

SPS Medication Safety Update May 2023

Recent critical patient safety alerts, reports, and publications

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Patient Safety Alerts



- [Class 1 alert: Recall of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors, due to the potential for device failure \(NatPSA/2023/004/MHRA\)](#)
 - Manufacturers are recalling all unexpired batches of Emerade (adrenaline) 500 & 300 micrograms auto-injectors owing to failure to deliver the product correctly on testing. No further supplies will be available, and patients will need to be switched to an appropriate alternative.
- [CAS alert- Shortage of pyridostigmine 60mg tablets \(NatPSA/2023/006/DHSC\)](#)
 - Pyridostigmine 60mg tablets are out of stock until week commencing 12 June. GP practices and specialist clinical teams are to identify patients on treatment, and those with insufficient supplies to be referred to their prescriber for pyridostigmine 12mg/mL oral solution

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

- [Class 3 Medicines Recall: Hikma Farmacêutica Portugal S.A., Gemcitabine 1g/26.3ml & 2g/52.6ml Solution For Infusion Vial, EL\(23\)A/16](#)
 - Due to a limited number of complaints received regarding loose caps, Hikma Farmacêutica Portugal S.A is recalling the batches as a precautionary measure from pharmacies and wholesalers
- [Class 4 Medicines Defect Information: Novartis Pharmaceuticals, Simulect \(basiliximab\) 10mg & 20mg powder and solvent for Solution for injection or infusion, EL \(23\)A/17](#)
 - The solvent (water for injections in ampoules) co-packaged with the batches listed in the alert may contain glass fragments 20-800µm in size. The included solvent should therefore be discarded carefully and replaced with an alternative water for injection.
- [Class 4 Medicines Defect Information: Orifarm UK Ltd, Buccolam 10mg Oromucosal solution, EL \(23\)A/18](#)
 - The Patient Information Leaflet in one batch of Buccolam 10mg Oromucosal solution has missing information regarding having to break the seal on the inner container before use.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

- [Class 4 Medicines Defect Information: Drugsrus Limited / Dawa Limited, Metronidazole 200 mg/5 ml Oral Suspension, EL \(23\)A/19](#)
 - A small number of bottles of Metronidazole 200 mg/5 ml Oral Suspension 100ml are leaking from the cap.
- [Influenza season 2022/23: ending the prescribing and supply of antiviral medicines in primary care \(CEM/CMO/2023/002\)](#)
 - Circulation of influenza in the community has returned to baseline levels, therefore prescribers in primary care should no longer prescribe antiviral medicines, for the prophylaxis and treatment of influenza, and community pharmacists should no longer supply antiviral medicines.
- [MHRA maintains prescription-only status of Aquiette \(oxybutynin\) 2.5mg Tablets for symptoms of overactive bladder \(OAB\)](#)
 - The MHRA has concluded that a medical prescription continues to be required to ensure the safe use of this product, noting an overactive bladder diagnosis requires medical supervision to ensure the correct treatment is received, and other health conditions are not overlooked.
- [Adrenaline Auto-Injectors \(AIs\) safety campaign](#)
 - Information for patients, healthcare professionals and wider public to help better understand the importance of AIs as a potential life-saving medicine covers background of AIs and provides infographics on the correct use of AIs during anaphylaxis reactions.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

Drug Safety Update- April

- Isotretinoin (Roaccutane ▼): new safety measures to be introduced in the coming months, including additional oversight on initiation of treatment for patients under 18 years
 - Following advice from an expert working group, the CHM will review implementation of updated recommendations, including requirement for 2 prescribers to agree on the need for treatment when using in those <18 years, and new warnings on psychiatric and sexual side effects
- Janus kinase (JAK) inhibitors: new measures to reduce risks of major cardiovascular events, malignancy, venous thromboembolism, serious infections and increased mortality
 - Following review, these risks are now considered class effects of JAK inhibitors and it is advised to avoid unless there are no suitable alternatives in those who are ≥65yrs, current or past long-time smokers & those with risk factors for cardiovascular disease or malignancy.
- Nitrofurantoin: reminder of the risks of pulmonary and hepatic adverse drug reactions
 - Healthcare professionals should advise patients to be vigilant for new or worsening respiratory symptoms and symptoms and signs of liver dysfunction while taking nitrofurantoin and promptly investigate any symptoms that may indicate a pulmonary or liver adverse reactions.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

Drug Safety Update- May

- [Direct-acting oral anticoagulants \(DOACs\): paediatric formulations; reminder of dose adjustments in patients with renal impairment](#)
 - Risk minimisation materials are available to support the safe use of new paediatric formulations of rivaroxaban and dabigatran etexilate. Recommendations for DOACs in adults with renal impairment is provided.
- [Glucose solutions: recommendations to minimise the risks associated with the accidental use of glucose solutions instead of saline solutions in arterial lines](#)
 - Accidental use of glucose-containing solutions as flush fluid for arterial lines may contaminate blood samples and result in falsely high glucose readings.
- [Febuxostat: updated advice for the treatment of patients with a history of major cardiovascular disease](#)
 - Use with caution in people with pre-existing major cardiovascular disease, particularly, in those with evidence of high urate crystal and tophi burden or those initiating urate-lowering therapy.

Pharmacovigilance Risk Assessment Committee (PRAC)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- PRAC meeting 10 - 12 May 2023
 - New Review
 - [Hydroxyprogesterone](#) - due to concerns about results from a study which suggested that people who were exposed to hydroxyprogesterone caproate in the womb may have an increased risk of cancer compared with those who were not
 - Other safety messages
 - [Fluoroquinolone antibiotics](#): reminder of measures to reduce the risk of long-lasting, disabling and potentially irreversible side effects. Although use of fluoroquinolone antibiotics has decreased, they may still be prescribed outside their recommended uses.
 - Gavreto (pralsetinib): measures to minimise increased risk for tuberculosis – new DHCP letter
 - Voxzogo (vosoritide): introduction of a new type of syringe – new DHPC letter

Committee for Medicinal Products for Human Use (CHMP)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- [European CHMP endorses update to statement on interchangeability of biosimilar medicines in EU](#)
 - In a joint statement drafted on 21st April 2023, the Biosimilar Medicines Working Party and the Heads of Medicines' Agencies Biosimilar Working Group explain the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective.
 - Following the publication of this statement, both the EMA and National Competent Authorities have received questions for clarification from healthcare professionals and other members of the public. A [Q&A document](#) addresses these follow-up questions.

Direct HCP communication

Direct to Healthcare professionals letters (sent March 2023)

- [Hydroxycarbamide 100 mg/ml oral solution \(Xromi\): Changes to the oral syringes copackaged with Xromi](#)
- [Ozempic ▼ solution for injection in pre-filled pen \(semaglutide\): supply shortage in the UK](#)
- [Cibinqo \(abrocitinib\), Jyseleca \(filgotinib\), Olumiant \(baricitinib\), Rinvoq \(upadacitinib\) and Xeljanz \(tofacitinib\) – Updated recommendations to minimise the risks of malignancy, major adverse cardiovascular events, serious infections, venous thromboembolism and mortality with use of Janus kinase inhibitors \(JAKi\)](#)
- [Sabril 500mg granules for oral solution \(vigabatrin\): Interim Supply of Italian Stock to Mitigate Supply Disruption](#)

Direct HCP communication

Direct to Healthcare professionals letters (sent April 2023)

- [Caprelsa \(vandetanib\): restriction of indication](#)
- [Ketalar 10 mg/ml Injection 20ml vial: Temporary supply of an unlicensed imported product from Switzerland](#)
- [Naseptin Nasal Cream: Caution advised when prescribing and dispensing due to reformulation to remove allergen](#)
- [Brabio \(glatiramer acetate\) 20 mg/ml solution for injection, pre-filled syringe, once daily dosage: Patient information leaflet update](#)

SPC changes

- [Akizza \(ethinylestradiol/gestodene\) tablets](#)
 - SPC contraindicates concomitant use of Akizza with medicinal products containing sofosbuvir/velpatasvir/voxilaprevir owing to ALT elevations. Manufacturers recommend Akizza-users prescribed these treatments must switch to an alternative method of contraception.
- [Naseptin \(Chlorhexidine and neomycin\) Nasal Cream](#)
 - This product has now been reformulated with medium chain triglycerides replacing the arachis oil (peanut oil) excipient. Contra-indications for use in patients with peanut and/or soya have therefore been removed.
- [Zlatal \(methotrexate\) solution for injection in pre-filled syringe](#)
 - SPC now notes that, in treatment of males, the precautionary measure of reliable contraception that should continue after treatment has been reduced to 3 months. Other brands of methotrexate injection currently still recommend 6 months of contraception after treatment cessation.
- [Rukobia \(fostemsavir\) 600 mg prolonged-release tablets](#)
 - SPC updated to state that, so as to avoid transmission of HIV, it is recommended that women living with HIV do not breast-feed. It is not known whether fostemsavir/temsavir are excreted in human breast-milk. Data in rats have shown excretion of fostemsavir/temsavir in milk.

SPC changes

- [Ilaxten \(bilastine\) 2.5 mg/ml oral solution](#)
 - Information about the ethanol content of Ilaxten. The product contains 0.44 mg of ethanol in each 4mL dose (11 mg/100 mL or 0.011% w/v). This ethanol content in 4mL is equivalent to less than 0.02mL beer or 0.005mL wine.
- [Powergel 2.5% gel \(ketoprofen\)](#)
 - Information about the ethanol content of Powergel. 1g gel (contains 307mg). A caution that ethanol may cause a burning sensation when used on damaged skin has been added.
- [Viagra \(sildenafil\) 100 mg film-coated tablets](#)
 - Caution when starting sildenafil in patients treated with sacubitril/valsartan (SV), as addition of a single dose of sildenafil to SV in patients with hypertension was associated with a significantly greater BP reduction compared to administration of SV alone.
- [Yargesa \(miglustat\) 100mg Hard Capsules](#)
 - Reliable contraceptive methods should be maintained while male patients are taking miglustat and for 3 months following discontinuation [previously just during treatment].

SPC changes

- [Nexplanon \(etonogestrel\) 68 mg implant](#)
 - Inspect for breaches of packaging integrity prior to use by a visual check for damages (e.g. torn, punctured, etc). If the packaging has any visual damage that could compromise sterility, the applicator should not be used.
- [Actilyse Cathflo \(alteplase\) 2 mg powder for solution for injection and infusion](#)
 - Changes include removal of information mentioning the stopper contains natural rubber (a derivatives of latex) and gentamicin, and inclusion/update to advice on use during pregnancy and breastfeeding, plus addition of new section related to 'Fertility'.
- [Juluca 50 mg/25 mg \(rilpivirine/ dolutegravir\) film-coated tablets](#)
 - Dolutegravir crosses the placenta in humans (median foetal umbilical cord concentrations 1.3-fold greater compared with the maternal peripheral plasma concentration in pregnant women living with HIV); there is insufficient data on its effects on neonates. Breastfeeding section updated, a median dolutegravir breast milk to maternal plasma ratio of 0.033 has been shown.
- [Vocabria \(cabotegravir\) 30 mg film-coated tablets](#)
 - Adverse events added to the SPC include hypersensitivity, urticaria and angioedema (uncommon), and suicidal ideation, suicide attempt (both uncommon), particularly in patients with a pre-existing history of psychiatric illness.

SPC changes

- [Mycobutin \(rifabutin\) 150mg capsules](#)
 - Drug-drug interaction information with antiretroviral (ARV) products containing bictegravir, rilpivirine, or doravirine have been updated to note expected decrease in plasma concentrations of ARVs which may lead to loss of virologic response and possible development of resistance.
 - Updated with warning that as rifabutin is a CYP450 3A inducer, co-administration with antiretroviral products including but not limited to bictegravir, rilpivirine, or doravirine is not recommended due to expected decrease in their plasma concentrations.
- [Sofradex \(gramicidin, framycetin, dexamethasone\) Ear / Eye Drops](#)
 - SPC discusses ototoxicity risk when aminoglycosides are given systemically or applied topically to open wounds or damaged skin. Although no cases were identified with topical preparations of neomycin, framycetin or gentamicin, potential for a similar effect cannot be ruled out.
- [Zoladex \(goserelin\) LA 10.8mg](#)
 - Memory impairment has been added as a side-effect of unknown frequency.
- [Efudix 5% Cream \(fluorouracil\)](#)
 - A warning regarding the possibility of increased absorption through ulcerated or inflamed skin has been added to section 4.4 and leukocytosis has been added as an adverse effect of 'very rare' frequency.

SPC changes

- [Engerix B 20 micrograms/1 ml Suspension for injection in pre-filled syringe](#)
 - This SPC has been updated to note that it should not be administered in the buttock or intradermally since this may result in a lower immune response. It should under no circumstances be administered intravascularly.
- [Fendrix \(hepatitis b antigen\)](#)
 - This SPC has been updated to note that Fendrix should not be administered intradermally or intramuscularly into the gluteal muscle as this may result in a lower immune response. It should under no circumstances be administered intravascularly.
- [Twinrix \(Adult & Paediatric\) suspension for injection in pre-filled syringe \(hepatitis A and B vaccine\)](#)
 - SPCs updated to note that the vaccines should not be administered intradermally or intramuscularly into the gluteal muscle as this may result in a lower immune response. In patients with bleeding disorders they may be given subcutaneously. They should not be given intravascularly
- [RoActemra \(tocilizumab\)](#)
 - Updated to include Stevens-Johnson Syndrome as a rare adverse drug reaction.

Manufacturer Risk Minimisation Materials

- [RMMs to help reduce risk associated with using Belkyra \(deoxycholic acid\)](#)
 - An injector's guide provides important information on safe and effective use to minimise the risk of injection site nerve injury and associated motor neuropraxia, injection site skin ulceration and necrosis.
- [RMMs to help reduce risk associated with using Rinvoq \(upadacitinib\)- all strengths](#)
 - Materials comprise Patient Card & Healthcare Professional Guide covering serious & opportunistic infections including TB, testing & screening before prescribing, varicella zoster viral reactivation, contraception, pregnancy & breast-feeding, MACE, VTE, malignancy & GI perforation
- [RMMs: Important safety information concerning Orphacol[®] \(cholic acid\)](#)
 - This guide discusses diagnosis and management of 3β -hydroxy- Δ^5 -C₂₇-steroid oxidoreductase deficiency and Δ^4 -3-oxosteroid- 5β -reductase deficiency, and the expected and potential risks associated with treatment, especially prescription of a suprathreshold dose and gallstones.

Manufacturer Risk Minimisation Materials

- [RMMs to help reduce risk associated with using Ultomiris \(ravulizumab\)- all strengths](#)
 - Materials comprise Patient Alert card, Patient's Guide, Parent/Guardian Guide describing symptoms & steps for early detection & management of meningococcal infections in infants and young children and Physician's Guide on measures to minimise risk of serious side effects.
- [RMMs to help reduce risk associated with using Lamzede \(velmanase alfa\) 10 mg powder for solution for infusion](#)
 - Materials comprise important information on minimising the risk of hypersensitivity reactions and medication errors in home settings and an infusion diary booklet.
- [RMMs for IV iron](#)
 - This prescription information guide on IV iron products discusses side effects that should be discussed with the patient before prescribing, contraindications, and monitoring during and after treatment, to help manage and minimise the risk of hypersensitivity reactions.
- [RMMs Guidance on the administration of Nebido® \(testosterone undecanoate\)](#)
 - This leaflet for healthcare professionals provides information on how to administer Nebido®, the possible adverse events of pulmonary oil microembolism and suspected anaphylactic reactions, and the recommended treatment schedule and follow-up.

Drug shortages

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

New Shortages highlighted by SPS supply tool

[Disodium folinate \(Sodiofolin\) 400mg/8ml solution for injection vials](#) (MSN/2023/049)

[Rifampicin 300mg / Isoniazid 150mg tablets](#) (MSN/2023/050)

[Glucagon 1mg powder for injection kit \(GlucaGen\)](#) (MSN/2023/051)

[Micronised progesterone \(Utrogestan\) 100mg capsules](#) (MSN/2023/052)

Discontinuations highlighted by SPS supply tool in last month- Nil

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

Note: the [Medicines Supply Tool](#) has moved on the SPS website. Update your links and bookmarks - its new home is in the '[Tools](#)' section

Specialist Pharmacy Service



- [Medication Safety Update](#)
 - April slide deck of resources providing a comprehensive repository of critical medication safety alerts, notifications, publications and updates.
- [SPS Spotlight Monthly Digest](#)
 - A slide deck summarising SPS outputs, resources and signposting to upcoming events and activities. Please distribute to relevant healthcare professionals in all areas of the health system and their teams.
- [Using angiotensin-II receptor antagonists during breastfeeding](#)
 - Very limited data suggest breastmilk levels are likely to be low, but other medicine classes are preferred. Recommendations apply to full term, healthy infants
- [Switching between imatinib preparations](#)
 - Update: Reference to indication for imatinib removed from PIL.

Specialist Pharmacy Service



- [Choosing between available adalimumab products](#)
 - Update: To reflect that Hyrimoz products are not formulated with a latex-containing substance and can be considered latex-free.
- [Differences between metolazone preparations and safety considerations](#)
 - Update: Link to MHRA drug safety update advice and additional resources section added.
- [PGD Templates](#)
 - We are updating links and titles for a number of our PGD template pages, if a bookmarked link returns 'page not found' please visit the PGD Templates homepage or use the search function
- [Understanding Patient Group Directions and Integrated Care Boards](#)
 - We outline the responsibilities of ICBs in England as commissioners of NHS services using PGDs, and link to resources that provide further support and advice.
- [Understanding the characteristics of Comirnaty 3 \(THREE\) Concentrate vaccine](#)
 - An overview of the Comirnaty 3 micrograms/dose concentrate vaccine and signposts to other useful resources

Specialist Pharmacy Service



- [Understanding the characteristics of Spikevax Original/Omicron BA.4-5 vaccine](#)
 - An overview of the Spikevax Original/Omicron BA.4-5 vaccine and signposts to other useful resources.
- [Preparing Spikevax Original/Omicron BA.4-5](#)
 - An example SOP for preparing Spikevax Original/Omicron BA.4-5 Vaccine.
- [Ordering, receiving and storing COVID-19 vaccines](#)
 - Updated: Added reference to recording the journey time for Spikevax vaccines in SOP HCV-1.
- [Transporting COVID-19 vaccines](#)
 - Updated: Added in reference to tracking journey time for Spikevax in SOP HCV6.

Specialist Pharmacy Service



SPS Webinar

Medication safety across the system: time critical medicines

- Date: 28 June 2023 (12:30-14:00), online via WebEx
 - Despite efforts to improve safety related to time critical medicines, patients are still experiencing harm in the NHS. These harms may occur at each stage of the medicines journey and in any setting across the system. This session will equip healthcare professionals with insights, support, and shared learning, to support a reinvigorated approach to improve practice with an aims to minimise these harms.

Guest speakers confirmed so far

- Clare Addison - Lead Nurse for Adult Safeguarding, Surrey and Sussex Healthcare NHS Trust. Co-Lead for South East Parkinson's Network (Keynote)
- Pauline Lockey - Patient Safety Clinical Lead Medication Safety, NHS England
- Patsy Cotton - Parkinson's Nurse Specialist, Parkinson's UK
- Suzanne Cooper - Principal Pharmacist Medicines Governance and Medication Safety Officer, Russells Hall Hospital | The Dudley Group NHS Foundation Trust
- Lesley Barnfather - Pharmacy Technician Specialist, Lead WMA project
- Professor Bryony Dean Franklin - Professor of Medication Safety, UCL School of Pharmacy; Executive Lead Pharmacist, Imperial College Healthcare NHS Trust; Director, NIHR North West London Patient Safety Research Collaboration
- Elizabeth McKechnie - Medication Safety Lead Pharmacist, University Hospitals of Leicester NHS Trust

National guidance, publications and resources

NHS England

- [Adult breathlessness pathway \(pre-diagnosis\): diagnostic pathway support tool](#)
 - This support tool has been produced to align clinical practice in primary care with guideline recommendations in order to provide high-quality care, optimise patient outcomes and reduce unwarranted variation for patients with chronic breathlessness in primary care across England.
- [Prioritising new diagnostic capacity for cancer services](#)
 - ICBs with 'Faster Diagnosis Standard' performance <70% in Feb will have to present & deliver plan for using their additional funded diagnostic capacity (community diagnostic centres & acute) to deliver improvements in their most challenged cancer pathways & diagnostic modalities.
- [The national medical examiner system](#)
 - In Apr 2023, the Government confirmed next steps towards statutory medical examiner system across England & Wales to provide independent scrutiny of deaths, and to give bereaved people a voice. That work will take place for full introduction of the statutory system from Apr 2024.

National guidance, publications and resources

NHS England

- [COVID-19 vaccination programme: vaccination of 6 months to 4 year olds in a clinical risk group](#)
 - Accepted advice from the JCVI includes offering two 3mcg doses of the Comirnaty 3 Concentrate vaccine with an interval of at least 8wks between the first & second doses in children aged 6m to 4yrs in a clinical risk group. Vaccination in this group will commence late spring 2023.
- [Decision support tool: making a decision about recurrent tonsillitis in children and adults](#)
 - This decision support tool contains information about recurrent tonsillitis and the possible treatments available
- [Decision support tool: is valproate the right epilepsy treatment for me?](#)
 - This tool is for anyone who could become pregnant, considering or taking valproate for epilepsy. It has been produced as part of NHS-wide effort to reduce use of valproate in people who can get pregnant, and to help those that do continue with valproate to prevent pregnancies.

National guidance, publications and resources

- [Quality and Outcomes Framework \(QOF\) guidance for 2023/24](#)
 - The guidance includes two new cholesterol indicators (CHOL 001 and 002) to ensure all patients with established CV disease receive treatment to reduce cholesterol, in line with NICE guidance, and to introduce an outcome measure for use of these treatments.
- [Interim clinical commissioning policy: Remdesivir and molnupiravir for non-hospitalised patients with COVID-19](#)
 - This policy outlines the treatment options for remdesivir and molnupiravir in non-hospitalised adults and children aged 12 years and older with COVID-19 who are symptomatic and showing no evidence of clinical recovery in accordance with the stated criteria. Appeals are underway against NICE's draft MTA negative recommendations for remdesivir and molnupiravir. This policy aims to provide clarity on access to remdesivir and molnupiravir for the period during which the appeal process is being conducted.
- [Provisional Never Events 2022/23 data: 1 April 2022 and 31 March 2023](#)
 - 384 serious incidents include 16 cases of drug administration by the wrong route, 7 cases of insulin overdose, and one case each of methotrexate overdose (weekly dose given too early), mis-selection of strong potassium solution, and mis-selection of high strength midazolam.
- [NHS rolls out order-to-home hepatitis C tests via NHS website for tens of thousands at risk](#)
 - Self-testing kits will be free to order online as part of NHS England's Hepatitis C Elimination Programme to reach people who may not be engaged with drug and alcohol support, prison and probation services, and those previously exposed to the virus or unable to approach their GP.

National guidance, publications and resources

UK Health Security Agency

- [New study launched to assess levels of antimicrobial resistance in healthy people](#)
 - Up to 2,000 people will be invited to submit stool samples and nose & throat swabs for the study, which will help scientists understand more about levels of antibiotic resistant bacteria found in the public, including carbapenem-producing Enterobacteriaceae (CPE), ESBLs and MRSA.
- [COVID-19 vaccination: information for healthcare practitioners \(update\)](#)
 - Updated to align with revised Green Book chapter 14a, recommendations for spring 2023 campaign and introduction of a primary immunisation for children aged 6 months to 4 years at higher risk, and new content in the inadvertent administration errors section
- [Adverse Weather and Health Plan](#)
 - This new annual document, which brings together the previous Heatwave Plan and Cold Weather Plan, will include supporting scientific evidence, updated Weather-Health alerts, and supporting materials and guidance on how to stay safe during severe weather events.
- [Hot weather and health: guidance and advice](#)
 - This collection of documents provides guidance for health professionals and the public on how to address risks posed by extreme heat. It includes information on protecting vulnerable people, and advice for those planning events and mass gatherings during periods of hot weather.

National guidance, publications and resources

Office for Health Improvement and Disparities

- [Increasing blood pressure checks in community pharmacy: cardiovascular disease impact](#)
 - Document contains data for possible scenarios of CVD avoided from increasing the numbers of people seen for BP checks in community pharmacies (CP) in England. This supports policy options on increasing CP BP services and supports statements on the impact of these policies.

Cochrane Database of Systematic Reviews

- [Antidepressants for pain management in adults with chronic pain: a network meta-analysis](#)
 - Review (176 studies, 25 antidepressants, n=28,664,) found that duloxetine was the only treatment where there was certainty of efficacy in chronic pain (OR for substantial pain relief: 1.91, 95%CI 1.69-2.17). There were no reliable data for long term efficacy of any treatment.

UK Parliament Committees

- [Expert Panel: Evaluation of Government commitments made on pharmacy services in England](#)
 - The Expert Panel will evaluate nine Government commitments across five areas: community pharmacy, integrated care (including patient safety), hospital pharmacy, education, training and the pharmacy workforce, and extended services.

Health Foundation

- [Five principles for implementing the NHS Impact approach to improvement in England](#)
 - Principles incl: Set right pace for sustained improvement; set expectations that build commitment; enable learning across systems; build capability at provider/ICS level to navigate/reconcile competing priorities & align national policy around NHS Impact approach to improvement.

National guidance, publications and resources

Royal Pharmaceutical Society

- [Royal Pharmaceutical Society consulting on error standards](#)
 - These draft standards, aimed to be published in early 2024 describe good practice and good systems of care for reporting errors, learning, sharing, taking action and review as part of a patient safety culture. The consultation runs until 2nd June.
- [Royal Pharmaceutical Society position statement on genomics](#)
 - In this position statement supported by key stakeholders, the RPS is calling for pharmacy professionals to be included in the implementation, delivery and evaluation of a wide range of genomic services, building on already established roles in in some areas of clinical practice.
- [Daffodil Standards on end-of-life care for community pharmacies](#)
 - Eight standards jointly published by the RPS and charity Marie Curie aim to improve care by supporting the delivery of compassionate, holistic care to patients living with an advanced serious illness, or at the end of their lives, and their carers and wider family network.

National guidance, publications and resources

NIHR Dissemination Centre

- [NIHR Alert: How to keep prescribing safe over the longer-term](#)
 - Expert commentaries are provided on research identifying five strategies to increase the long-term success of prescribing interventions, based on studying the implementation of PINCER (pharmacist-led IT intervention) and computerised decision support across England.
- [NIHR Alert: How to reduce medications for people with multiple long-term conditions](#)
 - Commentaries are provided on the TAILOR study, a review of previous research that found deprescribing is generally safe and acceptable if done in a structured way. It also identified factors that help clinicians deprescribe.
- [NIHR Alert: Antibiotic review kit changed prescribing behaviour and was linked to a reduction in antibiotic use](#)
 - Commentaries are provided on a UK study of an antibiotic review kit which reported a 4.8% annual reduction in antibiotic use in hospitals vs previous use. Hospitals are encouraged to use the toolkit in staff training and embed within prescribing processes and stewardship work.

All Wales Medicines Strategy Group

- [Understanding unlicensed medicines](#)
 - This document provides guidance for improving the management of unlicensed 'specials' and off-label medicines in all sectors of healthcare in NHS Wales.

National guidance, publications and resources

Department of Health and Social Care

- [Hypertension \(High Blood Pressure\) resources](#)
 - Ahead of World Hypertension Day on 17th May 2023, these resources have been produced to support communications to build awareness of the risks, diagnosis, management and monitoring of hypertension. The resources are designed for use in a range of healthcare settings.
- [Type 2 Diabetes Prevention Week 2023 Toolkit](#)
 - The campaign aims to raise awareness of the risk of type 2 diabetes and how to avoid it. It will encourage the public to check their risk via the Diabetes UK Know Your Risk tool.

European Medicines Agency

- [Guidance for industry to prevent and mitigate medicine shortages](#)
 - EMA has published guidance describing various stakeholders involved in medicine supply chain and their responsibilities and role in prevention and management of medicine shortages. It provides ten recommendations to minimise the occurrence of medicine shortages and their impact.

Prevention of Future Death Reports (Regulation 28)



Courts and Tribunals Judiciary

- Nil relevant this month

Primary research- Medication Safety

- [When I use a word . . . Medical definitions: adverse events, effects, and reactions](#)
 - Article by previous editor of Meyler's Side Effects of Drugs discusses origins/differences between terms adverse event, adverse drug reaction & adverse drug effect & suggests terms to be avoided (well tolerated, toxicities, & side effect, latter restricted to colloquial use).
 - British Medical Journal
- [Polypharmacy and associated cumulative anticholinergic burden are important predictors of falls risk \(Letter to the editor\)](#)
 - In UK study (n=411; mean age 83.8 yrs), incidence of polypharmacy was 80.8%, anticholinergic burden score was significantly linked to higher falls rate (OR 1.150;1.020-1.290,p= 0.025) and each unit rise in score had stronger effect on increasing falls risk vs age & comorbidities.
 - British Journal of Clinical Pharmacology
- [Improving the spontaneous reporting of suspected adverse drug reactions; an overview of systematic reviews](#)
 - Review found educational initiatives were associated with improvements in quality of ADR reports. Improving availability of electronic reporting was also effective. Evidence for economic incentives was often clouded by the potential effects of other concomitant initiatives.
 - British Journal of Clinical Pharmacology
- [Minimizing prescribing errors: A phenomenological exploration of the views and experiences of independent prescribing pharmacists](#)
 - Themes from an interview study (n=14) found risk averse nature, expert role & experience of checking prescriptions were perceived as strengths for independent prescribing (IP) but inadequate diagnostic skills, inadequate IP training & complex patients increased risk of IP errors.
 - British Journal of Clinical Pharmacology

Primary research- Medication Safety

- [10 clinical tips for advancing patient safety when using syringe pump systems for microinfusion intravenous drug therapy](#)
 - 1: Train all users on their specific infusion pump system, 2: Establish and maintain proper protocol management for i.v. drug infusions, 3: Use infusion syringes that have been validated by the syringe pump manufacturer, 4: Use the smallest appropriate sized Luer lock syringe, 5: Keep the compliance and resistance of the infusion pump system as low as possible, 6: Minimise the number of infusion pumps connected to the same venous catheter lumen, 7: Avoid vertical displacement of an infusion pump during drug delivery, 8: Avoid very low flow rates, 9: Use the most sensitive occlusion alarm pressure reasonably possible, 10: Minimise pump start-up delays and flow irregularities during pump changeover
 - Eur J Anaesthesiol.
- [Enhancing active learning of medication errors in the PharmD curriculum through a multi-perspective video-based experience](#)
 - An immersive instructional series of video-based activities for pharmacy student evaluation of medication errors via root cause analysis (RCA). Pharmacy students reported significantly improved self-perceived skills in handling and preventing medication errors, but not in attitudes, following the immersive instructional activity.
 - Curr Pharm Teach Learn
- [Potentiality of algorithms and artificial intelligence adoption to improve medication management in primary care: a systematic review](#)
 - This study highlights how a proper application of AI in primary care is possible, since it provides an important tool to support the physician with drug management in non-hospital environments.
 - BMJ Open.
- [National initiative to promote public involvement in medicine safety: the use of a cross-sectional population survey to identify candidate behaviours for intervention development in Scotland](#)
 - Survey (1000 respondents) found only 29.8% sought advice from a pharmacist regarding a new medication, with those aged >35 years less likely to engage in this behaviour. Potentially unsafe behaviours in the use and disposal of medicines were identified.
 - BMJ Open

Primary research- Medication Safety

- [Examining medication ordering errors using AHRQ network of patient safety databases](#)
 - Incorrect dose and incorrect drug orders were the most commonly reported and harmful types of medication ordering errors. Future studies should aim to develop and test interventions focused on CPOE to prevent medication ordering errors, prioritizing wrong-dose and wrong-drug errors.
 - J Am Med Inform Assoc
- [Evaluation of the effectiveness of electronic prescription in reducing medical and medical errors \(systematic review study\)](#)
 - e-prescribing seems to reduce the risk of medication errors and ADE. However, the studies differed significantly in terms of setting, design, quality and results. More randomized controlled trials (RCTs) are needed to further improve the evidence of health informatics information.
 - Ann Pharm Fr.
- [Understanding complexity in a safety critical setting: A systems approach to medication administration](#)
 - 'Medication errors' are a significant concern and are associated with a higher incidence of adverse events and unintentional patient harm than any other aspect of healthcare. This article describes a study that applied the Event Analysis of Systemic Teamwork (EAST) model to study the hospital medication administration system to identify opportunities to optimise performance and patient safety. The research has shown that this approach enables mapping networks and their interdependencies to optimise the system as a whole rather than its parts in isolation.
 - Appl Ergon
- [CONSORT Harms 2022 statement, explanation, and elaboration: updated guideline for the reporting of harms in randomised trials](#)
 - Article describes CONSORT Harms 2022, an updated guideline to support better reporting of harms in RCT publications and elaborates on reporting guidance for each item relevant to the complete reporting of harms assessed in trials.
 - British Medical Journal

Primary research- Medication Safety

- [Development and Interrater Agreement of a Novel Classification System Combining Medical and Surgical Adverse Event Reporting](#)
 - This cross-sectional study found the new QICS classification scheme was applicable to wide-ranging clinical scenarios with a focus on patient-centered outcomes including near miss events. In addition, QICS allowed for the comparison of patient outcome data in a multitude of settings.
 - JAMA Otolaryngology Head Neck Surgery
- [Factors influencing in-hospital prescribing errors: A systematic review](#)
 - The findings of this systematic review could be used to identify points of engagement for future intervention studies and help hospitals determine how to optimize prescribing. A multifaceted intervention, targeting multiple factors might help to circumvent the complex challenge of in-hospital prescribing errors.
 - British Journal of Clinical Pharmacology
- [Thematic reviews of patient safety incidents as a tool for systems thinking: a quality improvement report](#)
 - This paper will present extracts of the themed review template trialled and argues that thematic reviews, in this context, allowed for a better understanding of the system of safety around the mismanagement of the deteriorating patient.
 - BMJ Publishing Group
- [Polypharmacy stewardship: a novel approach to tackle a major public health crisis](#)
 - This paper presents a novel concept of broad-spectrum polypharmacy stewardship.
 - The Lancet Healthy Longevity

Primary research- Medication Safety

- [Deprescribing interventions for gabapentinoids in adults: a scoping review](#)
 - This paper highlights the emerging issue of rising gabapentinoid misuse along with a lack of evidence for safe and effective deprescribing of gabapentinoid.
 - British Journal of Clinical Pharmacology
- [Reducing Opioid Use for Chronic Pain With a Group-Based Intervention: A Randomized Clinical Trial](#)
 - RCT (n=608) found a multicomponent intervention (including education and skill-based learning) improved self-reported discontinuation of opioids at 12 months vs usual care (29% vs 7%, OR 5.55, 95%CI 2.80-10.99) with no difference in pain interference with daily life activities.
 - Journal of the American Medical Informatics Association