SPS Medication Safety Update December 2024

Recent critical patient safety alerts, reports, and publications

Slides prepared by Zaid Ali – MA Pharmacist

The first stop for professional medicines advice

18/12/2024

Patient Safety Alerts

Shortage of Pancreatic enzyme replacement therapy – Additional actions

Issued 18th December 2024
Deadline 31st January 2025

There are limited supplies of pancreatic enzyme replacement therapies (PERT).
• Creon® 10,000 and 25,000 capsules remain in limited supply until 2026.
• Nutrizym® 22 capsules and Pancrex V® capsules and powder are intermittently available but are unable to fully cover the gap in supply.

This National Patient Safety Alert provides further background, clinical information and actions for providers.
This alert contains **actions which are in addition** to those outlined in the National Patient Safety Alert (NatPSA/2024/007/DHSC) issued on 24th May 2024.

Recent regulator and statutory body activity

Class 2 Medicines Recall: Wockhardt UK Limited, WockAIR 160 microgram/4.5 microgram, inhalation powder, EL(24)A/62

Wockhardt UK Limited is recalling this batch as a precautionary measure following the identification of a low number of units which may have a defect in the 'top case' resulting in a dose not being able to be dispensed.

Class 3 Medicines Recall: Syri Limited, T/A SyriMed, Baclofen 10mg/5ml Oral Solution, EL(24)A/56

Syri Limited is recalling this batch of product as a precautionary measure due to crystallisation observed over time in the oral solution.

Class 3 Medicines Recall: Kent Pharma UK, Phenoxymethylpenicillin 250mg/5ml Oral Solution Sugar Free, EL (24)A/60

Kent Pharma UK is recalling a batch of phenoxymethylpenicillin 250mg/5mL oral solution sugar free due to a low phenoxymethylpenicillin assay.

Recent regulator and statutory body activity

Class 4 Medicines Defect Information: Morningside Healthcare Limited, Tramadol Hydrochloride 50 mg capsules & Tramadol Hydrochloride Morningside 50 mg Prolonged-Release capsules, EL(24)A/57

Morningside Healthcare Limited has informed the MHRA of a packaging issue identified in batch MRA2303 of Tramadol Hydrochloride Morningside 50 mg Prolonged-Release Capsules and batch MRF2301 of Tramadol Hydrochloride 50 mg Capsules.

Class 4 Medicines Defect Information: Strides Pharma UK Ltd, Liothyronine Sodium 5 & 20 micrograms Tablets, EL(24)A/58

Strides Pharma UK Ltd has informed MHRA of an error in the patient information leaflet (PIL) for Liothyronine Sodium 20 micrograms Tablets and Liothyronine Sodium 5 micrograms Tablets.

Class 4 Medicines Defect Information: Rosemont Pharmaceuticals Limited, Mycophenolate Mofetil 1g/5ml Oral Suspension, EL(24)A/59

Rosemont Pharmaceuticals Limited has informed the MHRA that the Press-In-Bottle-Adaptor (PIBA) supplied with the batches listed above may cause the medicine to leak when attempting to withdraw a dose.

Class 4 Medicines Defect Information: Brillpharma Limited, Oxybutynin hydrochloride Brillpharma 2.5 mg/5 ml Oral Solution, EL(24)A/61

L M Manufacturing Limited has informed the MHRA that the patient information leaflet (PIL) in the cartons for the batch listed for Oxybutynin hydrochloride Brillpharma 2.5 mg/5 ml Oral Solution include an out of date PIL, dated July 2021.

Pharmacovigilance Risk Assessment Committee (PRAC)

Veoza (fezolinetant): new recommendations to minimise risk of liver injury

Veoza is a medicine used to treat moderate-to-severe vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause.

The PRAC has agreed to a direct healthcare professional communication (DHPC) informing of the risk of drug-induced liver injury (DILI) with Veoza (fezolinetant) and has recommended monitoring of liver function before and during treatment.

Severe elevations of the liver enzymes alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (>10x upper limit of normal) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP) have been reported post marketing in women taking Veoza. In some cases, elevated liver function tests (LFTs) were associated with signs or symptoms suggestive of liver injury such as fatigue, pruritus, jaundice, dark urine, decreased appetite, or abdominal pain.

Direct HCP communication

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

Welireg ▼ (belzutifan) Patient alert cards

- As agreed with the MHRA, a patient alert card should be provided to all UK patients prescribed Welireg to specifically provide guidance related to the risks of treatment associated hypoxia.

Movymia 20 micrograms/80 microliters solution for injection▼ (teriparatide): Interim Supply of French Stock to Mitigate Supply Disruption

- To ensure continuity in supply, STADA Arzneimittel AG has obtained approval from the MHRA to supply French product (batch number E35006AA; 3000 units) which are expected to be on the UK (Great Britain) market from November 2024 to December 2024.

IMVANEX suspension for injection Smallpox and mpox vaccine (Live Modified Vaccinia Virus Ankara) Modified Vaccinia Ankara – Bavarian Nordic Live virus no less than 5 x 107 Inf.U Interim Supply of EU Stock to Mitigate Supply Disruption

- To ensure continuity of supply, Bavarian Nordic A/S has obtained approval from the MHRA to supply EU Imvanex product (batch number FDP00624; batch size: 50,000 doses), which is expected to be on the UK market from 30-Nov-2024 to 28-Feb-2033 (when stored at -80°C).

Elrexfio®▼ (elranatamab) 40 mg/mL solution for injection (44 mg/1.1 mL vials): interim supply from France

- To ensure continuity in supply, Pfizer has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Elrexfio▼ (elranatamab) from France (FR) (batch number LE7652; batch size 200 vials), which is expected to be on the UK market from 16 December 2024 to 17 February 2025.

SPC changes

Revised SPC: Bimatoprost 0.3 mg/ml eye drops

SPC now advises before treatment started, patients should be informed of risk of prostaglandin analogue periorbitopathy (very common ADR), which can lead to deepening of eyelid sulcus, ptosis, enophthalmos, eyelid retraction, involution of dermatochalasis & inferior scleral show.

Revised SPC: Hydrea (hydroxycarbamide) 500 mg Hard Capsules

SPC updated to note that hydroxyurea may falsely elevate sensor glucose results from certain continuous glucose monitoring systems. This may lead to missed hypoglycaemic episodes and can also cause hypoglycaemia if sensor glucose results are relied upon to dose insulin.

Revised SPC: Tildiem (diltiazem) 60mg Modified-Release Tablets

SPC updated to note caution should be exercised when co-administering with DOACs, particularly in patients at high risk of bleeding, and to note diltiazem may also lead to increased colchicine exposure, and their combined use is not recommended.

Revised SPC: Alecensa (alectinib) 150 mg Hard Capsules

Update regarding duration for which female patients of child-bearing potential must use highly effective contraceptive methods after last dose of alectinib, from 3 months to 5 weeks, based on the latest guidelines on contraception requirements for drugs with aneugenic potential.

SPC changes

Revised SPC: Frumil 40 mg/5 mg (amiloride hydrochloride anhydrous, furosemide) tablets

SPC updated to note aliskiren reduces plasma concentration of oral furosemide. A reduced effect of furosemide might therefore be observed in patients treated with both concomitantly; the patient should be monitored for reduced diuretic effect and the dose adjusted accordingly.

Revised SPC: Strattera (atomoxetine) 4 mg/mL oral solution

Sections on ‘Serotonin syndrome’ and ‘Serotoninergic medications’ added, paediatric information added to section on ‘Aggressive behaviour, hostility or emotional lability’, and bruxism added as adverse effect of unknown frequency.

Revised SPC: Munuza (tobramycin) 300 mg/5 ml nebuliser solution

SPC updated to include increased risk of ototoxicity as a caution for use and to note that alternative treatments or genetic testing prior to administration should be considered in patients with a maternal history of relevant mutations or aminoglycoside induced deafness.

Revised SPC: Advagraf (tacrolimus) prolonged release capsules, all strengths

SPCs updated to include data associated with use during pregnancy or lactation from an interim analysis of an ongoing non-interventional post authorization safety study. Among kidney and liver transplant patients exposed to tacrolimus, 45% - 55% of their live births were premature.

SPC changes

Revised SPC: Elrexfio (elranatamab) 40 mg/mL solution for injection

SPC updated to include cytomegalovirus infection as a possible adverse effect (frequency common) and a warning and precaution for use relating to infections.

Revised SPC: Xifaxanta (rifaximin) 200 mg Film-coated Tablets

SPC updated to include a warning and precaution for use relating to severe skin infections. Summary of safety profile also updated.

Revised SPCs: Femoston-conti (dydrogesterone, estradiol hemihydrate) and Femoston (dydrogesterone, estradiol hemihydrate) film-coated tablets – all strengths

SPC contraindicates use in patients with (or history of) meningioma, a rare adverse effect. Monitoring for signs and symptoms is advised and if diagnosed with meningioma, estradiol/dydrogesterone treatments must be stopped as tumour shrinkage is observed after discontinuation.

Revised SPC: Lyrica (pregabalin) capsules

Updated SPC now states that patients treated with pregabalin should be monitored for signs and symptoms of pregabalin misuse, abuse or dependence, such as development of tolerance, dose escalation and drug-seeking behaviour.

Drug shortages and discontinuations

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

Specialist Pharmacy Service

Self-administration of medicines

- Self-administering medicines in all care settings and at home can benefit both individuals and organisations; it should be encouraged where safely achievable
- Page recently updated by expert working group to broaden scope to be setting agnostic.

Vitamin B12 deficiency: treatment during pregnancy

- Intramuscular hydroxocobalamin and oral cyanocobalamin are treatment options for the management of clinically relevant vitamin B12 deficiency during pregnancy.
- Page fully updated to reflect recommendations in NICE NG239.

Using dental antibiotic prophylaxis for hydrocephalus shunts

- Considerations for whether the risk of shunt infection from transient bacteraemia during invasive dental procedures warrants non-routine antibiotic prophylaxis.

National guidance, publications and resources

Medication not given: administration of time critical medication in the emergency department

- HSSIB investigation reports present findings from a patient safety event and identifies factors relevant to learning in other NHS organisations.

Folic acid supplementation: advice to health professionals from the UK chief medical officers, chief nursing officers and chief midwifery officers

- There is a risk that some women will stop taking folic acid supplementation following fortification of flour, incorrectly assuming that it is no longer required. To mitigate this, the chief medical officers, chief nursing officers and chief midwifery officers for the UK, are writing to health professionals to ask that they continue to promote the importance of folic acid supplementation directly to women of child-bearing age through existing communication channels, including face to face interactions.

National guidance, publications and resources

Vaccine safety and adverse events following immunisation: the green book, chapter 8

- Changes include new paragraphs defining anxiety related adverse events, new section on hypotonic-hyporesponsive episodes, extensive re-write of the anaphylaxis section, and changes to managing common vaccine-induced adverse events to include management of fever following Bexsero.

HRT vaginal cream now available without a prescription

- Ovesse is the first vaginal oestrogen cream to be available over the counter, for women with vaginal atrophy due to menopause. The manufacturer Aspen has produced a Pharmacy Guide and a Pharmacy Checklist to support pharmacists supplying Ovesse.

Prevention of Future Death Reports (Regulation 28)

Ref: 2024-0644 - Dependence and Overuse of benzodiazepines and codeine

- Death due to excess prescribed medication which the patient had become dependent on and addicted to. She had access to excess medication because of medical prescribing decisions and arrangements leading up to a bank holiday period.

Ref: 2024-0656: Overdose of prescribed medicine

- Death due to excess consumption of prescribed medication
- Duplication of a prescription occurred, due to the patient changing his choice of pharmacy, and effective steps were not taken to ensure cancellation of the initial prescription leading to the patient having double the intended quantity of medication.

Prevention of Future Death Reports (Regulation 28)

Ref: 2024-0651: Suicide as a result of a deterioration in mental health exacerbated by ineffective PRN medication

- Death by suicide following patient being unable to access PRN medication identified in personalised crisis plan.
- Lack of single point of contact or single decision maker regarding prescriptions contributed to the patient's mental heath deterioration.