SPS Medication Safety Update December 2023 Recent critical patient safety alerts, reports, and publications

Prepared by

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Medicines & Healthcare products Regulatory Agency
Specialist Pharmacy Service
NHS England

Patient Safety Alerts

NHS England

Currently 32 confirmed cases in England & Scotland (primary & secondary care) – up from 20 cases in November. Update includes urgent actions required by 17th December.

National Patient Safety Alert

UK Health Security Agency

Potential contamination of some carbomer-containing lubricating eye products with *Burkholderia cenocepacia* – measures to reduce patient risk

Date of issue:	07/12/2023	Reference no:	NatPSA/2023/015/UKHSA

This alert is for action by: Acute trusts, private providers/independent treatment centres providing NHS care, ambulance trusts, mental health trusts, community trusts, general practice and hospital and community pharmacy, and other health and care providers using/providing carbomer-containing lubricating eye products.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards).

- Ensure affected products are removed from clinical settings.
- Avoid use of all carbomer-containing lubricating eye products for:
  - individuals with cystic fibrosis (CF)
  - patients being cared for in critical care
  - severely immunocompromised
  - patients awaiting lung transplantation
- Submit any isolate from a new infection with Burkholderia cepacia complex, including any new isolations from CF patients to the UKHSA AMRHAI reference laboratory for identification and typing.
- Contact for queries: HCAIAMR.IOS@ukhsa.gov.uk

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National Patient Safety Alert

Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients

Date of Issue:	28 November 2023	Reference No:	NatPSA/2023/013/MHRA

This alert is for action by: Integrated Care Boards (in England), Health Boards (in Scotland), Health Boards (in Wales), and Health and Social Care Trusts (in Northern Ireland)

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive lead for quality (or equivalent) in Integrated Care Boards in England, Health Boards in Scotland, Health Boards in Wales, and Health and Social Care Trusts in Northern Ireland, alongside the Chief Pharmacist (or equivalent) and supported by the Medical Directors of organisations involved in the prescribing of valproate and clinical leads in neurology, psychiatry, paediatrics, learning disability and/or autism, contraception and sexual health, and general practice, with others included to meet local needs and clinical situations.

Current safety measures continue to apply. In addition, regulatory change in January 2024 means that:

- A. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
- B. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation change

- MHRA asks that a new or existing group co-ordinate implementation. This will include updating guidelines and pathways, work to understand needs of affected population, review of local audit results and identification of clinical resource to meet the identified needs of the population and implement the new regulatory measures.
- See MHRA review of safety data and expert advice on management of risks of valproate, information about the risk of taking valproate during pregnancy, guidance on valproate safety measures and advice for healthcare professionals to help prepare for new measures.
- Contact for queries: HCAIAMR.IOS@ukhsa.gov.uk

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National Patient Safety Alert

Department of Health & Social Care

NHS England

National Patient Safety Alert

Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba®) products

Date of issue:	8-Dec-23	Reference no:	NatPSA/2023/016/DHSC
This alert is for action by: All organisations involved in prescribing, dispensing and administering Tresiba® products.			
This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in diabetes, GP practices, pharmacy services in all sectors, private healthcare providers, those working in the Health and Justice sector.			

- Following a shortage of Tresiba® (insulin degludec) FlexTouch® 100units/ml (3ml pre-filled pens), the MSO network highlighted that some patients may have been switched to Tresiba® FlexTouch® 200units/ml (3ml pre-filled pens) and incorrectly advised to reduce the number of insulin units (MSO network highlighted 5 reports). Errors have occurred at the prescribing, dispensing and administration stages and one case describes a patient requiring hospital treatment.

- MHRA asks all providers to ensure patients on Tresiba® FlexTouch® 200units/ml pens are made aware that their pen dials up in unit increments rather than volume and no dose change is necessary.

- MHRA has specific actions for primary care providers and secondary care providers. This includes the recommendation to follow the advice in the Medicine Supply Notification and when prescribing Tresiba® 100units/ml Penfill® cartridges, ensure patient is also supplied with a compatible Novo Nordisk insulin delivery system and appropriate needles.
- Contact for queries: HCAIAMR.IOS@ukhsa.gov.uk

Medicines & Healthcare products Regulatory Agency

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NHS England

Recent regulator and statutory body activity

Medicines & Healthcare products Regulatory Agency

- Ozempic▼(semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products
  Falsified Ozempic▼ and Saxenda products found in the UK. Healthcare professionals asked to remind patients to always obtain from a qualified healthcare provider and not to use if they suspect products are falsified as this may lead to serious health consequences. Healthcare professionals should remain vigilant for symptoms linked to hypoglycaemia in patients who may have obtained a falsified product containing insulin.

- Nirmatrelvir, ritonavir (Paxlovid▼): be alert to the risk of drug interactions with ritonavir
  Risk of harmful drug interactions with the ritonavir component of Paxlovid▼ due to its inhibition of the enzyme CYP3A, which metabolises many commonly used drugs. Prescribers should obtain a current medication history before initiating and check product information for drug interactions.

- Indiana Ophthalmics LLP field safety notice regarding potential contamination of Carbomer eye gel
  Urgent Field Safety notice to inform about the potential risk of microbial contamination in Carbomer eye Gel. Requires all products specified to be removed from clinical settings, procurement of these stocks are ceased and recall from market. Relates to the safety alert on slide 2.

Recent regulator and statutory body activity

Medicines & Healthcare products Regulatory Agency

Class 4 Medicines Defect Information

- Class 4 Medicines Defect Information: Strandhaven Ltd t/a Somex Pharma, Clarithromycin 250mg and 500mg film-coated tablets, EL (23)A/42 Patient Information Leaflets (PILs) in listed batches are missing latest safety information advising patient not to take clarithromycin & tell doctor if they are taking lomitapide or have hypokalaemia/ hypomagnesaemia & inform doctor/pharmacist if on anticoagulant. Healthcare professionals are asked to provide an updated PIL if possible; if not they should advise patients of the missing information.
- Class 4 Medicines Defect Information: Strandhaven Ltd t/a Somex Pharma, Tramadol Hydrochloride 50mg Capsules, Hard, EL (23)A/41
  PILs in listed batches do not include up to date safety information on drug interactions with antidepressants, sleep-related breathing disorders, adrenal insufficiency, hiccups, and serotonin syndrome, and the need for medical advice if they occur. Healthcare professionals are asked to provide an updated PIL if possible; if not they should advise patients of the missing information
- Class 4 Medicines Defect Information: Atnahs Pharma UK Limited, Clobazam Atnahs 5mg/5ml and 10mg/5ml Oral Suspension, EL(23)A/43
  SmPC and PIL in packs of affected batches missing significant information in relation to use of the product in children (contraindicated), pregnancy, depression, drug dependence, numerous interactions and adverse effects. Healthcare professionals advised to provide advice accordingly or do not prescribe and/or dispense. If supplying, provide a copy of the PIL to patients.

Class 3 Medicines Recall Information

- Class 3 Medicines Recall: AstraZeneca UK Ltd., Fluenz Tetra nasal spray suspension, EL(23)A/39
  Printed expiry date for affected batches is incorrect and needs to be reduced by up to 5 days as a precautionary measure.
- MHRA Class 3 Medicines Recall: Posaconazole Biocon 100mg Gastro-resistant Tablets (Biocon Pharma UK Limited)
  A specific of batch is being recalled due to an out of trend result for unspecified impurities during testing for stability. The batch is likely to be out of specification before the expiry date and therefore the batch is being recalled as precautionary measure.

Recent regulator and statutory body activity

Health Services Safety Investigations Body (HSSIB)

- Nil of note this month

Healthcare Safety Investigation Branch

- Change needed in how GP continuity of care is prioritised at a national level

The investigation identified no requirement in the GP contract nor any standard framework to help to deliver this. HSSIB recommends that the new GP contract supports practices to deliver continuity of care. It also recommends GP IT systems updated to ensure patient continuity of care is maintained when patients visit GP practices multiple times with unresolving symptoms.

- Electronic patient record (EPR) systems: recurring themes arising from safety investigations

Blog discusses key themes including lack of interoperability between the EPR and other IT systems across services. Three cases were discussed in which patients suffered harm because of this. The new NHS 'federated' data platform will enable every NHS trust and ICS to connect and share information. Organisations will need to; plan for interoperability, perform user-centred design input to help design systems and commit to usability testing with the staff and patients who will use the system, in the environment the EPR system will be used in, to best reflect 'real world' work.

Pharmacovigilance Risk Assessment Committee (PRAC)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- GLP-1 receptor agonists' review: PRAC requests further clarifications from marketing authorisation holders

  PRAC was unable to draw any conclusions on a causal association between GLP-1 receptor agonists and thoughts of self-harm/suicide. Further questions to be addressed by marketing authorisation holders have been agreed and the topic will be discussed again in April 2024.

- PRAC recommends measures to minimise the risk of serious side effects with medicines containing pseudoephedrine

  PRAC has recommended new measures medicines containing pseudoephedrine to minimise the risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), including avoiding use in those with severe or uncontrolled hypertension or with severe acute (sudden) or chronic (long-term) kidney disease or failure. Patients should be advised to stop using these medicines immediately and seek treatment if they develop symptoms of PRES or RCVS, such as severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures and visual disturbances. The MHRA announced earlier this year that they are "reviewing available evidence" on potentially serious side effects linked to medicines containing pseudoephedrine.

- FDA Drug Safety Communication: Rare but serious drug reaction linked to use of levetiracetam or clobazam

  These drugs can cause Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), which may start as a rash but can quickly progress, resulting in injury to internal organs, hospitalisation, and even death. FDA is requiring warnings to be added to the prescribing information.

Direct HCP communication

- Specific brands of carbomer eye gel: recall of AACARB eye gel, AACOMER eye gel and PUROPTICS eye gel: potential risk of infection, DSI/2023/11

  An investigation by UKHSA has identified a potential association of a Burkholderia cenocepacia bacterial contamination with the named eye gels. As a precautionary measure these eye gels are being recalled. UKHSA considers the risk to the public from Burkholderia cenocepacia to be very low, but some patient groups are at higher risk of adverse effects.

- Aripiprazole (Abilify and generic brands): risk of pathological gambling

  Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders (e.g. excessive eating, spending, or abnormally high sex drive) and should advise patients and their families to be alert to these risks

- Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions

  As vitamin B12 contains cobalt, healthcare professionals prescribing these products to patients with known cobalt allergy should advise patients to be vigilant for signs and symptoms of cobalt sensitivity (e.g. skin reactions such as a rash or hives) and treat as appropriate.

SPC changes

- Revised SPC: Motilium (domperidone) 10mg Film-coated Tablets

  Updated to include restless legs syndrome and urticaria as side-effects, to note an observed increase of plasma levodopa concentration (max 30-40%) when taken with domperidone, and to discuss recommended dosing in severe renal impairment.

- Revised SPC: Vaxzevria (Covid-19 Vaccine AstraZeneca)

  Updated to include a warning about acute disseminated encephalomyelitis in section 4.4

- Revised SPC: Co-Amoxiclav 1000 mg/200 mg Powder for Solution for Injection/Infusion (Sandoz)

  Updated to note hypersensitivity reactions can progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Linear IgA disease, acute pancreatitis and drug-induced enterocolitis syndrome also added as ADRs.

- Revised SPC: VFEND (voriconazole) 200 mg powder for solution for infusion

  Now includes warning for the increased risk of skin toxicity with concomitant use of voriconazole and methotrexate, and potentially other drugs associated with ultraviolet reactivation.

- Revised SPC: Cefalexin products

  SPC now notes that there have been reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy with cephalosporins. Most cases occurred in patients with renal impairment on doses above the recommended maximum and resolved following discontinuation.

- Revised SPC: Kaletra 100 mg/25 mg and 200 mg/50mg (lopinavir/ritonavir) film-coated tablets

  Warning on interaction with dabigatran or edoxaban added as serum concentrations may be increased due to P-gp inhibition by lopinavir/ritonavir. Clinical monitoring and/or dose reduction of these DOACs should be considered when co-administered with Kaletra.

SPC changes

- Revised SPC: Adcortyl (triamcinolone acetonide) Intra-Articular/Intradermal Injection 10mg/ml

  Central serous chorioretinopathy added to SPC as adverse reaction of unknown frequency.

- Revised SPC: Propofol 10mg/ml (1%) and 20mg/ml (2%) emulsion for injection or infusion

  SPC now warns that co-administration of propofol with midazolam is likely to result in enhanced sedation and respiratory depression, therefore a dose reduction of propofol should be considered when used concomitantly with midazolam.

- Revised SPC: Tecentriq (atezolizumab) 1,875 mg solution for injection

  SPC now warns haemophagocytic lymphohistiocytosis (HLH), including fatal cases, which have been reported with atezolizumab. For suspected HLH, atezolizumab to be permanently discontinued & patients referred to a specialist.

- Revised SPC: Rinvoq (upadacitinib hemihydrate) 45 mg prolonged-release tablets

  SPC updated to include gastrointestinal perforation as an uncommon adverse event.

- Revised SPC: Iluvien (fluocinolone acetonide) 190 micrograms intravitreal implant in applicator

  Warning added that visual disturbance may be reported with systemic/topical corticosteroids. Patient with such symptoms should be considered for ophthalmology referral for evaluation of possible causes, e.g. cataract, glaucoma or rare eye diseases.

- Revised SPC: Padcev (enfortumab vedotin) 20 mg and 30 mg powder for concentrate for solution for infusion

  SPC now includes section on risk of pneumonitis and interstitial lung disease. Studies report the ADRs occurred in 15 (2.2%) & 2 (0.3%) of 680 patients on enfortumab 1.25 mg/kg, respectively. Data also provided on severity, discontinuation rates, and time course of symptoms.

SPC changes

- Revised SPC: Palladone SR capsules - all strengths

  Statement introduced on dose conversion when switching between oral and parenteral hydromorphone advising the switch should be guided by sensitivity of the individual patient. Oral starting dose should not be overestimated as oral bioavailability is ~32%.

- Revised SPC: Prolia (denosumab)

  SPC updated with data from study data in children with osteogenesis imperfecta, aged 2-17 years. Studies terminated early due to life-threatening events & hospitalisations due to hypercalcaemia

- Revised SPC: Quinsair (levofloxacin) 240 mg nebuliser solution

  SPC updated with warning that there are no pharmacological therapies established to be effective for treating the symptoms of long lasting or disabling side effects associated with fluoroquinolones.

- Revised SPC: Seroxat (paroxetine) 10mg tablets

  Leukopenia added to SPC as an uncommon adverse drug reaction.

- Revised SPC: Tildiem (diltiazem) – all products

  Increased risk of LFT elevations added to warning about interaction with lomitapide. Lupus-like syndrome added as ADR of unknown frequency & warning that non-cardiogenic pulmonary oedema (inc. delayed onset) rarely reported after overdose.

- Revised SPC: Octas (mesalazine) 1600 mg modified-release tablets

  SPC updated to include drug reaction with eosinophilia and systemic symptoms (DRESS) as an adverse effect and to note mesalazine may produce red-brown discolouration after contact with sodium hypochlorite bleach.

SPC changes

- Revised SPC: Erythromycin ethyl succinate 250 mg/5 ml Granules for Oral Suspension

  Addition of a contraindication with lomitapide due to markedly increased transaminase levels with concomitant use, a warning to use with caution with corticosteroids and information on risk of congenital malformations after use during pregnancy.

- Revised SPC: Furosemide Injection BP (hameln)

  Addition of lichenoid reactions as a rare adverse effect.

- Revised SPC: Moxifloxacin 400 mg film-coated tablets

  Now includes MHRA warnings on the risk of disabling and potentially long-lasting or irreversible side effects, sometimes affecting multiple systems, with fluoroquinolone antibiotics. Changes include advice to use this only when other antibiotics inappropriate.

- Revised SPC: Nivestim (filgrastim) solution for injection/infusion - all strengths

  Addition of warning that myelodysplastic syndrome and acute myeloid leukaemia have been associated with the use of pegfilgrastim, in conjunction with chemotherapy and/or radiotherapy in breast and lung cancer patients

- Revised SPC: Brintellix (vortioxetine hydrobromide) 20 mg film-coated tablets

  SPC updated to include dyspepsia, akathisia, bruxism, trismus, restless leg syndrome, tremor, discontinuation syndrome, vision blurred, and galactorrhoea as adverse reactions.

- Revised SPC: Protium (pantoprazole) i.v. 40 mg powder for solution for injection

  SPC updated to include information on severe cutaneous adverse reactions, reports of false-positive results in some urine screening tests for tetrahydrocannabinol, and updated information on undesirable effects.

Manufacturer RMM

- Risk minimisation materials: Tepkinly (epcoritamab) patient card
  Patient card, to be carried at all times, discusses the risk and symptoms of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, which may be serious or fatal if not treated promptly.
- Risk minimisation materials: Caffeine Citrate 10mg/mL solution for injection and 10mg/mL oral solution
  Card contains important points to consider, including monitoring, dosing instructions (including to specify dose clearly as caffeine citrate), and to caution not to confuse with another available formulation of caffeine citrate solution, which is a different strength.
- Risk Minimisation Materials for Tyenne (tocilizumab) 162 mg solution for injection in pre-filled pen
  Materials include a dosing guide (for both the IV and SC formulations), a healthcare professional brochure (both of which form part of the Risk Management Plan), and a patient brochure and alert card, to help patients understand the risks with the treatment.
- Risk Minimisation Materials for Byooviz (ranibizumab)
  Materials include separate patient booklets for each indication, providing an overview of how the treatment works, how it is administered and what to expect, key signs and symptoms of potential adverse reactions & when to seek urgent medical attention.
- Risk Minimisation Materials for Actiq (fentanyl) lozenges
  Materials include a patient/carer guide, a pharmacist's guide for dispensing, and a physician's guide for prescribing, to support their safe and appropriate use for the treatment of cancer breakthrough pain.
- Risk Minimisation Materials for Fentanyl (Effentora) 100 mcg Buccal Tablets
  Materials include a patient/carer guide, a pharmacist's guide for dispensing, and a physician's guide for prescribing, to support their safe and appropriate use for the treatment of cancer breakthrough pain.

Drug shortages and discontinuations

Recent medicine shortages and discontinuations are available via the SPS Medicines Supply Tool (registration required to access). This is not a comprehensive list. Only critical safety medication shortages have been highlighted.

Drug Shortages

- Oxybutynin 5mg modified-release tablets
- Tetracosactide 1mg/1ml suspension for injection ampoules
- Dactinomycin 500microgram powder for solution for injection vials
- Microgynon 30 ED tablets
- Fludarabine phosphate 50mg/2ml concentrate for solution for injection
- Atenolol 5mg/10ml solution for injection ampoules
- Diazepam 2mg/5ml oral solution sugar free
- Propantheline bromide 15mg tablets
- Lanreotide 60mg/0.5ml, 90mg/0.5ml and 120mg/0.5ml solution for injection pre-filled syringes
- Mannitol 50g/500ml (10%), 75g/500ml (15%) infusion viaflo bags & 50g/500ml (10%) polyfuser infusion bottles (includes advice for MSO's)

Discontinuations

- Hydrogen Peroxide 3%, 6% and 9% solution

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Breast feeding

Using vitamin D during breastfeeding

Medication adherence

Defining and understanding medication adherence
Visual impairment: supporting adherence
Reminding to take medicines: supporting adherence
Swallowing difficulties: supporting adherence
Explaining how to use or take medicines: supporting adherence
Manual dexterity: supporting adherence
Complex medication regimens: supporting adherence

Unlicensed medicines

Governance principles for unlicensed medicines
Making unlicensed medicines
Purchasing Specials

Webinars

Applying national medicines programmes within Health & Justice practice
Lipid Management in primary care

PGDs

Understanding roles and responsibilities of PGD signatories

Other

Medication Restrictions for Patients having CAR-T Therapy
Deprescribing of antidepressants for depression and anxiety

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NHS England

Prevention of Future Death Reports (Regulation 28)

Courts and Tribunals Judiciary

Ref: 2023-0516 (Cyclizine related death) 8th December 2023

Death of a complex patient following cyclizine overdose. Concerns raised over lack of awareness of the risks of cyclizine abuse by healthcare professionals.

Ref: 2023-0513 (Propranolol overdose) 12th December 2023

Death following propranolol overdose. Concerns relate to significant delays in getting the patient to hospital. Included here following HSIB report as a reminder of the potential risks of propranolol overdose.

Ref: 2023-0487 (Pregabalin) 17th November 2023

Death following a suspected drug overdose in a known drug user and subsequent cardiac arrest. Concerns raised over lack of monitoring of signs of abuse when the patient was started on pregabalin.

Ref: 2023-0485 (Warfarin and tramadol) 20th November 2023

Death following subarachnoid haemorrhage caused by significantly raised INR on patient on warfarin and started tramadol for back pain.
Concerns raised due to relatively unknown reaction between tramadol and warfarin.

Ref: 2023-0512 (Serotonin syndrome) 24th November 2023

Death due to serotonin syndrome following venlafaxine overdose. Concern raised over the use of the sedative used in intensive care (presumed to be fentanyl) which is felt to have caused a reprecipitation of serotonin toxicity as patient developed paralytic ileus which is presumed to have delayed the absorption of the modified release antidepressant.

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National guidance, publications and resources

- BNF/BNFC newsletter November 2023

Updates include MHRA advice on quinolone side-effects, valproate safety measures and photosensitivity with methotrexate, updated stroke guidance, and new monographs (mavacamten, cipaglucosidase alfa, daridorexant, deucravacitinib [adults], risankizumab, semaglutide [children]).

- Adrenaline auto-injector prescription for patients at risk of anaphylaxis: BSACI guidance for primary care

Among other points, this guidance recommends GPs provide 2 adrenaline auto injectors for those at significant risk of anaphylaxis & to always carry them. Where uncertain about anaphylaxis risk, prescribing adrenaline is a safety net, pending review in a specialist allergy clinic.

- Pharmacy supervision – open consultation

This consultation sets out proposals to enable pharmacists to authorise pharmacy technicians to carry out, or supervise others carrying out, the preparation, assembly, dispensing, sale and supply of medicines. Closing date for comments is 29th February 2024.

- Government begins legal process for regulation of Physicians Associates

As part of its Long-Term Workforce Plan, the government begins a legal process to allow the GMC to regulate medical associates, e.g. Physician Associates (PAs). This will support the safe expansion of these roles to support GPs and improve safety and access for patients.

- Politicians, experts, and patient representatives call for the UK government to reverse the rate of antidepressant prescribing

Letter from this group, published in the BMJ, notes antidepressant prescriptions have almost doubled in England in the last decade to 85.6m in 2022-23, and this number is set to rise. They claim long term use is linked to weight gain, sexual dysfunction, bleeding, falls, and poorer long-term outcomes.

Primary research- Medication Safety

- Opioid-related deaths and their counterpart by occurrence-era, age-group and co-implicated drugs: Scotland versus England and Wales

  Between 2012-2014 & 2018-2020, Scotland's opioid-related deaths (ORDs) increased by 54% and non-ORDs by 34%. Increase in drug misuse deaths in England & Wales was more modest. Cocaine was implicated in 83% of Scotland's 2690 non-ORDs during 2006-2020 and any benzodiazepine in 53% of 8409 ORDs

- DTB select: Safety update: statins and myasthenia gravis (MG)

  Article provides context on recent MHRA Drug Safety Update on small number of reports of new-onset or worsening of MG associated with statins, noting it's unclear how effective it will be to warn all patients to be alert to symptoms rather than focusing on those with existing MG.

- Coroner advises NHS England to take action to raise awareness about interaction between tramadol and warfarin following death of a patient

  Patient on warfarin for number of years prescribed tramadol for lower back pain on 2 occasions. Before anticoagulant clinic review could take place, she was admitted with INR of 11.6 & died from bleed on brain despite immediate reversal. This interaction is in SPC but not currently in BNF.