb Pharmaceuticals Limited has informed the MHRA that a potential product quality issue has been detected, relating to incomplete crimping of the metal crimp cap of OPDIVO 10mg/mL concentrate for solution for infusion (nivolumab) (1VLX10ML).

[Manufacturer Recall: 0.9% Sodium Chloride Solutions for Irrigation, Inhalation, and Eyewash: recall from manufacturer Legency Remedies, DSI/2024/004]

Batches of Legency Remedies Pvt Ltd irrigation, inhalation and eye wash saline products manufactured between April and November 2023 are being recalled due to potential microbiological contamination.

[Counterfeits and unbranded copies of LifeVac anti-choking devices may fail to work correctly or worsen choking incidents if used, DSI/2024/003]

SPC changes or Manufacturer RMM

Revised SPC: Mavenclad (cladribine) 10 mg tablets
SPC updated to reflect broadening of the therapeutic indication to include treatment of relapsing forms of multiple sclerosis (previously only for highly active multiple sclerosis).

Educational Risk Minimisation Materials to help reduce the risk associated with using Farydak (Panobinostat) 10mg hard capsules
Farydak patient cards for cycles 1-8 and 9-16 are intended to help patients keep track of their treatment regimen and maintain compliance

Risk Minimisation Materials for Tyruko (natalizumab biosimilar)
Physician's guidelines discuss the risk and nature of PML, risk factors for its development, its diagnosis and treatment, specific steps to be taken to minimise this risk and the identification and management of possible sequelae. A patient alert card is also available.

Revised SPC: Lioresal (baclofen) liquid
SPC updated to add warning and precaution of hypertonia as a symptom of withdrawal/abrupt discontinuation. Undesirable effects added: face swelling and peripheral oedema, alopecia, hypersensitivity, and sexual dysfunction (frequency not known).

Revised SPC: Questran and Questran Light (colestyramine) 4g/sachet Powder for Oral Suspension
Information added on concomitant use with a statin, avoiding use in patients with exudative/bloody diarrhoea, timing of administration in relation to absorption of other drugs, risk of constipation or its aggravation, and drug interactions with digoxin and spironolactone.

Revised SPC: Neupogen (filgrastim) solution for injection- all strengths
Extramedullary haematopoeisis added to SPC as adverse drug reaction of rare frequency

Revised SPC: Equasym (methylphenidate) XL Capsules- all strengths
Contusion added to SPC as adverse drug reaction of unknown frequency

Revised SPC: Elvanse Adult (lisdexamfetamine) capsules
Epistaxis has been added as a potential adverse effect of treatment of uncommon frequency

SPC changes or Manufacturer RMM

Revised SPC: Quinoric (hydroxychloroquine sulfate) 200mg Film-Coated Tablets
SPC updated to note physicians should assess benefits/risk of continuing treatment in those with significant liver function abnormalities, and a heading for azithromycin and macrolide antibiotics has been added to the interactions section.

Revised SPC: Dalacin (clindamycin) capsules
SPC now states that the risk of the known possible adverse effect of oesophagitis and oesophageal ulcer is increased if taken in a lying position and/or with a small amount of water.

Revised SPC: Matrifen (fentanyl) transdermal patches
Dysphagia has been added as an uncommon potential adverse effect of treatment

Revised SPC: Nortriptyline tablets
SPC notes unmasking of Brugada syndrome has been reported with nortriptyline. Nortriptyline should generally be avoided in patients with, or suspected of having Brugada syndrome. Risk factors for Brugada syndrome include a family history of cardiac arrest or sudden death.

Revised SPC: DuoResp Spiromax (budesonide, formoterol) 320 micrograms/9 micrograms inhalation powder
This is now also licensed for use as a reliever therapy for adults and adolescents (12 years and older) with mild asthma. The shelf-life after first opening has been extended from 6 months to 12 months.

Revised SPC: Omeprazole 10 mg oral solution (Glenmark Pharmaceuticals)
The SPC has been updated with the new indication of the treatment of Zollinger-Ellison syndrome

Revised SPC: Bonviva (ibandronic acid) tablets
Atypical fractures of long bones other than the femur has been added as a potential adverse effect of treatment (frequency unknown). These fractures occur after minimal, or no trauma and some patients experience prodromal pain prior to presenting with a completed fracture.