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

Presented by

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NHS England

NHS England

National Patient Safety Alert

Discontinuation of Kay-Cee-L ® (potassium chloride 375mg/5ml) (potassium chloride 5mmol/5ml) syrup

21st October 2024

Kay-Cee-L ® (potassium chloride 5mmol/5ml) syrup will be discontinued from late November 2024 due to manufacturing and commercial issues.

- Sando-K ® (potassium bicarbonate 400mg and potassium chloride 600mg) effervescent tablets remain available and can support a full increase in demand. One effervescent tablet contains 12mmol potassium.
- Unlicensed potassium chloride oral solutions manufactured within the UK are available via Specials manufacturers, lead times vary.
    - Part-dosing of Sando-K® effervescent tablets is not routinely recommended but can be done if unlicensed specials are not available.

Patient Safety Alerts

NHS England

National Patient Safety Alert

Shortage of Molybdenum-99/Technetium99m generators

25th October 2024

There are limited supplies of Molybdenum-99 used to manufacture Technetium-99m generators until mid-November 2024. Technetium-99m is used in diagnostic imaging and procedures, and during some surgeries.

NHS provider trusts with a radiopharmacy unit must:

- continue to review patient appointment lists to prioritise urgent patients and postpone less urgent patients.
- work with your British Nuclear Medicine Society (BNMS) nominated regional radiopharmacy lead to participate in local mutual aid arrangements being led by BNMS and UK Radiopharmacy Group (UKRG)
- ensure arrangements are in place for patients who may require emergency scans in and out of hours
- escalate issues to regional teams as needed to ensure timely resolution of problems
- maintain records of delayed activity and rearranged appointments

Further information can be found on the SPS website

Recent regulator and statutory body activity

Medicines & Healthcare products Regulatory Agency

GLP-1 receptor agonists: reminder of the potential side effects and to be aware of the potential for misuse
Healthcare professionals are reminded to inform patients about the common and serious side effects associated with glucagon-like peptide-1 receptor agonists (GLP-1RAs).

Insulin pumps and continuous glucose monitoring (CGM) equipment: guidance for users on reporting suspected adverse incidents and safety concerns to the MHRA's Yellow Card scheme
Healthcare professionals are to support new guidance for users of diabetes management equipment, their families, care givers and representatives.

Bromocriptine: monitor blood pressure when prescribing bromocriptine for prevention or inhibition of post-partum physiological lactation
A safety review has been conducted by the MHRA following a Yellow Card report concerning a patient who was taking bromocriptine. The review concluded that blood pressure monitoring of patients prescribed with this drug is essential especially during the first days of treatment.

#MedSafetyWeek 2024 (4-10 November)
This year will be the ninth annual #MedSafetyWeek social media campaign and it will take place on 4 to 10 November 2024. The theme will be 'the importance of using medicines in the right way to prevent side effects, and to report side effects when they do occur'.

NHS primary care patient safety strategy
This strategy outlines the primary care implementation of the NHS Patient Safety Strategy, and is for all areas of primary care, though with some improvements implemented first in general practice to enable the successes and learning to be used in the rollout to community pharmacy, optometry and dental services.

Medicines & Healthcare products Regulatory Agency
Specialist Pharmacy Service
NHS England

Recent regulator and statutory body activity

Medicines & Healthcare products Regulatory Agency

Class 2 Medicines Recalls

Pfizer Limited, Oxbryta 500mg Tablets (voxelotor), EL(24)A/44

Pfizer Limited is recalling all distributed batches of Oxbryta 500 mg Tablets. Pfizer Limited has informed the MHRA that the product is being withdrawn due to emerging data from clinical trials and registry-based studies.

Bristol Laboratories Ltd, Phenobarbital Bristol Labs 15mg Tablets, EL(24)A/50

Bristol Laboratories Ltd. are recalling one batch of Phenobarbital Bristol Labs 15mg Tablets as a precautionary measure due to the potential of contamination of small metallic particles within the tablets.

Class 3 Medicines Recalls

Glenmark Pharmaceuticals Europe Ltd Cyanocobalamin 50 mcg Tablets, EL(24)A/46

Glenmark Pharmaceuticals Europe Ltd is recalling the affected batches as a precautionary measure due to out of specification results for unknown impurities during routine stability testing and additional re-testing.

Viatris UK Healthcare Ltd, Trandolapril 2mg and 4mg capsules, EL(24)A/47

Generics (UK) Ltd T/A Mylan UK is recalling specific batches of trandolapril after re-testing showed out of specification results.

Class 4 Medicines Defect Information

Sandoz Ltd., Risperidone 1mg, 2mg, 3mg Tablets, EL(24)A/43

Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Risperidone 1mg, 2mg and 3mg and Tablets.

Sandoz Ltd., Rosuvastatin 20mg, 40mg Tablets, EL(24)A/45

Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Rosuvastatin 20mg and 40mg Tablets.

Sandoz Ltd., Linezolid 600 mg film-coated tablets, EL(24)A/48

Sandoz Ltd. has informed the MHRA that there is missing safety information in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) for Linezolid 600 mg film-coated tablets.

Kent Pharma UK, Paracetamol 500mg Effervescent Tablets, EL(24)A/49

Kent Pharma UK has identified an error in the Patient Information Leaflet (PIL) for Paracetamol 500mg Effervescent Tablets.

Pharmacovigilance Risk Assessment Committee (PRAC)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Review of medicines containing finasteride and dutasteride started

The European PRAC will assess all available data linking finasteride and dutasteride to suicidal ideation and behaviours, and evaluate the impact of this on the benefit-risk balance of these medicines.

New safety information for healthcare professionals: risk of medication errors due to change of dosing syringe for Keppra and Levetiracetam UCB oral solution

The European PRAC discussed a direct healthcare professional communication that will advise of the risk of medication errors due to a change to the dosing syringe including in the product packaging for children aged 6 months to 4 years, from a 3mL to a 5mL syringe.

Direct HCP communication

In September 2024, the following letters were sent or provided to relevant healthcare professionals:

- Oxbryta (voxelotor): Withdrawal from UK market
- BLENREP▼ (Belantamab mafodotin): Revocation of the Great Britain conditional Marketing Authorisation for BLENREP (belantamab mafodotin)
- Valproate - containing medicines▼: new measures regarding the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception
- Tyenne 162 mg solution for injection in pre-filled pen (PFS) - PLGB 08828/0357: Temporary Supply of German labelled stock
- NOXAFIL® (posaconazole) new Gastro-Resistant Powder and Solvent for Oral Suspension not interchangeable with existing Oral Suspension including generics.
- Fresenius Kabi compounded parenteral nutrition products: use of Inline filters during administration now required
- Creon® Micro Pancreatin 60.12mg Gastro-resistant Granules: Interim Supply of Spanish Stock to Mitigate Supply Disruption

SPC changes

Revised SPCs: All preparations of Ozempic (semaglutide), Rybelsus (semaglutide), Wegovy (semaglutide), Mounjaro (tirzepatide) & Trulicity (dulaglutide)

Updated with warning pulmonary aspiration reported in patients on GLP-1 RAs undergoing general anaesthesia (GA)/deep sedation (DS). Increased risk of residual gastric content due to delayed gastric emptying should thus be considered prior to performing procedures with GA/DS.

Revised SPCs: Crestor (rosuvastatin) – all formulations

Information on genetic polymorphisms has been updated. Genotypes of SLCO1B1 (OATP1B1) c.521CC & ABCG2 (BCRP) c.421AA have been associated with increased rosuvastatin exposure. For those with the c.521CC or c.421AA genotype, half the usual dose (& max 20mg daily) is recommended.

Revised SPC: Gardasil 9 (human papillomavirus 9-valent vaccine) suspension for injection

SPC updated to include 'Injection site nodule' as a possible adverse effect.

Revised SPC: MenQuadfi (meningococcal Group A, C, W135 and Y conjugate vaccine) solution for injection

Anaphylaxis (very rare) and hypersensitivity (frequency unknown) have been added as potential adverse effects of treatment.

Revised SPC: Siklos (hydroxycarbamide) 100 mg film-coated tablets

SPC updated to note that hydroxycarbamide may interfere with certain continuous glucose monitoring (CGM) sensors resulting in falsely high CGM sensor glucose readings (compared to actual blood glucose readings).

Revised SPC: Copaxone (glatiramer) 20 mg/ml solution for injection in pre-filled syringe

Updated to warn anaphylactic reactions may occur shortly following administration of glatiramer, even months up to years after initiation of treatment. Fatalities have been reported. Some signs and symptoms of anaphylactic reactions may overlap with post-injection reactions.

Manufacturer RMM

RMM – Lorgys (pegzilarginase)

RMM – Zilbrysq (zilucoplam sodium)

RMM - Piasky (crovalimab)

RMM - Upstaza (eladocagene exuparvovec)

RMM – Leqembi (lecanemab)

RMM – Myozyme (alglucosidase alfa)

Drug shortages and discontinuations

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

Discontinuation of NovoRapid (insulin aspart) FlexTouch100units/ml solution for injection 3ml pre-filled pens

Clinicians should pro-actively review all patients currently prescribed NovoRapid FlexTouch pens and consider switching them to another NovoRapid delivery device, taking into account manual dexterity, vision, ability to use new device correctly, and whether additional support is required for administration.

NovoRapid FlexPens (pre-filled pens) and Penfill (cartridges) remain available.

Shortage of Cisatracurium besilate 150mg/30ml solution for injection ampoules

NHS providers trust pharmacy procurement teams should work with appropriate clinical leads and their local Medication Safety Officer (MSO) to:

- review local stock holding of cisatracurium besilate 150mg/30ml solution for injection;
- plan a switch from cisatracurium besilate to alternative NMBA, in line with the likely stock depletion date, in consultation with the lead anaesthetist(s) and other relevant specialists (see Supporting Information);
- ensure prescribing systems and relevant guidelines and protocols are updated to reflect any switches; and
- ensure all impacted clinical areas are made aware of this issue

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

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New: Managing medicines for people with sulfonamide allergy

Points to consider when prescribing and supplying medicines to people with sulfonamide allergy.

New: Managing the risk of confusion between intravenous penicillin salts

Safety concerns related to the risk of confusion between salts of benzylpenicillin are system wide and have potential to affect any patient in a care setting where any of the salts are used. Resource covers patient harm, high risk scenarios, administration, risks, and mitigation.

New: Safe management of therapeutic drug monitoring

Organisations must ensure safe management systems are in place to support the management of drugs requiring therapeutic drug monitoring.

New: Understanding when a check adds value to medication processes

The aim of this article is to help with understanding when checks add value to medication processes. It covers what a check is, the principles of an effective check and factors to consider if introducing an independent second check to a medication process.

New: Pharmacy First Podcast Series

Pharmacy colleagues and expert clinicians talk about issues surrounding the new service in community pharmacy and try to debunk some of the clinical myths.

Update: Using mesalazine tablets appropriately

An overview of differences between mesalazine tablet preparations and clinical considerations when switching between preparations.

National guidance, publications and resources

Food Standards Agency: Food supplements containing caffeine

Guidance produced following a death in 2021

Royal Pharmaceutical Society & Royal College of General Practitioners: Repeat Prescribing Toolkit

The toolkit was commissioned by NHS England and is a recommendation from the 2021 National Overprescribing Review. It aims to improve patient care, addressing inconsistencies and potential oversupply, whilst reducing unnecessary medicines waste, saving NHS resources.

UK Health Security Agency: Interventions to reduce harms for people who inject drugs in prisons

Rapid review included 16 studies, and identifies and summarises evidence for the effectiveness of interventions to reduce infection-related harms for people who inject drugs in prisons and places of detention. Options include opioid substitution treatment and education programmes

ONS: Deaths related to drug poisoning in England and Wales: 2023 registrations

Deaths related to drug poisoning in England and Wales from 1993 to 2023, by cause of death, sex, age and substances involved in the death.

Prevention of Future Death Reports (Regulation 28)

Courts and Tribunals Judiciary

Ref: 2024-0552 - Accidental ingestion of hypoglycaemic medication

- Hyponatraemia led to a death following accidental ingestion of hypoglycaemic medication.
- Had taken husbands medicines from his dosette box instead of hers. Both patients were elderly and had cognitive impairment. Dosette boxes were identical to each other except for a small pharmacist's label with small type with the relevant patient's name.

Ref: 2024-0558 – Zomorph and pregabalin prescribed to a previous opioid addict

- High and fatal level of his prescribed zomorph and pregabalin.
- Previously had been addicted to heroin and remained opioid free for many years. Started on opioids in primary care for pain. Report states there needs to be a very well thought out rationale with careful monitoring to avoid increasing the chances of a patient relapsing into addiction if prescribing opioids.

Primary research- Medication Safety

Mortality associated with clozapine: what is the evidence?

Article suggests the relative risk of fatality with clozapine is overestimated, and overall, it lowers mortality partly by reducing schizophrenia-related suicides. It suggests clozapine should be used earlier and more widely, but with better monitoring and management of toxicity.

Source: British Journal of Psychiatry