

SPS/UKMi Observatory

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Observatory of recent safe medication
practice research, reports, and publications

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Recent regulator and statutory body activity



Improvement



No new national patient safety alerts

CAS Alert: Clinical Commissioning Rapid Policy Statement: Tecovirimat as treatment for patients hospitalised due to monkeypox virus infection.

Publication date: 20 September 2022

- Tecovirimat is now available to symptomatic patients hospitalised due to a severe or complicated monkeypox infection in line with the published UK interim clinical policy statement.
- Supply is being managed via specialist regional adult infectious diseases centres.
- Clinicians are actively encouraged to support recruitment of patients with laboratory confirmed monkeypox infection and with active skin or mucosal lesions, but who do not require hospital admission, to the PLATINUM trial.

Recent regulator and statutory body activity



Class 2 Medicines Recall: Hikma Pharmaceuticals USA Inc, Lorazepam 2mg/ml Injection, Lorazepam 4mg/ml Injection (unlicensed medicines)

- Hikma Pharmaceuticals USA Inc are recalling the below batches due to an out of specification result with related substances during testing for retain samples.
- Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Class 2 Medicines Recall: Novartis Pharmaceuticals UK, Sandimmun Oral Solution

- Novartis Pharmaceuticals UK are recalling a batch of Sandimmun Oral Solution due to the presence of crystals in the solution.
- Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Class 4 Medicines Defect Information: Quadrant Pharmaceuticals Limited, Bezalip Mono 400mg Tablets, EL (22)A/38

- The PIL included in some batches is an older version of the PIL, which does not include the most up to date safety information.

Class 4 Medicines Defect Information: Rosemont Pharmaceuticals Ltd, Atorvastatin 4mg/ml Oral Suspension & Sildenafil 10mg/ml Oral Suspension , EL (22)A/39

- Expiry dates stamped on the base of the bottle are incorrect for 2 batches of Atorvastatin Oral Suspension and 2 batches of Sildenafil Oral Suspension.

Urgent FSN: Tandem Diabetes Care: t:slim X2 Insulin Pump

- Potential risks for users of a t:slim X2 pump within its normal specifications.
- Under-delivery of insulin, which may result in hyperglycemia. In severe cases of hyperglycemia.
- Recommend patients to update their pump software to mitigate these risks

Recent regulator and statutory body activity



Drug Safety Update

No change to MHRA advice on the safety and effectiveness of COVID-19 vaccines for those who are pregnant or breastfeeding

Reassure the public that the COVID-19 vaccines are safe and effective during pregnancy and breastfeeding. This follows false claims on social media that advice has changed in this patient group.

Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations

Prescribers and dispensers should use caution if switching patients between different long-acting formulations of methylphenidate (Concerta XL, Medikinet XL, Equasym XL, Ritalin LA, and generics) as different instructions for use and different release profiles may affect symptom management.

Rucaparib (Rubraca ▼): withdrawal of third-line treatment indication

The third-line treatment indication for rucaparib has been withdrawn following a review of the findings of the ARIEL-4 trial, which showed lower overall survival for rucaparib treatment versus standard chemotherapy in patients with high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

Pharmacovigilance Risk Assessment Committee (PRAC)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New CHMP measures to minimise risk of meningioma with medicines containing nomegestrol or chlormadinone

- High-dose nomegestrol (3.75 – 5 mg) or high-dose chlormadinone (5 – 10 mg) should be used at the lowest effective dose and for the shortest duration possible.
- Patients should be monitored for symptoms of meningioma.
- UK: Zoely 2.5 mg/1.5 mg film-coated contraceptive tablets

PRAC review: topiramate and the risk of neurodevelopmental disorders in children whose mothers were taking topiramate during pregnancy.

PRAC review: pholcodine linked to anaphylactic reactions to neuromuscular blocking agents (NMBA).

- MHRA to review evidence linking cough medicine with anaphylaxis risk



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MHRA
Regulating Medicines and Medical Devices



Improvement

Direct HCP communication

No additional communications

Manufacturer RMM or SPC changes

Arthrotec 75 modified release tablets (diclofenac and misoprostol) The SPC has been updated to include hydrogenated castor oil as an excipient and to state that this substance may cause stomach upset and diarrhoea.

Pseudoephedrine (Galpseud) linctus Ischaemic optic neuropathy has been added to the list of undesirable effects in the SPC. Frequencies not known: cannot be estimated from the available data.

Zintasa (mesalazine) 400mg Tablets The SPC now notes Zintasa is contraindicated in children under the age of 2 years and there are no longer any dosage recommendations for children aged from 2-17 years.

Amfexa (dexamfetamine sulfate) Tablets – all strengths SPC updated in line with PRAC recommendations: amfetamines can cause a significant elevation in plasma corticosteroid levels; this increase is greatest in the evening & amfetamines may interfere with urinary steroid determinations.

Paludrine/Avloclor Anti-Malarial Travel Pack Chloroquine & Proguanil Anti-Malarial Tablets SPC updated with addition of warning of potential increased risk of CV events and CV mortality with use of chloroquine with macrolide antibiotics and hydroxychloroquine with azithromycin. Benefits/risks should be considering

Manufacturer RMM or SPC changes

Adoport (tacrolimus) Hard Capsules The SPC updated with reports of increased tacrolimus blood levels during concomitant use of tacrolimus with cannabidiol. This may be due to inhibition of intestinal P-glycoprotein, leading to increased bioavailability of tacrolimus. Tacrolimus and cannabidiol should be co-administered with caution, closely monitoring for side effects. Monitor tacrolimus whole blood trough concentrations and adjust the tacrolimus dose if needed

- **Cannabis – based medicinal products – potential drug interactions:** SPS interaction page on cannabis-based medicines are co-administered with any medications that are CYP inhibitors or inducers.

RMM: Amiodarone Patient Alert Card (Ennogen Pharma Ltd)

- Outlines key safety information for patients taking amiodarone including signs and symptoms of amiodarone-induced lung damage, liver damage, worsening cardiac arrhythmias and thyroid problems.

Drug shortages and discontinuations

Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Medicine	Out of stock	Alternatives
Disopyramide 150mg capsules (Viatris UK Healthcare Ltd)	<ul style="list-style-type: none"> Discontinued with immediate effect Identify all patients currently prescribed disopyramide 150mg capsules 	<ul style="list-style-type: none"> Disopyramide 100mg capsules (Neon) Disopyramide 250mg MR tablets (Neon)
Hydrocortisone sodium phosphate 100mg/1ml solution for injection ampoules	<ul style="list-style-type: none"> Very limited supply, stocks are likely to be exhausted in the coming months. Further stock is anticipated in mid-March 2023. 	<ul style="list-style-type: none"> Hydrocortisone sodium succinate 100mg powder for solution for injection/infusion (100mg x 1 pack with diluent and 100mg x 10 pack without diluent) See MSN for details.
Sanofi Rifinah® 300mg/150mg tablets.	Resupply expected w/c 12 September 2022.	<ul style="list-style-type: none"> Rifinah® 150mg/100mg tablets remain available but are unable to support any increase in demand. Rifampicin 300mg capsules and isoniazid 50mg and 100mg tablets remain available and can support a partial uplift in demand. Unlicensed imports of rifampicin and isoniazid 300mg/150mg tablets have been sourced. Lead times may vary.
Rifadin 100mg/5ml syrup (Sanofi)	Resupply expected 14 October 2022	<ul style="list-style-type: none"> Rifampicin 150mg and 300mg capsules remain available. Unlicensed Rifadin 100mg/5ml oral suspension available

Drug shortages and discontinuations

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Medicine	Out of stock	Alternatives
Temazepam 10mg and 20mg tablets	<ul style="list-style-type: none">Limited supply till 5th December 2022	<ul style="list-style-type: none">Temazepam 10mg/5ml solution cannot support uplift in demandSwitch to alternative at equivalent dose.Unlicensed imports
Pancuronium bromide 4mg/2ml solution for injection ampoules (Pfizer)	<ul style="list-style-type: none">DiscontinuedRemaining stock is due to expire at the end of September 2022.	<ul style="list-style-type: none">Alternative non-depolarising neuromuscular blocking agentsUnlicensed imports of pancuronium bromide 4mg/2ml solution for injection.

Specialist Pharmacy Services



Differences between metolazone preparations and safety considerations

In recent years metolazone has only been available in the UK as an unlicensed (imported) product, a licensed formulation is now available. Healthcare professionals need to be aware of the differences between licensed and unlicensed products to ensure safe care.

Safety considerations when using Vitamin D

The number of available products has resulted in variability of clinical guidance in recommended reference sources and clinical use. Healthcare professionals who should be aware of the risks of toxicity and safe practice principles which may prevent patient harm.

Understanding the characteristics of Comirnaty Bivalent vaccine

This webpage provides an overview of the Comirnaty Bivalent vaccine and signposts to other useful resources.

Specialist Pharmacy Services



Using intravenous paracetamol preparations safely in paediatrics

In response to concerns over the potential to administer overdoses of intravenous paracetamol in paediatrics SPS has published a resource describing the risks and suggested mitigation strategies.

National guidance, publications and resources

Patients switched to edoxaban without being properly informed

Pharmaceutical Journal. August 2022

Primary Care Cardiovascular Society, Primary Care Pharmacy Association and UK Clinical Pharmacy Association published guidance on implementing NHS England's DOAC commissioning recommendations.

HRT Taskforce presents recommendations to support future supply

DHSC 30 August 2022 Press release.

National protocol for Spikevax® bivalent Original/Omicron COVID-19 vaccine

To ensure continuity in supply, MHRA has agreed for initial batches to be supplied to market via a Batch Specific Variation. These batches will have different tradename (in particular, word 'Bivalent' is not included), and different carton & vial labels to licensed product.

National guidance, publications and resources

Folic acid to be added to non-wholemeal flour across the UK to help prevent life-threatening brain and spinal conditions in fetuses.

1 Sep 2022 – 23 Nov 2022

Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 - Defra - Citizen Space

At home early medical abortions made permanent in England and Wales

DHSC Press Release: 30 August 2022

GinaOver-the-counter HRT product Gina (estradiol 10 microgram) vaginal tablet now available

Gina is licensed for treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women aged ≥ 50 years.

Novo Nordisk has produced both a Pharmacy Guide and a Pharmacy Checklist.

Material Regulation 28 – to prevent future deaths

Death the related to pain relief medication

- Breast cancer with lymph-node involvement, and severe, chronic pain. Sacral sore compounded her pain further.
- Repeat pain prescriptions from GP.
- Admitted to A&E with gastroenteritis. Unresponsive in A&E and not able to resuscitate.
- Post mortem died of Combined toxicity of fentanyl, fluoxetine, tramadol, amitriptyline, gabapentin and diazepam.
- Recommendation: a systematic review of all patients receiving repeat prescriptions of multiple analgesics and formulate individual plans for each patient.
- GP practices who have a significant number of patients with complex analgesia regimes do not universally engage practice pharmacists to complement the¹⁶ knowledge of doctors and enhance the advice provided to patients.