



## TAG Mail: January to April 2024 Cumulative Listing of Reports, Publications, Medication Safety

### Fortnightly TAG Mail – resources list

11<sup>th</sup> April 2024

#### Open email discussions

- 1. Hospital-funded Shingrix:** Are DTCs are receiving requests to approve use and funding of Shingrix in their immunocompromised patient populations that are outside the NIP criteria and what is your approach to these potentially very expensive requests? **Closes 24th April 2024**
- 2. Hospital/district approaches to supplying and stocking COVID-19:** Hospitals are requested to outline any strategies they are considering/implementing concerning supply of COVID-19 antivirals to ED patients and stocking of COVID-19 antivirals for inpatient use. **Closes 1st May 2024**

#### Recently completed email discussions

- Handling of medicines by perfusionists
- DTC assessment process for non-GMO phage therapy applications
- DTC pharmacists in NSW
- Patient prioritisation for discharge medication list provision
- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

#### Upcoming TAG meetings

NSW TAG Editorial Committee Meeting: Monday 15<sup>th</sup> April 2024 11.00-12.30pm

#### Updated TAG publications

Updated SGLT2 inhibitor Consumer Leaflet - [link](#).

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions, publications or upcoming meetings.

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#### EDITOR'S PICKS

AIM: - Management of Inpatient Elevated Blood Pressures - [link](#)

NHS England: Pharmacogenomics tutorial for pharmacists/pharmacy technicians - [link](#)

ISMP: Guardians of Grafts: Reducing Medication Errors in Transplant Recipients - [link](#)

BJCP: Assessing pain in persons with opioid use disorder: - [link](#)

BMJ Open: Implementation of an intervention aimed at deprescribing benzodiazepines in a large US healthcare system using patient education materials- [link](#)

BMJQS: Estimating the impact on patient safety of enabling the digital transfer of patients' prescription information in the English NHS - [link](#)

Drug Safety: Drug-drug interactions and actual harm to hospitalized patients: a multicentre study examining the prevalence pre- and post-electronic medication system implementation - [link](#)

EHJ: Low-dose colchicine for atherosclerosis: long-term safety - [link](#)

EHJ: Use of new and emerging cancer drugs: what the cardiologist needs to know - [link](#)

EJHP: Appropriateness of antithrombotics in geriatric inpatients with atrial fibrillation - [link](#)

HLC: Discharge Information About Adverse Drug Reactions Indicates Lower Self-Reported Adverse Drug Reactions and Fewer Concerns in Patients After Percutaneous Coronary Intervention - [link](#)

HTA: Evaluation of venous thromboembolism risk assessment models for hospital inpatients- [link](#)

IMJ: The increasing costs of medicines and their implications for patients, physicians and the health system - [link](#)

IJCP: Novel opportunities for clinical pharmacy research: development of a machine learning model to identify medication related causes of delirium in different patient groups - [link](#)

IJCP: Clinical pharmacy key performance indicators for hospital inpatient setting - [link](#)

JAGS: - Melatonin does not reduce delirium severity in hospitalized older adults - [link](#)

JAMA Network Open: Drug Efficacy in the Treatment of Antipsychotic-Induced Akathisia - [link](#)  
JAMA Oncology: Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies - [link](#)  
Lancet D&E: Effects of statin therapy on diagnoses of new-onset diabetes and worsening glycaemia in large-scale randomised blinded statin trials– [link](#)  
MJA: Editorial-Interventions for reducing the prescribing of pharmaceutical opioids in Australia: are they effectively reducing opioid harm? – [link](#) – and [research article](#)  
NEJM: - Nirmatrelvir for Vaccinated or Unvaccinated Adult Outpatients with Covid-19 - [link](#) – [SPS commentary](#)  
PEC: Medication Errors in Pediatric Emergency Departments - [link](#)  
Prescrire International: Prescrire's ratings of new drugs in 2023

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## OTHER NEWS

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### **Australian Commission on Safety and Quality in Health Care (ACSQHC)**

- Launch of clinical care standard for psychotropic medicines - [link](#)

### **CATAG**

Medicines Advice Initiative Australia (MAIA) project: Cumulative Medicines toolkit: Practice tool and Teaching tool - [link](#)

Collaborating with Consumers project: Understanding medicines access programs - [link](#)

### **NSW Health**

- Measles alert for Western Sydney [[31 March 2024](#)] – and [factsheet](#)

- Maintaining health during and after floods and storms - [link](#)

### **TGA**

- Update on the rescheduling of bromoxynil products - April 2024 - [link](#)

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## REPORTS AND PUBLICATIONS – AUSTRALIA

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### **Agency for Clinical Innovation, NSW (ACI)**

The latest weekly Evidence Digest can be found [here](#)

- Digital mental health interventions for young people evidence check - [link](#)

### **Australian Government Department of Health**

- Unleashing the Potential of our Health Workforce – Scope of Practice Review – Issues Paper 1 - [link](#)

### **Australian Institute for Health and Welfare (AIHW)**

- Australia's disability strategy 2021–2031 - [link](#)

### **MIMS monthly updates [April 2024](#)**

- New Products

-- Fezolinetant ([Veoza](#)) for moderate to severe vasomotor symptoms (VMS) associated with menopause

-- Prasterone ([Intrarosa](#)) for vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms

-- Recombinant respiratory syncytial virus pre-fusion F protein (RSVPreF3) vaccine ([Arexvy](#)) for active immunisation of individuals 60 years and older for the prevention of LRTD caused by RSV per official recommendations

- New Presentation

-- Melatonin ([Voguily](#)) is now available as capsules and as an oral solution

- New Indications

-- Empagliflozin ([Jardiance](#)) is now indicated to reduce the risk of kidney disease progression in adults with chronic kidney disease (CKD) stages 2 and 3A with urine albumin to creatinine ratio (UACR)  $\geq$  30 mg/g, or CKD stages 3B, 4 and 5 irrespective of UACR.

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

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ABN: 82 707 308 091

-- Pembrolizumab (rch) ([Keytruda](#)) is now indicated as monotherapy for the adjuvant treatment of patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC who have undergone complete resection and platinum-based chemotherapy.

#### TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
- Tibsovo ([ivosidenib](#)) for the treatment of acute myeloid leukaemia that carries a particular mutation

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### REPORTS AND PUBLICATIONS – INTERNATIONAL

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#### Agency for Healthcare Research and Quality (AHRQ) USA

- Rapid Evidence Product: Prevention in Adults of Transmission of Infection With Multidrug-Resistant Organisms - [link](#)
- Rapid Research: Failure To Rescue – Rapid Response Systems - [link](#)

#### Canadian Agency for Drugs and Technologies in Health

- Long-Term Use of Omalizumab for Chronic Idiopathic Urticaria - [link](#)

#### electronic Medicines Compendium (eMC) (UK)

- [New products](#)
- Ayyakyt (avapritinib) - monotherapy for adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) harbouring the platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation
- Genvoya (elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide fumarate) - new (lower) strength licensed for treatment of HIV without any known mutations linked to resistance to integrase inhibitor class, emtricitabine or tenofovir in patients aged from 2 years and with body weight ≥14 kg
- Povidone iodine 5% w/v eye drops solution for the pre-operative preparation of the surgical field (eyelids, lashes and cheeks) and irrigation of the ocular surface (cornea, conjunctiva and palpebral fornices). Each 4ml single use container provides 200 mg of povidone iodine
- Rivaroxaban 2.5mg generic version licensed for use in combination with aspirin alone or aspirin + clopidogrel or ticlopidine, for prevention of atherothrombotic events after ACS with elevated cardiac biomarkers, or for CAD or symptomatic PAD at high risk of ischaemic events
- Velsipity (etrasimod) for patients aged ≥16 years with moderately to severely active ulcerative colitis who have had inadequate response, lost response, or were intolerant to either conventional therapy or a biological agent
- [Revised SPCs](#)
- DuoResp Spiromax (budesonide, formoterol) now also licensed for use as a reliever therapy for adults and adolescents (12 years and older) with mild asthma. The shelf-life after first opening has been extended from 6 months to 12 months
- Omeprazole - new indication of the treatment of Zollinger-Ellison syndrome

#### Food and Drug Administration (FDA) USA

- FDA Approves First Prescription App for Depression - [link](#)
- New Drug approvals
- Vafseo ([vadadustat](#)) to treat anemia due to chronic kidney disease
- Voydeya (danicopan) to treat extravascular haemolysis with paroxysmal nocturnal hemoglobinuria
- [Zevtera](#) (ceftobiprole medocartil sodium) to treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia
- idecabtagene vicleucel ([Abecma](#)) CAR-T therapy approved for multiple myeloma after 2 or more lines of therapy
- New indications
- FDA grants accelerated approval to fam-trastuzumab deruxtecan-nxki ([Enhertu](#)) for unresectable or metastatic HER2-positive solid tumors
- iloperidone ([Fanapt](#)) for acute treatment of manic or mixed episodes associated with bipolar I disorder

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- dolutegravir/lamivudine ([Dovato](#)) - indication for HIV expanded to include adolescents
- ciltacabtagene autoleucl ([Carvykti](#)) - earlier treatment approved for multiple myeloma after 1 or more lines of therapy

### **Medicines and Healthcare products Regulatory Agency (MHRA)**

- MHRA approves combined antibiotic cefepime/enmetazobactam (Exblifep 2g/0.5 g powder for concentrate for solution for infusion) - [link](#)
- Fosdenopterin approved to treat adult patients with molybdenum cofactor deficiency (MoCD) Type A - [link](#)

### **NHS England**

- Medicines Learning Portal: Pharmacogenomics tutorial for pharmacists/pharmacy technicians - [link](#)
- Quality & outcomes framework guidance for 2024/25, including new cholesterol indicator ([CHOL004](#))

### **NHS Scotland/Scottish Medicines Consortium**

- Accepted for use:
  - [dostarlimab](#) (Jemperli) in combination with platinum-containing chemotherapy for patients with mismatch repair deficient/microsatellite instability-high primary advanced or recurrent endometrial cancer
  - [mavacamten](#) (Camzyos) for symptomatic obstructive hypertrophic cardiomyopathy
  - [ritlecitinib](#) (Litfulo) for severe alopecia areata in adults and adolescents 12 years of age and older
- Accepted for restricted use:
  - [daridorexant](#) (Quviviq) for adult insomnia patients with symptoms present for at least 3 months whose daytime functioning is impacted
  - [tirzepatide](#) (Mounjaro) for adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

### **National Institute for Health and Care Excellence (NICE) UK**

- Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy ([TA962](#))
- Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer ([IPG784](#))
- Dostarlimab with platinum-based chemotherapy for treating advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency ([TA963](#))
- Twin and triplet pregnancy- updated guidance ([NG137](#))
- Cabozantinib with nivolumab for untreated advanced renal cell carcinoma ([TA964](#))

### **National Institute for Health and Care Research (NIHR)**

- Irritable bowel syndrome: low-dose antidepressant improves symptoms - [link](#)
- Surgery is better than nasal sprays for people with severely blocked airways - [link](#)

### **Scottish Intercollegiate Guideline Network (SIGN) UK**

- SIGN170 Optimising glycaemic control in people with type 1 diabetes – [link](#) - [toolkit](#)

### **Specialist Pharmacy Services NHS UK**

- Understanding complementary medicines - [link](#)

### **UK Health Security Agency**

- National criteria for prompt intravenous-to-oral switch (IVOS) of antimicrobials in children and young people (including newborns) - [link](#) – [SPS commentary](#)

### **World Health Organisation (WHO)**

- Consolidated guidelines on person-centred viral hepatitis strategic information: using data to support country scale-up of hepatitis prevention, diagnosis and treatment services - [link](#)
- Co-administration of treatment for drug-resistant tuberculosis and hepatitis C: rapid communication - [link](#)

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- WHO publishes new guidelines on hepatitis B - [link](#)
- WHO launches guidance on conducting reviews of tuberculosis programmes - [link](#)
- WHO unveils a digital health promoter harnessing generative AI for public health - [link](#)
- Telehealth quality of care tool - [link](#)

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## MEDICATION SAFETY

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### All Wales Therapeutics and Toxicology Centre

- The All Wales Policy for Medicines Administration, Recording, Review, Storage & Disposal ([Update](#))

### electronic Medicines Compendium (eMC) (UK)

#### - [Revised SPCs](#)

- Benlysta (belimumab) - frequency of ADRs urticaria and rash from 'uncommon' to 'common', and diarrhoea and nausea from 'very common' to 'common'
- Bonviva (ibandronic acid) - atypical fractures of long bones other than the femur added as a potential ADR of treatment (frequency unknown). These fractures occur after minimal, or no trauma and some patients experience prodromal pain prior to presenting with a completed fracture
- Copaxone (glatiramer) - moderate amount of data (300-1000 pregnancy outcomes) indicate no malformative or fetoneonatal toxicity, & animal studies do not indicate reproductive toxicity. Manufacturers advise use may be considered during pregnancy, if necessary
- Dalacin (clindamycin) - risk of the known possible adverse effect of oesophagitis and oesophageal ulcer is increased if taken in a lying position and/or with a small amount of water
- Edronax (Reboxetine) - serotonin syndrome included as possible ADR, frequency 'not known'
- Elvanse Adult (lisdexamfetamine) - epistaxis added as potential ADR of uncommon frequency
- Equasym (methylphenidate) - contusion added as ADR of unknown frequency
- Eylea (afibercept) - unopened vial may be stored outside refrigerator below 25 °C for up to 24 hrs
- Gavreto (pralsetinib) - male patients with female partners of childbearing potential must use effective contraception, including a barrier method during treatment with pralsetinib and for at least 1 week following the last dose of treatment
- Lemsip Cough for Mucus Cough & Catarrh (guaifenesin & cetylpyridinium chloride) - contra-indicated in children under 6 years. Caution in use is also advised in patients with porphyria
- Matrifen (fentanyl) transdermal - dysphagia added as uncommon potential ADR
- Mektovi (binimetinib) - occurrence of tumour lysis syndrome, which may be fatal, has been linked to use of binimetinib in association with encorafenib. Risk factors include high tumour burden, pre-existing chronic renal insufficiency, oliguria, dehydration, hypotension and acidic urine
- Neupogen (filgrastim) - extramedullary haematopoiesis added as ADR of rare frequency
- Ninlaro (ixazomib citrate) rare ADRs added: toxic epidermal necrolysis (TEN), anaphylactic reaction, and angioedema. Further warning and precaution information on TEN is also detailed
- Nortriptyline - unmasking of Brugada syndrome has been reported with nortriptyline. Nortriptyline should generally be avoided in patients with or suspected of having Brugada syndrome. Risk factors for Brugada syndrome include a family history of cardiac arrest or sudden death
- Ontozry (cenobamate) - suicidal ideation and behaviour have been reported in patients treated with anti-epileptic medicinal products including cenobamate (uncommon frequency)
- Questran and Questran Light (colestyramine) – info added on concomitant use with a statin, avoiding use in patients with exudative/bloody diarrhoea, timing of administration in relation to absorption of other drugs, risk of constipation or its aggravation, and drug interactions with digoxin and spironolactone
- Remsima (infliximab) – the period in which administration of live vaccines to infants exposed to infliximab in utero is not recommended has been extended from 6 months to 12 months, after birth. Additionally, dyslipidaemia has been added as an uncommon ADR
- Sodium Oxybate - shelf-life for unopened product has been changed from 3 to 5 years, and shelf-life after first opening has been changed from 40 to 90 days
- Sutent (sunitinib) - hyperammonemic encephalopathy added as a potential ADR of treatment (unknown frequency). In patients who develop unexplained lethargy or changes in mental status, ammonia level should be measured and appropriate clinical management should be initiated

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- Upstaza (eladocagene exuparvovec) - feeding disorders included as a possible 'common' ADR, frequencies of irritability changed from 'very common' to 'common' and decubitus ulcer from 'common' to 'very common', paragraph included about cerebrospinal fluid leaks
- Zelboraf (vemurafenib) – stomatitis added as a common potential ADR of treatment
- Risk minimisation materials
- Farydak ([Panobinostat](#)) - patient cards for cycles 1-8 and 9-16 are intended to help patients keep track of their treatment regimen and maintain compliance

#### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [April 4, 2024](#) including: Look-alike vials of Adrenalin and Retacrit
- Guardians of Grafts: Reducing Medication Errors in Transplant Recipients - [link](#)

#### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload - [link](#)
- Drug Safety Update [March 2024](#)
- Pseudoephedrine – Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) - [link](#)

#### **Medsafe (New Zealand Medicines and Medical Devices Safety Authority)**

- Calcium channel blockers and the possible risk of new-onset eczema - [link](#)

#### **MIMS monthly updates [April 2024](#)**

- New Contraindications
- Morphine sulfate pentahydrate ([DBL Morphine Sulfate Injection](#)) is now contraindicated in respiratory failure; bronchial asthma or other obstructive airways disease (regardless of disease duration, severity); emphysema (any severity); severe depressed level of consciousness; diabetic ketoacidosis; and alcoholism or delirium tremens (regardless of disease duration).
- Nirmatrelvir and ritonavir ([Paxlovid](#)) is now contraindicated for concomitant use with sildenafil when used for pulmonary hypertension; avanafil and vardenafil when used for erectile dysfunction; and zolpidem.

#### **Specialist Pharmacy Services NHS UK**

- Using tetracycline antibiotics during breastfeeding - [link](#)
- Calculating kidney function - [link](#)

#### **TGA**

- Update on the shortage of Bicillin L-A (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection - [link](#)
- Substandard semaglutide vials - [link](#)

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### **PAPERS OF INTEREST**

#### **American Journal of Cardiology**

- Atrial Thrombosis Prevalence Before Cardioversion or Catheter Ablation of Atrial Fibrillation: An Updated Systematic Review and Meta-Analysis of Direct Oral Anticoagulants Versus Vitamin K Antagonists - [link](#)
- Cardiovascular Outcomes with Empagliflozin and Dapagliflozin in Patients Without Diabetes - [link](#)

#### **American Journal of Gastroenterology**

- Comparative Efficacy of P-CAB vs Proton Pump Inhibitors for Grade C/D Esophagitis: A Systematic Review and Network Meta-analysis - [link](#)

#### **American Journal of Health-System Pharmacy (AJHP)**

- Evaluation of pharmacy-supplied half and quarter tablets at an academic medical center - [link](#)
- Impact of a calcium replacement protocol during massive transfusion in trauma patients at a level 2 trauma center - [link](#)

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- Integration of electronic project management software in an investigational drug service pharmacy within an academic medical center - [link](#)
- Implementation of CYP2C19 and CYP2D6 genotyping to guide antidepressant use in a large rural health system - [link](#)

### **Annals of Emergency Medicine**

- Topical Diclofenac Versus Oral Ibuprofen Versus Diclofenac + Ibuprofen for Emergency Department Patients with Acute Low Back Pain: A Randomized Study – [link](#)

### **Annals of Internal Medicine**

- Management of Inpatient Elevated Blood Pressures: A Systematic Review of Clinical Practice Guidelines - [link](#)
- Long-Term Effect of Salt Substitution for Cardiovascular Outcomes: A Systematic Review and Meta-Analysis - [link](#)

### **Arthritis & Rheumatology**

- Effect of secukinumab versus adalimumab biosimilar on radiographic progression in patients with radiographic axial spondyloarthritis: Results from a head-to-head randomized phase IIIb study - [link](#)

### **British Journal of Clinical Pharmacology**

- Assessing pain in persons with opioid use disorder: Approaches, techniques and special considerations - [link](#)
- Association between reversal agents (sugammadex vs. neostigmine) for neuromuscular block and postoperative pulmonary complications: A retrospective analysis - [link](#)
- OpenSAFELY: The impact of COVID-19 on azathioprine, leflunomide and methotrexate monitoring, and factors associated with change in monitoring rate - [link](#)

### **British Journal of General Practice**

- Prednisolone in COPD: the overlooked harm - [link](#)

### **British Medical Journal (BMJ)**

- Derivation and external validation of a simple risk score for predicting severe acute kidney injury after intravenous cisplatin: cohort study - [link](#)
- Use of progestogens and the risk of intracranial meningioma: national case-control study - [link](#)
- Practice pointer: Group A beta-haemolytic streptococcal infection in children - [link](#)
- Quantifying possible bias in clinical and epidemiological studies with quantitative bias analysis: common approaches and limitations - [link](#)

### **BMJ Open**

- Implementation of an intervention aimed at deprescribing benzodiazepines in a large US healthcare system using patient education materials: a pre/post-observational study with a control group - [link](#)

### **BMJ Quality and Safety**

- Estimating the impact on patient safety of enabling the digital transfer of patients' prescription information in the English NHS - [link](#)

### **Circulation**

- Sodium Glucose Co-transporter 2 Inhibitors and Major Adverse Cardiovascular Outcomes: A SMART-C Collaborative Meta-Analysis - [link](#)
- Topical Versus Intravenous Tranexamic Acid in Patients Undergoing Cardiac Surgery: The DEPOSITION Randomized Controlled Trial - [link](#)
- A Prospective Randomized Trial of Direct Oral Anticoagulant Therapy with A Fully Magnetically Levitated LVAD: The DOT-HM3 Study - [link](#)

- Randomized Evaluation of a Remote Management Program to Improve Guideline-directed Medical Therapy: The Diabetes Remote Intervention to Improve Use of Evidence-based Medications (DRIVE) Trial - [link](#)

### **Cochrane**

- Etidronate for the primary and secondary prevention of osteoporotic fractures in postmenopausal women - [link](#)  
- Inhaled bronchodilators for the prevention and treatment of chronic lung disease in preterm infants - [link](#)

### **Diabetes Care**

- Association Between Treatment Adherence and Continuous Glucose Monitoring Outcomes in People With Diabetes Using Smart Insulin Pens in a Real-World Setting - [link](#)  
- Point-of-Care HbA1c in Clinical Practice: Caveats and Considerations for Optimal Use - [link](#)  
- Timing of Moderate to Vigorous Physical Activity, Mortality, Cardiovascular Disease, and Microvascular Disease in Adults With Obesity - [link](#)

### **Drug and Therapeutics Bulletin**

- DTB Select: Donanemab in early symptomatic Alzheimer's disease - [link](#)  
- Medicines and global warming: a complex problem - [link](#)

### **Drug Safety**

- Drug-drug interactions and actual harm to hospitalized patients: a multicentre study examining the prevalence pre- and post-electronic medication system implementation - [link](#)

### **European Heart Journal**

- Oral anticoagulation in device-detected atrial fibrillation: effects of age, sex, cardiovascular comorbidities, and kidney function on outcomes in the NOAH-AFNET 6 trial - [link](#)  
- Low-dose colchicine for atherosclerosis: long-term safety - [link](#)  
- Use of new and emerging cancer drugs: what the cardiologist needs to know - [link](#)

### **European Journal of Hospital Pharmacy**

- Appropriateness of antithrombotics in geriatric inpatients with atrial fibrillation: a retrospective, cross-sectional study - [link](#)  
- Haemodynamic effects of intravenous acetaminophen in critically ill paediatric patients: a retrospective chart review - [link](#)

### **Health Technology Assessment**

- Evaluation of venous thromboembolism risk assessment models for hospital inpatients: the VTEAM evidence synthesis - [link](#)  
- Bisphosphonate alternative regimens for the prevention of osteoporotic fragility fractures: BLAST-OFF, a mixed-methods study - [link](#)

### **Heart, Lung and Circulation**

- Discharge Information About Adverse Drug Reactions Indicates Lower Self-Reported Adverse Drug Reactions and Fewer Concerns in Patients After Percutaneous Coronary Intervention - [link](#)

### **Hospital Pediatrics**

- Decreasing prescribing errors in antimicrobial stewardship program-restricted medications - [link](#)

### **Internal Medicine Journal**

- The increasing costs of medicines and their implications for patients, physicians and the health system - [link](#)

### **International Journal of Clinical Pharmacy**



- Novel opportunities for clinical pharmacy research: development of a machine learning model to identify medication related causes of delirium in different patient groups - [link](#)
- Clinical pharmacy key performance indicators for hospital inpatient setting: a systematic review - [link](#)

### **JAMA**

- Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability - [link](#) – [SPS commentary](#)
- Risk Assessment and Prevention of Falls in Older Community-Dwelling Adults: A Review - [link](#)
- Common Oral Conditions: A Review - [link](#)
- Reducing Hospitalizations and Multidrug-Resistant Organisms via Regional Decolonization in Hospitals and Nursing Homes – [link](#) – [SPS commentary](#)
- Integrated Hepatitis C–Opioid Use Disorder Care Through Facilitated Telemedicine: A Randomized Trial - [link](#)
- Clinical Benefit and Regulatory Outcomes of Cancer Drugs Receiving Accelerated Approval - [link](#)
- JAMA Patient Page: I Read Health Information Online—Can I Trust It? - [link](#)
- Systemic Lupus Erythematosus: A Review - [link](#)
- Mortality Among Users of Anabolic Steroids - [link](#)

### **JAMA Cardiology**

- Antibiotic Prophylaxis and Infective Endocarditis Incidence Following Invasive Dental Procedures: A Systematic Review and Meta-Analysis - [link](#)
- Influenza Vaccine Immune Response in Patients with High-Risk Cardiovascular Disease: A Secondary Analysis of the INVESTED Randomized Clinical Trial - [link](#)
- Plozasiran (ARO-APOC3) for Severe Hypertriglyceridemia: The SHASTA-2 Randomized Clinical Trial - [link](#)

### **JAMA Dermatology**

- Human Leukocyte Antigens and Sulfamethoxazole/Cotrimoxazole–Induced Severe Cutaneous Adverse Reactions: A Systematic Review and Meta-Analysis - [link](#) – [SPS commentary](#)
- Emergency Contraception for Patients Taking Isotretinoin - [link](#)

### **JAMA Internal Medicine**

- d-Mannose for Prevention of Recurrent Urinary Tract Infection Among Women: A Randomized Clinical Trial - [link](#)

### **JAMA Network Open**

- Estimated Sustainable Cost-Based Prices for Diabetes Medicines - [link](#)
- Drug Efficacy in the Treatment of Antipsychotic-Induced Akathisia - [link](#)

### **JAMA Neurology**

- Progress in Pharmacologic Management of Neuropsychiatric Syndromes in Neurodegenerative Disorders - [link](#)
- Early Seizure Prophylaxis in Mild and Moderate Traumatic Brain Injury: A Systematic Review and Meta-Analysis - [link](#)

### **JAMA Oncology**

- Patient Page: Cancer Care in the Era of Artificial Intelligence - [link](#)
- Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies - [link](#)

### **Journal of the American Geriatrics Society**

- Melatonin does not reduce delirium severity in hospitalized older adults: Results of a randomized placebo-controlled trial - [link](#)

### **Journal of the American College of Cardiology**

- Angiotensin Receptor-Nephrilysin Inhibition in Patients With STEMI vs NSTEMI - [link](#)

- Association of Antiarrhythmic Drug Therapy With Syncope and Pacemaker Implantation in Patients With Atrial Fibrillation - [link](#)
- Efficacy and Safety of Dapagliflozin in Patients with Acute Heart Failure - [link](#)

#### **Journal of Infection**

- Within-episode repeat antibiotic prescriptions in patients with respiratory tract infections: A population-based cohort study - [link](#)

#### **Journal of the National Cancer Institute**

- Association of metformin use and cancer incidence: a systematic review and meta-analysis - [link](#)

#### **Journal of Pharmacy Practice and Research (JPPR)**

- Risk of Pseudomonas aeruginosa antimicrobial resistance using time series analysis of antibiotic usage - [link](#)

#### **Lancet**

- Valvular heart disease: from mechanisms to management - [link](#)
- Pharmacotherapy for adults with overweight and obesity: a systematic review and network meta-analysis of randomised controlled trials - [link](#)
- Ticagrelor alone versus ticagrelor plus aspirin from month 1 to month 12 after percutaneous coronary intervention in patients with acute coronary syndromes (ULTIMATE-DAPT): a randomised, placebo-controlled, double-blind clinical trial - [link](#)

#### **Lancet Diabetes & Endocrinology**

- Effects of statin therapy on diagnoses of new-onset diabetes and worsening glycaemia in large-scale randomised blinded statin trials: an individual participant data meta-analysis – [link](#) - [SPS commentary](#)
- Endocrine health in survivors of adult-onset cancer - [link](#)

#### **Lancet Respiratory Medicine**

- High-dose, short-duration versus standard rifampicin for tuberculosis preventive treatment: a partially blinded, three-arm, non-inferiority, randomised, controlled trial - [link](#)

#### **Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**

- Association of Average Daily Morphine Milligram Equivalents and Falls in Older Adult Chronic Opioid Users - [link](#)
- Evolution of Telehealth—Its Impact on Palliative Care and Medication Management - [link](#)
- Evaluation of Oral Amoxicillin/Clavulanate for Urinary Tract Infections Caused by Ceftriaxone Non-Susceptible Enterobacterales - [link](#)

#### **Medical Journal of Australia**

- Australian consensus statement on doxycycline post-exposure prophylaxis (doxy-PEP) for the prevention of syphilis, chlamydia and gonorrhoea among gay, bisexual and other men who have sex with men - [link](#) – and [response](#)
- Editorial: Interventions for reducing the prescribing of pharmaceutical opioids in Australia: are they effectively reducing opioid harm? – [link](#) – and [research article](#)
- The uptake of long-acting depot buprenorphine for treating opioid dependence in Australia, 2019–2022: longitudinal sales data analysis - [link](#)

#### **New England Journal of Medicine**

- Nirmatrelvir for Vaccinated or Unvaccinated Adult Outpatients with Covid-19 - [link](#) – [SPS commentary](#)
- Prevention of Cardiovascular Disease in Type 1 Diabetes - [link](#)
- Apolipoprotein A1 Infusions and Cardiovascular Outcomes after Acute Myocardial Infarction - [link](#)
- Beta-Blockers after Myocardial Infarction and Preserved Ejection Fraction - [link](#)

- Empagliflozin after Acute Myocardial Infarction - [link](#) – [SPS commentary](#)
- Olezarsen for Hypertriglyceridemia in Patients at High Cardiovascular Risk - [link](#)
- Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes - [link](#)

### **Pediatric Emergency Care**

- Medication Errors in Pediatric Emergency Departments: A Systematic Review and Recommendations for Enhancing Medication Safety - [link](#)

### **Pharmacotherapy**

- Simulated cost-effectiveness of a novel precision-guided dosing strategy in adult patients with Crohn's disease initiating infliximab maintenance therapy - [link](#)
- Vancomycin AUC<sub>0–24</sub> estimation using first-order pharmacokinetic methods in pediatric patients - [link](#)

### **Prescrire International – [April 2024 issue](#) including:**

- Editorial: Evaluating drugs for today's patients, without neglecting tomorrow's patients - [link](#)
- GLP-1 agonists: depression, suicidal thoughts or behaviour?
- RSVpreF vaccine (Abrysvo<sup>o</sup>) during pregnancy to prevent RSV infection in the woman's child after birth
- Prescrire's ratings of new drugs in 2023

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## **WEBINARS & PODCASTS**

### **Australian Prescriber Podcasts**

- [Episode 161](#) – Managing hypercholesterolaemia

### **MJA Podcasts**

- [Episode 11](#): Pregnancy supplements – how much is too much?
- [Episode 10](#): How GPs can help women improve their self-compassion and reduce depression

### **Victorian Institute of Forensic Medicine**

- Residential Aged Care Communiqué Episode #17: Diabetes mellitus - [link](#)

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## **UPCOMING EVENTS**

### **AHHA**

- Webinar: Advancing VBHC in Australia: Lessons from the NHS Wales, online, 2 May 2024 12:30-13:30 – [register](#)
- Post-Budget Health Leaders Roundtable, Canberra, 17 May 2024 10:00-16:00 - [register](#)

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## **Fortnightly TAG Mail – resources list**

**28<sup>th</sup> March 2024**

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### **NSW TAG ACTIVITIES**

#### **Open email discussions**

1. **DTC assessment process for non-GMO phage therapy applications:** Do NSW TAG members have a process for DTC assessment of these applications and, if so, would they be willing to share it? Closes 3<sup>rd</sup> April 2024
2. **Handling of medicines by perfusionists:** How are hospitals managing oversight of this type of medicine use? Are other sites using Standing Orders for perfusionists (as suggested by the Medication Handling PD)? Do sites have a perfusionists' imprest list? Has it been expanding and does it include restricted medicines? Is administration documented and if so, where? Closes 3<sup>rd</sup> April 2024.

#### **Recently completed email discussions**

- DTC pharmacists in NSW
- Patient prioritisation for discharge medication list provision

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988  
Ph: 0407418 072 | Email: [nswtag@stvincents.com.au](mailto:nswtag@stvincents.com.au) | [www.nswtag.org.au](http://www.nswtag.org.au)  
An initiative of NSW clinical pharmacologists & pharmacists  
ABN: 82 707 308 091

- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

### Upcoming TAG meetings

NSW TAG General Meeting: Thursday 4<sup>th</sup> April 2024 11.30-1pm

NSW TAG Management Committee 3<sup>rd</sup> May 2024 9.45am-11am

### Updated TAG publications

Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form  
Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions, publications or upcoming meetings.

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## EDITOR'S PICKS

AJHP: Standardization of key performance indicators and metrics for investigational drug services: Consensus recommendations among IDS specialists - [link](#)

AJHP: Evaluating the utility of procalcitonin and a clinical decision support tool to determine duration of antimicrobial therapy for respiratory tract infections - [link](#)

BJCP: Assessment and evaluation of prescribing competencies: A SR and recommendations - [link](#)

BJCP: The risk of delirium after sedation with propofol or midazolam in ICU patients - [link](#)

BJCP: Differences in prescribing errors between electronic prescribing and traditional prescribing among medical students - [link](#)

BJCP: Innovations in pharmacovigilance studies of medicines in older people - [link](#)

BMJ: Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation – [link](#)

CPC: Smoking cessation patient resources: the perioperative care benefits - [link](#)

EJHP: The threatened medicines information pharmacist! - [link](#)

Hosp Pharm: Analysis of intervention employability in pharmacy-related medication safety reports at a tertiary medical center - [link](#)

JAMA: Management of Outpatients with Diabetes at High Risk of Hypoglycemia - [link](#)

JAMA Dermatology: Adjuvant Immunotherapy in Stage II Melanoma - [link](#)

JAMA Oncology: Neoadjuvant Chemoimmunotherapy for NSCLC - [link](#)

JPPR: Cultivating optimal analgesic prescribing practices in a metropolitan hospital network: evaluating an analgesic stewardship program - [link](#)

JPPR: Standard of practice in pharmacy informatics - [link](#)

Lancet Neurology: Review: Secondary stroke prevention in people with atrial fibrillation - [link](#)

MJA- Perspectives: Contemporary management of advanced colorectal cancer - [link](#)

NEJM: Risk of Autism after Prenatal Topiramate, Valproate, or Lamotrigine Exposure - [link](#)

SIGN: Optimising glycaemic control in people with type 1 diabetes, a decision-support toolkit - [link](#)

SPS: Understanding contamination control in pharmacy aseptic services - [link](#)

WHO: Global burden of preventable medication-related harm in health care: a systematic review - [link](#)

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## OTHER NEWS (new additions in bold)

### NSW Health

- Stay safe from mosquitoes this Easter long weekend - [link](#)
- NSW Health consults with staff on updating COVID-19 vaccination requirements - [link](#)
- Measles alert for western Sydney - [link](#)
- Hepatitis C Testing and Care in Alcohol and Other Drug Services ([IB2024\\_015](#))
- Pension Based Fees ([IB2024\\_016](#))
- Clinical Governance in NSW ([PD2024\\_010](#))
- The Use of the Emergency Care Assessment and Treatment (ECAT) Protocols ([PD2024\\_011](#))

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## REPORTS AND PUBLICATIONS – AUSTRALIA

### Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found [here](#)

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

Ph: 0407418 072 | Email: [nswtag@stvincents.com.au](mailto:nswtag@stvincents.com.au) | [www.nswtag.org.au](http://www.nswtag.org.au)

An initiative of NSW clinical pharmacologists & pharmacists

ABN: 82 707 308 091

- NSW Paediatric PCA or NCA chart (SMR130.026) [[presentation](#)]
- NSW Weight Based Paediatric PCA or NCA chart [SMR130031] ([presentation](#))

### **Australian Institute for Health and Welfare (AIHW)**

- Treatment pathways for people hospitalised for acute coronary syndrome - [link](#)
- Better cardiac care measures for Aboriginal and Torres Strait Islander people: eighth national report 2023 - [link](#)
- Acute rheumatic fever and rheumatic heart disease in Australia, 2022 - [link](#)
- Dementia in Australia - [link](#)

### **PBS Updates- [link](#)**

- Stocktake of PBS medicines available for endometriosis and related conditions Report
- Updates to the HTA Policy and Methods Review Reference Committee – 26 March 2024
- Drug Utilisation Sub-Committee (DUSC) Utilisation Analysis Public Release Documents and Outcome Statement

### **Pharmacy Council of NSW**

- Guidelines on dose administration aids and staged supply of dispensed medicines - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - MELATONIN-[LINK](#), IMMELA, MELAKSO, VOQUILY for short-term treatment of jet lag in adults aged 18 and over, and for sleep disorders in children and adolescents with neurodevelopmental disorders
  - Alhemo ([concizumab](#)) is approved to prevent or reduce frequency of bleeding in patients who have haemophilia B with FIX inhibitors

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

### **Agency for Healthcare Research and Quality (AHRQ) USA**

- ADHD Diagnosis and Treatment in Children and Adolescents - [link](#)

### **British National Formulary**

- BNF/BNFC newsletter: [March 2024](#)

### **Canadian Agency for Drugs and Technologies in Health**

- Utilization Analysis of Tofacitinib and Other Drugs Among Individuals With Ulcerative Colitis: Feasibility Analysis, updated - [link](#)
- Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors in Type 2 Diabetes Mellitus, Heart Failure, and Chronic Kidney Disease, updated - [link](#)

### **Centre for Perioperative Care UK**

- Smoking cessation patient resources: the perioperative care benefits - [link](#)

### **electronic Medicines Compendium (eMC) (UK)**

- [New products](#)
  - Adacel (diphtheria, tetanus and pertussis vaccine) pre-filled for active immunization in persons from 4 years of age as a booster following primary immunization, and for passive protection against pertussis in early infancy following maternal immunization during pregnancy
  - Entresto (valsartan, sacubitril) capsules for opening – for children and adolescents aged ≥1 year with symptomatic chronic heart failure with left ventricular systolic dysfunction. The capsules should be opened and the granules sprinkled onto a small amount (1-2 teaspoons) of soft food
  - Sendolor (morphine hydrochloride trihydrate) for severe acute pain, cancer pain and breakthrough cancer pain, for IV, subcutaneous, intramuscular, epidural or intrathecal administration

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Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

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An initiative of NSW clinical pharmacologists & pharmacists

ABN: 82 707 308 091

- Tyruko 300 mg (natalizumab biosimilar) for use as a single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) despite a full and adequate course of treatment with at least one disease modifying therapy, & in those with rapidly evolving severe RRMS
- Vanflyta (quizartinib) in combination with cytarabine & anthracycline induction and cytarabine consolidation chemotherapy, followed by quizartinib maintenance monotherapy for adult patients with newly diagnosed FLT3-ITD positive acute myeloid leukaemia
- Verorab (rabies vaccine) - inactivated rabies vaccine for pre- and post- exposure prophylaxis
- [Revised SPCs](#)
- AmBisome (amphotericin) - updated with dosing recommendation for Cryptococcal meningitis for people living with HIV; amended dosing recommendations for mycoses and mucormycosis
- HyQvia (human normal immunoglobulin) - license extension for use as immunomodulatory therapy in adults, children and adolescents (0 to 18 years) in chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilisation with IV immunoglobulin
- Imfinzi (durvalumab) - durvalumab + tremelimumab has been studied in children aged 1-17 years with neuroblastoma, solid tumour and sarcoma (outside the authorised indications), however the results did not allow the conclusion that the benefits of such use outweigh the risks

### European Medicines Agency (EMA)

- CHMP changes to the terms of the marketing authorisation
- enzalutamide ([Xtandi](#)) – also as monotherapy or in combination with androgen deprivation therapy for treatment of adult men with high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer who are unsuitable for salvage radiotherapy
- selpercatinib ([Retsevmo](#)) - to include its use for the treatment of adults with advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted
- CHMP approvals
- bempedoic acid ([Nilemdo](#)) to reduce cardiovascular risk
- bimekizumab ([Bimzelx](#)) for severe hidradenitis suppurativa
- CHMP marketing authorisations
- irinotecan hydrochloride trihydrate ([Onivyde](#) pegylated liposomal) for first-line treatment of metastatic adenocarcinoma of the pancreas
- aztreonam / avibactam ([Emblaveo](#)) for treatment of multi-drug resistant bacterial infection
- dantrolene sodium / hemiheptahydrate ([Aqilus](#)) for treatment of malignant hyperthermia
- insulin icodec ([Awiqli](#)) - long-acting basal insulin given subcutaneously once a week
- intravitreal bevacizumab gamma ([Lytenava](#)) for treatment of neovascular (wet) age-related macular degeneration
- iptacopan ([Fabhalta](#)) for paroxysmal nocturnal haemoglobinuria
- dopamine hydrochloride ([Neoatrimon](#)) for hypotension
- porcine pancreas enzymes ([Micrazym](#)) in the EU – evidence comparable to Creon

### Food and Drug Administration (FDA) USA

- Approvals- [link](#)
- atidarsagene autotemcel ([Lenmeldy](#)) - gene therapy approved for metachromatic leukodystrophy
- bempedoic acid ([Nexletol](#)) - new indication approved for CV risk reduction
- [givinostat](#) (Duvyzat ) for Duchenne Muscular Dystrophy in patients aged 6 years and older – [PI/label](#)
- [mirvetuximab soravtansine-gynx](#) for FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer
- pemivibart ([Pemgarda](#)) – EUA for monoclonal antibody to prevent COVID-19 in immunosuppressed individuals
- [ponatinib](#) with chemotherapy for newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia
- ravulizumab ([Ultomiris](#)) - C5 complement inhibitor for neuromyelitis optica spectrum disorder
- [resmetirom](#) for adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced fibrosis – [PI/label](#)

- [Sotatercept-Csrk](#) (Winrevair) - for treatment of adults with pulmonary arterial hypertension
- Tevimbra ([tislelizumab-jsqr](#)) to treat unresectable or metastatic esophageal squamous cell carcinoma
- Tryvio ([aprocitentan](#)) to treat hypertension

### **Medicines and Healthcare products Regulatory Agency (MHRA)**

- Ganaxolone (Ztalmy) for epileptic seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in children - [link](#)

### **MIMS UK**

- Understanding diabetes technologies: free MIMS online supplement - [link](#)

### **NHS England**

- Clinical commissioning policy: prescribing of gender affirming hormones (masculinising or feminising hormones) as part of the children and young people's gender service – [link](#) – [SPS commentary](#)
- Guidance: Desflurane decommissioning and clinical use - [link](#)

### **NHS Scotland - Scottish Medicines Consortium**

- Accepted for restricted use:
- Nirmatrelvir and ritonavir ([Paxlovid](#)®) for the treatment of Covid-19 in adults

### **National Institute for Health and Care Excellence (NICE) UK**

- Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management ([NG240](#))
- Momelotinib for treating myelofibrosis-related splenomegaly or symptoms ([TA957](#))
- Ovarian cancer: identifying and managing familial and genetic risk ([NG241](#))
- Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: early value assessment ([HTE17](#))
- Desflurane for maintenance of anaesthesia ([ES41](#))
- Daratumumab in combination for treating newly diagnosed systemic amyloid light-chain amyloidosis ([TA959](#))
- Ritlecitinib for treating severe alopecia areata in people 12 years and over ([TA958](#))

### **National Institute for Health and Care Research (NIHR)**

- NIHR Commentaries
- Children in intensive care have better outcomes with lower oxygen targets - [link](#)
- Irritable bowel syndrome: low-dose antidepressant improves symptoms - [link](#)

### **Parliamentary and Health Service Ombudsman UK**

- End of life care: improving DNACPR conversations for everyone - [link](#)

### **Scottish Intercollegiate Guideline Network (SIGN) UK**

- Optimising glycaemic control in people with type 1 diabetes, a decision-support toolkit - [link](#)

### **Specialist Pharmacy Services NHS UK**

- Understanding contamination control in pharmacy aseptic services - [link](#)

### **UK Health Security Agency**

- National measles guidelines - update to measles post exposure prophylaxis section - [link](#)

### **World Health Organisation (WHO)**

- Global burden of preventable medication-related harm in health care: a systematic review - [link](#)
- WHO launches new toolkit empowering health professionals to tackle climate change - [link](#)

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## **MEDICATION SAFETY**

### **electronic Medicines Compendium (eMC) (UK)**

### - [Revised SPCs](#)

- Benlysta (belimumab) – updated to advise progressive multifocal leukoencephalopathy (PML) reported with Benlysta for SLE, to watch for cognitive, neurological or psychiatric symptoms/signs, & action to take if they occur. If PML suspected, Benlysta, must be stopped until PML excluded
- Braftovi (encorafenib) - Tumour Lysis Syndrome added as an ADR with a frequency of 'unknown'
- Clomid (clomifene) should not be given if history of significant, medically confirmed vision disorders related to use of Clomid is known. Information on visual disturbances updated to note some cases have been prolonged or irreversible, especially with increased dose or duration
- Cresemba (isavuconazonium) updated with improved guidance for healthcare professionals in relation to how to manage co-administration of cyclophosphamide with isavuconazole
- Fenpaed Ibuprofen - Fixed drug eruption added as undesirable effect (frequency unknown)
- Lioresal (baclofen) - hypertonia as a symptom of withdrawal/abrupt discontinuation. Undesirable effects added: face swelling and peripheral oedema, alopecia, hypersensitivity, and sexual dysfunction (frequency not known)
- Miprosed (midazolam) - Kounis syndrome added as possible ADR, frequency 'unknown'
- Spikevax bivalent original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL, Spikevax XBB.1.5 0.1 mg/mL - chronic urticaria as ADR of unknown frequency. It is already noted that urticaria can occur uncommonly with acute or delayed onset (~2 weeks post dose). SPC advises not to give subsequent doses to those with prior severe allergic reactions
- Quinoric (hydroxychloroquine sulfate) - benefits/risk of continuing treatment should be assessed in those with significant liver function abnormalities, and a heading for azithromycin and macrolide antibiotics has been added to the interactions section
- Targinact (oxycodone hydrochloride, naloxone hydrochloride dehydrate) - undesirable effects reclassified as frequency not known: drug dependence (previously rare), drug withdrawal syndrome (previously uncommon), and drug tolerance (previously uncommon)
- Toradol (ketorolac) may cause oligohydramnios resulting from foetal renal dysfunction from the 20th week of pregnancy. It should not be given during the first and second trimester, unless clearly necessary, and is contra-indicated during the third trimester
- Venzip (venlafaxine hydrochloride) XL - risk of hypoglycaemia related to overdose. Severe poisoning symptoms may occur in adults after intake of approximately 3grams of venlafaxine
- Vibramycin-D (doxycycline) - 'Fixed eruption' added as a possible "rare" ADR
- VidPrevtyn Beta (covid-19 Vaccine; recombinant, adjuvanted) - new safety data from 6236 patients in a Phase 3 study. Booster vaccine given ≥4 months after primary series vaccine, with median duration follow up 58 days (84% completing ≥6 weeks follow up). Safety profile consistent with adverse reactions from previous study
- Yescarta (axicabtagene ciloleucel) - JC virus reactivation leading to progressive multifocal leukoencephalopathy (PML) in patients also taking other immunosuppressants. Cases with fatal outcome reported & PML should be considered in those with new/worsening neurological symptoms
- Viread (tenofovir disoproxil fumarate) - 'Bone mineral density decreased' listed as a possible "common" ADR. Warning regarding bone effects amended
- Risk minimisation materials
- Tyruko (natalizumab biosimilar) Physician's guidelines discuss the risk and nature of PML, risk factors for its development, its diagnosis and treatment, specific steps to be taken to minimise this risk and the identification and management of possible sequelae. A patient alert card is also available

### FDA

- Approves safety labelling changes regarding DPD deficiency for fluorouracil injection products - [link](#)
- Warns Consumers to Avoid Certain Topical Pain Relief Products Due to Potential for Dangerous Health Effects - [link](#)

### Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! [March 21, 2024](#)
- Implement Strategies to Prevent Persistent Medication Errors and Hazards: 2024 - [link](#)
- Magnesium sulfate almost administered instead of dexmedetomidine
- Fleet enemas, not as benign as they seem



### **MedEffect, Canada**

- Ezetrol (ezetimibe) and the Risks of Drug-Induced Liver Injury and Severe Cutaneous Adverse Reactions - [link](#)

### **Specialist Pharmacy Services NHS UK**

- Treating impetigo topically during breastfeeding - [link](#)
- Using macrolide antibiotics during breastfeeding - [link](#)
- Treating nausea during breastfeeding - [link](#)
- Medication safety update [March 2024](#)

### **TGA**

- Updated warnings of faricimab (Vabysmo) retinal vasculitis risk - [link](#)
- Metalyse (tenecteplase) 40 mg powder for injection to be discontinued - [link](#)
- Shortages of Estradot (estradiol) transdermal patches to continue - [link](#)
- Product Information safety updates - [March 2024](#)
- Updates to the Prescribing Medicines in Pregnancy database - [March 2024](#)

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## **PAPERS OF INTEREST**

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### **American Journal of Health-System Pharmacy (AJHP)**

- Considerations of gender-affirming care for transgender and gender-diverse youth - [link](#)
- Iatrogenic hyperchloremia: An overview in hospitalized patients for pharmacists - [link](#)
- Impact of pharmacist-driven referral to increase specialty pharmacy prescription capture - [link](#)
- Standardization of key performance indicators and metrics for investigational drug services (IDS): Consensus recommendations among IDS specialists - [link](#)
- The paradigm to overcome in acute decompensated heart failure - [link](#)
- Evaluating the utility of procalcitonin and a clinical decision support tool to determine duration of antimicrobial therapy for respiratory tract infections - [link](#)
- Analysis of appropriateness and safety when discharging patients on triple-antithrombotic therapies - [link](#)

### **Arthritis & Rheumatology**

- Effect of Recent Antirheumatic Drug on Features of Rheumatoid Arthritis–Associated Lymphoproliferative Disorders - [link](#)
- Risk of Venous Thromboembolism with Tofacitinib Versus Tumor Necrosis Factor Inhibitors in Cardiovascular Risk-enriched Rheumatoid Arthritis Patients - [link](#)

### **British Journal of Clinical Pharmacology**

- The risk of delirium after sedation with propofol or midazolam in intensive care unit patients - [link](#)
- Assessment and evaluation of prescribing competences: A systematic review and recommendations - [link](#)
- Frailty in clinical drug trials: Frailty assessments, subgroup analyses and outcomes - [link](#)
- Differences in prescribing errors between electronic prescribing and traditional prescribing among medical students: A randomized pilot study - [link](#)
- Therapeutic drug monitoring, liquid biopsies or pharmacogenomics for prediction of human drug metabolism and response - [link](#)
- Innovations in pharmacovigilance studies of medicines in older people - [link](#)

### **British Journal of General Practice**

- Preventive interventions to improve older people's health outcomes: systematic review and meta-analysis - [link](#) – [SPS commentary](#)
- Risk of Parkinson's disease in people with New Onset Anxiety over 50 years - Incidence and Associated Features - [link](#) – [SPS commentary](#)

### **British Medical Journal (BMJ)**

- Impact of chronic oral glucocorticoid treatment on mortality in patients with COVID-19: analysis of a population-based cohort - [link](#)
- Statins, risk, and personalised care - [link](#)
- Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation: repeated cross sectional analysis – [link](#) – [SPS commentary](#)
- Community based complex interventions to sustain independence in older people: systematic review and network meta-analysis – [link](#) – [SPS commentary](#)
- Practice Pointer: Dry eye disease management - [link](#)
- State of the Art Review: Effectiveness and safety of drugs for obesity - [link](#)

### **BMJ Open**

- Association between benzodiazepine coprescription and mortality in people on opioid replacement therapy: a population-based cohort study - [link](#) – [SPS commentary](#)
- Exploring the pharmacists' role in optimising antithrombotic therapy in primary care: a qualitative study - [link](#)
- Finerenone cardiovascular and kidney outcomes by age and sex: FIDELITY post hoc analysis of two phase 3, multicentre, double-blind trials - [link](#)

### **Cochrane**

- Prophylactic corticosteroids for cardiopulmonary bypass in adult cardiac surgery - [link](#)
- Probiotics for induction and maintenance of remission in ulcerative colitis - [link](#)
- Psychological therapies for depression in older adults residing in long-term care settings - [link](#)

### **Diabetes Care**

- Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial - [link](#)
- Individualizing Treatment of Type 2 Diabetes After Metformin: More Insights From GRADE - [link](#)
- Effects of tirzepatide versus basal insulins in people with type 2 diabetes and different baseline glycemic patterns: post hoc analyses of the SURPASS-3 and SURPASS-4 trials - [link](#)

### **Drug and Therapeutics Bulletin**

- DTB Select: Does oseltamivir prevent hospitalisation in people with influenza? - [link](#)
- DTB Select: Effect of topical testosterone on pre-diabetes and diabetes - [link](#)
- DTB Select: Use of oral penicillin challenge in low-risk penicillin allergy - [link](#)
- Slynd: does a drospirenone progestogen-only pill offer an advantage? - [link](#)

### **European Heart Journal**

- Inorganic nitrate benefits contrast-induced nephropathy after coronary angiography for acute coronary syndromes: the NITRATE-CIN trial - [link](#)

### **European Journal of Hospital Pharmacy**

- Economic impact of a clinical pharmacist in the orthopaedic sector: a review of the literature - [link](#)
- The threatened medicines information pharmacist! - [link](#)

### **Health Technology Assessment**

- A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial) - [link](#)
- Early switch from intravenous to oral antibiotic therapy in patients with cancer who have low-risk neutropenic sepsis: the EASI-SWITCH RCT - [link](#)
- Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease: the ALL-HEART RCT and economic evaluation - [link](#)

### **Hosp Pharm**

- Analysis of intervention employability in pharmacy-related medication safety reports at a tertiary medical center - [link](#)

### **International Journal of Clinical Pharmacy**

- The efficacy of zuranolone versus placebo in postpartum depression and major depressive disorder: a systematic review and meta-analysis - [link](#)

### **JAMA**

- Management of Outpatients with Diabetes at High Risk of Hypoglycemia - [link](#)  
- Use of Lecanemab for Patients with Cardiovascular Disease - The Challenge of Uncertainty - [link](#)  
- Stroke Risk After COVID-19 Bivalent Vaccination Among US Older Adults - [link](#) – [SPS commentary](#)  
- Patient page: What Is Perinatal Depression? - [link](#) ; What Is Priapism? - [link](#)  
- Eosinophilic Gastrointestinal Disease – [link](#)  
- Selective Androgen Receptor Modulators—Transformative Drugs or Heralds of the Next Drug Epidemic? - [link](#)

### **JAMA Cardiology**

- Ticagrelor or Clopidogrel Monotherapy vs Dual Antiplatelet Therapy After Percutaneous Coronary Intervention: A Systematic Review and Patient-Level Meta-Analysis - [link](#)

### **JAMA Dermatology**

- Adjuvant Immunotherapy in Stage II Melanoma—Further Risk Stratification is Needed - [link](#)  
- Expert Recommendations on Use of Topical Therapeutics for Vitiligo in Pediatric, Adolescent, and Young Adult Patients - [link](#)  
- Outcome Measurement Instruments Used to Evaluate Dermatologic Adverse Events in Cancer Trials: A Systematic Review - [link](#)

### **JAMA Network Open**

- Intensive vs Conventional Blood Pressure Control After Thrombectomy in Acute Ischemic Stroke - [link](#)  
- Habitual Short Sleep Duration, Diet, and Development of Type 2 Diabetes in Adults - [link](#)

### **JAMA Neurology**

- Risk of Major Congenital Malformations and Exposure to Antiseizure Medication Monotherapy - [link](#)  
- Early Use of Erenumab vs Nonspecific Oral Migraine Preventives: The APPRAISE Randomized Clinical Trial - [link](#)  
- High-Efficacy Therapy Discontinuation vs Continuation in Patients 50 Years and Older with Nonactive MS - [link](#)

### **JAMA Oncology**

- Neoadjuvant Chemoimmunotherapy for NSCLC: A Systematic Review and Meta-Analysis - [link](#)  
- PARP Inhibitors for Breast Cancer Treatment: A Review - [link](#)

### **JAMA Psychiatry**

- Bright Light Therapy as Add-On to Inpatient Treatment in Youth With Moderate to Severe Depression: A Randomized Clinical Trial - [link](#)  
- Baseline Antipsychotic Dose and Transition to Psychosis in Individuals at Clinical High Risk: A Systematic Review and Meta-Analysis - [link](#)

### **Journal of Infection**

- A multicentre observational study to investigate feasibility of a direct oral penicillin challenge in de-labelling 'low risk' patients with penicillin allergy by non-allergy healthcare professionals (SPACE study): Implications for healthcare systems - [link](#)

### **Journal of Pharmacy Practice and Research (JPPR)**

- Cultivating optimal analgesic prescribing practices in a metropolitan hospital network: evaluating an analgesic stewardship program - [link](#)
- Standard of practice in pharmacy informatics - [link](#)
- Reasonable adjustments to application of the Medication Safety Standard for adult patients living with intellectual disability in Australian hospital settings - [link](#)

### **Lancet Diabetes & Endocrinology**

- Tight versus liberal blood-glucose control in the intensive care unit: special considerations for patients with diabetes - [link](#)

### **Lancet Neurology**

- Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021 - [link](#)
- Review: Secondary stroke prevention in people with atrial fibrillation: treatments and trials - [link](#)

### **Lancet Psychiatry**

- Heterogeneity of outcome measures in depression trials and the relevance of the content of outcome measures to patients: a systematic review - [link](#)
- Establishing a research agenda for the study and assessment of opioid withdrawal - [link](#)

### **Lancet Respiratory Medicine**

- Efficacy of oral corticosteroids for acute preschool wheeze: a systematic review and individual participant data meta-analysis of randomised clinical trials - [link](#) – [SPS commentary](#)

### **Medical Journal of Australia**

- Perspectives: Contemporary management of advanced colorectal cancer: the Australian experience - [link](#)

### **New England Journal of Medicine**

- Oral Iptacopan Monotherapy in Paroxysmal Nocturnal Hemoglobinuria - [link](#) – [SPS commentary](#)
- Ribociclib plus Endocrine Therapy in Early Breast Cancer - [link](#)
- Risk of Autism after Prenatal Topiramate, Valproate, or Lamotrigine Exposure - [link](#)

### **Pediatrics (American Academy of Pediatrics)**

- Treatments for ADHD in Children and Adolescents: A Systematic Review - [link](#)

### **Pharmaceutical Journal**

- Fourteen nitazenes made Class A controlled drugs - [link](#)

### **Pharmacotherapy**

- Exploring variations in recommended first-choice therapy for complicated urinary tract infections in males: Insights from outpatient settings across age, race, and ethnicity - [link](#)

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## **WEBINARS & PODCASTS**

### **Australian Prescriber Podcasts**

- [Episode 160](#) – Ongoing challenges of off-label prescribing

### **MJA Podcasts**

- [Episode 9](#): Reducing psychological distress among patients after cardiac surgery

### **SHPA**

- [MedsAware](#): Deprescribing Action Week - available until 21 April 2024

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## **Fortnightly TAG Mail – resources list**

**14<sup>th</sup> March 2024**

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## NSW TAG ACTIVITIES

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### Open email discussions

- 3. Patient prioritisation for discharge medication list provision:** A TAG member would like to know how other hospitals prioritise their patients for the creation/supply of pharmacist-generated discharge medication lists. **Closes 18th March 2024.**
- 4. DTC pharmacists in NSW:** what FTE is assigned to the DTC pharmacist role; is the DTC pharmacist role district or facility based; is the DTC pharmacist also the secretariat for the DTC; who does the DTC pharmacist report to; do you have a Position Statement, and if so, would you be willing to share; is the DTC Pharmacist role combined with any other Pharmacist role, and if so, what (and FTE is possible); and, does the DTC have additional administrative support? **Closes 21st March 2024**
- 5. DTC assessment process for non-GMO phage therapy applications:** do NSW TAG members have a process for DTC assessment of these applications and, if so, would they be willing to share it? **Closes 24th March 2024**
- 6. Handling of medicines by perfusionists:** How are hospitals managing oversight of this type of medicine use? Are other sites using Standing Orders for perfusionists (as suggested by the Medication Handling PD)? Do sites have a perfusionists' imprest list? Has it been expanding and does it include restricted medicines? Is administration documented and if so, where? **Closes 28th March 2024.**

### Recently [completed](#) email discussions

- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

### Upcoming TAG meetings

NSW TAG General Meeting: Thursday 4<sup>th</sup> April 2024 11.30-1pm

NSW TAG Management Committee 3<sup>rd</sup> May 2024 9.45am-11am

### Updated TAG [publications](#)

Coming soon: Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions, publications or upcoming meetings.

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## EDITOR'S PICKS

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AHHA: Climate change disasters impact in human health- [link](#)

Deeble Institute: Value-based health care: Lessons from NHS Wales - [link](#)

AHRQ: Adverse events associated With COVID-19 pharmaceutical treatments - [link](#)

NHS England: - UK survey report of pharmacy professionals' involvement in research - [link](#)

AJHP: Optimized adult epidural infusion preparations to reduce waste and improve operational efficiency - [link](#)

BMJ: - Ultra-processed food exposure and adverse health outcomes- [link](#)

DOM: - Glycaemic control and macrovascular and microvascular outcomes in type 2 diabetes: Systematic review and meta-analysis of cardiovascular outcome trials of novel glucose-lowering agents - [link](#)

Drug Safety: - Exploring the Role of Guidelines in Contributing to Medication Errors- [link](#)

EJHP: Development of hospital pharmacy services at transition of care points – [link](#)

IJQHC: - How are we handling protein drugs in hospitals? - [link](#)

JAMA Network Open: Telemedicine vs telephone consultations and medication prescribing errors among referring physicians – [link](#)

Lancet: mRNA-based therapeutics: looking beyond COVID-19 vaccines - [link](#)

MDPI: - Influences of software changes on oxycodone prescribing at an Australian ED- [link](#)

MJA: Clinical artificial intelligence in Australian hospitals - [link](#)

NEJM: Microplastics and nanoplastics in atheromas and cardiovascular events - [link](#)

SHTI: Effects of an electronic medication system on medication administration errors - [link](#)

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## OTHER NEWS

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### NSW Health

- Measles alert for Sydney Domestic Airport and Sydney CBD - [link](#)

### TGA

- Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption - [link](#)

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## REPORTS AND PUBLICATIONS – AUSTRALIA

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### Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found [here](#)

### Australian Healthcare and Hospitals Association (AHHA)

- These three climate disasters will have the biggest impact on human health by 2050 - [link](#)

### Australian Institute for Health and Welfare (AIHW)

- Spinal injuries in Australia 2020–21 - [link](#)

- Medicare-subsidised GP, allied health and specialist health care across local areas: 2022-23 - [link](#)

### Deeble Institute

- Perspectives Brief No. 30: Value-based health care: Lessons from NHS Wales - [link](#)

- Perspectives Brief No.29: Engaging older persons and carers as co-researchers - [link](#)

### MIMS monthly updates

- New Products

-- Nirsevimab ([Beyfortus](#)), a recombinant long-acting monoclonal antibody indicated for the prevention of RSV lower respiratory tract disease in neonates, infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season in accordance with official recommendations

- New Indications

-- Brentuximab vedotin ([Adcetris](#)) for previously untreated CD30+ stage III or IV Hodgkin lymphoma in combination with doxorubicin, vinblastine, and dacarbazine.

-- Dostarlimab ([Jemperli](#)) in combination with carboplatin and paclitaxel for adults with primary advanced or recurrent mismatch repair deficient/ microsatellite instability-high endometrial cancer

-- Nivolumab ([Opdivo](#)) as monotherapy for the adjuvant treatment of adults and adolescent patients 12 years and older with completely resected Stage IIB, IIC, III or IV melanoma

-- Pneumococcal 20 valent polysaccharide conjugate vaccine ([Prevenar 20](#)) for active immunisation to prevent pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals from 6 weeks of age and older in accordance with official recommendations

-- Ravulizumab (rch) ([Ultomiris](#) 100 mg/mL) for adults with Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin 4 antibody-positive. Not for acute treatment of an NMOSD relapse.

-- Relugolix, estradiol and norethisterone acetate ([Ryvego](#)) for symptomatic endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis

### PBS

- PBS arrangements due to discontinuation of Ordine 10 (morphine hydrochloride trihydrate) oral liquids effective - 1 March 2024 - [link](#)

### TGA

- Shortage updates for Vyvanse (lisdexamfetamine dimesilate) capsules - [link](#)

- Substitution approved for gliclazide 30 mg tablet shortages - [link](#)

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages

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- AusPARs:
  - [Exarane/Exarane Forte](#) (enoxaparin sodium) for prevention of thrombo-embolic disorders/ thrombosis; prophylaxis of venous thromboembolism; treatment of deep vein thrombosis/ unstable angina/ non-Q-wave myocardial infarction/ acute ST-segment elevation myocardial infarction
  - Nurtec ODT ([rimegepant](#)) for acute treatment of migraine and prophylactic treatment of episodic migraine in adults
- Australian prescription medicine decision summaries:
  - [Spy Agent Green](#), an imaging agent (dye)
  - Onakta ([tirbanibulin](#)) for the topical field treatment of non-hyperkeratotic, nonhypertrophic actinic keratosis of the face or scalp in adults
  - Veoza ([fezolinetant](#)) for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Agency for Healthcare Research and Quality (AHRQ) USA

- Rapid Evidence Product: Adverse Events Associated With COVID-19 Pharmaceutical Treatments - [link](#)

### All Wales Medicines Strategy Group

- All Wales protocol for the appropriate prescribing of antipsychotics for people living with dementia - [link](#)

### Canadian Agency for Drugs and Technologies in Health

- Aerosol Therapy with Inhalers During Mechanical Ventilation - [link](#)
- Ketamine for Adults with Substance Use Disorders - [link](#)
- Opioid-Sparing Effects of IV Acetaminophen for Patients Undergoing Surgery - [link](#)

### Department of Health and Social Care UK

- Government's response to the Science, Innovation and Technology Committee's report 'The antimicrobial potential of bacteriophages' - [link](#)
- Safeguarding adults protocol updated: pressure ulcers and raising a safeguarding concern - [link](#)

### electronic Medicines Compendium (eMC) (UK)

- [New products](#)
- Coagadex (human coagulation factor X) for treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency. All age groups.
- Xgeva (denosumab) prefilled syringe – for prevention of skeletal-related events in adults with advanced malignancies involving bone and the treatment of giant cell tumour of bone. For this indication, it has previously only been available as a single use vial.
- [Revised SPC](#)
- Imbruvica (ibrutinib) - data added from Study CLL3011, which provides follow-up data over a median of 52 months showing that overall survival hazard ratio was 0.458 [95% CI (0.257 to 0.818, p=0068) for patients on ibrutinib and venetoclax vs. chlorambucil and obinutuzumab

### Food and Drug Administration (FDA) USA

- New Drug approvals
- first interchangeable [denosumab](#) biosimilars to Prolia and Xgeva in US to treat certain types of osteoporosis and prevent bone events in cancer
- tocilizumab ([Tyenne](#)), 2nd biosimilar to Actemra
- [zanubrutinib](#) for relapsed or refractory follicular lymphoma in combination with obinutuzumab
- [Letybo](#) (letibotulinumtoxinA-wlbg) temporarily improve the appearance of moderate-to-severe glabellar lines
- [inotuzumab ozogamicin](#) (Besponsa) for CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) expanded to include children
- [amivantamab-vmjw](#) for EGFR exon 20 insertion-mutated non-small cell lung cancer indications

- New indication
- alirocumab ([Praluent](#)) for children aged 8 years and older with HeFH to reduce LDL-C
- [nivolumab](#) in combination with cisplatin and gemcitabine for unresectable or metastatic urothelial carcinoma
- [semaglutide](#) (Wegovy) to reduce CV risk in adults with CV disease who are either obese or overweight – [SPS commentary](#)

### The Kings Fund

- Thoughts on the NHS's productivity decline - [link](#)

### Medicines and Healthcare products Regulatory Agency (MHRA)

- MHRA approves
- new [denosumab](#) formulation via new International Recognition Procedure (IRP) – [SPS commentary](#)
- [piflufolastat](#) as diagnostic tool for adults with prostate cancer - [link](#)
- [rozanolixizumab](#) to treat adults with generalised myasthenia gravis
- [ganaxolone](#) for treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
- [etrasimod](#) for treatment of moderately to severely active ulcerative colitis over 16 years
- [quizartinib](#) for first-line treatment of acute myeloid leukaemia

### NHS England

- Report of a UK survey of pharmacy professionals' involvement in research - [link](#)
- Antimicrobial resistance and antimicrobial stewardship pharmacy undergraduate competency framework - [link](#)

### NHS Scotland

- Accepted for use:
- [lvosidenib](#) (Tibsovo®) for treatment of adults with acute myeloid leukaemia
- [Olaparib](#) (Lynparza®) for treatment of prostate cancer
- [Talazoparib](#) (Talzenna®) for treatment of adults with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer
- Accepted for restricted use:
- [Foslevodopa-foscarbidopa](#) (Produodopa®) for treatment of advanced Parkinson's disease
- Not recommended:
- [Axicabtagene ciloleucel](#) (Yescarta®) for the treatment of relapsed or refractory B-cell lymphomas

### National Institute for Health and Care Excellence (NICE) UK

- Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments ([TA954](#))
- Etrasimod for moderately to severely active ulcerative colitis in people aged 16 and over ([TA956](#))
- Vitamin B12 deficiency in over 16s: diagnosis and management ([NG239](#)) – [SPS commentary](#)
- Digital technologies for delivering multidisciplinary weight-management services: early value assessment - health technology evaluation ([HTE14](#))
- Digital technologies for managing non-specific low back pain: early value assessment - health technology evaluation ([HTE16](#))
- Lung cancer: diagnosis and management, updated ([NG122](#))
- COVID-19 rapid guideline: managing COVID-19, updated ([NG191](#))
- Dupilumab for treating moderate to severe prurigo nodularis ([TA955](#))
- Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema ([TA953](#))
- Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 - guidance ([TA878](#))

### Specialist Pharmacy Services NHS UK

- Occupational health services (OHS) and medicines mechanisms - [link](#)
- Preparing to use tocilizumab biosimilar - [link](#)
- Ensuring time-critical use of rasburicase - [link](#)
- Preparing to use eculizumab biosimilar - [link](#) – [SPS commentary](#)



## World Health Organisation (WHO)

- HIV drug resistance: Brief report 2024 - [link](#) ; New report documents increase in HIV drug resistance to dolutegravir - [link](#)
- Guideline on haemoglobin cut-offs to define anaemia in individuals and populations - [link](#)
- New manual released to support diagnosis of mental, behavioural and neurodevelopmental disorders added in ICD-11 - [link](#)
- WHO launches Pharmaceutical Quality Assurance guidelines, 10th edition - [link](#)

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## MEDICATION SAFETY

### Australian and New Zealand College of Anaesthetists (ANZCA) & Faculty of Pain Medicine

- IV paracetamol in short supply - [link](#)

### electronic Medicines Compendium (eMC) (UK)

#### - [Revised SPCs](#)

- Ajovy (fremanezumab) - interactions with medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely, and there are no adequate data on developmental risk associated with use in pregnant women, and no data on presence in human milk
- Cabazitaxel tillomed (cabazitaxel) - due to the genotoxic risk of cabazitaxel, men should use contraceptive measures during and for 4 months after cessation of treatment
- Coagadex (human coagulation factor X) - most common ADRs were infusion site erythema, infusion site pain, fatigue and back pain
- Diflucan (fluconazole) - for longer treatment, contraception may be considered, as appropriate, in women of childbearing potential throughout the treatment period and for 1 week after the final dose. Data from a meta-analysis on cardiac malformations have been added – [SPS commentary](#)
- Forxiga (dapagliflozin) - cases of phimosis/acquired phimosis reported concurrent with genital infections and in some cases, circumcision was required
- Fosavance (alendronic acid/colecalciferol) - atypical fractures (FCs) of other bones (ulna,tibia) reported after long-term (LT) treatment; they may occur after minimal/no trauma & there may be prodromal pain prior to experiencing completed FC. Ulna FC may be linked to repetitive stress due to LT use of walking aids
- Increlex (mecasermin) - pre-prandial glucose monitoring recommended at treatment initiation and until well-tolerated dose established. Monitoring should continue regardless of pre-prandial condition, if possible at time of event, if frequent and/or severe symptoms of hypoglycaemia occur
- Kineret (anakinra) - isolated cases of injection site amyloid deposits reported in patients with neonatal-onset multisystem inflammatory disease/chronic infantile neurological, cutaneous, articular syndrome who received high doses over prolonged periods. Rotation of injection site advised
- Lokelma (sodium zirconium cyclosilicate) – updated interaction study data in healthy volunteers showing co-administration of Lokelma 15 g with tacrolimus 5 mg resulted in a decreased tacrolimus AUC and Cmax by 37% and 29% respectively, therefore, tacrolimus should be taken  $\geq 2$  hours before or after Lokelma
- Oxypro (oxycodone) - “Sphincter of Oddi dysfunction” (SoO) added as an ADR (frequency not known). Because it can cause SoO dysfunction, which can raise intrabiliary pressure & increase risk of pancreatitis, it should be used with caution in patients with pancreatitis/ biliary tract disease
- Rifampicin products - shown to decrease mifepristone (MF) AUC by 6.3-fold and its metabolites 22-hydroxy mifepristone and N-demethyl MF by 20-fold and 5.9-fold, respectively, suggesting reduced efficacy of MF when given concomitantly with potent CYP inducer such as rifampicin
- Scheriproct (prednisolone/cinchocaine) Ointment - epidemiological studies suggest possible increased risk of oral clefts in newborns of women treated with glucocorticoids (GCs) during 1st trimester. Topical GCs should be avoided in this period. It also notes corticosteroids are excreted in small amounts in breast milk
- Spravato (esketamine hydrochloride) - respiratory depression is a rare & transient ADR that may occur at high doses after rapid injection when used for anaesthesia. Spravato should only be used in patients with clinically significant cardiovascular or respiratory conditions if potential benefit outweighs harm risk

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- Tostran (testosterone) - instructions on how to prime the canister pump before first use.
- Truvada (tenofovir disoproxil fumarate, emtricitabine) - decreased bone mineral density is a common ADR, and the warning/precaution on bone effects has been further strengthened
- Xgeva (denosumab) - single use vial & administration should only be performed by an HP
- Zavicefta (ceftazidime pentahydrate, avibactam sodium) - 'Kounis syndrome' (acute coronary syndrome associated with an allergic reaction) as an adverse effect (frequency unknown). This follows post-marketing reports of hypersensitivity reactions which progressed to Kounis syndrome
- Zyban (bupropion hydrochloride) - panic attack is an undesirable effect (frequency unknown)
- Risk minimisation materials
- alglucosidase alfa ([Myozyme](#)): Safety information packet for HPs containing guidance on risks associated with treatment, their clinical management, and immunological testing which will help to further characterise the potential mechanism of infusion-associated reactions and hypersensitivity reactions
- Cerdelga ([eliglustat](#)) prescriber guide contains a checklist of actions to be completed before and after treatment initiation, and information on CYP2D6 genotyping assessment (Sanofi Genzyme offers CYP2D6 metaboliser status testing free of charge in the UK). A patient alert card is also available
- [Epysqli](#) (eculizumab biosimilar) - Physician's Guide contains information on prevention measures, detection, careful monitoring &/or proper management of selected safety concerns associated with eculizumab. Also a patient/parent information guide, a patient safety card & certificate of vaccination
- Kevzara ([sarilumab](#)) Patient Alert card: contains important safety information for patients to be aware of before, during & after treatment, including symptoms of serious infections & gastrointestinal perforation, the need for screening for tuberculosis prior to treatment, & monitoring requirements
- Tasmar ([tolcapone](#)) patient diary: contains information on risks of liver injury (rare but potentially fatal) and neuroleptic malignant syndrome associated with use of tolcapone and the monitoring that will take place during treatment, with space to record liver function tests throughout the first year

#### EMA

- European PRAC concludes available data do not support a causal association between Comirnaty and Spikevax and cases of postmenopausal bleeding - [link](#)

#### Health Canada – MedEffect Notice

- Health Product InfoWatch, [February 2024](#)

#### Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! [March 7, 2024](#)
- Drug Diversion Prevention Beyond Controlled Substance Medications - [link](#)
- Worth repeating...SUMatriptan injection wrong route errors continue
- Accidental overdoses and adverse effects from compounded GLP-1 agonists
- Safe drug administration during fasting

#### Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Recent cases of lead poisoning with Ayurvedic medicines – [link](#)
- Prescriber Update – [March 2024](#)

#### MIMS monthly updates

- New Contraindications
- Apomorphine hydrochloride hemihydrate ([Movapo](#), Movapo Pen and Movapo PFS) for concomitant use with 5HT3 antagonists including antiemetics (eg ondansetron, granisetron, palonosetron)
- Clomifene citrate ([Clomid](#)) in patients with known history of significant, medically confirmed vision disorders related to the use of Clomid (prior or ongoing treatment)
  - Factor VIII inhibitor bypassing fraction ([Feiba NF](#)) in acute myocardial infarction, unless indicated in life-threatening bleeding events
- Itraconazole ([Lozanoc](#)) for concomitant use with apixaban, rivaroxaban, dabigatran, mobocertinib, finerenone and voclosporin, including 2 weeks after itraconazole treatment, and in chronic

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lymphocytic leukaemia/ small lymphocytic lymphoma patients during the dose initiation, titration, and ramp-up phases of venetoclax treatment

### **MIMS, UK**

- Propranolol overdose reports: what's happening on the frontline? - [link](#)
- Montelukast neuropsychiatric reactions: How can prescribers adapt their practice? - [link](#)

### **Specialist Pharmacy Services NHS UK**

- Treating heartburn and dyspepsia during breastfeeding - [link](#)
- Treating insomnia during breastfeeding - [link](#)
- Using gastrointestinal antispasmodics during breastfeeding - [link](#)

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## **PAPERS OF INTEREST**

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### **Age and Ageing**

- Effects of rhythm-control and rate-control strategies on cognitive function and dementia in atrial fibrillation: a systematic review and meta-analysis - [link](#)

### **American Journal of Health-System Pharmacy (AJHP)**

- Comparative effectiveness of sacubitril/valsartan versus angiotensin receptor blockers in patients with heart failure with preserved ejection fraction: A real-world study - [link](#)
- Development of optimized adult epidural infusion preparations to reduce waste and improve operational efficiency - [link](#)
- Study to assess the impact of analytics software on operating room controlled substance management and drug diversion - [link](#)
- Cost evaluation of continuation of therapy with dalbavancin compared to standard-of-care antibiotics alone in hospitalized persons who inject drugs, with severe gram-positive infections - [link](#)
- Characterizing redundancy in pharmacy residency research projects - [link](#)
- A review of fecal microbiota, live-jslm for the prevention of recurrent *Clostridioides difficile* infection - [link](#)

### **Annals of Internal Medicine**

- Long-Term Effect of Randomization to Calcium and Vitamin D Supplementation on Health in Older Women: Postintervention Follow-up of a Randomized Clinical Trial - [link](#)
- In the clinic: Acute Colonic Diverticulitis - [link](#)

### **British Journal of Clinical Pharmacology**

- Sodium-glucose cotransporter-2 inhibitors and the risk of lung cancer among patients with type 2 diabetes - [link](#)
- Statin use and the risk of Parkinson's disease in persons with diabetes: A nested case-control study - [link](#)

### **British Journal of General Practice**

- A systematic review of interventions to improve medication adherence in adults with mental-physical multimorbidity in primary care - [link](#)

### **British Medical Journal (BMJ)**

- Ultra-processed food exposure and adverse health outcomes: umbrella review of epidemiological meta-analyses - [link](#) – [SPS commentary](#)
- Illness trajectories of incurable solid cancers - [link](#)
- Using illness trajectories to inform person centred, advance care planning - [link](#)
- Opinion: Let's talk differently about obesity - [link](#)
- Practice Pointer: Advance and future care planning - [link](#)
- NHS rolls out dostarlimab (Jemperli) for advanced primary or recurrent endometrial cancer - [link](#)
- MHRA investigates risks associated with montelukast after concerns over neuropsychiatric reactions - [link](#) – [SPS commentary](#)

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- Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management—summary of NICE [guidance](#)

### **BMJ Open**

- Comparative effectiveness of baricitinib and alternative biological DMARDs in a Swiss cohort study of patients with RA - [link](#)

### **Circulation**

- Are Recommendations That Favour Other Agents Over Angiotensin-Converting Enzyme Inhibitors in Africans With Hypertension Justified? - [link](#)

### **Diabetes Care**

- Differential Effects of Type 2 Diabetes Treatment Regimens on Diabetes Distress and Depressive Symptoms in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE): A Randomized Clinical Trial - [link](#)

- Perinatal Outcomes in Early and Late Gestational Diabetes Mellitus After Treatment From 24-28 Weeks' Gestation: A TOBOGM Secondary Analysis - [link](#)

### **Diabetes, Obesity and Metabolism**

- Does metformin reduce the risk of cancer in obesity and diabetes? A systematic review and meta-analysis - [link](#)

- Glycaemic control and macrovascular and microvascular outcomes in type 2 diabetes: Systematic review and meta-analysis of cardiovascular outcome trials of novel glucose-lowering agents - [link](#)

- Glycaemic control and macrovascular and microvascular outcomes: A systematic review and meta-analysis of trials investigating intensive glucose-lowering strategies in people with type 2 diabetes - [link](#)

### **Drug and Therapeutics Bulletin**

- DTB select: Safety update: valproate safety and educational materials - [link](#)

- Do regulatory safety warnings on medicines miss the mark? - [link](#)

### **Drug Safety**

- Exploring the Role of Guidelines in Contributing to Medication Errors: A Descriptive Analysis of National Patient Safety Incident Data - [link](#)

### **European Heart Journal**

- Pulmonary arterial hypertension treatment: an individual participant data network meta-analysis - [link](#)

- Semaglutide and cardiovascular outcomes by baseline HbA1c in diabetes: the SUSTAIN 6 and PIONEER 6 trials - [link](#)

- Intravenous iron for heart failure, iron deficiency definitions, and clinical response: the IRONMAN trial - [link](#)

### **European Journal of Hospital Pharmacy**

- Development of hospital pharmacy services at transition of care points: a scoping review - [link](#)

- Extravasation of brentuximab vedotin, an antibody-drug conjugate, in a patient with anaplastic large cell lymphoma - [link](#)

### **Gastroenterology**

- Standard of Care Versus Octreotide in Angiodysplasia-Related Bleeding (the OCEAN Study): A Multicenter Randomized Controlled Trial - [link](#)

### **Health Technology Assessment**

- Thromboprophylaxis during pregnancy and the puerperium: a systematic review and economic evaluation to estimate the value of future research - [link](#)

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## Heart

- The role of COVID-19 vaccines in preventing post-COVID-19 thromboembolic and cardiovascular complications - [link](#)

## International Journal for Quality in Health Care

- How are we handling protein drugs in hospitals? A Human Factors and Systems Engineering Approach to compare two hospitals and suggest a best practice - [link](#)

## JAMA

- GLP-1 Agonists for Obesity- A New Recipe for Success? - [link](#)
- HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women - [link](#)
- Patient page: What is Cushing Syndrome? - [link](#)
- A Review: Cardiac Amyloidosis Due to Transthyretin Protein - [link](#) ; Allergic Rhinitis - [link](#)
- Disease-Modifying Drugs for Adult-Onset Rheumatoid Arthritis - [link](#)
- Diagnosis and Management of Myotonic Dystrophy Type 1 - [link](#)
- ADHD Pharmacotherapy and Mortality in Individuals With ADHD – [link](#) – [SPS commentary](#)

## JAMA Internal Medicine

- Clinical outcomes of rapid respiratory virus testing in emergency departments: A systematic review and meta-analysis - [link](#) – [SPS commentary](#)
- Dementia Prevention and Treatment: A Narrative Review - [link](#)
- Opioid Prescribing and Outcomes in Patients With Sickle Cell Disease Post–2016 CDC Guideline - [link](#)
- Clinical Decision Support for Hypertension Management in Chronic Kidney Disease: A Randomized Clinical Trial - [link](#)

## JAMA Network Open

- Telemedicine vs telephone consultations and medication prescribing errors among referring physicians: a cluster randomized crossover trial – [link](#)
- Institutional and Regional Variation in Opioid Prescribing for Hospitalized Infants in the US- [link](#)

## JAMA Neurology

- Batoclimab vs Placebo for Generalized Myasthenia Gravis: A Randomized Clinical Trial - [link](#)
- LDL-C Levels and Bleeding Risk in Patients Taking DAPT After Minor Ischemic Stroke or TIA - [link](#)
- Treatment of Refractory Status Epilepticus with Continuous Intravenous Anaesthetic Drugs - [link](#)
- Clopidogrel Plus Aspirin vs Aspirin Alone in Patients With Acute Mild to Moderate Stroke - [link](#)

## JAMA Pediatrics

- Development and Validation of an Automated Classifier to Diagnose Acute Otitis Media in Children - [link](#)

## JAMA Psychiatry

- All-Cause and Cause-Specific Mortality Among Individuals with Hypochondriasis - [link](#)

## Journal of Clinical Oncology

- Impact of Helicobacter pylori Infection and Treatment on Colorectal Cancer in a Large, Nationwide Cohort - [link](#) – [SPS commentary](#)

## Journal of General Internal Medicine

- Identifying the Best Initial Oral Antibiotics for Adults with Community-Acquired Pneumonia: A Network Meta-Analysis - [link](#) – [SPS commentary](#)

## Journal of Pharmacy Practice and Research (JPPR)

- Factors associated with an increased risk of vitamin B12 deficiency in patients with type 2 diabetes mellitus on metformin - [link](#)

### **Lancet**

- Worldwide trends in underweight and obesity from 1990 to 2022: a pooled analysis of 3663 population-representative studies with 222 million children, adolescents, and adults - [link](#)  
- Seminar: Crohn's disease - [link](#)  
- Updates on the management of inflammatory bowel disease from periconception to pregnancy and lactation - [link](#)  
- mRNA-based therapeutics: looking beyond COVID-19 vaccines - [link](#)

### **Lancet Diabetes & Endocrinology**

- Duration of fracture prevention after zoledronate treatment in women with osteopenia: observational follow-up of a 6-year randomised controlled trial to 10 years - [link](#) – [SPS commentary](#)  
- Undiagnosed type 2 diabetes: an invisible risk factor – [link](#) – [SPS commentary](#)

### **Lancet HIV**

- Uncovering HIV and malaria interactions: the latest evidence and knowledge gaps - [link](#)

### **Lancet Infectious Diseases**

- Accelerating antibiotic access and stewardship: a new model to safeguard public health - [link](#)  
- Prevalence of subclinical pulmonary tuberculosis in adults in community settings: an individual participant data meta-analysis - [link](#) – [SPS commentary](#)

### **Lancet Oncology**

- Correlations of response rate and progression-free survival with overall survival in immunotherapy trials for metastatic non-small-cell lung cancer: an FDA pooled analysis - [link](#)

### **Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**

- A Systematic Review of Naldemedine and Naloxegol for the Treatment of Opioid-Induced Constipation in Cancer Patients - [link](#)  
- Rational Prescribing of Pancreatic Enzymes for Patients with Pancreatic Cancer - [link](#)  
- Influences of Software Changes on Oxycodone Prescribing at an Australian Tertiary Emergency Department: A Retrospective Review - [link](#)

### **Medical Journal of Australia**

- Why clinical artificial intelligence is (almost) non-existent in Australian hospitals and how to fix it - [link](#)

### **Morbidity and Mortality Weekly Report**

- Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus–Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season - [link](#)

### **New England Journal of Medicine**

- Enfortumab Vedotin and Pembrolizumab in Untreated Advanced Urothelial Cancer - [link](#)  
- Microplastics and Nanoplastics in Atheromas and Cardiovascular Events - [link](#)  
- Health Effects of Fossil Fuel-Derived Endocrine Disruptors - [link](#)

### **Pharmacotherapy**

- Optimal starting dosing regimen of intravenous oxytocin for labor induction based on the population kinetic-pharmacodynamic model of uterine contraction frequency - [link](#)

### **Studies in Health Technology and Informatics**

- Stepped-wedge cluster RCT to assess the effects of an electronic medication system on medication administration errors - [link](#)

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## CONSULTATIONS

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### TGA

- Consultation: Clarification of how Clinical Decision Support System (CDSS) software is regulated, closes 6 May 2024 - [link](#)

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## WEBINARS & PODCASTS

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### Australian Prescriber Podcasts

- [Episode 159](#) – Therapeutic Guidelines Dermatology

### MJA Podcasts

- [Episode 7](#): Australia's national bowel cancer screening program

### Purple Pen Podcast

- [PPP 159](#) - Deprescribing psychotropics

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## UPCOMING EVENTS

(New additions listed in TAGMail)

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### AHHA

- From Hurting to Healing: Driving Workforce Wellbeing - 26 March 2024 12:30-13:30 - [link](#) – [register here](#)

### FDA

- FDA Drug Topics: Navigating FDA's Drug Information Resources - March 26, 2024 – [register here](#)

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## Fortnightly TAG Mail – resources list      29<sup>th</sup> February 2024

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### NSW TAG ACTIVITIES

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#### Open email discussions

7. **Patient prioritisation for discharge medication list provision:** A TAG member would like to know how other hospitals prioritise their patients for the creation/supply of pharmacist-generated discharge medication lists. Closes 8th March 2024.
8. **NSW TAG Collaborative to develop medicine-related documents:** See email sent to NSW TAG members 27/2/2024. Closes 15th March 2024.
9. **Missing medications from wards:** A member has been experiencing medications going missing in the wards after being dispensed from pharmacy. A recent example concerned Paxlovid where five boxes were sent to the same patient over 2 days because the medication had gone missing. The incidents are being entered into IMS+. Are hospitals experiencing similar issues? Have any strategies been implemented to reduce such occurrences? Extended to 8th March 2024
10. **Medication reviews for inpatients in remote Multi-Purpose Services.** A rural member has been requested to provide inpatient medication reviews for patients in remote Multi-Purpose Services (MPSs) in their local health district. Currently, the hospital accepts virtual pharmacy referrals for new hospital admissions (but not from MPSs). Are other hospitals with oversight of MPSs also being requested to provide inpatient medication reviews/providing a medication review service to MPSs and if so, how are they managing this workload? Extended to 8th March 2024

#### Recently completed email discussions

- Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection
- Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

#### Upcoming TAG meeting dates

NSW TAG General Meeting: Thursday 4<sup>th</sup> April 2024 11.30-1pm

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## Updated TAG publications

Coming soon: Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions, publications or upcoming meetings.

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## EDITOR'S PICKS

AJHSP: Artificial intelligence in pharmacy: A guide for clinicians - [link](#)

AJHSP: Recent and anticipated novel drug approvals for 2024 - [link](#)

Aust Prescr: Managing hypercholesterolaemia - [link](#); Therapeutic inertia - [link](#); Morphine oral liquid availability - [link](#)

BJCP: Quality indicators for appropriate in-hospital pharmacotherapeutic stewardship: An international modified Delphi study - [link](#) – [SPS commentary](#)

BJCP: Clinical decision-making in benzodiazepine deprescribing by healthcare providers vs. AI-assisted approach - [link](#)

BMJ: Effect of exercise for depression: systematic review and network meta-analysis of randomised controlled trials - [link](#) – [SPS commentary](#)

BMJ QS: Between-hospital variation in indicators of quality of care: a systematic review - [link](#)

Circulation: RNA Therapeutics for the Cardiovascular System - [link](#)

Cochrane: - Evening versus morning dosing regimen drug therapy for hypertension - [link](#)

IMJ: COVID-19 vaccination: are more jabs needed or are we now immune? - [link](#)

ISMP: Three Additions to 2024-2025 Targeted Medication Safety Best Practices for Hospitals - [link](#)

IJCP: Antipsychotic prescribing and drug-related readmissions in multimorbid older inpatients - [link](#)

JAMA Internal medicine: Age-Related Risk of Serious Fall Events and Opioid Analgesic Use - [link](#)

JPPR: Standard of practice in pain management for pharmacy services - [link](#)

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## OTHER NEWS

### NSW Health

- High-Risk Medicines Management ([PD2024\\_006](#))

--includes new standards for anti-cancer drugs and insulin

- NSW Health Procurement (Goods & Services) ([PD2024\\_009](#))

- Measles alert for western Sydney - [link](#) - Legionnaires' disease alert for Sydney - [link](#)

- Public health warning: Opioid overdoses after using drugs people believed to be cocaine or

methamphetamine - [link](#) - Warning: High-dose MDMA tablets (ecstasy) circulating in NSW - [link](#)

### Pharmacy Board of Australia

- Regulators come together as one million Australians turn to medicinal cannabis treatments - [link](#)

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## REPORTS AND PUBLICATIONS – AUSTRALIA

### Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found [here](#)

- New program to improve patient and staff experience in emergency care - [link](#) – [ECAT implementation plan](#)

- Management of adults with COVID-19 in the post-acute phase - [link](#)

- Model of care for the management of low back pain: Summary - [link](#)

- Using virtual care to enhance palliative care experiences - [link](#)

### Australian Government Department of Health

- Helping young Australians learn about the harms of vaping - [link](#)

- ATAGI Statement on the Administration of COVID-19 Vaccines in 2024 – [fact sheet](#)

- Getting vaccinated against influenza – Resource collection – [collection](#)

- ATAGI Statement on the Clinical Use Of Arexvy (RSV PRE-F3) Vaccine for RSV – [fact sheet](#)

- ATAGI Statement on the Administration of Seasonal Influenza Vaccines in 2024 – [fact sheet](#)

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### **Australian Institute for Health and Welfare (AIHW)**

- National Drug Strategy Household Survey 2022–2023 - [link](#) – with many supplementary reports on specific agents e.g. non-medical use of pharmaceutical stimulants - [link](#)
- OECD health care quality and outcomes indicators, Australia 2022–23 - [link](#)
- GEN: Younger people in residential aged care - [link](#)
- Family, domestic and sexual violence - [link](#)

### **PBS**

- PBS subsidy arrangements for gliclazide 30 mg tablets SSSI - 29 February 2024 - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - [Vegzelma](#) (bevacizumab) in combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic colorectal cancer
  - [MS-2 Step \(composite pack\)](#) approval granted to make changes in Product Information (PI) and Risk Management Plan (RMP)
- Australian prescription medicine decision summaries:
  - [Erwinase](#) as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) patients, who have developed hypersensitivity to pegylated asparaginase obtained from *E. coli*

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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### **The Academy of Medical Sciences UK**

- Prioritising early childhood to promote the nation's health, wellbeing and prosperity - [link](#)

### **All Wales Medicines Strategy Group**

- All Wales adult asthma management and prescribing guideline, [updated](#)

### **British In Vitro Diagnostics Association**

- Calls for CRP testing at POC to tackle threat of AMR - [link](#)

### **British National Formulary**

- BNF/BNFC newsletter: [February 2024](#)

### **Canadian Agency for Drugs and Technologies in Health**

- Cost-Effectiveness of Respiratory Syncytial Virus Vaccines for Adults - [link](#)
- Reference list: POC Testing for Acetaminophen - [link](#)

### **Department of Health and Social Care UK**

- Roadmap for meeting the PrEP needs of those at significant risk of HIV – [link](#) – [SPS commentary](#)

### **electronic Medicines Compendium (eMC) (UK)**

- [New products](#)
  - Epsqli (eculizumab biosimilar) – highly similar to the reference product Soliris
  - Ivermectin 3mg tablets – for GI strongyloidiasis (anguillulosis), suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to *Wuchereria bancrofti*, and human sarcoptic scabies. This is the first oral ivermectin product to be licensed in the UK
- [New/expanded indications](#)
  - Libtayo (cemiplimab) - use with platinum-based chemotherapy for 1st line treatment of non-small cell lung cancer expressing PD-L1 (in  $\geq 1\%$  of tumour cells), with no EGFR, ALK or ROS1 aberrations, in adults with locally advanced (not candidates for chemoradiation) or metastatic disease

### **European Centre for Disease Control (ECDC)**

- Hypervirulent Resistant K pneumoniae On the Rise in EU - [link](#)

### European Medicines Agency (EMA)

- Antimicrobial consumption and resistance in bacteria from humans and food-producing animals: Fourth joint inter-agency report on integrated analysis of antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA – [link](#) – [SPS commentary](#)

- CHMP recommended changes to the terms of the marketing authorisation:

-- [pembrolizumab](#) in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults

-- [Apremilast Accord](#) - a generic of Otezla, for psoriatic arthritis, psoriasis and Behcet's disease

-- [Celdemic](#) (influenza vaccine) - for active immunisation against the H5N1 subtype of Influenza A virus in adults and children aged  $\geq 6$  months, based on a robust immune response three weeks after two doses of the vaccine given three weeks apart. The most common side-effects include injection site pain, myalgia, and fatigue

-- [Incellipan](#) (influenza vaccine) – as above in an officially declared pandemic

-- [danicopan](#) (Voydeya) for residual haemolytic anaemia in adults with paroxysmal nocturnal haemoglobinuria (PNH) - [link](#)

-- [Nintedanib Accord](#) - a generic of Ofev, for idiopathic pulmonary fibrosis, other chronic fibrosing interstitial lung diseases with a progressive phenotype, and systemic sclerosis associated interstitial lung disease

-- [retifanlimab](#) (Zynyz) - first-line for adult Merkel cell carcinoma not amenable to surgery or radiation

-- [sparsentan](#) (Filspari) for adult primary immunoglobulin A nephropathy (IgAN)

-- [tislelizumab](#) (Tizveni) for locally advanced or metastatic non-small cell lung cancer

-- [tofersen](#) (Qalsody) for amyotrophic lateral sclerosis - [link](#)

-- ustekinumab biosimilar ([Pyzchiva](#)) - highly similar to Stelara, for psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease

- CHMP recommended extension to the existing indication:

-- [abrocitinib](#) (Cibinqo) – for moderate-to-severe atopic dermatitis in adolescents 12 years and older

-- [ciltacabtagene autoleucl](#) - to include adults with relapsed and refractory multiple myeloma who have received  $\geq 1$  prior therapy (currently says  $\geq 3$  prior therapies) and are refractory to lenalidomide

-- hydroxycarbamide (Xromi)- to include prevention of vaso-occlusive complications of sickle cell disease in patients from 9 months of age (currently restricted to use in those over 2 years of age)

-- [ivacaftor](#) - use in children from 1 month of age who are at least 3kg (currently from 4 months and weighing at least 5kg) and new presentation of Kalydeco granules (13.4 mg granules in sachet)

-- [luspatercept](#) - for transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (currently restricted to those with ring sideroblasts, who had unsatisfactory response/ are ineligible for erythropoietin-based therapy)

### electronic Medicines Compendium (eMC) (UK)

- New or expanded indications

-- Keytruda (pembrolizumab) - 1st line use in locally advanced unresectable or metastatic biliary tract carcinoma in adults, in combination with gemcitabine & cisplatin added.

-- Libtayo (cemiplimab)- New indication of use with platinum-based chemotherapy for 1st line treatment of non-small cell lung cancer expressing PD-L1 (in  $\geq 1\%$  of tumour cells), with no EGFR, ALK or ROS1 aberrations, in adults with locally advanced (not candidates for chemoradiation) or metastatic disease

### Food and Drug Administration (FDA) USA

- New Drug approvals

-- [lifileucl](#) (Amtagvi), first cellular therapy for unresectable or metastatic melanoma

-- [osimertinib](#) with chemotherapy for EGFR-mutated non-small cell lung cancer

-- [Exblifep](#) (cefepime, enmetazobactam) , cephalosporin/beta-lactamase inhibitor for complicated urinary tract infections – [label \(PI\)](#) - [letter](#)

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- Xolair ([omalizumab](#)), first medication to help reduce allergic reactions to multiple foods after accidental exposure
- adalimumab ([Simlandi](#)), new high-concentration, citrate-free biosimilar to Humira
- teclistamab ([Tecvayli](#)), new biweekly maintenance for multiple myeloma in complete remission
- acetylcysteine antidote ([Legubeti](#)), new oral dosage form for acetaminophen overdose

#### **General Pharmaceutical Council UK**

- Statement on the reclassification of codeine linctus to a prescription-only medicine - [link](#)

#### **Monthly Index of Medical Specialities MIMS UK**

- Practical steps to reduce health inequalities in your practice - [link](#)

#### **NHS England**

- Martha's rule to be rolled out in English hospitals from April - [link](#) – [SPS commentary](#)

#### **National Institute for Health and Care Excellence (NICE) UK**

- Tuberculosis ([NG33](#)) - 1.1.3.10 discussing criteria for offering BCG vaccination to selected neonates, final bullet 'have a family history of TB in the past 5 years' removed – [SPS commentary](#)
- Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations ([TA952](#))
- Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over ([TA953](#))

#### **National Institute for Health and Care Research (NIHR)**

- NIHR commentaries: Alcohol dependence: telephone support plus financial incentives helped people take acamprosate - [link](#)

#### **Nuffield Trust UK**

- Antibiotic prescribing indicators - [link](#)

#### **OECD**

- Securing Medical Supply Chains in a Post-Pandemic World - [link](#)

#### **The King's Fund (UK)**

- Mental health 360 - [link](#)

#### **UK Health Security Agency**

- Tuberculosis in England, 2023 report (data up to end of 2022) - [link](#) – [SPS commentary](#)
- Hepatitis A infection: prevention and control guidance – [update](#) – [SPS commentary](#)
- Pertussis: guidelines for public health management - [link](#)

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### **MEDICATION SAFETY**

#### **electronic Medicines Compendium (eMC) (UK)**

- [Revised SPCs](#)

- Bavencio (avelumab) – in patients with pre-existing autoimmune disease (AID), study data suggests risk of immune-related adverse reactions may be increased compared with the risk in those without AID. Sarcoidosis added as uncommon ADR
- Decapeptyl (triptorelin pamoate) - idiopathic intracranial hypertension (pseudotumor cerebri) reported in paediatric patients. Patients should be warned for signs and symptoms including severe or recurrent headache, vision disturbances and tinnitus
- Hydrea (hydroxycarbamide) - potential ADRs include systemic and cutaneous lupus erythematosus (very rare), haemolytic anaemia, interstitial lung disease, pneumonitis, alveolitis, allergic alveolitis and cough (all frequency unknown)

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- Imbruvica (ibrutinib) - treatment should be withheld for any new onset or worsening grade 2 cardiac failure or grade 3 cardiac arrhythmias, and a table of recommended dose modifications for events of cardiac failure or cardiac arrhythmia events added
- Imfinzi (durvalumab) - immune-mediated arthritis and uveitis added to list of immune-mediated ADRs observed in patients treated with durvalumab alone or in combination with tremelimumab
- Imjudo (tremelimumab) - uveitis added as rare ADR, and immune-mediated arthritis as uncommon
- Ketalar (ketamine) - hepatotoxicity (such as mixed liver injury, cholestatic liver injury and biliary dilation) reported in patients with extended use (>3 days). Hence, not recommended for long-term use
- Keytruda (pembrolizumab)- ADRs of leukopenia & dizziness frequency changed from very common to common. Optic neuritis added as rare
- Linezolid - hyponatraemia and/or SIADH observed in some patients. Serum sodium levels should be monitored regularly in patients at risk of hyponatraemia (e.g. elderly patients; those taking medicines that may lower blood sodium levels)
- Trileptal (oxcarbazepine) - potential for congenital abnormalities in the offspring of women treated with combination therapies greater than those receiving monotherapy
- Rocephin (ceftriaxone) – information added about displacement volumes and solvent volume for reconstitution of the vials
- Risk minimisation materials
- Aclasta ([zoledronic acid monohydrate](#)) - Patient Reminder Card regarding osteonecrosis of the jaw risk, reported very rarely in patients receiving this medicine for osteoporosis, the possible need for dental examination prior to treatment, and measures to take to reduce risk whilst receiving treatment
- alemtuzumab ([Lemtrada](#)) – Health professional guide provides information about potential serious risks and recommendations on risk mitigation through patient counselling, monitoring and management. Patient guide and alert card also available
- Cerezyme ([imiglucerase](#)) - home infusion manual for health professionals. Also, a manual for patients, which discusses Gaucher disease, the treatment, and how it is prepared and administered in the home setting
- Enspryng ([satralizumab](#)) - Patient card with important safety information on increased susceptibility to infection, including a list of signs of infection for which medical attention should be sought, and actions for the treating healthcare professional to take if infection is suspected
- Fabrazyme ([agalsidase beta](#)) - home infusion manual for health professionals. Also a manual for patients, which discusses organisation of treatment and how it is prepared and administered at home, and a log book
- [Fibrovein](#) (sodium tetradecyl sulphate) - key safety concerns associated with this product and measures to be taken before treatment discussed, including consideration of contra-indications, practitioner training, correct preparation and administration, and follow-up

### **Food and Drug Administration (FDA) USA**

- Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication - [link](#)
- US FDA withdraws approval of [melphalan flufenamide](#) (Pepaxto) in multiple myeloma
- [FDA Drug Topics](#): Tips to Navigating Drug Interaction Information in the US Prescribing Information

### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [February 22, 2024](#) including:
- Three Additions to 2024-2025 Targeted Medication Safety Best Practices for Hospitals - [link](#)

### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- Valproate: important new regulatory measures for oversight of prescribing to new patients and existing female patients - [link](#)– [SPS commentary](#)
- Update on MHRA safety review of medicines containing pseudoephedrine [link](#)
- Drug Safety Update [February 2024](#)
- Codeine linctus (codeine oral solutions): reclassification to prescription-only medicine – [link](#) – [SPS commentary](#)

-- Pseudoephedrine: very rare risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) – [link](#) – [SPS commentary](#)

### **Specialist Pharmacy Service**

- Using benzodiazepines during breastfeeding - [link](#)
- Tocilizumab biosimilar: Patient Information Sheet – [link](#)
- Using penicillin antibiotics during breastfeeding - [link](#)
- Medication safety update [February 2024](#)

### **TGA**

- Transfer of Ordine (morphine) oral liquid products to Arrotex - [link](#)
- Product Information safety updates - [February 2024](#)
- Safety Advisory: Medicines containing Withania somnifera (Withania, Ashwagandha) - potential for gastrointestinal symptoms and very rare cases of liver injury - [link](#)

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## **PAPERS OF INTEREST**

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### **Age and Ageing**

- Sodium-glucose cotransporter-2 inhibitors (SGLT2) in frail or older people with type 2 diabetes and heart failure: a systematic review and meta-analysis - [link](#)

### **American Journal of Health-System Pharmacy (AJHP)**

- Using name overlap analysis to understand medication name search safety - [link](#)
- Artificial intelligence in pharmacy: A guide for clinicians - [link](#)
- Clinical dashboard development and implementation to standardize data capture and reporting across health-system specialty pharmacies - [link](#)
- Recent and anticipated novel drug approvals for 2024 - [link](#)
- The need for an emergency planning and preparedness strategic plan for pharmacy leadership - [link](#)
- Impact of a pharmacy technician on an interprofessional antithrombotic stewardship program at an academic medical center - [link](#)
- Key considerations in navigating ticagrelor's reported effect on heparin-induced thrombocytopenia functional assays in a landscape of limited data - [link](#)

### **Annals of Internal Medicine**

- A Risk Profile Using Simple Hematologic Parameters to Assess Benefits from Baricitinib in Patients Hospitalized With COVID-19: A Post Hoc Analysis of the Adaptive COVID-19 Treatment Trial-2 - [link](#)
- The Management of Posttraumatic Stress Disorder and Acute Stress Disorder: Synopsis of the 2023 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guideline - [link](#)

### **Arthritis & Rheumatology**

- Effect of Intravenous Zoledronic Acid on Total Knee Replacement in Patients with Symptomatic Knee Osteoarthritis and Without Severe Joint Space Narrowing: A Prespecified Secondary Analysis of the ZAP2 Trial - [link](#)
- Hydroxychloroquine in Lupus Pregnancy and Risk of Preeclampsia - [link](#)
- Weight Loss for Patients with Gout and Concomitant Obesity: A Proof-of-Concept Randomized Trial - [link](#)

### **Australian Prescriber [February 2024](#)**

- Managing pre-existing diabetes prior to and during pregnancy - [link](#)
- Managing hypercholesterolaemia - [link](#)
- Therapeutic inertia - [link](#)
- Diagnosis and management of eosinophilic oesophagitis - [link](#)
- Severe liver injury following use of RAD-140, a selective androgen receptor modulator, for body building - [link](#)
- TGA Medicines Safety Update and Australian Prescriber—back to the future ([take 2](#))
- Use caution when prescribing baclofen off label - [link](#)

- New warnings of romosozumab (Evenity) cardiovascular risks - [link](#)
- Morphine oral liquid availability - [link](#)
- News drugs: Andexanet alfa for reversal of direct factor Xa inhibitor anticoagulation - [link](#)

### **British Journal of Clinical Pharmacology**

- Maternal exposure to folate antagonists and susceptibility to congenital heart disease in offspring: A systematic review and meta-analysis - [link](#) – [SPS commentary](#)
- Genetic biomarkers of methotrexate response and safety in Crohn's disease: Data from the Spanish ENEIDA registry - [link](#)
- Quality indicators for appropriate in-hospital pharmacotherapeutic stewardship: An international modified Delphi study - [link](#) – [SPS commentary](#)
- Advanced prescription of injectable anticancer drugs: Safety assessment in a European Comprehensive Cancer Centre using the risk matrix approach - [link](#)
- Prevalence of potentially inappropriate medications among newly treated patients with type 2 diabetes in UK primary care - [link](#)
- Eculizumab dose tapering should take into account the nonlinearity of its pharmacokinetics - [link](#)
- The development and evaluation of dose-prediction tools for allopurinol therapy (Easy-Allo tools) - [link](#)
- Estimation of adherence to urate-lowering therapy in people living with gout using Australia's Pharmaceutical Benefits Scheme and patient-reported dosing - [link](#)
- Clinical characteristics of acute lacosamide poisoning: Pavia Poison Control Centre experience - [link](#)
- Clinical decision-making in benzodiazepine deprescribing by healthcare providers vs. AI-assisted approach - [link](#)
- Older adults' adherence to medications and willingness to deprescribe: A substudy of a randomized clinical trial - [link](#)
- Call to action: Harmonization of pharmacovigilance regulations for post-marketing pregnancy and breastfeeding safety studies - [link](#)

### **British Journal of Obstetrics and Gynaecology**

- Fezolinetant impact on health-related quality of life for vasomotor symptoms due to the menopause: Pooled data from SKYLIGHT 1 and SKYLIGHT 2 randomised controlled trials - [link](#)

### **British Medical Journal (BMJ)**

- Effect of exercise for depression: systematic review and network meta-analysis of randomised controlled trials - [link](#) – [SPS commentary](#)
- Association of non-alcoholic fatty liver disease with cardiovascular disease and all cause death in patients with type 2 diabetes mellitus: nationwide population based study – [link](#) – [SPS commentary](#)
- Advances in diagnosis and treatment of bladder cancer - [link](#)
- Practice pointer: Challenges in diagnosing asthma in children - [link](#)
- Infection specialists call for more clarity on prescribing fluoroquinolones - [link](#)
- US FDA breakthrough therapy designation and consumer drug advertising: a recipe for confusion - [link](#)
- News: British Generic Manufacturers Association warns of worsening medicine shortages - [link](#)
- Review: Management of chronic pancreatitis - [link](#)
- Regression discontinuity design studies: a guide for health researchers – [link](#)

### **BMJ Open**

- Predictors at diagnosis for start of biologic disease-modifying antirheumatic drugs in patients with early rheumatoid arthritis: a cohort study - [link](#)
- Impact of immunosuppressive therapy on SARS-CoV-2 mRNA vaccine effectiveness in patients with immune-mediated inflammatory diseases: a Danish nationwide cohort study - [link](#)
- Mortality and health-related quality of life in older adults with long-term use of opioids, z-hypnotics or benzodiazepines: a prospective observational study at 5 years follow-up - [link](#)

- Randomised, blinded, cross-over evaluation of the palatability of and preference for different potassium binders in participants with chronic hyperkalaemia in the USA, Canada and Europe: the APPETIZE study - [link](#)
- What is the quantity, quality and type of systematic review evidence available to inform the optimal prescribing of statins and antihypertensives? A systematic umbrella review and evidence and gap map - [link](#) – [SPS commentary](#)

### **BMJ Quality and Safety**

- Between-hospital variation in indicators of quality of care: a systematic review - [link](#)

### **Circulation**

- Neurodevelopmental Outcomes for Individuals With Congenital Heart Disease: Updates in Neuroprotection, Risk-Stratification, Evaluation, and Management: A Scientific Statement From the American Heart Association - [link](#)
- Postprocedural Anticoagulation After Primary Percutaneous Coronary Intervention for ST-Segment–Elevation Myocardial Infarction: A Multicenter, Randomized, Double-Blind Trial - [link](#)
- Cardiogenic Shock in Older Adults: A Focus on Age-Associated Risks and Approach to Management: A Scientific Statement From the American Heart Association - [link](#)
- RNA Therapeutics for the Cardiovascular System - [link](#)

### **Cochrane**

- Macrolide antibiotics (including azithromycin) for cystic fibrosis - [link](#)
- Non-clotting factor therapies for preventing bleeds in people with congenital hemophilia A or B - [link](#)
- Infliximab for maintenance of medically-induced remission in Crohn's disease - [link](#)
- Evening versus morning dosing regimen drug therapy for hypertension - [link](#)

### **Diabetes Care**

- Risk of Anaphylaxis Among New Users of GLP-1 Receptor Agonists: A Cohort Study - [link](#)
- Continuous Glucose Monitoring–Based Metrics and Hypoglycemia Duration in Insulin-Experienced Individuals With Long-Standing Type 2 Diabetes Switched From a Daily Basal Insulin to Once-Weekly Insulin Icodec: Post Hoc Analysis of ONWARDS 2 and ONWARDS 4 - [link](#)
- Accuracy and Feasibility of Real-time Continuous Glucose Monitoring in Critically Ill Patients After Abdominal Surgery and Solid Organ Transplantation - [link](#)
- Cardiovascular and Kidney Risks in Individuals With Type 2 Diabetes: Contemporary Understanding With Greater Emphasis on Excess Adiposity - [link](#)

### **European Heart Journal**

- Booster vaccination with SARS-CoV-2 mRNA vaccines and myocarditis in adolescents and young adults: a Nordic cohort study – [link](#) – [SPS commentary](#)
- Severe mental illness: cardiovascular risk assessment and management - [link](#)
- Mechanisms of rosuvastatin-related acute kidney injury following cardiac surgery: the STICS trial - [link](#)

### **European Journal of Clinical Pharmacology**

- Effects of first-line nucleot(s)ide analogues on lipid profiles in patients with chronic hepatitis B: a network meta-analysis - [link](#)
- Proton pump inhibitors associated with an increased risk of mortality in elderly: a systematic review and meta-analysis - [link](#)
- Efficacy and safety of adalimumab in pediatric patients with Crohn's disease: A systematic review and meta-analysis - [link](#)
- Antidepressant deprescribing: State of the art and recommendations—A literature overview - [link](#)
- Age of onset for increased dose-adjusted serum concentrations of antidepressants and association with sex and genotype: An observational study of 34,777 individuals - [link](#)
- Drug-drug interaction perpetrators of oxycodone in patients with cancer: frequency and clinical relevance - [link](#)

### **European Journal of Hospital Pharmacy**

- Effect of a smart temperature logger on correctly storing biological disease-modifying antirheumatic drugs at home: a pre-post study - [link](#)
- Physicochemical stability of pevonedistat at 50, 100 and 200 µg/mL diluted in 0.9% sodium chloride and at 10 mg/mL in partially used vials - [link](#)

### **Front Psychiatry**

- Understanding the causes of medication errors and adverse drug events for patients with mental illness in community care (DISCOVER): a qualitative study - [link](#)

### **Internal Medicine Journal**

- COVID-19 vaccination: are more jabs needed or are we now immune? - [link](#)
- The impact of coronavirus-19 vaccination on anti-nuclear cytoplasmic antibody vasculitis hospitalisations in a Sydney health network - [link](#)
- Cushing syndrome and tertiary adrenal insufficiency from prolonged concomitant use of budesonide and Posaconazole - [link](#)
- Lurbinectedin in small cell lung cancer: real-world experience of a multicentre national early access programme - [link](#)

### **International Journal of Clinical Pharmacy**

- Antipsychotic prescribing and drug-related readmissions in multimorbid older inpatients: a post-hoc analysis of the OPERAM population - [link](#)

### **JAMA**

- What Is Bipolar Disorder? - [link](#)
- Diagnosis and Management of Paroxysmal Supraventricular Tachycardia - [link](#)
- Adverse Events After XBB.1.5-Containing COVID-19 mRNA Vaccines - [link](#)
- Chronic Thromboembolic Pulmonary Hypertension - [link](#)

### **JAMA Cardiology**

- Interventions for Optimization of Guideline-Directed Medical Therapy: A Systematic Review - [link](#)
- Lipoprotein(a), C-Reactive Protein, and Cardiovascular Risk in Primary and Secondary Prevention Populations - [link](#)

### **JAMA Internal Medicine**

- Age-Related Risk of Serious Fall Events and Opioid Analgesic Use - [link](#)
- Body Composition in Anti-Obesity Medication Trials—Beyond Scales - [link](#)
- Management of Resistant Hypertension—An Update - [link](#)
- Individualizing Care for Older Adults with Diabetes Amid the Revolution in Pharmacotherapy - [link](#)

### **JAMA Neurology**

- Sublingual Edaravone Dextroamphetamine for the Treatment of Acute Ischemic Stroke, The TASTE-SL Randomized Clinical Trial - [link](#) – [SPS commentary](#)

### **Journal of Clinical Oncology**

- US Food and Drug Administration Approval Summary: Elacestrant for Estrogen Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer - [link](#) – [SPS commentary](#)
- Topical Diclofenac for Prevention of Capecitabine-Associated Hand-Foot Syndrome: A Double-Blind Randomized Controlled Trial - [link](#)
- Long-Term Outcomes of Medical Management vs Bariatric Surgery in Type 2 Diabetes - [link](#) – [SPS commentary](#)

### **Journal of Pharmacy Practice and Research (JPPR)**



- Standard of practice in pain management for pharmacy services - [link](#)

### **Lancet**

- Heart failure with preserved ejection fraction: everything the clinician needs to know - [link](#)
- Targeted prophylactic anticoagulation based on the TRiP(cast) score in patients with lower limb immobilisation: a multicentre, stepped wedge, randomised implementation trial – [link](#) – [SPS commentary](#)
- Diagnosis and management of ANCA-associated vasculitis - [link](#)
- Long-term efficacy of a recombinant hepatitis E vaccine in adults: 10-year results from a randomised, double-blind, placebo-controlled, phase 3 trial - [link](#) – [SPS commentary](#)
- Reviews: Hyperthyroidism - [link](#) - Behçet's syndrome - [link](#)

### **Lancet Diabetes & Endocrinology**

- 5-year follow-up of the randomised Diabetes Remission Clinical Trial (DiRECT) of continued support for weight loss maintenance in the UK: an extension study - [link](#)

### **Lancet Digital Health**

- Characterisation of digital therapeutic clinical trials: a systematic review with natural language processing - [link](#)

### **Lancet Gastroenterology and Hepatology**

- A biomarker-stratified comparison of top-down versus accelerated step-up treatment strategies for patients with newly diagnosed Crohn's disease (PROFILE): a multicentre, open-label randomised controlled trial - [link](#)

### **Lancet Infectious Diseases**

- Managing treatment failure in Neisseria gonorrhoeae infection: current guidelines and future directions - [link](#)
- Effect of BCG vaccination against Mycobacterium tuberculosis infection in adult Brazilian health-care workers: a nested clinical trial - [link](#) – [SPS commentary](#)

### **Lancet Neurology**

- Comparative effectiveness of azathioprine and mycophenolate mofetil for myasthenia gravis (PROMISE-MG): a prospective cohort study - [link](#)
- Clinical trials for progressive multiple sclerosis: progress, new lessons learned, and remaining challenges - [link](#)
- Potential treatment targets for migraine: emerging options and future prospects - [link](#)

### **Lancet Respiratory Medicine**

- Reframing sepsis immunobiology for translation: towards informative subtyping and targeted immunomodulatory therapies - [link](#)

### **Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**

- Medication Review: What's in a Name and What Is It about? - [link](#)
- Development of a Prediction Model to Identify the Risk of Clostridioides difficile Infection in Hospitalized Patients Receiving at Least One Dose of Antibiotics - [link](#)
- Strategies to Improve Therapeutic Adherence in Polymedicated Patients over 65 Years: A Systematic Review and Meta-Analysis - [link](#)
- A Review of Olanzapine in the Treatment of Cancer Anorexia-Cachexia Syndrome - [link](#)

### **Medical Journal of Australia**

- Perspective: Enhanced recovery after surgery: an update for the generalist - [link](#)
- Perspective: Inflammation: the next target for secondary prevention in coronary artery disease - [link](#)

### **Nature Medicine**

-To do no harm — and the most good — with AI in health care - [link](#)

### **New England Journal of Medicine**

- Cefepime–Taniborbactam in Complicated Urinary Tract Infection - [link](#)
- Electronic Nicotine-Delivery Systems for Smoking Cessation - [link](#) – [SPS commentary](#)
- Behçet’s Syndrome - [link](#)
- Treatment-Resistant Depression in Older Adults - [link](#)
- A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis – [link](#) – [SPS commentary](#)
- Rusfertide, a Hepcidin Mimetic, for Control of Erythrocytosis in Polycythemia Vera - [link](#)
- Benralizumab versus Mepolizumab for Eosinophilic Granulomatosis with Polyangiitis - [link](#)
- Omalizumab for the Treatment of Multiple Food Allergies - [link](#) – [SPS commentary](#)

### **Pediatric Quality & Safety**

- Antimicrobial Stewardship and Improved Antibiotic Utilization in the Pediatric Cardiac Intensive Care Unit – [link](#)
- Improving Anticoagulation Care for Pediatric Oncology Patients: A Quality Improvement Initiative - [link](#)

### **Pharmaceutical Journal**

- Changing the culture of fluoroquinolone prescribing - [link](#)

### **Pharmacotherapy**

- International consensus recommendations for the use of prolonged-infusion  $\beta$ -lactams – [Comment on](#) - [Response to comment on](#)

**Prescribe International** - [March 2024](#) includes:

- Editorial: 40 years without sales representatives - [link](#)
- Pregabalin and gabapentin: sometimes fatal overdoses

### **Prescriber UK**

- NICE recommends belumosudil for graft-versus-host disease - [link](#)

### **Research in Social and Administrative Pharmacy**

- Economic evaluations of telepharmacy services in non-cancer settings: A systematic review - [link](#)

### **Thorax**

- Greenhouse gas emissions associated with suboptimal asthma care in the UK: the SABINA healthCARE-Based environmental cost of treatment (CARBON) study - [link](#)

### **Vaccine**

- Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis – [link](#) - [SPS commentary](#)

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## **CONSULTATIONS (new additions in bold)**

### **TGA**

- Consultation: Adoption of International Scientific Guidelines in Australia R01-2023, closes [4 March 2024](#)
- Consultation: Medicine shortages in Australia – Challenges and opportunities, closes [12 March 2024](#)

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## **WEBINARS & PODCASTS**

### **Australian Prescriber Podcasts**

- [Episode 158](#): National Medicines Policy 2.0

### **MJA Podcasts**

- [Episode 6](#): Raising awareness of heart valve disease

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- [Episode 5](#): Cancer and heart health: discussing cardiotoxic cancer medications

### Purple Pen Podcast

- [PPP 158](#) – Psoriasis
- [PPP 157](#) - Tinnitus

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## UPCOMING EVENTS

(New additions listed in TAGMail - click [here](#) for the running list of other events)

### Agency for Clinical Innovation, NSW (ACI)

- What are effective Frailty Strategies? Reflections of the last 5 years of the Frailty Initiative (online) Thursday 21 Mar 2024 14:00-15:00 – register [here](#)
- Patient Reported Measures Research Symposium (free, online), Friday 17 May 2024 9:00-16:00 – register [here](#)

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## Fortnightly TAG Mail – resources list 15<sup>th</sup> February 2024

### CONGRATULATIONS

Adj Assoc Prof Rosemary Burke was awarded a Public Service Medal for outstanding public service in the implementation and running of the COVID-19 vaccination program and Special Health Accommodation pharmacy support for the NSW Department of Health. Rosemary is the Director of Pharmacy and Chief Pharmacy Information Officer, Sydney Local Health District. Rosemary is a long-standing and highly valued member of NSW TAG and has led major national and NSW TAG medication safety and electronic medicines management initiatives.

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## NSW TAG ACTIVITIES

### New open email discussions

#### 1. Missing medications from wards

A member has been experiencing medications going missing in the wards after being dispensed from pharmacy. A recent example concerned Paxlovid where five boxes were sent to the same patient over 2 days because the medication had gone missing. The incidents are being entered into IMS+. Are hospitals experiencing similar issues? Have any strategies been implemented to reduce such occurrences? Presumably, ADCs can mitigate this risk but in the meantime.....Closes **28<sup>th</sup> February**

#### 2. Medication reviews for inpatients in remote Multi-Purpose Services

A rural member has been requested to provide inpatient medication reviews for patients in remote Multi-Purpose Services (MPSs) in their local health district. Currently, the hospital accepts virtual pharmacy referrals for new hospital admissions (but not from MPSs). Are other hospitals with oversight of MPSs also being requested to provide inpatient medication reviews/providing a medication review service to MPSs and if so, how are they managing this workload? Closes **28<sup>th</sup> February**

#### 3. Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection

A NSW TAG member has the following query regarding the long-term supply of lidocaine 2% + 1:200,000 adrenaline injection. They are looking to benchmark their practice with other LHDs. How is your hospital/district managing the supply issue:

- compounding or obtaining 3<sup>rd</sup> party compounded product,
- using an alternative, such as ropivacaine 0.75%,
- supplying drugs separately and anaesthetists mixing as needed in theatres, or
- doing something else? Closes **21st February 2024**.

#### 4. Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

Following recent DTC accreditation, one of the accreditors questioned strips of medications, rather than original boxes, being in the locked patient bedside drawers and also how medications are transported from the treatment room to the patient bedside, again original packaging vs strips.

What are other hospitals doing in terms of keeping strips of medications in patient's drawers? These would be medications that are on ward imprest, kept within their original packaging in the treatment

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room but a strip may be placed in the patient's locked drawer, e.g. paracetamol. And following on from that, do nursing staff take medications in original packaging from the treatment room to the patient bedside or would they just take strips of medication? The Medication Handling policy mentions supply of medications from pharmacy in original packaging, unless dispensed for specific patients, but not specifically storage on the wards.' Closes **21st February 2024**

### Upcoming TAG meeting dates

NSW Management Committee 21<sup>st</sup> February 2024

Members are reminded to respond by **23<sup>rd</sup> February** to the [Doodle poll](#) for their availability regarding the next NSW TAG General Meeting.

Contact *Sasha Bennett* at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions or upcoming meetings.

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## EDITOR'S PICKS

**AJHP:** Phenytoin enzyme induction for management of supratherapeutic tacrolimus levels due to drug-drug interaction with nirmatrelvir/ritonavir: Case series and discussion - [link](#)

**AJMQ:** Prospective study of the multisite spread of a medication safety intervention: factors common to hospitals with improved outcomes - [link](#)

**ACD:** Medication errors involving intravenous paracetamol in children: experience from enquiries to the National Poisons Information Service – [link](#) – [SPS commentary](#)

**BMJ QS:** Editorial: It is up to healthcare professionals to talk to us in a way that we can understand: informed consent processes in people with an intellectual disability - [link](#)

**Heart:** Colchicine in atherosclerotic cardiovascular disease - [link](#)

**IJCP:** - Financial impact of medication reviews by clinical pharmacists to reduce in-hospital adverse drug events: a return-on-investment analysis - [link](#)

**IMJ:** Variation in approaches to acute ANCA-associated vasculitis in Australia and New Zealand: rituximab, plasma exchange and glucocorticoids - [link](#)

**ISMP:** The Dark Side—Safety Issues When Protecting Medications from Light - [link](#)

**MDPI:** New Adverse Drug Reaction Signals from 2017 to 2021: Genuine Alerts or False Alarms? - [link](#)

**Parliamentary and Health Service Ombudsman:** Discharge from mental health care: making it safe and patient-centred - [link](#)

**Pharmaceutical Journal:** Everything you need to know about nitazenes - [link](#)

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## OTHER NEWS (new additions in bold) Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Get ready to implement the National Safety and Quality Mental Health Standards for Community Managed Organisations - [link](#)

### NSW Health

- Measles alert for Sydney - [link](#) ; Cryptosporidiosis alert for NSW – [link](#) ; Measles alert for northern NSW – [link](#) ; New sustainable water technology to be on 'tap' at NSW hospitals - [link](#) ; Australia's oldest hospital recognised with Nightingale Award - [link](#)

- Authorised Nurse Immuniser and Authorised Midwife Immunisers ([PD2024\\_004](#))

- Early Response to High Consequence Infectious Diseases ([PD2024\\_005](#))

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## REPORTS AND PUBLICATIONS – AUSTRALIA

### Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found [here](#)

- Clinical practice guide for assessment and management of adults, children and young people with symptoms of long COVID - [link](#)

### AHHA

- Adapting to the digital age of healthcare data - [link](#)

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### **Australian Institute for Health and Welfare (AIHW)**

- Australia's Health Performance Framework – 6 indicators - [link](#)
- GEN Aged Care Data: Residential Aged Care Quality Indicators July to September 2023 - [link](#)
- Mental Health Services - [link](#)
- Specialist paediatric palliative care delivered to children who died in 2021 - [link](#)

### **PBS**

- PBS subsidy arrangements for fluoxetine 10 mg capsules following the issuance of Serious Scarcity and Substitutable Medicines Instrument (SSSI) - 1 February 2024 - [link](#) - 2 February 2024 - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - [Minjuvi](#) for adults with relapsed or refractory diffuse large B-cell lymphoma who are not eligible for autologous stem cell transplant
  - Comirnaty Original/Omicron BA.4-5 ([tozinameran/famtozinameran](#)) to prevent COVID-19 in individuals 5 years of age and older
  - [Doptelet](#) for thrombocytopenia in adult patients with chronic liver disease and chronic immune thrombocytopenia
  - Comirnaty Omicron XBB.1.5 ([raxtozinameran](#)) COVID-19 VACCINE to prevent COVID-19 in individuals 6 months to 12 years old
- Australian prescription medicine decision summaries:
  - [Onbevzi](#), biosimilar to Avastin (bevacizumab), for use in several types of cancer

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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### **Academy of Medical Royal Colleges**

Evidence-based Interventions - Clinical guidance: Release 4 — Urology – [link](#) – [SPS commentary](#)

### **Agency for Healthcare Research and Quality (AHRQ) USA**

- Rapid Evidence Product:
  - Feb 09, 2024: Computerized Clinical Decision Support To Prevent Medication Errors and Adverse Drug Events - [link](#)
  - Feb 01, 2024: Deprescribing To Reduce Medication Harms in Older Adults - [link](#)
- New Tool Helps Manage Opioid Use in Older Adults - [link](#)

### **The Academy of Medical Sciences UK**

- Prioritising early childhood to promote the nation's health, wellbeing and prosperity - [link](#)

### **British National Formulary**

- BNF/BNFC newsletter: [January 2024](#)

### **Department of Health and Social Care UK**

- Hospital discharge service guidance, updated - [link](#)

### **electronic Medicines Compendium (eMC) (UK)**

- [New products](#)
- Aqumeldi (enalapril) 0.25 mg orodispersible tablets – for heart failure in children from birth to < 18
- Clarinaze Hayfever Relief (mometasone) 0.05% – seasonal allergic rhinitis symptoms
- Cardioxane (dexrazoxane) infusion for prevention of chronic cumulative cardiotoxicity caused by anthracycline use in breast cancer patients who have received a prior cumulative dose of 300 mg/m<sup>2</sup> of doxorubicin or 540 mg/m<sup>2</sup> of epirubicin when further anthracycline treatment is required
- Dimethyl fumarate gastro-resistant hard capsules (Celix) - generic of Tecfidera® for adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis

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- Enspryng (satralizumab) pre-filled syringe for monotherapy or in combination with immunosuppressive therapy for neuromyelitis optica spectrum disorders in adults and adolescents from 12 years of age who are anti-aquaporin-4 IgG seropositive
- Nuvaxovid XBB.1.5 dispersion for injection (Novovax), COVID-19 Vaccine (recombinant, adjuvanted) for 12 years of age and older. Administer at least 3 months after most recent dose of a COVID-19 vaccine
- Mounjaro KwikPen (tirzepatide) for adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, and for weight management, including weight loss and maintenance
- Omjara (mometotinib) for disease-related splenomegaly or symptoms in adults with moderate-severe anaemia and primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis & are JAK inhibitor naïve/have tried ruxolitinib
- Rezzayo (rezafungin) infusion - invasive candidiasis in adults – [Prescriber link](#)
- Vecicom (tapentadol) 100mg 150mg 200mg 250mg Prolonged-release Tabs - severe chronic pain
- Vyvgart (efgartigimod) - new subcutaneous formulation for add-on to standard therapy for adults with generalised Myasthenia Gravis who are anti-acetylcholine receptor antibody positive
- [New/expanded indications](#)
- Brukinsa (zanubrutinib) for adults with refractory/ relapsed follicular lymphoma after >2 prior systemic therapies. Includes dosing information for use in combination with Obinutuzumab
- Cuvitru (human normal immunoglobulin) - new indication for secondary immunodeficiencies in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4g/l – [SPS commentary](#)
- Dexamethasone for adult and adolescent patients (aged ≥ 12 years with body weight ≥ 40 kg) with Covid-19 who require supplemental oxygen therapy
- Enhertu (trastuzumab deruxtecan) - new indication for adult patients with advanced NSCLC whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy
- Keytruda (pembrolizumab) now also for treatment of gastric or gastro-oesophageal junction (GEJ) adenocarcinoma. Indication for oesophageal carcinoma changed
- Plavix (clopidogrel) - ST segment elevation acute myocardial infarction indication expanded, in combination with ASA, to patients undergoing percutaneous coronary intervention (including stent placement)
- Praluent (alirocumab) – extended use for primary hypercholesterolaemia and mixed dyslipidaemia with heterozygous familial hypercholesterolaemia in paediatric patients 8 years and older
- Yervoy (ipilimumab) - for melanoma in adolescents (aged ≥12 years; already licensed for adults);

### European Medicines Agency (EMA)

- European CHMP adopts/recommends:
  - selpercatinib ([Retsevmo](#)) new indication - adults & adolescents with RET fusion-positive thyroid cancer that is radioactive iodine-refractory (if radioactive iodine is appropriate)
  - idecabtagene vicleucef ([Abecma](#)) extended indication - adult patients with relapsed and refractory multiple myeloma who have received at least two (currently three) prior therapies
  - pegcetacoplan ([Aspaveli](#)) indication extension - patients with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia & have not had previous treatment with a C5 inhibitor
  - cefepime / enmetazobactam ([Exblifep](#)) approval – UTIs and pneumonia - as effective as piperacillin / tazobactam in complicated UTIs, including pyelonephritis, in a phase 3 RCT
  - efbemalenograstim alfa ([Ryzneuta](#)) approval - to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. An immunostimulant/colony stimulating factor that belongs to the class of haematopoietic growth factors (G-CSF), shown to reduce the duration of severe neutropenia during the first cycle of chemotherapy to a similar extent to pegfilgrastim
  - ataluren ([Translarna](#)) – not recommended for renewal as accumulated evidence has not confirmed effectiveness in patients with Duchenne muscular dystrophy caused by a nonsense mutation
  - leriglitazone ([Nezglval](#)) – authorisation refused to treat male adults and children aged ≥2 years with cerebral adrenoleukodystrophy
  - pegcetacoplan ([Syfovre](#)) – authorisation refused to treat geographic atrophy caused by age-related macular degeneration

## Food and Drug Administration (FDA) USA

- New Drug approvals
- [irinotecan liposome](#) for first-line treatment of metastatic pancreatic adenocarcinoma
- budesonide ([Eohilia](#)) - new oral suspension dosage form approved for eosinophilic esophagitis in patients aged 11 years and older – [PI/label](#)

## Medicines and Healthcare products Regulatory Agency (MHRA)

- Paclitaxel coated devices (PCD) used in the treatment of peripheral arterial disease: update to previous MHRA guidance on use ([DSI/2024/001](#))
- MHRA approvals for Comirnaty (Pfizer/BioNTech) and Nuvaxovid (Novavax) COVID-19 vaccines - will enable thawing and re-labelling of the vaccine outside of the NHS - [link](#)
- - Yellow Card Biobank to investigate how a patient's genetic makeup can impact the safety of Direct Oral Anticoagulants (DOACs) - [link](#)

## NHS England

- NHS Type 2 Diabetes Path to Remission Programme service specification (2023) - [link](#)

## NHS Scotland

- Accepted for use:
- [dupilumab](#) (Dupixent®) for adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy
- secukinumab (Cosentyx®) for active moderate-severe hidradenitis suppurativa (HS) in adults with an inadequate response to conventional systemic therapy
- Accepted for restricted use:
- [difelikefalin](#) (Kapruvia®) for moderate-to-severe pruritus associated with chronic kidney disease in patients on haemodialysis
- [loncastuximab tesirine](#) (Zynlonta®) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL)
- Not recommended:
- [cabozantinib](#) (Cabometyx®) for locally advanced or metastatic differentiated thyroid carcinoma, refractory or not eligible for radioactive iodine

## NHS Improvement

- Transition to NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks - [link](#)

## National Institute for Health and Care Excellence (NICE) UK

- Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over ([TA949](#))
- Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over ([TA950](#))
- Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer ([TA951](#))
- Suspected sepsis: recognition, diagnosis and early management, updated ([NG51](#))
- Caesarean birth, updated ([NG192](#))

## National Institute for Health and Care Research (NIHR)

- NIHR [Alert](#): Even short periods of diabetes remission are linked to lower risk of heart attack & stroke
- Abrocitinib, tralokinumab and upadacitinib for treating moderate-to-severe atopic dermatitis - [link](#)
- NIHR [alert](#): How common are side-effects of treatment to prevent gout flares when starting allopurinol?

## Parliamentary and Health Service Ombudsman

- Discharge from mental health care: making it safe and patient-centred - [link](#)

### **Patient Safety Commissioner UK**

- The Hughes Report: Options for redress for those harmed by valproate and pelvic mesh - [link](#)

### **Royal Pharmaceutical Society**

- Refreshes professional standards for Homecare Services - [link](#)

### **Specialist Pharmacy Services NHS UK**

- Using St Mark's electrolyte solution - [link](#)
- The licence and supporting evidence for natalizumab biosimilar - [link](#) – [SPS commentary](#)
- Preparing to use natalizumab biosimilar – [link](#) – [SPS commentary](#)
- Requirements for Governance and Preparation of Gene Therapy - [link](#)
- Introduction to PGDs - [link](#)

### **STAMMA UK**

- Stammering & patient contact - [link](#)

### **UK Health Security Agency**

- National measles guidelines [updated](#)

### **World Health Organisation (WHO)**

- Tuberculosis preventive treatment: rapid communication - [link](#)
- Clinical management of diphtheria: guideline, [2 February 2024](#)
- WHO publishes the WHO Medically Important Antimicrobials List for Human Medicine - [link](#)
- European Medicines Agency (EMA) adopts a positive scientific opinion on arPraziquantel - [link](#)

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## **MEDICATION SAFETY**

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### **electronic Medicines Compendium (eMC) (UK)**

- [Revised SPCs](#)
- Affenid XL (methylphenidate) - more information about possible effects of methylphenidate on ability to drive and operate machines included
- Brufen (ibuprofen) - Kounis syndrome reported, defined as CV symptoms secondary to an allergic or hypersensitive reaction associated with coronary artery constriction and potential MI
- Brukinsa (zanubrutinib). Advises avoidance/dose modification when co-administered with moderate CYP3A enzyme inducers
- Cipralext (citalopram) - hyperprolactinaemia added as an undesirable effect of unknown frequency
- Distaclor (cefaclor) - neurotoxicity including encephalopathy, myoclonus & seizures. If cefaclor-associated neurotoxicity is suspected, discontinuation should be considered
- Depo-Medrone (methylprednisolone acetate) - "Post injection pain flare (following intra-articular, periarticular, and tendon sheath injections)"
- Eucreas (vildagliptin/metformin) - cutaneous vasculitis as an ADR (frequency unknown)
- Entocort CR (budesonide) - hypersensitivity reactions such as angioedema added as known possible ADR of unknown frequency
- Finasteride oral tablets - suicidal ideation added as a potential ADR (frequency unknown)
- Froben (flurbiprofen) - can mask symptoms of infection with advice for caution if a patient currently has an infection. It also includes updated information use during pregnancy – [SPS commentary](#)
- Imodium (loperamide) Instants and Instant Melts - contain maltodextrin which contains glucose and should thus be avoided by patients with rare glucose-galactose malabsorption
- Keytruda (pembrolizumab) - Frequency of ADR myositis changed from "very common" to "common"
- Koselugo (selumetinib hydrogen sulfate) - administration with or without food. Additional pharmacokinetic study data added to support this
- Lenvima (lenvatinib) - gastrointestinal perforation included as a common ADR of monotherapy and in combination with pembrolizumab

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- Lopinavir/Ritonavir Mylan - interaction with DOACs added. Clinical monitoring and/or dose reduction of the DOAC should be considered when a DOAC transported by P-gp but not metabolised by CYP3A4, including dabigatran and edoxaban, is co-administered with lopinavir/ritonavir
- Mavenclad (cladribine) - interaction studies show cladribine has no effects on the plasma levels of ethinylestradiol and levonorgestrel. The requirement to add a barrier method of contraception for women using systemic contraceptives has been removed
- Maxtrex (methotrexate) - photosensitivity observed in some patients. Exposure to intense sunlight or UV rays should be avoided and use a sun-protection product with a high protection factor
- MST Continus, MXL, Sevredol (morphine sulfate) - generalised exanthematous pustulosis, central sleep apnoea syndrome, pancreatitis and spasm of the sphincter of Oddi added as ADRs of unknown frequency. Also interaction with gabapentin/pregabalin which increases risk of respiratory depression
- Naprosyn EC (naproxen) - from 20th week of pregnancy onward, naproxen use may cause oligohydramnios resulting from foetal renal dysfunction. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester
- Naseptin (neomycin, chlorhexidine) contains cetostearyl alcohol which may cause local skin reactions (e.g., contact dermatitis)
- Neupro (rotigotine) - occasional reports of dystonic reactions including dystonia, abnormal posture, torticollis & pleurothotonus (Pisa Syndrome) in patients with Parkinson's disease after initiation/incremental dose increase. Regimen should be reviewed & dose adjustment considered
- Nexviadyme (avalglucosidase alfa) - updated dosing information for patients with Infantile Onset Pompe disease with insufficient response on 20 mg/kg. Dose increase to 40 mg/kg every other week should now be considered if no safety concerns. Updates of extension study data also included
- Opdivo (nivolumab) - cytokine release syndrome as possible "common" ADR
- Paracetamol and Codeine Extra - updated to note that alcohol and drugs which induce hepatic microsomal enzymes e.g. antiepileptic drugs, may increase the hepatotoxicity of paracetamol, particularly after overdose
- Produodopa (foscarbidopa and foslevodopa) - information about how to determine the hourly infusion rate of Produodopa included. Phase 3 clinical data added to pharmacodynamics section
- Ropinirole - hiccups (frequency uncommon), spontaneous penile erection (frequency not known)
- Rydapt (midostaurin) - no dose adjustment required in patients aged over 65 years. In patients aged  $\geq 60$  years, it should be used only in patients eligible to receive intensive induction chemotherapy with adequate performance status and without significant comorbidities
- Telfast (fexofenadine) - blurred vision as ADR of unknown frequency; concomitant use with P-gp inhibitors or inducers can affect exposure to fexofenadine, a P-gp substrate
- Tysabri (natalizumab) - shelf life of the diluted solution has changed from 8 to 24 hours. The diluted product should be used as soon as possible and within 24 hours if stored at 2°C to 8°C. It should be allowed to warm to room temperature prior to infusion
- Ventolin (salbutamol) Evohaler - overuse of short-acting beta-agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control and increased risk of severe asthma exacerbations and mortality. Patients who take more than twice a week "as needed" salbutamol should be re-evaluated for proper treatment adjustment
- Vyvgart (efgartigimod alfa) - live or live-attenuated vaccines generally not recommended for patients being treated with efgartigimod alfa. If required, they should be administered at least 4 weeks before treatment and at least 2 weeks after the last dose of efgartigimod alfa
- Yervoy (ipilimumab) - Cytokine Release Syndrome added as an ADR occurring at a frequency of <1%. It has been reported as an infusion reaction (possibly resulting from a rapid injection rate)
- Zithromax (azithromycin) - following use of azithromycin in neonates (treatment up to 42 days of life), infantile hypertrophic pyloric stenosis has been reported. Parents/caregivers should be informed to contact a physician if vomiting or irritability with feeding occurs
- Zomorph (morphine sulfate) - dosing information in children aged over 6, with a recommended starting dose in the range of 0.2 to 0.8 mg morphine per kg bodyweight 12 hourly. Use in children under six years of age is contra-indicated
- Risk minimisation materials

-- Elfabrio ([pegunigalsidase alfa](#)) - information for HPs, patients & caregivers, and an infusion diary booklet to help minimise the risk of hypersensitivity reactions and medication errors for patients in the home infusion setting

#### **EMA**

- EMA's safety committee (PRAC) reminds healthcare professionals of risk of serious and potentially fatal adverse reactions with Paxlovid (nirmatrelvir, ritonavir) when used in combination with certain immunosuppressants - [link](#)

#### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [February 8, 2024](#) includes  
-- The Dark Side—Safety Issues When Protecting Medications from Light - [link](#)  
-- Worth repeating... Respiratory Syncytial Virus (RSV) vaccines are not approved for children; AREXVY is not approved during pregnancy!  
-- Limit ketorolac therapy to 5 days

#### **Specialist Pharmacy Service**

- Medication Safety Update [January 2024](#)  
- Using NSAIDS during breastfeeding - [link](#)  
- Using nitrofurantoin during breastfeeding - [link](#)

#### **TGA**

- Safety advisory – Spiriva Respimat® Solution for Inhalation 2.5µg - [link](#) ; Products tested that contain undeclared substances - sildenafil, tadalafil and vardenafil - [link](#)  
- Recall: Henry Blooms Herb-a-lax - [link](#)

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### **PAPERS OF INTEREST**

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#### **American Journal of Cardiology**

- Cardiovascular Safety of Azithromycin in Patients Hospitalized With COVID-19: A Prespecified Pooled Analysis of the COALITION I and COALITION II Randomized Clinical Trials - [link](#)

#### **American Journal of Health-System Pharmacy (AJHP)**

- Phenytoin enzyme induction for management of suprathreshold tacrolimus levels due to drug-drug interaction with nirmatrelvir/ritonavir: Case series and discussion - [link](#)  
- Physical compatibility of colistin with analgesics during simulated Y-site administration - [link](#)  
- Optimal follow-up schedule for patients taking PCSK9 monoclonal antibodies in a health system: Analysis of specialty pharmacy clinical interventions - [link](#)  
- Minimization of preventable drug waste through use of a vial combination calculator tool - [link](#)  
- Loncastuximab tesirine: Risk for dose variance - [link](#)  
- Implementation and evaluation of an EHR-integrated perpetual inventory system in a large tertiary hospital oncology pharmacy - [link](#)

#### **Am J Med Qual**

- Prospective study of the multisite spread of a medication safety intervention: factors common to hospitals with improved outcomes - [link](#)

#### **Annals of Internal Medicine**

- Immune-Related Adverse Events of Immune Checkpoint Inhibitors - [link](#)

#### **Archives of Disease in Childhood**

- Medication errors involving intravenous paracetamol in children: experience from enquiries to the National Poisons Information Service – [link](#) – [SPS commentary](#)

#### **British Journal of Clinical Pharmacology**

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- Breast milk oxycodone concentrations in mothers given oxycodone for post-Caesarean delivery pain management - [link](#) – [SPS commentary](#)
- Appropriateness of direct oral anticoagulant prescribing in older subjects with atrial fibrillation discharged from acute medical wards - [link](#)
- Bleeding in patients on concurrent treatment with a selective serotonin reuptake inhibitor (SSRI) and low-dose acetylsalicylic acid (ASA) compared with SSRI or low-dose ASA alone—A systematic review and meta-analysis - [link](#)
- Economic evaluation of personalized vs. standard dosing of 5-fluorouracil in first-line chemotherapy for metastatic colorectal cancer in Australia - [link](#)
- Population pharmacokinetics and dose optimization of levofloxacin in elderly patients with pneumonia - [link](#)

### **British Journal of General Practice**

- Familial hypercholesterolaemia in UK primary care: a Clinical Practice Research Datalink study of an under-recognised condition - [link](#)

### **British Medical Journal (BMJ)**

- Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis - [link](#)
- Intrapartum care—updated summary of NICE guidance - [link](#)
- Biogen abandons aducanumab (Aduhelm) after controversial approval left it unfunded by Medicare - [link](#)
- Practical Prescribing: Thiazide diuretics - [link](#)
- Attention deficit/hyperactivity disorder (ADHD) in children: more focus on care and support, less on diagnosis - [link](#)
- Medical misinformation on social media—are the platforms equipped to be the judge? - [link](#)
- Pulmonary embolism - [link](#)

### **BMJ Open**

- Treatment pathways, economic burden and clinical outcomes in new users of inhaled corticosteroid/long-acting B2-agonist dual therapy with chronic obstructive pulmonary disease in a primary care setting in England: a retrospective cohort study - [link](#)
- Comparative effectiveness of biologics in patients with rheumatoid arthritis stratified by body mass index: a cohort study in a Swiss registry – [link](#)
- Use of drugs for hyperlipidaemia and diabetes and risk of primary and secondary brain tumours: nested case–control studies using the UK Clinical Practice Research Datalink (CPRD) - [link](#)

### **BMJ Quality & Safety**

- Editorial: It is up to healthcare professionals to talk to us in a way that we can understand: informed consent processes in people with an intellectual disability - [link](#)

### **Circulation**

- Pharmacological Management of Cardiac Arrhythmias in the Fetal and Neonatal Periods: A Scientific Statement from the American Heart Association - [link](#)
- Estimated Lifetime Cardiovascular, Kidney, and Mortality Benefits of Combination Treatment With SGLT2 Inhibitors, GLP-1 Receptor Agonists, and Nonsteroidal MRA Compared With Conventional Care in Patients With Type 2 Diabetes and Albuminuria - [link](#)
- Cardiovascular Outcomes in GRADE (Glycemia Reduction Approaches in Type 2 Diabetes: A Comparative Effectiveness Study) - [link](#) – [SPS commentary](#)
- Opportunities in the Postpartum Period to Reduce Cardiovascular Disease Risk After Adverse Pregnancy Outcomes: A Scientific Statement from the American Heart Association - [link](#)

### **Cochrane**

- Erector spinae plane block for postoperative pain - [link](#)
- Methotrexate for juvenile idiopathic arthritis - [link](#)

- Favipiravir for treating COVID-19 - [link](#)
- Non-immunosuppressive treatment for IgA nephropathy - [link](#)
- Pharmacological interventions for pruritus in adult palliative care patients - [link](#)

### **Diabetes Care**

- Association of Baseline Factors With Glycaemic Outcomes in GRADE: A Comparative Effectiveness Randomized Clinical Trial - [link](#)
- Atypical Diabetes: What Have We Learned and What Does the Future Hold? - [link](#)

### **Drug and Therapeutics Bulletin**

- Republished Case report: Delirium secondary to anticholinergics - [link](#)
- Republished Case report: Intravenous acetaminophen associated with acute liver failure - [link](#)
- DTB Select: Tramadol-warfarin interaction – [link](#) – [SPS commentary](#)
- Republished Case report: Drug-induced haemolysis: another reason to be cautious with nitrofurantoin - [link](#)
- Republished Case report: Severe azathioprine-induced liver injury 22 months after initiation of treatment - [link](#)
- Republished case report: Hydrocortisone-induced symptomatic sinus bradycardia - [link](#)
- DTB Select: Do COX-inhibitors improve emergency contraception efficacy? - [link](#) – [SPS commentary](#)
- Safety update: omega-3-acid ethyl esters and atrial fibrillation - [link](#)
- Very low calorie diets and total diet replacement in type 2 diabetes: where are we now? – [link](#)

### **European Heart Journal**

- Legacy benefits of blood pressure treatment on cardiovascular events are primarily mediated by improved blood pressure variability: the ASCOT trial - [link](#)
- Viewpoint: Icosapent ethyl for hypertriglyceridaemia and atherosclerosis: greater RESPECT for increased therapeutic use - [link](#)
- Ischaemic heart disease in patients with cancer - [link](#)

### **European Journal of Hospital Pharmacy**

- Analysis of the use of antibiotics by AWaRe categories during the COVID-19 pandemic in hospitals across Scotland: a national population-based study - [link](#) – [SPS commentary](#)
- RETRACTION—Specific features of rational pharmacotherapy in elderly patients - [link](#)
- Combination of a propofol emulsion with alpha-2 adrenergic receptor agonists used for multimodal analgesia or sedation in intensive care units: a physicochemical stability study - [link](#)

### **Heart**

- Percutaneous coronary intervention versus medical therapy in stable angina: a matched cohort study - [link](#)
- Colchicine in atherosclerotic cardiovascular disease - [link](#)

### **Internal Medicine Journal**

- Variation in approaches to acute ANCA-associated vasculitis in Australia and New Zealand: rituximab, plasma exchange and glucocorticoids - [link](#)
- Development of a list of Australian potentially inappropriate medicines using the Delphi technique - [link](#)
- Quality use of publicly subsidised tapentadol in Australia: a population-based analysis - [link](#)

### **International Journal of Clinical Pharmacy**

- Whole blood thiamine, intravenous thiamine supplementation and delirium occurrence in the intensive care unit: retrospective cohort analyses - [link](#)
- First generation antipsychotic-associated serious adverse events in women: a retrospective analysis of a pharmacovigilance database - [link](#)
- Effects of inpatient creatinine testing frequency on acute kidney injury identification and staging: a historical cohort study - [link](#)

- Financial impact of medication reviews by clinical pharmacists to reduce in-hospital adverse drug events: a return-on-investment analysis - [link](#)

### **JAMA**

- Delivering Effective Messages in the Patient-Clinician Encounter - [link](#)
- What Is Ulcerative Colitis? - [link](#)
- Time to Treatment With Intravenous Thrombolysis Before Thrombectomy and Functional Outcomes in Acute Ischemic Stroke: A Meta-Analysis – [link](#) – [SPS commentary](#)
- Apixaban to Prevent Recurrence After Cryptogenic Stroke in Patients With Atrial Cardiopathy: The ARCADIA Randomized Clinical Trial - [link](#) – [SPS commentary](#)
- Methylprednisolone as Adjunct to Endovascular Thrombectomy for Large-Vessel Occlusion Stroke: The MARVEL Randomized Clinical Trial - [link](#) – [SPS commentary](#)
- What Is Childhood Leukaemia? - [link](#)

### **JAMA Internal Medicine**

- Sodium-Glucose Cotransporter 2 Inhibitors and Nephrolithiasis Risk in Patients with Type 2 Diabetes - [link](#)
- Effect of Testosterone on Progression From Prediabetes to Diabetes in Men With Hypogonadism: A Substudy of the TRAVERSE Randomized Clinical Trial - [link](#) – [SPS commentary](#)
- Outcomes of Various Classes of Oral Antidiabetic Drugs on Nonalcoholic Fatty Liver Disease - [link](#)

### **JAMA Network Open**

- Ketamine Compared with Morphine for Out-of-Hospital Analgesia for Patients with Traumatic Pain - [link](#)
- Efficacy and Safety of 5-Day Oral Ensitrelvir for Patients with Mild to Moderate COVID-19: The SCORPIO-SR Randomized Clinical Trial - [link](#)

### **JAMA Neurology**

- Risk of Stroke and Myocardial Infarction among Initiators of Triptans - [link](#) – [SPS commentary](#)
- Highly Effective Therapies as First-Line Treatment for Pediatric-Onset Multiple Sclerosis - [link](#)
- Time to Anticoagulation Reversal and Outcomes After Intracerebral Hemorrhage - [link](#)

### **JAMA Psychiatry**

- Associations of the Gut Microbiome with Treatment Resistance in Schizophrenia - [link](#)

### **Journal of the American College of Cardiology**

- Randomized Trial of Macitentan/Tadalafil Single-Tablet Combination Therapy for Pulmonary Arterial Hypertension - [link](#)

### **Journal of Pharmacy Practice and Research (JPPR)**

- Ageing well with human immunodeficiency virus - [link](#)
- Effectiveness of pharmaceutical care for improving medication-related quality of life and adherence to treatment among people living with schizophrenia: a randomised controlled trial - [link](#)
- Improving the antibiotic duration of therapy with the implementation of antimicrobial lanyard cards and education in a regional hospital - [link](#)

### **Lancet**

- Oral gepotidacin versus nitrofurantoin in patients with uncomplicated urinary tract infection (EAGLE-2 and EAGLE-3): two randomised, controlled, double-blind, double-dummy, phase 3, non-inferiority trials – [link](#) – [SPS commentary](#)
- Viral gastroenteritis - [link](#)

### **Lancet Diabetes & Endocrinology**

- Air pollution exposure and cardiometabolic risk - [link](#)

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### **Lancet Gastroenterology and Hepatology**

- Safety and efficacy of autologous haematopoietic stem-cell transplantation with low-dose cyclophosphamide mobilisation and reduced intensity conditioning versus standard of care in refractory Crohn's disease (ASTIClite): an open-label, multicentre, randomised controlled trial - [link](#)
- Acute severe ulcerative colitis management: unanswered questions and latest insights - [link](#)

### **Lancet Haematology**

- Diagnosis and management of pyruvate kinase deficiency: international expert guidelines - [link](#)

### **Lancet Infectious Diseases**

- Mucormycosis after CD19 chimeric antigen receptor T-cell therapy: results of a US Food and Drug Administration adverse events reporting system analysis and a review of the literature - [link](#)
- Global guideline for the diagnosis and management of cryptococcosis: an initiative of the ECMM and ISHAM in cooperation with the ASM - [link](#)

### **Lancet Psychiatry**

- Pharmacological treatments for psychotic depression: a systematic review and network meta-analysis – [link](#) – [SPS commentary](#)

### **Lancet Respiratory Medicine**

- Hydrocortisone plus fludrocortisone for community acquired pneumonia-related septic shock: a subgroup analysis of the APROCCHSS phase 3 randomised trial - [link](#) – [SPS commentary](#)

### **Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**

- New Adverse Drug Reaction Signals from 2017 to 2021—Genuine Alerts or False Alarms? - [link](#)
- Enteral Delivery of Pravastatin Sodium Tablets: Effect of Compounding into a Liquid Form and Co-Administration of Enteral Nutrition - [link](#)

### **New England Journal of Medicine**

- Skin Antisepsis before Surgical Fixation of Extremity Fractures - [link](#)
- Trial of N-Acetyl-L-Leucine in Niemann–Pick Disease Type C - [link](#) – [SPS commentary](#)
- A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis - [link](#)
- Coccidioidomycosis and Histoplasmosis in Immunocompetent Persons - [link](#)
- Tenecteplase for Stroke at 4.5 to 24 Hours with Perfusion-Imaging Selection - [link](#)

### **Neurology**

- Phosphodiesterase Type 5 Inhibitors in Men with Erectile Dysfunction and the Risk of Alzheimer Disease: A Cohort Study - [link](#) – [SPS commentary](#)

### **Obstetrics and Gynecology**

- Naltrexone compared with Buprenorphine or Methadone in Pregnancy: A Systematic Review - [link](#)
- Efficacy and Safety of Fezolinetant for the Treatment of Menopause-Associated Vasomotor Symptoms: A Meta-analysis - [link](#)

### **Pharmaceutical Journal**

- Everything you need to know about nitazenes - [link](#)

### **Pharmacotherapy**

- Use of bivalirudin after initial heparin management among adult patients on long-term venovenous extracorporeal support as a bridge to lung transplant: A case series - [link](#)

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## **CONSULTATIONS**

### **Australian Commission on Safety and Quality in Health Care (ACSQHC)**

- Updating the National Guidelines for On-Screen Presentation of Discharge Summaries - Closing 20 February 2024 - [link](#)

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## WEBINARS & PODCASTS

### Australian Prescriber Podcasts

- Episode 157 – Top 10 drugs 2021-22 and 2022-23 - [link](#)

### MJA Podcasts

- [Episode 4](#): The health and wellbeing of children and young people

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## UPCOMING EVENTS

(New additions – see [cumulative listing](#) for older events )

### FDA Division of Drug Information is presenting a [series](#) of CE webinars

- FDA Drug Topics: Tips to Navigating Drug Interaction Information in the US Prescribing Information - February 27, 2024 - [link](#)

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## Fortnightly TAG Mail – resources list      1 February 2024

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We're piloting a new feature in TAGMail 2024- Editor's Picks- for those short on time!

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## NSW TAG ACTIVITIES

### Current open email discussions

#### 1. Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection

A NSW TAG member has the following query regarding the long-term supply of lidocaine 2% + 1:200,000 adrenaline injection. They are looking to benchmark their practice with other LHDs. How is your hospital/district managing the supply issue:

- compounding or obtaining 3<sup>rd</sup> party compounded product,
- using an alternative, such as ropivacaine 0.75%,
- supplying drugs separately and anaesthetists mixing as needed in theatres, or
- doing something else? Closes **15<sup>th</sup> February 2024**.

#### 2. Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

'Following recent DTC accreditation, one of the accreditors questioned strips of medications, rather than original boxes, being in the locked patient bedside drawers and also how medications are transported from the treatment room to the patient bedside, again original packaging vs strips.

What are other hospitals doing in terms of keeping strips of medications in patient's drawers? These would be medications that are on ward imprest, kept within their original packaging in the treatment room but a strip may be placed in the patient's locked drawer, e.g. paracetamol. And following on from that, do nursing staff take medications in original packaging from the treatment room to the patient bedside or would they just take strips of medication? The Medication Handling policy mentions supply of medications from pharmacy in original packaging, unless dispensed for specific patients, but not specifically storage on the wards.' Closes **15<sup>th</sup> February 2024**

### Upcoming TAG meeting dates

NSW Management Committee 21<sup>st</sup> February 2024

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions or upcoming meetings.

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## EDITOR'S PICKS

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**British Medical Journal (BMJ):** Reducing patient and planetary harms from high anticholinergic burden medication – [link](#) – [SPS commentary](#)

**BMJ Open:** Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses - [link](#)

**Diabetes Care:** The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care – [link](#) – [SPS commentary](#)

**European Heart Journal:** The ‘10 commandments’ for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes - [link](#)

**Heart:** - Cardiogeriatrics: the current state of the art - [link](#)

**International Journal for Quality in Health Care:** Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - [link](#)

**Journal of the American College of Cardiology:** When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review - [link](#)

**UK Clinical Pharmacy Association:** Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - [link](#)

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## **OTHER NEWS (new additions in bold)**

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### **NSW Health**

- Measles alert for Sydney International Airport [[24 January 2024](#)]

- Public health warning: tablets sold as MDMA (Ecstasy) found to contain a potent opioid [[29 January 2024](#)]

- Public Health Emergency Response Preparedness ([PD2024\\_002](#)) [23 January 2024]

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## **REPORTS AND PUBLICATIONS – AUSTRALIA**

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### **Agency for Clinical Innovation, NSW (ACI)**

The latest weekly Evidence Digest can be found [here](#)

### **Australian Government Department of Health**

- Shield yourself from shingles – Resources collection - [link](#)

### **Australian Institute for Health and Welfare (AIHW)**

- Australia's disability strategy update & annual report - [link](#)

- Specialist paediatric palliative care delivered to children who died in 2021 - [link](#)

- Aboriginal and Torres Strait Islander specific primary health care: results from the OSR and nKPI collections - [link](#)

- Medicare Benefits Scheme funded services: monthly data - [link](#)

### **MIMS monthly updates – [February 2024](#)**

- New Products

-- Tebentafusp ([Kimmtrak](#)) is a bispecific fusion protein, comprised of a T cell receptor (TCR) fused to an antibody fragment with specificity for the CD3 (cluster of differentiation 3) receptor, found on polyclonal T cells. The TCR has specificity for a gp100 peptide (expressed preferentially in melanoma cells) presented by human leukocyte antigen-A\*02:01 (HLA-A\*02:01). In vitro, tebentafusp bound to HLA-A\*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumour cells.

Kimmtrak is indicated for the treatment of HLA-A\*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Kimmtrak concentrate for intravenous infusion contains tebentafusp 0.1 mg per 0.5 mL and is available in packs of 1 vial

- New indications

-- [Raxtozinameran](#) (Comirnaty Omicron XBB.1.5) is now indicated for active immunisation to prevent COVID-19 in individuals 6 months of age and older in accordance with official recommendations

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- Tozinameran and famtozinameran ([Comirnaty Original/Omicron BA.4-5](#)) is now indicated (with provisional approval) for active immunisation to prevent COVID-19 in individuals 5 years of age and older in accordance with official recommendations
- Vosoritide ([Voxzogo](#)) is now indicated for the treatment of achondroplasia in all paediatric patients whose epiphyses are not closed

## **PBS**

- PBS Website Update - [1 February 2024](#)

## **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- Iomustine [10mg 40mg](#) ; lisdexamfetamine dimesylate [50mg 60mg](#) ; midodrine [50mg](#)
- AusPARs:
  - Sunlenca ([Lenacapavir sodium](#)) for the treatment of adults with multidrug resistant HIV 1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
  - Retevmo ([selpercatinib](#)) is provisionally approved for treatment of adults with locally advanced or metastatic RET fusion positive non-small cell lung cancer
- Australian prescription medicine decision summaries:
  - [Arexvy](#) (recombinant respiratory syncytial virus pre-fusion F protein) is approved for individuals 60 years and older for prevention of lower respiratory tract disease caused by respiratory syncytial virus
  - Wezlana ([ustekinumab](#)) for plaque psoriasis, psoriatic arthritis, Crohn's, ulcerative colitis

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

### **Canadian Agency for Drugs and Technologies in Health**

- Health Technology Review Updates: Biologic Drugs for Severe Asthma - [link](#) ; Buprenorphine Formulations for Opioid Use Disorder – [link](#) ; The Safety of Niraparib in Ovarian Cancer – [link](#) ; Ketamine for Adults With Treatment-Resistant Depression or Posttraumatic Stress Disorder: A 2023 Update – [link](#) ; Ketorolac for Renal Colic - [link](#)

### **Department of Health and Social Care UK**

- Improving the mental health of babies, children and young people (BCYP) - [link](#)
- Expanding access to naloxone: Final outcome – [link](#) – [SPS commentary](#)

### **electronic Medicines Compendium (eMC) (UK)**

- [New products](#)
- BCG-medac Powder and solvent for intravesical suspension for carcinoma-in-situ of the urinary bladder, prevention of recurrence of high-risk non-muscle invasive urothelial bladder carcinoma after resection, and treatment/ prevention of recurrence of aggressive variants of urothelial carcinoma
- Bekemv (eculizumab)- biosimilar to Soliris for use in adults and children for paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome – [SPS commentary](#)
- Camzyos (mavacamten)- selective, allosteric, and reversible cardiac myosin inhibitor for symptomatic adult obstructive hypertrophic cardiomyopathy
- Ebglyss (lebrikizumab) immunoglobulin (IgG4) monoclonal antibody that binds with high affinity to interleukin-13, licensed for moderate-to-severe atopic dermatitis in adults and adolescents ≥12 years of age of at least 40 kg who are candidates for systemic therapy
- Elrexfio (elranatamab)- bi-specific T-cell engaging antibody licensed as monotherapy in adults with relapsed & refractory multiple myeloma, who have received ≥3 prior therapies, including immunomodulatory agent, proteasome inhibitor & anti-CD38 antibody, with disease progression on last therapy
- Evkeeza (evinacumab), a recombinant human monoclonal antibody, which specifically binds to and inhibits ANGPTL3, for use as an adjunct to diet and other LDL-C lowering therapies for the treatment of adults and adolescents aged ≥12 years with homozygous familial hypercholesterolaemia
- Eylea (afibercept) for wet age-related macular degeneration (AMD) and visual impairment due to diabetic macular oedema (DMO). Each vial contains 0.263ml, providing an 8mg dose to be given monthly for 3 doses for AMD and DMO. Dosing interval may be extended for up to 4 months

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- Korserdu (elacestrant)- oral oestrogen receptor- $\alpha$  antagonist & degrader for use in postmenopausal women/men with ER+ve, HER2-ve locally advanced/metastatic breast cancer with an activating ESR1 mutation & disease progression after first line endocrine therapy including CDK 4/6 inhibitor
- Levorol (levomepromazine maleate) psychiatric conditions, e.g. schizophrenia, as alternative to chlorpromazine particularly to reduce psychomotor activity. Also, as an adjunct in terminal illness for the relief of pain, distress and refractory (non-chemotherapy related) nausea
- Loargys (pegzilarginase) a cobalt substituted recombinant human arginase 1 enzyme conjugated with a mPEG carrier for arginase 1 deficiency (hyperargininemia) in adults, adolescents and children aged 2 years and older
- Opdualag (nivolumab, relatlimab)- fixed dose combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) for the first line treatment of advanced (unresectable or metastatic) melanoma in adults & adolescents 12 years of age and older
- Quviviq (daridorexant) licensed for adult insomnia characterised by symptoms present for at least 3 months & considerable impact on daytime functioning – [SPS commentary](#)
- Sildenafil KRKA 100mg orodispersible tablets for the treatment of adult men with erectile dysfunction, are an alternative option for patients who have difficulty swallowing film-coated tablets.
- Strigol (macrogol 3350) Paediatric 6.86 g powder for oral solution – Lemon - each sachet contains macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride for chronic constipation and prevent re-impaction after successful disimpaction in children 2-11 years old and to treat faecal impaction in children aged  $\geq 5$  years
- New indications/extensions
- Keytruda (pembrolizumab) - as monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum based chemotherapy
- Mircera (methoxy polyethylene glycol-epoetin beta) - extension to cover treatment of symptomatic anaemia linked to chronic kidney disease in paediatric patients from 3 months to <18 years of age who are converting from another erythropoiesis stimulating agent (ESA) after haemoglobin stabilised with previous ESA
- Mirena (levonorgestrel) - duration of use extended to 8 years for contraception, and 5 years in induction of idiopathic menorrhagia.
- Opdivo (nivolumab) - adolescent melanoma indication (from age 12 years), and its related dosing

### European Medicines Agency (EMA)

- EMA Human medicines highlights 2023 - [link](#)
- EMA confirms recommendation for non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna - [link](#)

### Food and Drug Administration (FDA) USA

- FDA revises letter of authorization for the emergency use authorization for Paxlovid - [link](#)
- New Drug approvals
- erdafitinib for locally advanced or metastatic urothelial carcinoma - [link](#)
- ceftazidime/avibactam ([Avycaz](#)) - all indications approved for newborns of at least 31 weeks gestational age
- pembrolizumab ([Keytruda](#)) for hepatocellular carcinoma secondary to hepatitis B
- immune globulin IV ([Gammagard Liquid](#)) for chronic inflammatory demyelinating polyneuropathy
- dupilumab ([Dupixent](#)) for eosinophilic esophagitis expanded to include children aged 1 y and older who weigh at least 15 kg
- bupivacaine/meloxicam ([Zynrelef](#)) for soft tissue and orthopedic surgical procedures including foot and ankle expanded
- immune globulin SC ([HyQvia](#)) for chronic inflammatory demyelinating polyneuropathy

### General Pharmaceutical Council

- Joint statement on meeting regulatory standards during periods of global or national shortage of medicines – an update - [link](#)

### House of Commons Science and Technology Committee

- The antimicrobial potential of bacteriophages - [link](#)

### Medicines and Healthcare products Regulatory Agency (MHRA)

- Regulatory Roadmap published for new measures to support safe access to medical technology including AI and diagnostics - [link](#)
- Omjara licensed for anaemic myelofibrosis patients to treat the symptoms of their disease - [link](#)
- Rezzayo approved to treat adult patients with invasive candidiasis - [link](#)
- MHRA approves four-dose [Mounjaro](#) (tirzepatide) KwikPen for diabetes and weight management

### Monthly Index of Medical Specialities MIMS UK

- Mirena levonorgestrel-releasing intrauterine system (IUS) licensed for longer use - [link](#)

### NHS England

- Improving the physical health of people living with severe mental illness – [link](#) – [SPS commentary](#)
- Five key elements for discharge – supporting people with a learning disability and autistic people to leave hospital - [link](#)
- Guidance for risk assessment and infection prevention and control measures for measles in healthcare settings – [link](#) – [SPS commentary](#)
- Direct-to-consumer point-of-care in vitro diagnostic devices for group A streptococcal infections - [link](#)
- Blood matching genetic test to be made available on the NHS for patients with sickle cell disorder and thalassaemia to reduce transfusion side effects - [link](#)

### NHS Scotland (Scottish Medicines Consortium)

- Accepted for use:
  - [Burosumab](#) (Crysvita®) for X-linked hypophosphataemia
  - [Pembrolizumab](#) (Keytruda®) for microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) tumours
- Not recommended:
  - [Belantamab mafodotin](#) (Blenrep®) for multiple myeloma

### National Institute for Health and Care Excellence (NICE) UK

- Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer ([TA946](#))
- Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments ([TA947](#))
- Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments ([TA948](#))
- Updated NICE guidance recommends more targeting of antibiotics to those at the highest risk of suspected sepsis - [link](#)
- Other updates: Neonatal infection ([QS75](#)) ; Skin cancer ([QS130](#))

### National Institute for Health and Care Research (NIHR)

- NIHR Alert: How to improve investigations of medical harm - [link](#)

### Obesity Action Coalition

- Joint statement calls on the US FDA to stipulate that people with obesity must be included in drug trials - [link](#)

### Royal Pharmaceutical Society

- Royal Pharmaceutical Society revises position on prescribing and dispensing by same healthcare professional – [link](#) – [SPS commentary](#) – [position statement](#) – [SPS commentary](#)

### Specialist Pharmacy Services NHS UK

- Use of nefopam for chronic pain - [link](#)

- Natalizumab biosimilar: Patient Information Sheet - [link](#)
- Treating herpes virus infections during breastfeeding - [link](#)

### **The Queen's Nursing Institute**

- 70 years of end of life care in the community - [link](#)

### **UK Clinical Pharmacy Association**

- Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - [link](#)

### **World Health Organisation (WHO)**

- Guidelines on the Clinical Management of Sepsis - [link](#)
- World Health Organisation (WHO) warns of alarming 45-fold rise in measles in Europe - [link](#) – [SPS commentary](#)
- WHO awards countries for progress in eliminating industrially produced trans fats for first time - [link](#)
- Shortages impacting access to glucagon-like peptide 1 receptor agonist products; increasing the potential for falsified versions - [link](#)

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## **MEDICATION SAFETY**

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### **British National Formulary**

- Pharmacodynamic effects tables now in digital formats - [link](#)

### **electronic Medicines Compendium (eMC) (UK)**

#### **- [Revised SPCs](#)**

- Avelox (moxifloxacin), Ciproxin (ciprofloxacin) - possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted
- Buccolam (midazolam) - anaphylactic reaction (unknown frequency) added as ADR
- Cabometyx (cabozantinib) - pneumonia added as one of the most common serious ADRs in both renal cell carcinoma and differentiated thyroid carcinoma
- Cetirizine hydrochloride products- contraindication in patients with end-stage renal disease (GFR < 15 ml/min) and dosing information in renal impairment. Breast-feeding risk information and myalgia ADR of unknown frequency added
- CitraFleet (light magnesium oxide, sodium picosulfate, citric acid) - may induce aphthoid ulcers of the colonic mucosa, with reports of serious cases of colitis (including ischaemic colitis). Colitis should be considered in cases of severe and/or persistent abdominal pain, with/without rectal bleeding, after the ingestion of CitraFleet
- Doxorubicin Baxter - interstitial lung disease, which may have an acute onset, observed in patients receiving pegylated liposomal doxorubicin, including fatal cases
- Eliquis (apixaban) - anticoagulant-related nephropathy (ARN) added as ADR (frequency unknown). In patients with kidney disease, it may occur, possibly in relation to episodes of excessive anticoagulation and haematuria. Consider possibility of haemorrhage if evaluating the condition
- Elvanse (lisdexamfetamine) Hard Capsules – adult indication (use as part of a comprehensive treatment programme for ADHD in adults with pre-existing symptoms of ADHD in childhood), has been incorporated into the Elvanse SmPCs which previously only included paediatric indication
- Epilim (sodium valproate) products - new safety measures to reduce the known harms of valproate, including risk of birth defects and neurodevelopmental disorders following use in pregnancy, and the risk of impaired fertility in males – [SPS commentary](#)
- Epistatus (midazolam) - anaphylactic reaction added as possible ADR of unknown frequency (SPC notes added because this has been reported to occur when midazolam is injected in children and/or adults, which may be of relevance to oromucosal administration)
- Erleada (apalutamide) - risk of interstitial lung disease, including fatalities. Should be interrupted if there is acute onset &/or unexplained worsening of pulmonary symptoms, & if confirmed, it should be discontinued. Restless leg syndrome added as uncommon ADR
- Esmeron (rocuronium bromide) - mydriasis and fixed pupils as ADRs, in the context of a potential increased permeability or compromise of the integrity of the blood-brain barrier

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- Eumovate (clobetasone butyrate) - long term topical steroids use can result in the development of rebound eczema and dermatitis flares after stopping treatment (topical steroid withdrawal syndrome)
- Hydrocortisone creams & ointment - hydrocortisone 1% is classed as a mild corticosteroid – [SPS commentary](#)
- Kivexa (lamivudine, abacavir sulfate) - increased risk of cardiovascular events (notably myocardial infarction). It advises that action be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- Inovelon (rufinamide) - change in excipients, including information about sorbitol, benzoic acid and sodium content
- Kisplyx Lenvima (lenvatinib mesilate) - adrenal insufficiency added as possible ADR, frequency 'uncommon' for monotherapy and in combination with everolimus, and 'common' in combination with pembrolizumab
- Lokelma (sodium zirconium cyclosilicate) - constipation added as a common ADR
- Lorviqua (lorlatinib) - proteinuria added as a common ADR. The frequency is 3.4% for all grades and 0.4% for grade 3-4, which represents a more serious adverse effect
- Lyrica (pregabalin) - suicidal ideation added as a rare ADR
- Lyxumia (lixisenatide) - cholelithiasis and cholecystitis added as uncommon ADRs. The word "before" added to line in interaction section on administration of oral contraceptive "1 hour" before or 4 hours after lixisenatide did not affect AUC & t1/2 of ethinylestradiol and levonorgestrel
- Mirapexin (Pramipexole) - restless legs augmentation syndrome (earlier onset of symptoms in the evening/afternoon, increase in symptoms, and involvement of other extremities) added as very common ADR. If suspected, use lowest effective dose, or consider stopping treatment
- Mirena (levonorgestrel) - Updated information on risk in post-menopausal women, adverse reactions, and bleeding patterns also added
- Movicol (macrogol 3350) - warning that medicines in solid dose form taken within 1 hour of large volumes of Movicol may be flushed from the gastrointestinal tract and not absorbed
- Nortriptyline - high doses in late pregnancy may cause lethargy in the newborn and urinary retention in pregnant women. Serotonin syndrome has been added as an ADR of unknown frequency. Additionally, several years of treatment may needed be for recurrent depression
- Norvir (ritonavir) - piroxicam removed from the contraindications and interactions sections
- Otrivine (xylometazoline) - use with caution in patients taking tri or tetra-cyclic antidepressant treatment, as concomitant use may cause an increase in blood pressure due to the cardiovascular effects of these substances
- Premarin (conjugated oestrogens) - interaction of oestrogens with lamotrigine. Contraceptives containing oestrogens have been shown to reduce lamotrigine plasma concentrations due to induction of lamotrigine glucuronidation. It is expected that a similar interaction exists with HRT
- Paxlovid (nirmatrelvir, ritonavir) - Stevens-Johnson syndrome, toxic epidermal necrolysis & anaphylaxis added as rare ADR; hypertension as an uncommon ADR. Potential for increased verapamil, calcineurin inhibitor & mTOR inhibitor levels with concomitant Paxlovid noted, and related monitoring advice included
- Prezista (darunavir) - crystal nephropathy as a rare ADR identified in the post-marketing setting
- Resonium A (sodium polystyrene sulfonate) - risk of severe gastrointestinal disorders (such as bowel obstruction, ischaemia, necrosis or perforation) so use of polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility
- Rinvoq (upadacitinib hemihydrate)- hypoglycaemia in patients treated for diabetes added as a precaution. Dose adjustment of anti-diabetic medication may be necessary if hypoglycaemia occurs
- Rivastigmine Dr. Reddys - risk of electrocardiogram QT prolongation warning. Caution is advised in patients with pre-existing/family history of QTc prolongation or at higher risk of developing torsade de pointes. ECG monitoring may be required for some people
- Rybelsus (semaglutide) - dizziness added as a new common ADR
- Salofalk (mesalazine) - treatment should be stopped if renal function deteriorates, warnings on serious blood dyscrasias and cardiac hypersensitivity reactions (myocarditis and pericarditis), rash and pruritis added as common ADRs

- Sancuso (granisetron) patch - may mask progressive ileus and gastric distension. Serotonin syndrome and skin reactions added as ADRs of unknown frequency. Buprenorphine and opioids now listed as medicines that may lead to serotonin syndrome, when used with granisetron
- Sandrena (estradiol hemihydrate) - oestrogen containing contraceptives significantly decrease concentrations of lamotrigine when used together. Although this interaction with HRT and lamotrigine not studied, similar effects expected, leading to reduced seizure control
- Sevoflurane Baxter - delirium has been added as ADR of unknown frequency
- Shingrix Herpes zoster vaccine (recombinant, adjuvanted) - can be given concomitantly with any authorised or approved COVID-19 mRNA vaccine. This is based on data from the ZOSTER-091 study
- Spikevax (formerly COVID-19 Vaccine Moderna) XBB.1.5 vaccine - warning about use in immunocompromised individuals removed, safety data in organ transplant recipients and immunogenicity data in organ transplant recipients included
- Tecentriq (atezolizumab) - data from phase 3 IMvigor130 trial of atezolizumab as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma added
- Tecvayli (teclistamab) – recommendation to reduce the dosing frequency to 1.5 mg/kg by subcutaneous injection every two weeks for patients who have a complete response or better for a minimum of 6 months
- Tegretol (carbamazepine) - hypersensitivity reaction information added to advise class I (immediate) reactions including rash, pruritus, urticaria, angioedema & anaphylaxis have been reported, and treatment must be discontinued if they occur. Loratadine removed from list of interacting medicines
- Tobramycin - increased risk of ototoxicity in mitochondrial DNA mutations (particularly nucleotide 1555 A to G substitution in 12S rRNA gene), even if serum levels are within the recommended range during treatment. Alternative options should be considered in such patients
- Vabysmo (faricimab) injection - rare cases of retinal vasculitis and/or retinal occlusive vasculitis spontaneously reported in post-marketing and in patients treated with intravitreal therapies
- Varivax (varicella-zoster virus [live] vaccine) - syncope as post-marketing surveillance ADR
- Verzenio (abemaciclib) - potential increased risk for serious arterial thromboembolic events (ATEs), including ischaemic stroke and MI when administered with endocrine therapies. Benefits and risks of continuing abemaciclib in those who experience serious ATE should be considered
- Veyvondi (voniceg alfa) - co-administration of von Willebrand factor and factor VIII, (including pre-mixing these in a single syringe) information removed. Dosing information for long-term prophylaxis against bleeds in von Willebrand disease added
- Vfend (voriconazole) - newly calculated frequencies for following ADRs: squamous cell carcinoma (SCC) of skin (including cutaneous SCC in situ or Bowen's disease) from "not known" to "common", phototoxicity from "uncommon" to "common", and periostitis from "not known" to "uncommon."
- Xifaxanta (rifaximin) - severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis reported in association with use of rifaximin in patients with cirrhosis
- Yasmin (ethinylestradiol, drospirenone) - exogenous oestrogens may induce or exacerbate symptoms of acquired (as well as hereditary) angioedema. This ADR has an unknown frequency
- Zavesca (miglustat) - Crohn's disease diagnosed in patients with Niemann-Pick type C disease who are taking miglustat. In patients with chronic diarrhoea and/or abdominal pain that worsen or do not respond to treatment, the possibility of Crohn's disease should be considered
- Zejula (niraparib tosylate monohydrate) - myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) added as common ADRs. Patients with suspected AML/MDS should be referred to a haematologist. Contraceptive advice in women of childbearing age has changed from use for 1 month to 6 months after the last dose
- Ziagen (abacavir sulfate) - increased risk of cardiovascular events (notably myocardial infarction). Action should be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- Risk minimisation materials
- Abstral (fentanyl citrate) sublingual tablets. The prescriber's guide contains information on breakthrough pain, administration, titration, side-effects, switching and stopping treatment, breastfeeding, and provision of guidance to patients/carers. A patient/carers guide is also available

- Casgevy (exagamglogene autotemcel) Patient/carer guide contains information on the possibility of neutrophil engraftment failure (with associated increased risk of infections) and longer time to platelet engraftment (increased risk of bleeding). A patient alert card and administration guide also available
- eculizumab (Bekemv) Materials include a Physician's Guide, discussing risk of severe infection and sepsis, especially meningococcal infection, signs and symptoms of severe infection, how to minimise this risk (vaccination requirements; antibiotic prophylaxis) and other serious ADRs – [SPS commentary](#)
- Elrexfio (elranatamab) patient alert card. This patient card, which should be carried at all times, includes information on symptoms of cytokine release syndrome and neurological toxicity, including immune effector cell associated neurotoxicity syndrome, which may be fatal or life-threatening
- etranacogene dezaparvovec (Hemgenix) Materials include a healthcare professional guide discussing important risks related to this treatment (hepatotoxicity; thromboembolism; malignancy; germline and horizontal transmission; development of factor IX inhibitors) and how to minimise these – [SPS commentary](#)
- Litfulo (ritlecitinib) - Prescriber guide provides a checklist for assessments prior to prescribing, management, monitoring and safety considerations related to the Risk Management Plan for ritlecitinib. A Patient Card containing information on important side-effects is also available
- Opdualag (nivolumab and relatlimab) patient card. This medicine can cause serious immune-mediated side-effects that can affect different parts of the body. This card, which must be carried with the person being treated at all times, lists the side effects that can be life threatening and need to be addressed immediately
- PecFent (fentanyl citrate) nasal spray. A prescribers guide containing important information on its safe prescribing and use discusses dosing and titration, overdose, opioid use disorder, and includes a prescribers checklist. There is also a pharmacist's guide to dispensing and a patient/carer guide
- Zynlonta (loncastuximab tesirine) Patient Card with important safety information, including risk of photosensitivity reactions, such as sunburn-like reactions following exposure to light, itchy rash, skin blistering, darker skin patches, irritation, swelling & pain

#### **EMA**

- Precautionary measures to address potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines - [link](#)
- EMA confirms measures to minimise the risk of serious side effects with medicines containing pseudoephedrine - [link](#)

#### **Food and Drug Administration (FDA) USA**

- FDA adds Boxed Warning for increased risk of severe hypocalcaemia in patients with advanced chronic kidney disease taking denosumab (Prolia) – [link](#) – [SPS commentary](#)

#### **Health Canada – MedEffect Notice**

- Health Product InfoWatch, [January 2024](#)

#### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [January 25, 2024](#)
- Be Wary of Controlled and Non-Controlled Medication Replicas Sold Online - [link](#)

#### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- Drug Safety Update, [January 2024](#)
- Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate - [link](#) – [SPS commentary](#)
- Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors - [link](#)
- Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age - [link](#) – [SPS commentary](#)
- New valproate safety measures apply from 31 January - [link](#)

## **Medsafe (New Zealand Medicines and Medical Devices Safety Authority)**

- Medsafe successfully prosecutes seller of fake "Miracle Cure" - [link](#)

## **MIMS monthly updates – February 2024**

- New contraindications
- Iopromide ([Ultravist](#) 300 and 370) now contraindicated for intrathecal use
- Metoclopramide hydrochloride ([Maxolon](#)) tablets now contraindicated in children below 15 years
- Rifabutin ([Mycobutin](#)) is now contraindicated for concomitant use with rilpivirine prolonged-release suspension for injection

## **Specialist Pharmacy Service**

- Understanding drug interactions - [link](#)
- Using heparins during breastfeeding - [link](#)

## **TGA**

- Product Information safety updates - [January 2024](#)
- Nitrosamine impurities acceptable intakes update - [link](#)
- The following pose a serious risk to health and should not be taken: [Artri King tablets](#); [Commander Stamina Time tablets](#); [Throb Herbal supplement tablets](#); [Kamasutra herbal jelly for him bottle](#); [Excite for her tablets](#); [Kamasutra Herbal Jelly for him oral jelly sachets](#)

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## **PAPERS OF INTEREST**

### **American Journal of Cardiology**

- Early Initiation of PCSK9 Inhibitor Therapy Versus Placebo in Patients With Acute Coronary Syndrome: A Systematic Review and Meta-Analysis - [link](#)

### **American Journal of Gastroenterology**

- Antibiotics with or without rifaximin for acute hepatic encephalopathy (HE) in critically ill patients With cirrhosis: A double-blind, randomized controlled (ARiE) trial - [link](#)

### **American Journal of Health-System Pharmacy (AJHP)**

- Tenecteplase-associated orolingual angioedema: A case report and literature review - [link](#)
- Risk of bleeding with concomitant use of oral anticoagulants and aspirin: A systematic review and meta-analysis - [link](#)
- Implementation of clopidogrel pharmacogenetic clinical decision support for a preemptive return of results program - [link](#)
- Implementation of vancomycin AUC/MIC dosing vs traditional trough dosing and incidence of acute kidney injury at a rural community hospital - [link](#)

### **Annals of Internal Medicine**

- Effectiveness of Recombinant Zoster Vaccine Against Herpes Zoster in a Real-World Setting – [link](#) – [SPS commentary](#)
- Effectiveness of Existing Insomnia Therapies for Patients Undergoing Hemodialysis: A Randomized Clinical Trial - [link](#)
- Gabapentinoids and Risk for Severe Exacerbation in Chronic Obstructive Pulmonary Disease: A Population-Based Cohort Study - [link](#)
- Talking With Patients About the New Anti-amyloid Alzheimer Disease Medications - [link](#)

### **Arthritis & Rheumatology**

- Clinical characteristics of cryopyrin-associated periodic syndrome and long-term real-world efficacy and tolerability of canakinumab in Japan: results of a nationwide survey - [link](#)

### **British Journal of Clinical Pharmacology**

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- Gabapentinoids in Ireland 2010 to 2020: An observational study of trends in gabapentinoid prescribing, law enforcement drug seizures and post-mortem toxicology - [link](#)
- Observational studies to emulate randomized trials: Some real-world barriers - [link](#)
- A physiological approach to renal clearance: From premature neonates to adults - [link](#)

### **British Journal of General Practice**

- Cost-utility analysis of molnupiravir plus usual care versus usual care alone as early treatment for community-based adults with COVID-19 and increased risk of adverse outcomes in the UK PANORAMIC trial - [link](#)

### **British Journal of Psychiatry**

- Sensitivity to light in bipolar disorder: implications for research and clinical practice - [link](#)

### **British Medical Journal (BMJ)**

- Combining high quality data with rigorous methods: emulation of a target trial using electronic health records and a nested case-control design - [link](#)
- Efficacy and safety of tranexamic acid in acute haemorrhage - [link](#)
- Improving the transparency and reliability of observational studies through registration - [link](#)
- Why learning how to swallow pills is good for patients, parents, and the planet - [link](#)
- Effect of Risk Mitigation Guidance opioid and stimulant dispensations on mortality and acute care visits during dual public health emergencies: retrospective cohort study – [link](#) – [SPS commentary](#)
- Undisclosed financial conflicts of interest in DSM-5-TR: cross sectional analysis – [link](#) – [SPS commentary](#)
- Perinatal depression and its health impact – [link](#) – [SPS commentary](#)
- Inclisiran: the test case drug for the Government's life sciences strategy - [link](#)
- Anaemia Management in Chronic Kidney Disease - [link](#)
- Reducing patient and planetary harms from high anticholinergic burden medication – [link](#) – [SPS commentary](#)
- Therapeutic advances in rheumatoid arthritis - [link](#)

### **BMJ Open**

- Cannabis for medical use versus opioids for chronic non-cancer pain: a systematic review and network meta-analysis of randomised clinical trials - [link](#)
- NSAID prescribing and adverse outcomes in common infections: a population-based cohort study - [link](#)
- Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses - [link](#)
- Role of vitamin D supplementation in modifying outcomes after surgery: a systematic review of randomised controlled trials - [link](#)
- Association between antidepressant use during pregnancy and miscarriage: a systematic review and meta-analysis – [link](#) – [SPS commentary](#)

### **Circulation**

- Efficacy and Safety of Non-Vitamin-K Antagonist Oral Anticoagulants Versus Warfarin Across the Spectrum of Body Mass Index and Body Weight: An Individual Patient Data Meta-Analysis of Four Randomized Clinical Trials of 58 464 Patients With Atrial Fibrillation - [link](#)

### **Cochrane**

- Deep neuromuscular blockade in adults undergoing an abdominal laparoscopic procedure - [link](#)
- Early versus late administration of amino acids in preterm infants receiving parenteral nutrition - [link](#)
- Non-vitamin-K-antagonist oral anticoagulants (NOACs) after acute myocardial infarction: a network meta-analysis - [link](#)
- Probiotics for the postoperative management of term neonates after gastrointestinal surgery - [link](#)

### **Diabetes Care**

- Impact of Glucose-Lowering Medications on Health-Related Quality of Life in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) - [link](#)
- Comparative Effects of Randomized Second-line Therapy for Type 2 Diabetes on a Composite Outcome Incorporating Glycemic Control, Body Weight, and Hypoglycemia: An Analysis of Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) - [link](#)
- The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care – [link](#) – [SPS commentary](#)
- Optimal Dose and Type of Physical Activity to Improve Glycemic Control in People Diagnosed With Type 2 Diabetes: A Systematic Review and Meta-analysis – [link](#) – [SPS commentary](#)
- A Methodological Framework for Meta-analysis and Clinical Interpretation of Subgroup Data: The Case of Major Adverse Cardiovascular Events With GLP-1 Receptor Agonists and SGLT2 Inhibitors in Type 2 Diabetes - [link](#)

### Drug and Therapeutics Bulletin

- Low-dose aspirin and anaemia in older people - [link](#)
- Can antidepressants worsen COPD? - [link](#)
- Effect of semaglutide on major cardiovascular events - [link](#)
- ADHD medication shortages: more than just a supply issue - [link](#)

### European Heart Journal

- Green cardiovascular care: a call for sustainable transformation of cardiovascular practices - [link](#)
- Seeking synergy for novel weight - and glucose-lowering pharmacotherapy and exercise training in heart failure patients with preserved ejection fraction (HFpEF) - [link](#)
- How to diagnose and treat venous congestion in heart failure - [link](#)
- The '10 commandments' for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes - [link](#)
- Cannabis for chronic pain: cardiovascular safety in a nationwide Danish study – [link](#) – [SPS commentary](#)
- Aspirin-free antiplatelet strategies after percutaneous coronary interventions - [link](#)
- Cardiovascular disease risk communication and prevention: a meta-analysis - [link](#)
- Icosapent ethyl following acute coronary syndrome: the REDUCE-IT trial - [link](#)

### European Journal of Hospital Pharmacy

- Evaluation of the impact of pharmacist-led educational intervention on knowledge and skills of cancer patients with totally implantable venous access port: a single-centre, non-randomised controlled study - [link](#)
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab - [link](#)
- Enhancing pharmaceutical decision support system: evaluating antithrombotic-focused algorithms for addressing drug-related problems - [link](#)
- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags - [link](#)
- Management of heparin-induced thrombocytopenia during extracorporeal membrane oxygenation support: a case of neutropenia caused by argatroban anticoagulation - [link](#)
- Combination of a propofol emulsion with alpha-2 adrenergic receptor agonists used for multimodal analgesia or sedation in intensive care units: a physicochemical stability study - [link](#)

### Heart

- Postdischarge major bleeding, myocardial infarction, and mortality risk after coronary artery bypass grafting – [link](#) – [SPS commentary](#)
- Generalisability of trials on antithrombotic treatment intensification in patients with cardiovascular disease - [link](#)
- Review of the National Institute for Health and Care Excellence guidelines on chronic heart failure - [link](#)
- Cardiogeriatrics: the current state of the art - [link](#)

- Management of pregnancy-related disorders to prevent future risk of coronary artery disease - [link](#)
- Efficacy and safety of colchicine for the treatment of myopericarditis - [link](#)

### **International Journal of Clinical Pharmacy**

- Psychiatric adverse events associated with semaglutide, liraglutide and tirzepatide: a pharmacovigilance analysis of individual case safety reports submitted to the EudraVigilance database - [link](#)
- Exploring the safety profile of tremelimumab: an analysis of the FDA adverse event reporting system - [link](#)
- Data mining and analysis of adverse event signals associated with teprotumumab using the Food and Drug Administration adverse event reporting system database - [link](#)
- A comparison between the adverse event profiles of patients receiving palbociclib and abemaciclib: analysis of two real-world databases - [link](#)
- Comparison of the sensitivities of pharmacotherapy-related and disease-specific quality of life measures in response to pharmacist-led pharmaceutical care for cancer outpatients: a randomised controlled trial - [link](#)

### **International Journal for Quality in Health Care**

- Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - [link](#)

### **JAMA**

- T-Cell Lymphoma From CAR T-Cell Therapy—A New Safety Notice - [link](#)
- Perioperative toripalimab plus chemotherapy for patients with resectable Non–Small Cell Lung Cancer (NSCLC): The Neotorch randomized clinical trial - [link](#)
- Intranasal naloxone for opioid overdose - [link](#)
- International Consensus Criteria for Pediatric Sepsis and Septic Shock – [link](#) – [SPS commentary](#)
- Management of Candida auris - [link](#)

### **JAMA Cardiology**

- Impact of Bempedoic Acid on Total Cardiovascular Events: A Prespecified Analysis of the CLEAR Outcomes Randomized Clinical Trial - [link](#)
- Dapagliflozin and Mode of Death in Heart Failure with Improved Ejection Fraction- A Post Hoc Analysis of the DELIVER Trial - [link](#)

### **JAMA Dermatology**

- Causes and Clinical Presentation of Drug-Induced Dermatomyositis: A Systematic Review - [link](#)
- Sustained Remission Without Corticosteroids Among Patients with Pemphigus Who Had Rituximab as First-Line Therapy - [link](#)

### **JAMA Internal Medicine**

- Early Tecovirimat Treatment for Mpox Disease Among People With HIV – [link](#) – [SPS commentary](#)
- First Trimester Use of Buprenorphine or Methadone and the Risk of Congenital Malformations - [link](#) – [SPS commentary](#)

### **JAMA Network Open**

- Cumulative update of a systematic overview evaluating interventions addressing polypharmacy - [link](#)

### **JAMA Neurology**

- Argatroban in Patients With Acute Ischemic Stroke With Early Neurological Deterioration – [link](#) – [SPS commentary](#)
- SARS-CoV-2 Vaccination and Neuroimmunological Disease: A Review - [link](#)
- Concomitant Medications for Progressive Supranuclear Palsy: A Secondary Analysis of a Randomized Clinical Trial – [link](#)

### **JAMA Oncology**

- Rapid Advances in Resectable Non–Small Cell Lung Cancer: A Narrative Review - [link](#)
- Mirtazapine as Appetite Stimulant in Patients with Non–Small Cell Lung Cancer and Anorexia: A Randomized Clinical Trial - [link](#)

### **JAMA Psychiatry**

- Prescription Stimulant Use During Pregnancy and Risk of Neurodevelopmental Disorders in Children - [link](#)

### **Journal of the American College of Cardiology**

- When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review - [link](#)

### **Journal of Clinical Oncology**

- Health Care Transitions Among Adolescents and Young Adults with Cancer - [link](#)
- Cancer-Associated Thrombosis: Management of a Patient with an Isolated Calf Deep Vein Thrombosis - [link](#)

### **Journal of Clinical Pharmacology**

- Inclusion of Obese Participants in Drug Development: Reflections on the Current Landscape and a Call for Action - [link](#)

### **Lancet**

- Indomethacin with or without prophylactic pancreatic stent placement to prevent pancreatitis after ERCP: a randomised non-inferiority trial – [link](#) – [SPS commentary](#)
- Lancet series on Parkinson’s disease – [link](#) – [SPS commentary](#)

### **Lancet Diabetes & Endocrinology**

- Association of glycaemic index and glycaemic load with type 2 diabetes, cardiovascular disease, cancer, and all-cause mortality: a meta-analysis of mega cohorts of more than 100 000 participants - [link](#)

### **Lancet Haematology**

- Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation - [link](#)

### **Lancet HIV**

- Changes in incidence of hepatitis C virus reinfection and access to direct-acting antiviral therapies in people with HIV from six countries, 2010–19: an analysis of data from a consortium of prospective cohort studies - [link](#)
- Longitudinal trends in causes of death among adults with HIV on antiretroviral therapy in Europe and North America from 1996 to 2020: a collaboration of cohort studies - [link](#) – [SPS commentary](#)

### **Lancet Infectious Diseases**

- Oral linezolid compared with benzathine penicillin G for treatment of early syphilis in adults (Trep-AB Study) in Spain: a prospective, open-label, non-inferiority, randomised controlled trial – [link](#) – [SPS commentary](#)
- Efficacy and safety of a structured de-escalation from antipseudomonal  $\beta$ -lactams in bloodstream infections due to Enterobacterales (SIMPLIFY): an open-label, multicentre, randomised trial – [link](#) – [SPS commentary](#)
- Novel strain of multidrug non-susceptible *Neisseria gonorrhoeae* in the USA - [link](#)
- Efficacy and safety of an early oral switch in low-risk *Staphylococcus aureus* bloodstream infection (SABATO): an international, open-label, parallel-group, randomised, controlled, non-inferiority trial – [link](#) – [SPS commentary](#)

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### **Lancet Oncology**

- Low-dose versus standard-dose olanzapine with triple antiemetic therapy for prevention of highly emetogenic chemotherapy-induced nausea and vomiting in patients with solid tumours: a single-centre, open-label, non-inferiority, randomised, controlled, phase 3 trial - [link](#)

### **Lancet Psychiatry**

- Efficacy and effectiveness of antipsychotics in schizophrenia: network meta-analyses combining evidence from randomised controlled trials and real-world data – [link](#) – [SPS commentary](#)

### **Lancet Public Health**

- Nitazenes—heralding a second wave for the UK drug-related death crisis? - [link](#)

### **Lancet Respiratory Medicine**

- Profiling the dysregulated immune response in sepsis: overcoming challenges to achieve the goal of precision medicine - [link](#)

- Clarithromycin for early anti-inflammatory responses in community-acquired pneumonia in Greece (ACCESS): a randomised, double-blind, placebo-controlled trial – [link](#) – [SPS commentary](#)

- Risk factors for COVID-19-associated pulmonary aspergillosis: a systematic review and meta-analysis – [link](#) – [SPS commentary](#)

- Morphine for treatment of cough in idiopathic pulmonary fibrosis (PACIFY COUGH): a prospective, multicentre, randomised, double-blind, placebo-controlled, two-way crossover trial - [link](#)

### **New England Journal of Medicine**

- Navigating and Communicating about Serious Illness and End of Life - [link](#)

- Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy - [link](#)

- Oral Simnolrelvir for Adult Patients with Mild-to-Moderate Covid-19 - [link](#)

- Testosterone Treatment and Fractures in Men with Hypogonadism - [link](#) – [SPS commentary](#)

- Syphilis Complicating Pregnancy and Congenital Syphilis - [link](#)

- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma – [link](#) – [SPS commentary](#)

- Perspective: Secondary Cancers after Chimeric Antigen Receptor T-Cell Therapy – [link](#) – [SPS commentary](#)

- Responding to medical errors — implementing the modern ethical paradigm - [link](#)

### **Pain Physician**

- Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain from the American Society of Interventional Pain Physicians - [link](#)

### **Pediatrics (American Academy of Pediatrics)**

- 2023 American Heart Association and American Academy of Pediatrics Focused Update on Neonatal Resuscitation: An Update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care - [link](#)

### **Pharmaceutical Journal**

- Inclisiran: the 'extremely unusual' political influence behind the novel drug's approval - [link](#)

### **Prescribe International – February 2024** includes

- Olaparib (Lynparza®) as "maintenance" therapy for certain advanced ovarian cancers after first-line chemotherapy; Clomifene: serious, sometimes irreversible, vision disorders; Drugs that interfere with the placenta and affect the fetus – with editorial

### **Rheumatic & Musculoskeletal Diseases**

- Hormonal and reproductive factors in relation to the risk of rheumatoid arthritis in women: a prospective cohort study with 223 526 participants – [link](#) – [SPS commentary](#)

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## Thorax

- Genetic and T2 biomarkers linked to the efficacy of HDM sublingual immunotherapy in asthma – [link](#) – [SPS commentary](#)
- Use of inhaled corticosteroids and the risk of hospitalisation for pneumonia in children with asthma: a nationwide cohort study - [link](#)

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## CONSULTATIONS (new additions in bold)

### Australian Commission on Safety and Quality in Health Care (ACSQHC)

- NPAAC Standards - Tier 3B and 4, Closing 23 February 2024 - [link](#)
- Updating the National Guidelines for On-Screen Presentation of Discharge Summaries, Closing 20 February 2024 - [link](#)

## TGA

- Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, March 2024, Closes on 5 February 2024 - [link](#)

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## WEBINARS & PODCASTS

### Australian Prescriber Podcasts

- [Episode 156](#) – Physical health monitoring for people with schizophrenia

### MJA Podcasts

- [Episode 1](#): chronic cough in children and adults
- [Episode 2](#): the economics of Australia's health system

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## UPCOMING EVENTS

(New additions listed in TAGMail - click [here](#) for the running list of other events)

### Kids Research, Sydney Children's Hospitals Network

- How to get 'grant ready' – free workshop, Friday, 9 February, 9:30am-12:30pm, Teams and Royal Hospital for Women Lecture Theatre – register [here](#)

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## Fortnightly TAG Mail – resources list

18<sup>th</sup> January 2024



**NSW TAG wishes all TAGMail readers  
a happy, healthy and productive 2024**

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## NSW TAG ACTIVITIES

### Upcoming TAG meetings

Meeting for NSW TAG's feedback re Dept of Health's proposed Repurposing Medicines Program 12-1pm Thursday 25<sup>th</sup> January. Contact Sasha Bennett [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) if wish to provide input.

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## OTHER NEWS (new additions in bold)

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### NSW Health

- Measles alert for western Sydney - [link](#)
- Legionnaires' disease alert for Sydney CBD - [link](#)
- NSW community urged to stay COVID-safe this summer - [link](#)

### Pharmacy Board of Australia

- New accreditation standards for pharmacist prescriber education programs – [link](#)
- Pharmacist prescribing position statement update - [link](#)

### TGA

- [Repeal](#) of Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021 – advertising permission for nicotine repealed as part of the vaping regulation reforms

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## REPORTS AND PUBLICATIONS – AUSTRALIA

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### Agency for Clinical Innovation, NSW (ACI)

- The latest weekly Evidence Digests can be found [here](#)
- Diagnosis and management of adults with acute ureteric colic - [link](#) – [patient fact sheet](#)

### Australian Commission on Safety and Quality in Health Care (ACSQHC)

- National Safety and Quality Cosmetic Surgery Standards - [link](#)
- National Consensus Statement: Essential elements for safe and high-quality end-of-life care - [link](#)

### Australian Government Department of Health

- Launch of the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) Program - [link](#)
- Hospital data resources - [link](#)

### Australian Institute for Health and Welfare (AIHW)

- Australian facts: [Heart, stroke and vascular disease](#), [Diabetes](#), [Chronic kidney disease](#)

### CEC

- Fall Prevention in NSW. White Paper 2023 - [link](#)

### MIMS monthly updates – [January 2024](#)

- New Products
- [Raxtozinameran](#) (Comirnaty Omicron XBB.1.5). Indicated for active immunisation to prevent COVID-19 in those 5 years of age and older as per official recommendations.
- New Indications
- Incobotulinumtoxin A ([Xeomin](#)) for adult chronic sialorrhoea due to neurological disorders; and in children and adolescents aged 2 to 17 years for the symptomatic treatment of chronic sialorrhoea due to neurological/neurodevelopmental disorders and for spasticity of the lower and/or upper limbs
- Olaparib ([Lynparza](#)) expanded indications in breast cancer and prostate cancer.

### TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
- Andexxa ([andexanet alfa](#)) is provisionally approved for adult patients treated with a direct factor Xa inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding
- Imjudo ([tremelimumab](#)) for the treatment of unresectable hepatocellular carcinoma
- Imfinzi ([durvalumab](#)) for the treatment of unresectable hepatocellular carcinoma
- [Opdualag](#) (nivolumab and relatlimab), which is approved for the treatment of patients with unresectable or metastatic melanoma who are at least 12 years old
- Australian prescription medicine decision summaries:

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- Raniviz ([ranibizumab](#)) is approved to treat visual impairment issues
- Aquipta ([atogepant](#)) is approved for prophylaxis of migraine in adults
- Givlaari ([givosiran](#)) is approved to treat acute hepatic porphyria
- Sohonos ([palovarotene](#)) is approved to reduce the formation of heterotopic ossification
- Beyfortus ([nirsevimab](#)) is approved for the prevention of respiratory syncytial virus (RSV) in neonates, infants and vulnerable children up to the age of 24 months
- Spevigo ([spesolimab](#)) is approved for the treatment of flares in adult patients with generalised pustular psoriasis
- Heparin Interpharma ([heparin sodium](#)) is approved for prophylaxis and treatment of deep vein thrombosis in patients 18 years and older

### Victorian Institute of Forensic Medicine

- Clinical Communiqué Volume 10 Issue 4 December 2023 - [link](#)

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Canadian Agency for Drugs and Technologies in Health

- Leucovorin Dosing for Gastrointestinal Cancer – [link](#)
- Ketamine for Chronic Non-Cancer Pain: A 2023 Update - [link](#)
- Horizon scan: Emerging Drugs for Relapsed or Refractory Peripheral T-Cell Lymphoma - [link](#)
- Reference list: Screening for Thyroid Dysfunction Using Thyroid Stimulating Hormone Testing - [link](#)

### electronic Medicines Compendium (eMC) (UK)

- [New products](#)
- Colextra-D3 (Colecalciferol) 20,000 IU Soft Capsules for prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk. It may be used as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency
- Kalydeco (ivacaftor) granules in sachet - monotherapy for cystic fibrosis (CF) in children ≥1 month, weighing 3-25kg with specific CFTR mutations. Also licensed as part of ivacaftor/tezacaftor/elexacaftor regimen for CF in children aged 2-5yrs who have ≥1 F508del mutation
- Hydrocortisone 10mg/5ml and 5mg/5ml oral solutions licensed for replacement therapy in adrenal insufficiency in infants, children and adolescents (from 1 month to <18 years old)
- Veoza ([fezolinetant](#)) tablets - non-hormonal selective neurokinin 3 receptor antagonist licensed for the treatment of moderate to severe vasomotor symptoms associated with menopause
- New indications/expanded access
- Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide fumarate) - extension for use in paediatric patients from age 2 years, weighing at least 14kg for the treatment of HIV 1, without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir
- Evrysdi (risdiplam) for all age groups (previously for use from age 2 months and older). It now includes data from the RAINBOWFISH trial in 18 patients with pre-symptomatic spinal muscular atrophy between 16 and 40 days of age
- NuvaXovid dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted) - extension as a booster dose in the adolescent population from 12 to 18 years, including as a heterologous booster
- Zerbaxa (tazobactam and ceftolozane) - extension for Zerbaxa for complicated intra-abdominal infection, acute pyelonephritis and complicated urinary tract infections in paediatric patients

### European Medicines Agency (EMA)

- Human medicines: highlights of [2023](#) – and of [2024](#)
- CHMP approved new indications
- [HyQvia](#) (human normal immunoglobulin) for use in adults, children and adolescents with chronic inflammatory demyelinating polyneuropathy, as maintenance immunomodulatory therapy after stabilization with IVIg
- Tenecteplase ([Metalyse](#)) for thrombolytic treatment of acute ischaemic stroke in adults, within 4.5 hours from last known well and after exclusion of intracranial haemorrhage – also new formulation/strength of 5000 units (25 mg) powder for solution for injection

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CHMP approved extensions of use

- bezlotoxumab ([Zinplava](#)) for prevention/recurrence of CDI in all patients aged 1 year and older
- [VeraSeal](#) (human fibrinogen/human thrombin) for improvement of haemostasis and as suture support in vascular surgery for all age groups
- CHMP marketing authorisation
- [Dabigatran Etxilate Leon Farma](#) generic to Pradaxa – [SPS commentary](#)
- eribulin ([Mevlyq](#)) generic to Halaven for the treatment of breast cancer and liposarcoma
- [etrasimod](#) (Velsipity) for treatment of ulcerative colitis
- [ibuprofen Gen.Orph](#) generic to Pedea for the treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants
- [omaveloxolone](#) (Skyclarys) for the treatment of Friedreich's ataxia
- [Pomalidomide Viatris](#) generic to Imnovid for the treatment of multiple myeloma

### Food and Drug Administration (FDA) USA

- New Drug approvals
- Two gene therapies (Casgevy and Lyfgenia) to treat sickle cell disease - [link](#)
- [pembrolizumab](#) with chemoradiotherapy for FIGO 2014 Stage III-IVA cervical cancer
- [Filsuvez](#) (birch triterpenes) to treat wounds associated with dystrophic and junctional epidermolysis bullosa
- [Wainua](#) (eplontersen) to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis
- Berdazimer topical ([Zelsuvmi](#)) - topical nitric oxide–releasing agent for molluscum contagiosum in patients aged 1 year and older
- Roflumilast topical ([Zoryve](#)) - new foam dosage form and new indication approved for seborrheic dermatitis in patients aged 9 years and older
- Immune globulin IV ([Bivigam](#)) - indication for primary immunodeficiency expanded to include children aged 2 years and older
- Enfortumab Vedotin Plus Pembro for Urothelial Cancer - [link](#)
- Tralokinumab for Treating Eczema in Adolescents - [link](#)
- Antiparasitic for High-Risk Neuroblastoma - [link](#)
- Iptacopan to Treat Paroxysmal Nocturnal Hemoglobinuria - [link](#)
- Idacio ([Adalimumab-Aacf](#)), tumor necrosis factor (TNF) blocker

### Health Canada

- Handbook for healthcare professionals on biosimilar biologic drugs - [link](#)

### Health Services Safety Investigation Body

- Electronic patient record systems: recurring themes arising from safety investigations - [link](#)

### Medicines and Healthcare products Regulatory Agency (MHRA)

- Opdualag licensed for patients with advanced melanoma - [link](#)

### NHS Scotland - Scottish Medicines Consortium

- Accepted for use:
- [Bimekizumab](#) (Bimzelx®) for axial spondyloarthritis
- [Cemiplimab](#) (Libtayo®) for cutaneous squamous cell carcinoma
- [Cipaglucosidase alfa](#) (Pombiliti®) for Pompe disease – [SPS commentary](#)
- [Degarelix](#) (Firmagon®) for prostate cancer
- [Deucravacitinib](#) (Sotyktu®) for plaque psoriasis
- [Nivolumab](#) (Opdivo®) for non-small cell lung cancer
- [Trastuzumab](#) deruxtecan (Enhertu®) for unresectable or metastatic HER2-low breast cancer

### National Institute for Health and Care Excellence (NICE) UK

- Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer ([TA939](#))
- Risdiplam for treating spinal muscular atrophy, updated ([TA755](#))

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- Empagliflozin for treating chronic kidney disease ([TA942](#)) – [SPS commentary](#)
- Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes ([TA943](#))
- Targeted-release budesonide for treating primary IgA nephropathy ([TA937](#))
- Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer ([TA944](#))
- Velmanase alfa for treating alpha-mannosidosis - Highly specialised technologies guidance ([HST29](#))
- Sebelipase alfa for treating Wolman disease ([HST30](#))
- Cardiovascular disease: risk assessment & reduction, including lipid modification, updated ([NG238](#)) – [SPS commentary](#)
- Acne vulgaris: management ([NG198](#))
- NICE publishes additional resources to support implementation of guidance on digitally enabled therapies for adults with anxiety disorders ([HTE9](#)) or depression ([HTE8](#)) – [SPS commentary](#)
- Epilepsies in children, young people and adults ([QS211](#))
- Transition from children's to adults' services ([QS140](#))
- Bipolar disorder: assessment and management, updated ([CG185](#))

#### **National Institute for Health and Care Research (NIHR)**

- NIHR alert: Women need support to improve their health before pregnancy - [link](#)
- NIHR Alert: Tool could reduce blood test monitoring for most people on methotrexate - [link](#)
- The potential impact of policies and structural interventions in reducing cardiovascular disease and mortality: a systematic review of simulation based studies - [link](#)

#### **Neonatal & Paediatric Pharmacists Group**

- Guideline for peripheral use of adrenaline and noradrenaline in paediatric patients without central access - [link](#)

#### **Scottish Intercollegiate Guideline Network (SIGN) UK**

- Perinatal mental health conditions: [SIGN 169](#)

#### **Specialist Pharmacy Services NHS UK**

- Supporting adherence: [Complex medication regimens](#) ([SPS commentary](#)), [Defining and understanding medication adherence](#) ([SPS commentary](#)), [Explaining how to use or take medicines](#) ([SPS commentary](#)), [Manual dexterity](#) ([SPS commentary](#)), [Reminding to take medicines](#) ([SPS commentary](#)), [Swallowing difficulties](#) ([SPS commentary](#))
- Natalizumab biosimilar: patient information sheet - [link](#)
- Use of nefopam for chronic pain - [link](#)
- SPS spotlight monthly digest – [December 2023](#)

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### **MEDICATION SAFETY**

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#### **All Wales Therapeutics and Toxicology Centre**

- Withdrawal of national desflurane contract in Wales - [link](#)

#### **British National Formulary**

- BNF/BNFC Newsletter: [December 2023](#)
- includes: MHRA advice on reports of myasthenia gravis with statins, updated guidance for prevention of secondary cases of diphtheria, and updated safety information to highlight difference between benzylpenicillin sodium and benzathine benzylpenicillin

#### **electronic Medicines Compendium (eMC) (UK)**

- [Revised SPCs](#)
- Avelox (moxifloxacin) - possible risk of prolonged, disabling & potentially irreversible serious ADRs highlighted – [SPS commentary](#)
- Azacitidine Seacross - cutaneous vasculitis added as undesirable ADR (unknown frequency)

- Beovu (brovacizumab) dosing for wet age-related macular degeneration and the treatment timelines for the diabetic macular oedema indication updated
- Brintellix (vortioxetine hydrobromide) - dyspepsia, akathisia, bruxism, trismus, restless leg syndrome, tremor, discontinuation syndrome, vision blurred, and galactorrhoea included as ADRs
- Brukinsa (zanubrutinib) - updated information on interactions between zanubrutinib and moderate (fluconazole and diltiazem) and strong (voriconazole and clarithromycin) CYP3A inhibitors, which resulted in increased zanubrutinib exposures
- Ciproxin (ciprofloxacin) - possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted – [SPS commentary](#)
- EpiPen Adrenaline (epinephrine) - additional side effects under cardiac, respiratory & administration site disorders and to state “adrenaline excreted in breast milk would not have effect on nursing infant”
- Erythromycin ethyl succinate - 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 – [SPS commentary](#)
- Enbrel (etanercept) - glomerulonephritis is now listed as a potential ADR (frequency unknown)
- Femoston-conti estradiol hemihydrate/dydrogesterone) - contraceptives containing oestrogens shown to significantly decrease plasma concentrations of lamotrigine, potentially lowering seizure control, and although interaction between HRT & lamotrigine not been studied, it is expected that similar interaction exists
- Furosemide - lichenoid reactions as a rare ADR
- Kalydeco - concomitant use of CYP3A inhibitors updated to advise dose reduction is based on dose recommended for the age and weight and to refer to Table 2 for the recommended dose
- Mayzent (siponimod fumaric acid) information added on squamous cell carcinoma, herpes viral infection, cryptococcal meningitis and monitoring of treatment effect on lymphocytes
- Moxifloxacin - risk of disabling and potentially long-lasting or irreversible ADRs, sometimes affecting multiple systems, with fluoroquinolone antibiotics – use only when other antibiotics are inappropriate – [SPS commentary](#)
- Nivestim (filgrastim) - in post-marketing setting, myelodysplastic syndrome and acute myeloid leukaemia have been associated with the use of pegfilgrastim, an alternative G-CSF medicine, in conjunction with chemotherapy and/or radiotherapy in breast and lung cancer patients
- Octasa (mesalazine) - eosinophilia and systemic symptoms (DRESS) as an ADR and to note mesalazine may produce red-brown discolouration after contact with sodium hypochlorite bleach
- Protium (pantoprazole) - severe cutaneous ADRs, reports of false-positive results in some urine screening tests for tetrahydrocannabinol, and updated information on undesirable effects
- Rozlytrek (entrectinib) - use in patients with congestive heart failure (CHF) updated to note CHF reported in less than 5% of patients with/without a history of cardiac disease in clinical trials with entrectinib. Reactions resolved in 70% of those patients after appropriate management
- Suboxone Tablets (naloxone/buprenorphine) - recommended starting dose in adults and adolescents >15 years is 4 mg/1 mg and can be repeated up to a maximum dose of 12 mg/ 3 mg on day 1 to minimise undue withdrawal symptoms and retain the patient in treatment
- Targinact (oxycodone/naloxone) – more added on treatment goals and discontinuation. Central sleep apnoea syndrome (unknown frequency) and drug dependence (rare) added as ADRs, and toxic leukoencephalopathy after an oxycodone overdose – [SPS commentary](#)
- Tecfidera (dimethyl fumarate) - Tecfidera pregnancy registry study results included, in which 289 prospectively collected pregnancy outcomes were documented in patients with MS who were exposed to dimethyl fumarate
- Tezspire (tezepelumab) - anaphylactic reaction a possible ADR (unknown frequency)
- Tixylix Cough Syrup - pharmacodynamic properties now mentions that glycerol has demulcent properties and may possibly block sensory cough receptors in the respiratory tract
- Zamadol (tramadol hydrochloride) risk of dependence and addiction with opioids - [SPS commentary](#)
- Risk minimisation materials
- Casgevy (exagamglogene autotemcel): Patient Alert Card - for patients to carry with them at all times, & notifies healthcare professionals the patient has received this treatment. Patients are at increased risk of bleeding due to possibility of a prolonged period of thrombocytopenia prior to platelet engraftment

-- [Tresiba®](#) (insulin degludec) - safety information for healthcare professionals regarding two product strengths, 100units/mL & 200units/mL, and potential risk of dosing error. Both pens have dose display set in the dial in UNITS so no dose conversion is required if transferring patients between strengths – [SPS commentary](#) – and [poster](#) – [SPS commentary](#)

### **EMA**

- First version of the European Union (EU) list of critical medicines agreed to help avoid potential shortages in the EU – [link](#) – [SPS commentary](#)  
- PRAC meeting [highlights](#): New safety information for healthcare professionals: new precautionary measures for valproate-containing medicines; Start of safety review of CAR T-cell medicines  
- Potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines: PRAC recommends precautionary measures - [link](#)

### **Food and Drug Administration (FDA) USA**

- Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity - [link](#)  
- Updates to labelling for promethazine hydrochloride injection products - [link](#)  
- Updates to labelling for Two Cholesterol-Lowering Agents - [link](#)

### **Institute for Safe Medication Practices (ISMP) USA**

- Medication Safety Alert! [January 11, 2024](#)  
-- High-Alert Medication List for acute care settings updated for 2024 - [link](#)  
- Medication Safety Alert! [December 14, 2023](#)  
-- ISMP 26th Annual Cheers Awards: Hitting the Safety High Notes - [link](#)

### **MedEffect, Canada**

- Health Product InfoWatch, [December 2023](#)

### **Medicines and Healthcare products Regulatory Agency (MHRA) UK**

- MHRA update on new study on risk in children born to men taking valproate - [link](#)  
- Drug Safety Update [December 2023](#)  
-- Aripiprazole (Abilify and generic brands): risk of pathological gambling - [link](#)  
-- Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions – [link](#) – [SPS commentary](#)

### **Medsafe (New Zealand Medicines and Medical Devices Safety Authority)**

- Prescriber Update – [December 2023](#) includes  
-- Spotlight on dulaglutide - [link](#)  
-- Discuss possible effects on uterine bleeding in people taking oral anticoagulant therapy - [link](#)  
- DPP-4 inhibitors and the possible risk of ileus - [link](#)  
- Sodium valproate (Epilim) use in people who can father children: important new safety [information](#)

### **MIMS monthly updates – [January 2024](#)**

- New Contraindications  
-- Romosozumab ([Evenity](#)) in patients with a history of myocardial infarction or stroke  
-- Trimethoprim and sulfamethoxazole ([Septrin](#) Sugar Free Oral Liquid) in patients with documented megaloblastic anaemia due to folate deficiency, evidence of marked parenchymal damage or blood dyscrasia; in pregnancy (any stage) and in nursing mothers

### **Specialist Pharmacy Services NHS UK**

- Using vitamin D during breastfeeding - [link](#)  
- Managing interactions with methotrexate - [link](#)  
- Using metronidazole during breastfeeding - [link](#)  
- Medication safety update: [December 2023](#)  
- Managing interactions with direct oral anticoagulants (DOACs) - [link](#) – [SPS commentary](#)

- Understanding direct oral anticoagulant (DOAC) interactions - [link](#) – [SPS commentary](#)

### TGA

- Shortages: [Vyvanse](#) (lisdexamfetamine dimesilate) capsules and [update](#), [Bicillin L-A](#) (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection, Substitution approved for [fluoxetine 20 mg dispersible](#) tablets (Zactin Tabs)
- Product Information safety updates - [December 2023](#)
- Romosozumab (Evenity) - new warnings about the risk of heart attack and stroke - [link](#)
- Compounding safety information: semaglutide-like products - [link](#)
- Products containing undeclared sildenafil: [BAIWEI Maximum Powerful](#) tablets, [Bigger Longer More Time More Sperms](#) capsules, [Ying Da Wang](#) tablets - blood pressure may be lowered to dangerous levels
- Product containing undeclared sibutramine: [Li Da Daidaihua](#) capsules - increased risk of cardiac events and stroke
- Safety alert and product recalls: updated advice following *Ralstonia pickettii* contamination of some saline products - [link](#)

### UK Health Security Agency

- Vaccine update: issue 344, November 2023, pregnancy special - [link](#)

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## PAPERS OF INTEREST

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### Annals of Emergency Medicine

- Tranexamic acid for traumatic injury in the emergency setting: A systematic review and bias-adjusted meta-analysis of randomized controlled trials - [link](#)

### Annals of Internal Medicine

- Cumulative Incidence of Thiazide-Induced Hyponatremia: A Population-Based Cohort Study - [link](#) – [SPS commentary](#)

### Arthritis & Rheumatology

- Poly-refractory Rheumatoid Arthritis: An Uncommon Subset of Difficult to Treat Disease with Distinct Inflammatory and Non-inflammatory Phenotypes - [link](#)
- The incidence of uveitis in patients with axial spondylarthritis treated with biologics or targeted synthetics: a systematic review and network meta-analysis - [link](#)

### Australian Prescriber

- Physical health monitoring for people with schizophrenia - [link](#)
- Editorial: National Medicines Policy 2.0—what's changed and what's next? - [link](#)
- Gabapentinoids: a therapeutic review - [link](#)
- Ongoing challenges of off-label prescribing - [link](#)
- Top 10 drugs [2021–22](#); Top 10 drugs [2022–23](#)
- Herpes zoster (shingles) vaccination update - [link](#)
- New drugs: [Pneumococcal 15-valent and 20-valent conjugate vaccines](#) for prevention of pneumococcal disease; [Tirzepatide](#) for type 2 diabetes; [Vericiguat](#) for chronic heart failure

### BMC Med

- Development of prescribing indicators related to opioid-related harm in patients with chronic pain in primary care- a modified e-Delphi study - [link](#)

### British Journal of Clinical Pharmacology

- Pharmacokinetics of ceftazidime-avibactam in a critically ill patient under high-volume continuous venovenous haemodiafiltration: A first paediatric case report - [link](#)
- Plasma 6 $\beta$ -hydroxycortisol to cortisol ratio as a less invasive cytochrome P450 3A phenotyping method - [link](#)

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- The correlation between 4 adherence measurements methods in patients with rheumatoid arthritis using methotrexate - [link](#)
- Enteral Administration of Crushed Rilpivirine in a Patient with HIV: A Case Report - [link](#)
- Effect of changes in metabolic enzymes and transporters on drug metabolism in the context of liver disease: impact on pharmacokinetics and drug-drug interactions - [link](#)

### **British Journal of Psychiatry**

- Features of immunometabolic depression as predictors of antidepressant treatment outcomes: pooled analysis of four clinical trials - [link](#)

### **British Medical Journal (BMJ)**

- Europe suspends hundreds of generic drugs over serious data concerns - [link](#)
- Advances in the management of pancreatic cancer - [link](#)
- Management of chronic pain secondary to temporomandibular disorders: a systematic review and network meta-analysis of randomised trials – [link](#) – [SPS commentary](#)

### **BMJ Open**

- Clinical impacts of an integrated electronic health record-based smoking cessation intervention during hospitalisation - [link](#)
- Adverse drug events associated with nortriptyline compared with paroxetine and alternative medications in an older adult population: a retrospective cohort study in Southern California - [link](#)

### **BMJ Quality & Safety**

- Initial opioid prescription characteristics and risk of opioid misuse, poisoning and dependence: retrospective cohort study - [link](#)

### **Circulation**

- Dapagliflozin and Apparent Treatment-Resistant Hypertension in Heart Failure with Mildly Reduced or Preserved Ejection Fraction: The DELIVER Trial - [link](#)
- Current Status and Principles for the Treatment and Prevention of Diabetic Foot Ulcers in the Cardiovascular Patient Population: A Scientific Statement From the American Heart Association - [link](#)
- Flecainide is associated with a lower incidence of arrhythmic events in a large cohort of patients with catecholaminergic polymorphic ventricular tachycardia - [link](#)

### **Circ Heart Fail**

- Effect of Dapagliflozin Versus Placebo on Symptoms and 6-Minute Walk Distance in Patients with Heart Failure: The DETERMINE Randomized Clinical Trials - [link](#)

### **Cochrane**

- Pharmacological interventions for the prevention of bleeding in people undergoing elective hip or knee surgery: a systematic review and network meta-analysis - [link](#)
- Anticoagulation for people receiving long-term haemodialysis - [link](#)
- Vitamin B12 supplementation during pregnancy for maternal and child health outcomes - [link](#)
- Ibuprofen for acute postoperative pain in children - [link](#)
- Population-based interventions for preventing falls and fall-related injuries in older people - [link](#)
- Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis - [link](#)
- Maintenance therapy for chronic lymphocytic leukaemia - [link](#)
- Pharmacological interventions for pruritus in adult palliative care patients - [link](#)
- Diclofenac for acute postoperative pain in children - [link](#)
- Lamotrigine add-on therapy for drug-resistant focal epilepsy - [link](#)
- Anticholinergic deprescribing interventions for reducing risk of cognitive decline or dementia in older adults with and without prior cognitive impairment - [link](#)
- Corticosteroids for preventing postherpetic neuralgia - [link](#)

### **Diabetes Care**

- Diabetes Care Standards of Care in Diabetes 2024 – [link](#) – [SPS commentary](#)
- Fetal Overgrowth and Preterm Delivery in Women With Type 1 Diabetes Using Insulin Pumps or Multiple Daily Injections: A Post Hoc Analysis of the EVOLVE Study Cohort - [link](#)
- Outcomes With Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Baseline Insulin Resistance - [link](#)

### **Diabetes, Obesity and Metabolism**

- Glucagon-like peptide-1 receptor agonists and risk of thyroid cancer: A systematic review and meta-analysis of randomised controlled trials - [link](#)
- Efficacy and safety of semaglutide 2.4 mg for weight loss in overweight or obese adults without diabetes: An updated systematic review and meta-analysis including the 2-year STEP 5 trial - [link](#)
- Effect of sodium-glucose cotransporter-2 inhibitors on myocardial infarction incidence: A systematic review and meta-analysis of randomized controlled trials and cohort studies - [link](#)

### **European Heart Journal**

- Oral anticoagulation after atrial fibrillation catheter ablation: benefits and risks - [link](#)
- Oral strategies to target proprotein convertase subtilisin/kexin type 9 and lipoprotein(a): the new frontier of lipid lowering - [link](#)

### **European Journal of Hospital Pharmacy**

- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags - [link](#)
- Therapeutic drug monitoring of vancomycin in the case of augmented renal clearance: a case report of a paediatric patient - [link](#)
- No effects of nirmatrelvir/ritonavir on darunavir plasma trough concentrations: a case report - [link](#)
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab - [link](#)
- Inhaled aztreonam lysine in the management of Pseudomonas aeruginosa in patients with cystic fibrosis: real-life effectiveness - [link](#)
- Evaluation of the stability of aciclovir in elastomeric infusion devices used for outpatient parenteral antimicrobial therapy - [link](#)

### **Heart**

- Cardiovascular sequelae of trastuzumab and anthracycline in long-term survivors of breast cancer – [link](#) – [SPS commentary](#)
- Diagnosis and management of resistant hypertension - [link](#)

### **Internal Medicine Journal**

- Transitioning patients from intravenous to subcutaneous infliximab and vedolizumab for inflammatory bowel disease: what is the opportunity cost of improving access to healthcare? - [link](#)

### **International Journal of Clinical Pharmacy**

- The prevalence of hepatic and thyroid toxicity associated with imatinib treatment of chronic myeloid leukaemia: a systematic review - [link](#)
- Assessing safety concerns of interstitial lung disease associated with antibody-drug conjugates: a real-world pharmacovigilance evaluation of the FDA adverse event reporting system - [link](#)
- Valproic acid for agitation in the intensive care unit: an observational study of psychiatric consults - [link](#)

### **JAMA**

- Metformin Plus Insulin for Preexisting Diabetes or Gestational Diabetes in Early Pregnancy: The MOMPOD Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Dementia in Women Using Estrogen-Only Therapy - [link](#)

### **JAMA Cardiology**

- Dual Antiplatelet Therapy De-Escalation in Stabilized Myocardial Infarction With High Ischemic Risk: Post Hoc Analysis of the TALOS-AMI Randomized Clinical Trial - [link](#)
- Optimization of Evidence-Based Heart Failure Medications After an Acute Heart Failure Admission: A Secondary Analysis of the STRONG-HF Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Dermatology**

- Risk of Paradoxical Eczema in Patients Receiving Biologics for Psoriasis - [link](#)

### **JAMA Internal Medicine**

- Safety of GLP-1 Receptor Agonists and Other Second-Line Antidiabetics in Early Pregnancy - [link](#)

### **JAMA Network Open**

- Mortality and Morbidity Among Individuals with Hypertension Receiving a Diuretic, ACE Inhibitor, or Calcium Channel Blocker - [link](#)

### **JAMA Neurology**

- Brexpiprazole for the Treatment of Agitation in Alzheimer Dementia: A Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Oncology**

- Research letter: GLP-1 Receptor Agonists and Colorectal Cancer Risk in Drug-Naive Patients With Type 2 Diabetes, With and Without Overweight/Obesity - [link](#)

### **JAMA Psychiatry**

- Pharmacologic Treatment of Schizophrenia Beyond Dopamine Receptor Blockade—Has Its Time Come Yet? - [link](#)
- Benzodiazepine Use During Pregnancy and Risk of Miscarriage - [link](#)

### **Journal of the American College of Cardiology**

- Safety and Tolerability of Inclisiran for Treatment of Hypercholesterolemia in 7 Clinical Trials - [link](#)

### **Journal of Pharmacy Practice and Research (JPPR)**

- Editorial: The challenge of drug prescribing for older people - [link](#)
- Multidisciplinary care of older adults in the emergency department to influence deprescribing in older adults: a cohort study - [link](#)
- Vitamin B12 deficiency in older people: a practical approach to recognition and management - [link](#)

### **Lancet Haematology**

- Indication and management of allogeneic haematopoietic stem-cell transplantation in myelofibrosis: updated recommendations by the EBMT/ELN International Working Group - [link](#)

### **Lancet Infectious Diseases**

- Guidelines for the management of Toxoplasma gondii infection and disease in patients with haematological malignancies and after haematopoietic stem-cell transplantation: guidelines from the 9th European Conference on Infections in Leukaemia, 2022 - [link](#)

### **Lancet Neurology**

- Corticosteroids versus clobazam for treatment of children with epileptic encephalopathy with spike-wave activation in sleep (RESCUE ESES): a multicentre randomised controlled trial - [link](#)
- Blood–brain barrier dysfunction in multiple sclerosis: causes, consequences, and potential effects of therapies - [link](#)
- Neurological adverse events of immune checkpoint inhibitors and the development of paraneoplastic neurological syndromes - [link](#)

### **Lancet Psychiatry**

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- Psychopharmacology in children and adolescents: unmet needs and opportunities - [link](#)
- Clozapine: past, present, and future - [link](#)

### **Lancet Oncology**

- Effect of baseline oestradiol serum concentration on the efficacy of anastrozole for preventing breast cancer in postmenopausal women at high risk: a case-control study of the IBIS-II prevention trial - [link](#)

### **Medical Journal of Australia**

- Chronic suppurative lung disease and bronchiectasis in children, adolescents and adults in Australia and New Zealand: TSANZ position statement summary - [link](#)
- Considerations of delayed gastric emptying with peri-operative use of glucagon-like peptide-1 receptor agonists - [link](#)
- Cough in Children and Adults: Diagnosis, Assessment and Management (CICADA). Summary of an updated position statement on chronic cough in Australia - [link](#)

### **New England Journal of Medicine**

- Mirvetuximab Soravtansine in FR $\alpha$ -Positive, Platinum-Resistant Ovarian Cancer - [link](#)
- Chronic Lymphocytic Leukemia Therapy Guided by Measurable Residual Disease - [link](#) – [SPS commentary](#)
- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone (D-VRd) for Multiple Myeloma - [link](#)
- Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults – [link](#) – [SPS commentary](#)
- Cannabis-Related Disorders and Toxic Effects - [link](#)

### **Pediatrics**

- Vaccine Effectiveness Against Long COVID in Children - [link](#)
- Case report: Neonatal Opioid Withdrawal Syndrome Following Prenatal Use of Supplements Containing Tianeptine - [link](#)
- Advances in the Care of Infants With Prenatal Opioid Exposure and Neonatal Opioid Withdrawal Syndrome - [link](#)

### **Pharmaceutical Journal**

- Coroner advises NHS England to take action to raise awareness about interaction between tramadol and warfarin following death of a patient - [link](#)
- Pharmaceutical journal develops new series of articles mapped to Royal Pharmaceutical Society's 'competency framework for all prescribers' - [link](#)

### **Pharmacotherapy**

- Multicenter study evaluating target attainment of anti-Factor Xa levels using various enoxaparin prophylactic dosing practices in adult trauma patients - [link](#)
- Real world study on elexacaftor-tezacaftor-ivacaftor impact on cholesterol levels in adults with cystic fibrosis - [link](#)
- Is reversal of anticoagulants necessary in neurologically intact traumatic intracranial hemorrhage? - [link](#)
- Identification of risk factors associated with acute kidney injury in patients taking sodium-glucose cotransporter-2 inhibitors - [link](#)
- Clinical outcomes associated with anti-Xa-monitored enoxaparin for venous thromboembolism prophylaxis - [link](#)

### **Prescribe International – [January 2024](#) includes**

- Editorial "[Safety signals: why bother?](#)"; Abemaciclib (Verzenio<sup>®</sup>), palbociclib (Ibrance<sup>®</sup>) & ribociclib (Kisqali<sup>®</sup>) added to an aromatase inhibitor in certain breast cancers; When the cause of a disorder is not immediately obvious: could a drug be responsible?; Prescribing cascades: recognise them and take corrective action; Defending the right to compensation for the victims of drug-induced harms

### **Stroke**

- Management of Poststroke Hyperglycemia: Results of the TEXAIS Randomized Clinical Trial - [link](#)

### **Thorax**

- Influence of age on clinical characteristics, pharmacological management and exacerbations in children with asthma - [link](#)

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## **WEBINARS & PODCASTS**

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### **Australian Prescriber Podcasts**

- [Episode 153](#) – Blood glucose monitoring devices
- [Episode 154](#) – An update on wound management
- [Episode 155](#) – Digital health and prescribing

### **MJA Podcasts**

- The importance of medical record management - [link](#)

### **Purple Pen Podcast**

- [PPP156](#) - Cholesterol Update – link

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## **UPCOMING EVENTS**

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### **AHHA**

- A Discussion of the National Health Reform Agreement, member-only virtual roundtable, Tuesday 20th February 12pm to 1:30pm AEDT - [link](#)

### **FIP**

- Advancing future pharmacy and pharmaceutical sciences: Launch of the FIP AIM academic capacity assessment tool, webinar, 24 January 2024, 14:00 - 15:30 CET - [register](#)
- Climate change and vector-borne neglected tropical diseases: Positioning pharmacy practice to drive awareness, prevention and management, webinar, 30 January 2024, 15:00 - 16:30 CET - [register](#)
- Optimising cancer care: community pharmacy strategies to support patients on oral treatment, webinar, 1 February 2024, 15:00 - 16:30 CET - [register](#)