

# SPS/UKMi Observatory 30<sup>th</sup> November 2022

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

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# Recent regulator and statutory body activity



Improvement



## [National Patient Safety Alert: Class 4 Medicines Defect Information: Prenoxad \(naloxone\) 1mg/ml Solution for Injection, Macarthys Laboratories \(Aurum Pharmaceuticals Ltd/Ethypharm Group\), due to potential missing needles in sealed kits, NatPSA/2022/009/MHRA](#)

- Limited number of kits in a batch marketed in France have missing needles. No reports of UK marketed kits with missing needles have been received to date. Potential for kits to contain fewer than two (2) needles in all distributed batches cannot be excluded.
- Visually inspect the front of the kit against a light source to confirm two (2) needle packets are present in the kit. If needles cannot be clearly seen by the visual inspection of the kit(s), the kit(s) can be physically opened to confirm the presence of two (2) needles inside the kit(s).
- Immediately quarantine kit(s) without two (2) needles.
- If patients, individuals or members of the public report a kit without two (2) needles in the kit, arrange for a replacement and visually check for the presence of two needles before supplying the new kit.

# Recent regulator and statutory body activity



Improvement



## [CAS Alert: Influenza season 2022/2023: Use of antiviral medicines](#)

- Prescribers working in primary care may now prescribe, and community pharmacists may now supply antiviral medicines (oseltamivir and zanamivir) for the prophylaxis and treatment of influenza at NHS expense. This is in accordance with NICE guidance, and Schedule 2 to the National Health Service (General Medical Services Contracts (Prescription of drugs etc) Regulations 2004), commonly known as the Grey List or Selected List Scheme (SLS).
- Antiviral medicines may be prescribed for patients in clinical at-risk groups as well as anyone at risk of severe illness and/or complications from influenza if not treated.

# Recent regulator and statutory body activity



## [Class 4 Medicines Defect Information: Recordati Rare Diseases, Pedeia 5 mg/ml solution for injection, EL\(22\)A/45](#)

- PILs of specific batches do not contain safety information related to severe skin reactions
- the quality and safety of product is not impacted

## [Class 3 Medicines Recall: Medreich PLC, Mebeverine hydrochloride 135mg Film-coated tablets, EL\(22\)A/46](#)

- out of specification results for tablet dissolution during routine product release testing
- stop supplying the above batch immediately and quarantine all remaining stock

## [Class 4 Medicines Defect Information: Macarthy's Laboratories t/a Martindale Pharma, Venlafaxine XL 300 mg prolonged-release tablets, EL\(22\)A/47](#)

- GTIN in the 2D barcode and the printed variable data represents the branded version of the product (Venlalic<sup>®</sup> XL 300 mg prolonged-release tablets)
- the quality and safety of product is not impacted

## [Class 4 Medicines Defect Information: Morningside Healthcare Limited, Hyoscine Butylbromide 20 mg Film-coated Tablets, EL\(22\)A/48](#)

- affected batch may contain a PIL for Midodrine Hydrochloride 2.5 mg & 5 mg Tablets.
- the quality and safety of product is not impacted
- check PIL before dispensing – wrong PIL should be removed and a copy of the correct PIL provided

# Recent regulator and statutory body activity



## Drug Safety Update

Nil this month

# Recent regulator and statutory body activity



## Quality Matters:

- NPPG Position Statement on Using ENFit Syringes
  - <http://nppg.org.uk/position-statements/>
  - errors occurred where a medicine intended for administration via an enteral tube has inadvertently been given intravenously.
  - enteral feeding tube connections, known as ENFit, will only allow an ENFit syringe to be connected to an ENFit enteral line and also prevents ENFit syringes from connecting with standard luer fitting on IV lines.
- Sun Pharmaceuticals Pemetrexed Packaging
  - information on 500mg and 1000mg cartons refer to “1 vial of 50ml”
  - volume stated on the carton refers to the capacity of the vial, NOT the final volume following reconstitution.
- Caspofungin Reconstitution Instructions

# Pharmacovigilance Risk Assessment Committee (PRAC)



## Comirnaty and Spikevax: heavy menstrual bleeding added as a side effect

- Heavy menstrual bleeding has been reported after 1st, 2nd & booster doses of Comirnaty & Spikevax. The PRAC has recommended this should be added to product information as a side effect of unknown frequency. There is no evidence to suggest any impact on reproduction and fertility.

## EMA confirms measures to minimise risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders

- PRAC recommended these medicines should be used in following patients only if no suitable treatment alternatives are available: those aged  $\geq 65$  years or at increased risk of major CV problems or who smoke/have done so for a long time in past & those at increased risk of cancer. Recommendations endorsed by EMA.

## Ustekinumab (Stelara): warning on use of live vaccines in infants whose mothers received ustekinumab during pregnancy

- The PRAC has recommended adding a warning to the product information to advise that the administration of live vaccines is not recommended for six months following birth or until the infant's serum levels of ustekinumab are undetectable.

# Direct HCP communication

- Nil this month



# Manufacturer RMM or SPC changes

## Revised SPC: Crestor (rosuvastatin) all strength film-coated tablets

- Ticagrelor might affect renal excretion of rosuvastatin, increasing the risk for rosuvastatin accumulation. Although the mechanism is unknown, in some cases, concomitant use has led to impaired renal function, increased CPK level and rhabdomyolysis.

## Revised SPC: Asacol (mesalazine) 400mg and 800mg MR Tablets

- Cases of nephrolithiasis have been reported with use of mesalazine, including stones of 100% mesalazine content; adequate fluid intake is recommended during treatment.

## Revised SPC: Xeljanz (tofacitinib) film-coated tablets- all strengths

- Warnings for retinal venous thrombosis, advising that patients should be advised to seek medical care if symptomatic; and hypoglycaemia in patients receiving medication for diabetes, in which case dose adjustment of anti-diabetic medication may be necessary.

## Revised SPC: Symkevi 50 mg/75 mg and 100 mg/150 mg (ivacaftor, tezacaftor) film coated tablets

- Liver function decompensation, including liver failure leading to transplantation & death has been reported in cystic fibrosis patients with pre-existing cirrhosis and portal hypertension whilst receiving treatment with other CFTR modulator regimens

## Revised SPC: Exemestane 25mg film-coated tablets

- The adverse effects of increased hepatic enzymes, increased blood bilirubin and increased blood alkaline phosphatase have been added to the adverse effects table, and data from the final follow-up of the Intergroup Exemestane Study have been added to section 5.1.

# Manufacturer RMM or SPC changes

## Revised SPCs: Imbruvica (ibrutinib) Film-Coated Tablets

- Fatal and serious cardiac arrhythmias and cardiac failure has been reported with use of ibrutinib. Recommendations include clinical evaluation of cardiac history/function and dose reduction or withdrawal of treatment in symptomatic patients.

## Revised SPC: Elvanse (lisdexamfetamine dimesylate) Hard Capsules – all strengths

- Warning that lisdexamfetamine crosses placenta; undesirable effects section updated with data on weight from RCT in children ages 4 to 5 years, and pharmacodynamic & pharmacokinetic section also updated with data from studies in children ages 4 to 5 years.

## Revised SPC: Losartan (Cozaar and Cozaar-Comp) Film-Coated Tablets - all strengths

- Grapefruit juice contains components that inhibit CYP450 enzymes and may lower concentration of active metabolite of losartan which may reduce therapeutic effect, therefore concomitant consumption of grapefruit juice should be avoided.

## Revised SPC: Prograf (tacrolimus) - all presentations

- Warning of signs/symptoms that could indicate the development of thrombotic microangiopathy, which can sometimes lead to renal failure or a fatal outcome, and this risk can be increased with concomitant administration of mTOR inhibitors (e.g. sirolimus, everolimus).

## Revised SPC: Tarceva (erlotinib hydrochloride) film-coated tablets – all strengths

- Pneumatosis intestinalis and hepatitis (rare) & acute hepatitis (unknown). Following reports of drug induced liver injury, it now notes the frequency of liver function monitoring should be increased in patients with pre-existing hepatic impairment

# Manufacturer RMM or SPC changes

## RMM: Zypadhera (olanzapine powder and solvent for prolonged release suspension for injection) patient alert card

- Patient alert card lists the common side effects of this treatment and contains information on the risks of the medicine entering the blood stream too quickly, including the symptoms of this and the monitoring that should be carried out after each injection.

## RMM: Caprelsa (vandetanib) health professional guide, patient guide and patient alert card

- Health professional's guide outlines risk of teeth & bone abnormalities & medications errors in paediatric patients & includes a dosing & monitoring guide. Patient guide contains further information on dosing & is supported with a daily tracker adapted to all dose regimens. Patient alert card contains information on the possible side effects of QTc prolongation and posterior reversible encephalopathy syndrome and lists the signs/symptoms for which the patient should seek immediate medical attention.

## RMM: Multaq (dronedarone) prescriber guide

- Guide provides prescribers with a summary of requirements for screening before starting treatment, monitoring during treatment, when treatment should be discontinued, and patient counselling. Treatment should be initiated and monitored under specialist supervision.

# Manufacturer RMM or SPC changes

## New product: Mounjaro (tirzepatide) solution for injection in pre-filled pen

- Long acting dual GIP and GLP-1 receptor agonist licensed for treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin inappropriate, or in addition to other treatments.

## New product: Onureg (azacytidine) 200 and 300 mg film-coated tablets

- Licensed as maintenance therapy in adults (who are not for hematopoietic stem cell transplantation) with acute myeloid leukaemia who achieved complete remission (CR) or CR with incomplete blood count recovery following induction therapy with/without consolidation treatment.

## New product: Atomoxetine 4mg/ml Oral Solution (Aerona Clinical Limited)

- Licensed for treatment of ADHD in children  $\geq 6$  years, in adolescents and in adults as part of a comprehensive treatment programme. The solution should not be mixed in food or water as it can prevent the patient receiving a full dose or could negatively affect taste.

## New Product: Nuwig (simoctocog alfa) 1500 IU powder and solvent for solution for injection

- Nuwig is licenced for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency) in all age groups.

# Drug shortages and discontinuations

Medicine	Out of stock	Alternatives
Chlordiazepoxide 5mg and 10mg capsules	<p>Anticipated re-supply date:</p> <ul style="list-style-type: none"> <li>11 November 2022 (5mg capsules)</li> <li>10 January 2023 (10mg capsules)</li> </ul>	<p>Diazepam tablets are an alternative benzodiazepine option for treating alcohol withdrawal and suppliers can support an increase in demand.</p> <p>For all other indications, alternative benzodiazepines remain available and will be able to support an increase in demand.</p>
Fentanyl (Effentora) 200 microgram and 400 microgram buccal tablets	<p>Anticipated re-supply date: 2 December 2022</p>	<p>The following Effentora preparations remain available:</p> <ul style="list-style-type: none"> <li>Effentora 100 microgram buccal tablets – can support a partial uplift in demand</li> <li>Effentora 600 microgram and 800 microgram buccal tablets</li> </ul> <p>The following alternative formulations of immediate release fentanyl remain available and will be able to support increased demand:</p> <ul style="list-style-type: none"> <li>Actiq lozenges, Abstral sublingual tablets, Cynril lozenges, Fenhuma sublingual tablets, PecFent nasal spray</li> </ul>
Fluorouracil (2.5%) 500mg in 20ml solution for injection vials	<p>Anticipated re-supply date: 27 January 2023</p>	<p>The following presentations can provide a full uplift in demand</p> <ul style="list-style-type: none"> <li>Fluorouracil (2.5%) 2.5g/100ml solution for infusion vials from Medac UK</li> </ul> <p>The following presentations can support a partial uplift in demand</p> <ul style="list-style-type: none"> <li>Fluorouracil (5%) 500mg/10ml solution for injection vials.</li> <li>Fluorouracil (5%) 1g/20ml solution for injection vials</li> <li>Fluorouracil (5%) 2.5g/50ml solution for infusion vials</li> <li>Fluorouracil (5%) 5g/100ml solution for infusion vials</li> </ul>

# Drug shortages and discontinuations

Medicine	Out of stock	Alternatives
Ofloxacin 200mg tablets	Anticipated re-supply date: 17 January 2023	Alternative fluoroquinolone antibiotics are available and can support a full uplift in demand.  If alternative fluoroquinolones are unsuitable, Viartis (Mylan) ofloxacin 400mg tablets remain available and will be able to partially support an uplift in demand. This preparation includes a break line and can be divided into equal doses.
Capimune (ciclosporin) 25mg, 50mg and 100mg capsules	Anticipated re-supply date: 23 December 2022  Seek advice from the appropriate specialist team on switching to an available brand of ciclosporin (Deximune), ensuring appropriate monitoring requirements are followed	The following presentations can provide a full uplift in demand <ul style="list-style-type: none"> <li>• Deximune 25mg, 50mg and 100mg capsules</li> </ul> The following presentations can support a partial uplift in demand <ul style="list-style-type: none"> <li>• Neoral 25mg, 50mg and 100mg Soft gelatin capsules</li> </ul> Alternatives unable to provide any uplift <ul style="list-style-type: none"> <li>• Vanquoral 25mg, 50mg and 100mg capsules</li> <li>• Capsorin 25mg, 50mg and 100mg capsules</li> <li>• Sandimmun 25mg, 50mg and 100mg capsules</li> </ul>
Dipyridamole 100mg tablets	Anticipated re-supply date: 5 December 2022	Dipyridamole 200mg modified release capsules. In stock and can support a full uplift in demand.
Fluticasone propionate / Salmeterol (Fixkoh Airmaster) dry powder inhaler	Anticipated re-supply date: 23 December 2022	Alternative brands of fluticasone with salmeterol dry powder inhalers remain available.

# Drug shortages and discontinuations

Medicine	Out of stock	Alternatives
Gadobutrol (Gadovist) 1mmol/ml solution for injection 15ml vials	Anticipated re-supply date: 2 December 2022	The following alternative presentations remain in stock and can support an uplift in demand: <ul style="list-style-type: none"> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 30ml vials</li> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 7.5ml vials</li> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 65ml bottles</li> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 7.5ml p-f syringes</li> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 10ml p-f syringes</li> <li>• Gadobutrol (Gadovist) 1mmol/ml solution for injection 5ml p-f syringes</li> </ul>
Diamox (acetazolamide) 500mg powder for solution for injection vials	Anticipated re-supply date: early 2023	Acetazolamide 250mg tablets remain available. Unlicensed imports of alternative brands of acetazolamide 500mg powder for solution for injection can be sourced from: Alium Medical, Mawdsleys.
Atorvastatin (Lipitor) 20mg chewable tablets	Anticipated re-supply date: late December 2022	Atorvastatin 20mg film-coated tablets and atorvastatin 20mg/5ml oral suspension remain available and can support a full uplift in demand.  Atorvastatin (Lipitor) 10mg chewable tablets are in limited supply and cannot support an uplift in demand.  Serious Shortage Protocol (SSP) issued on 23/11/2022.

# Drug shortages and discontinuations

Medicine	Out of stock	Alternatives
Methylphenidate prolonged-release tablets	<p>Anticipated re-supply date:</p> <ul style="list-style-type: none"> <li>Delmosart 18mg modified-release tablets - 17 February 2023</li> <li>Delmosart 54mg modified-release tablets - 17 February 2023</li> <li>Xenidate XL 18mg tablets - 2 December 2022</li> <li>Xenidate XL 54mg tablet - 2 December 2022</li> <li>Xaggitin XL 27mg tablets - 23 December 2022</li> </ul> <p>Delmosart, Xaggitin XL and Xenidate XL tablets have a similar release profile to Concerta XL</p>	<p>The following branded generics remain available for the presentations listed below:</p> <p>Methylphenidate hydrochloride 18 mg prolonged-release tablet</p> <ul style="list-style-type: none"> <li>Concerta XL 18mg prolonged-release tablets</li> <li>Xaggitin XL 18mg prolonged-release tablets</li> </ul> <p>Methylphenidate hydrochloride 27 mg prolonged-release tablet</p> <ul style="list-style-type: none"> <li>Concerta XL 27mg prolonged-release tablets</li> <li>Xenidate XL 27mg prolonged-release tablets</li> <li>Delmosart 27mg prolonged-release tablets</li> </ul> <p>Methylphenidate hydrochloride 36 mg prolonged-release tablet</p> <ul style="list-style-type: none"> <li>Concerta XL 36mg prolonged-release tablets</li> <li>Xenidate XL 36mg prolonged-release tablets</li> <li>Delmosart 36mg prolonged-release tablets</li> <li>Xaggitin XL 36mg prolonged-release tablets</li> </ul> <p>Methylphenidate hydrochloride 54mg prolonged-release tablet</p> <ul style="list-style-type: none"> <li>Xaggitin XL 54mg prolonged-release tablets</li> <li>Concerta XL 54mg prolonged-release tablets</li> </ul>
Cabergoline 0.5mg and 2mg tablets	<p>Anticipated re-supply date: 6 January 2023</p>	<p>The following alternatives remain available</p> <ul style="list-style-type: none"> <li>Dostinex 0.5mg tablets - can support a full uplift in demand</li> <li>Cabaser 1mg tablets - can support a full uplift in demand</li> <li>Cabaser 2mg tablets - <b>cannot</b> support an uplift in demand</li> </ul>



# Specialist Pharmacy Services

## [Annual planning advice for new medicines, Prescribing Outlook](#)

- Annual output to support managed entry and budget planning for new medicines, new indications and patent expiries in the NHS

## [SPS Spotlight Monthly Digest – October 2022](#)

- Updates on existing materials and activities from across SPS, and signpost to upcoming events and activities

## [Switching between neostigmine and pyridostigmine in myasthenia gravis](#)

- Switching between neostigmine and pyridostigmine requires care and application of a stepped process.

## [Managing the risks associated with rapid over-infusion of parenteral nutrition in babies](#)

- There is a risk of severe harm or death if PN is unintentionally infused too rapidly in babies. Healthcare professionals need to ensure safe practice

## [Advising individuals with allergies, religious or other dietary practices and beliefs on their suitability for Comirnaty COVID-19 vaccines](#)

- This webpage contains guidance and information about allergy history and vaccine composition to support questions about suitability for vaccination with Comirnaty (Pfizer-BioNTech).

## [Advising individuals with allergies, religious or other dietary practices and beliefs on their suitability for Spikevax COVID-19 Vaccines](#)

- This webpage contains guidance and information about allergy history and vaccine composition to support questions about suitability for vaccination with Spikevax (Moderna).

# Specialist Pharmacy Services

## Temperature management for medicines storage

Changes in temperature can affect medicines. Learn to manage and monitor temperature, and identify actions for individual products when refrigeration fails.

- [Understanding why temperature management is important for medicines storage](#)
- [Monitoring the storage temperature of medicines](#)
- [Mapping the temperature of medicines storage areas](#)
- [Establishing alerts for temperature monitoring systems](#)
- [Using temperature sensors in medicines storage areas](#)
- [Managing temperature excursions](#)
- [Temperature control whilst transporting medicines](#)
- [Storing medicines at ambient temperatures](#)
- [Using a refrigerator or freezer to store medicines](#)

## Outsourcing of Storage or Preparation of ATIMPs Across Legal Boundaries

- This webpage contains guidance on the considerations for Pharmacy Clinical Trial Sites outsourcing activities involved in the delivery of Advanced Therapy Investigational Medicinal Products (ATIMPs)

## Assigning stability to Zerbaxa (ceftolozane/tazobactam) in elastomeric infusers

- Assessment of the degradation profile and toxicity data for Zerbaxa is available for its use in Outpatient Parenteral Antimicrobial Therapy (OPAT) services.

# National guidance, publications and resources

## [BMJ: Reduce unnecessary use of proton pump inhibitors](#)

- Article outlines deprescribing options for those on PPIs for >8 weeks (unless using for a specific indication) such as dose reduction, stopping, prn use, using alternative antacid, and non-drug approaches to avoid or manage heartburn and a management plan for rebound heartburn.

## [BMJ: Glucocorticoid induced adrenal insufficiency](#)

- Educate patients taking prednisolone  $\geq 5$  mg/day or equivalent for more than four weeks, 40 mg prednisolone or equivalent for longer than one week, or repeated short courses of glucocorticoids via any route ( $\geq 3$  per year), about the risk of glucocorticoid induced adrenal insufficiency (GC-AI)
- Advise patients at risk of GC-AI to increase their dose of glucocorticoid when unwell and issue them with a steroid emergency card

## [BSA: Prescribing Costs in Hospitals and the Community – England April 2017 to March 2022](#)

- In England in 2021/22, the cost of medicines prescribed in primary care and dispensed in community was £8.90 billion (50% of total expenditure), and £8.77 billion (49.3%) for medicines prescribed and issued in hospitals. BNF Chapter 8 had the highest spend across all settings.

## [BNF/BNFC Newsletter November 2022](#)

- Includes guidance on Covid vaccines, management of multiple sclerosis, nebulised asthma rescue therapy in children, prescribing of MR preps of methylphenidate & withdrawal of third-line treatment indication for rucaparib. Various dose changes & new monographs also discussed.

# National guidance, publications and resources

## [MHRA approves Nuvaxovid COVID-19 vaccine use as an adult booster for those aged 18 and above](#)

- Booster dose may be administered IM ~6 months after primary series of Nuvaxovid or primary series comprised of an mRNA vaccine or adenoviral vector vaccine (heterologous booster dose). Dose interval for latter is same as for a booster of the vaccine used for primary vaccination.

## [MHRA approves second Pfizer/BioNTech bivalent COVID-19 booster vaccine](#)

- Approval granted for 'bivalent' Covid vaccine that targets both the original strain & Omicron BA.4 & BA.5 sub-variants, for use in people aged  $\geq 12$  years. In each booster dose, half of vaccine (15 mcg) targets original virus strain and other half (15 mcg) targets Omicron (BA.4-5).

## [MHRA: Unique opportunity for healthcare professionals to influence future MHRA safety communications and safety reporting systems](#)

- Healthcare professionals asked to share their views on how they want to receive safety information from the UK medicines and medical devices regulator

## [NHSE: Services for the provision of antiviral drugs for the treatment and post-exposure prophylaxis of influenza-like illness \(ILI\) in at-risk patients including care home residents](#)

- Letter restates service expectations for system commissioners on requirements for the provision of influenza antivirals with a particular focus on care home residents, in addition to ongoing activity to vaccinate care home residents and staff against flu and Covid-19.

# National guidance, publications and resources

## [NHSE: Supporting our NHS people through menopause: guidance for line managers and colleagues](#)

- This guidance helps NHS organisations, line managers, and those working in the NHS understand more about the menopause, how they can support colleagues at work and those experiencing menopause symptoms. It includes advice on HR aspects as well as practical tips.

## [NHSE: Paediatric medicine renal service specification](#)

- This service specification aims to improve both life expectancy and quality of life for children with renal disease by providing optimal specialised care.

## [NIHR Alert: E-cigarettes may be better than nicotine patches in helping pregnant women stop smoking](#)

- Expert commentary is provided on a study of 1140 pregnant women in England and Scotland who were trying to stop smoking that suggests e-cigarettes are as safe as nicotine patches for pregnant women and may also be more effective at helping them to quit.

## [NIHR Alert: Antipsychotics are commonly prescribed to people with personality disorders, contrary to guidelines](#)

- Commentaries provided on research which found 1 in 4 with personality disorders without a severe mental illness are being prescribed antipsychotics in primary care despite UK guidelines advising against use in this specific population. Many were receiving these drugs for > 1-year

# National guidance, publications and resources

## [NIHR Alert: Many hospital policies create barriers to good management of opioid withdrawal](#)

- Commentaries are provided for a review of 86 policies for opioid withdrawal in NHS Trusts in England which found wide differences, with authors suggesting many policies created barriers to prompt provision of substitute opioids by promoting stigmatising attitudes and practices.

## [RPS: Revised RPS Professional Standards for Hospital Pharmacy](#)

- These standards intend to set out examples of good practice across NHS and independent hospital pharmacy services. The 2022 version includes two new sections: inclusion and wellbeing; and research, audit and quality improvement.

## [RPS: New research e-learning for pharmacy professionals](#)

- The RPS intends to release a total of nine e-learning modules by the end of 2022 to improve research awareness, knowledge and skills for pharmacists and pharmacy technicians. Topics covered include different research methods and practical considerations.

## [UKHSA: World Antimicrobial Awareness Week \(WAAW\) and European Antibiotic Awareness Day \(EAAD\) – 18 to 24 November 2022](#)

- The focus for WAAW and EAAD in England will be on raising the awareness of the risks of antimicrobial resistance in health and social care workers, as well as patients who have been prescribed antibiotics and is supported by a digital toolkit.

# Material Regulation 28 – to prevent future deaths

- [Ref: 2022-0366](#)
- Patient with COPD, entrocutaneous fistula, chronic gastric ulcer, PE, depression with a previous paracetamol overdose and alcohol dependence.
- Prolonged admission to hospital for perforation of gastric ulcer leading to months in hospital necessitating intubation and tracheostomy. Discharged home on Oramorph. After medication review by community pharmacist, Oramorph was discontinued and slow-release Zomorph prescribed alone. Readmitted to hospital with deterioration in breathing, shortness of breath and biphasic stridor. Diagnosed with cricoarythenoid fixation due to period of prolonged intubation. Discharged home with 2 weeks supply of Zomorph and 100mls of Oramorph. Found dead the next day. Bottle of Oramorph was nearly empty.
- Cause of death
  - morphine toxicity
- Concerns
  - system at the GP practice when examined by the pharmacist at the hospital did not show that the Oramorph prescription had been stopped
  - during hospital stay the patient was prescribed Oramorph and not Zomorph the drug she had been using at 20mg twice a day. A pharmacist recognised this discrepancy and asked for this to be reviewed. No such review took place and it was difficult to see on the electronic records system that such a review needed to take place (no highlights or flags to alert the doctors that such a review needed to take place).
  - the standard of record keeping by the medical staff was poor. No evidence of why decisions were made, what discussions were held and what advice was given.

# Material Regulation 28 – to prevent future deaths

- [Ref: 2022-0367](#)
- Patient with interstitial lung disease and a history of rheumatoid arthritis, for which she was prescribed methotrexate and leflunomide.
- Went on holiday to Turkey where developed pain to upper back with large area skin redness and peeling skin. Skin was treated, there appeared to be no signs of infection but as a precautionary measure, antibiotics were prescribed. Was admitted to hospital after being found on the bedroom floor. Was found to have low blood pressure and hypoglycaemia, with laboratory investigations showing severe neutropenia. Despite medical treatment, continued to deteriorate and died later the same day
- Cause of death
  - phototoxicity related to methotrexate
- Concerns
  - Phototoxicity is a condition that looks and feels like severe sunburn. It is a type of photosensitivity that occurs when a chemical (often a drug ingested or topically applied) combines with the UV light leading to skin damage in the region of sun exposure.
  - Methotrexate has been associated with phototoxicity. It is likely that phototoxicity has contributed to the development of the area of skin loss over the back.
  - Phototoxicity is an extremely rare side effect of methotrexate but does not appear in literature given to patients.