



NSW  
Therapeutic  
Advisory  
Group Inc.

Advancing  
quality use  
of medicines  
in NSW

## TAG Mail: August to December 2023

### Cumulative Listing of Reports, Publications, Medication Safety Fortnightly TAG Mail – resources list 7<sup>th</sup> December 2023

This is the last TAG Mail for 2023. It will resume on the 18<sup>th</sup> of January 2024.

**NSW TAG wishes everyone a very happy Festive Season and  
Best wishes for an enriching stress-free 2024.**



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#### NSW TAG ACTIVITIES

Open email discussions Contact [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

##### 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> December 2023**.

##### 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 **8<sup>th</sup> December 2023**.

##### Recently completed email discussions

- IPU processes and required documentation

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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

- DTC management of off-label GLP-1 analogues for the management of obesity, particularly in hospitals with Familial Metabolic Health Services or similar
- Local DTC management of andexanet alfa

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

### **CATAG Survey**

Several of the published Commission's Clinical Care standards (CCS) involve the use of medicines. As part of CATAG's work plan with the ACSQHC, CATAG agreed to conduct a survey of DTCs, about implementation of Clinical Care Standards (with specific reference to those standards and indicators about medicines). Australian DTCs are requested to respond.

The survey is available at <https://www.surveymonkey.com/r/WSL9FC3> Closes 22 December 2023.

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

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

- NMS 2023 webcast recording now available - [link](#)
  - Draft Chronic Obstructive Pulmonary Disease Clinical Care Standard- [link](#)
- Consultation period ends 18 December 2023.

#### **NSW Health**

- Reporting for Aged Care Services ([PD2023\\_042](#))
- Data Breaches Involving Personal or Health Information ([PD2023\\_040](#))
- Pharmaceutical and Safety Net Arrangements for Outpatients and Patients on Discharge ([PD2023\\_041](#))

#### **Pharmacy Board of Australia**

- Have your say on draft guidelines for practitioners who perform and who advertise non-surgical cosmetic procedures - [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](#)

- PROMS Methods for analysis and reporting - [link](#)
- PCA NCA Weight-based Chart (paediatric) - [link](#)

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

- Antibiotic shortages
- Clinicians working in the Aboriginal and Torres Strait Islander health sector- [link](#)
- Aboriginal and Torres Strait Islander – Consumer- [link](#)

#### **Australian Alliance for Artificial Intelligence in Healthcare**

- A National Policy Roadmap for Artificial Intelligence in Healthcare - [link](#)

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

- Launch of Australia's first National Health and Climate Strategy - [link](#) - [Resources collection](#)

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

- The health of people in Australia's prisons 2022 - [link](#)
- Family, domestic and sexual violence - [link](#)
- Hip fracture care pathways in Australia - [link](#)
- Health system spending on the response to COVID-19 in Australia 2019-20 to 2021-22 - [link](#)
- Health system spending on disease and injury in Australia, 2020-21 - [link](#)
- Geographical variation in health service use by people living with dementia - [link](#)

- National Cervical Screening Program monitoring report 2023 - [link](#)
- Eye health measures for Aboriginal and Torres Strait Islander people 2023 - [link](#)
- Ear and hearing health of Aboriginal and Torres Strait Islander people 2023 – [link](#)
- MyHospitals: Emergency department care [2022-23](#) and Elective surgery waiting times [2022-23](#)

### Deeble Institute

- Describing the Primary Care Journey for Patients with Musculoskeletal Pain – perspectives [brief](#)

### MIMS monthly updates – [December 2023](#)

- New Products
- Nelarabine (Nelarabine-Reach) - pro-drug of the deoxyguanosine analogue ara-G indicated for relapsing/ refractory T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma when disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. Approved via early access until 30 April 2024
- New Presentation
- Omeprazole (Omeprazole ADVZ) is now available as a powder for oral suspension, 2 mg/mL or 4 mg/mL in 90 mL of suspension

### PSA

- Medicine safety: mental health care- [link](#)

### TGA

- New regulations to place stronger controls on importation, manufacture and supply of vapes - [link](#)
- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### British National Formulary

- BNF/BNFC newsletter [October 2023](#) [November 2023](#)

### Commonwealth Fund

- The Cost of Not Getting Care: Income Disparities in the Affordability of Health Services Across High-Income Countries. Findings from the Commonwealth Fund 2023 International Health Policy Survey- [link](#)

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

- [New products](#)
- Tepkinly (epcoritamab) injection - bispecific antibody that binds to CD3 on T-cells and CD20 on B-cells, licensed for adults with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy – [SPS commentary](#)
- Casgevy 4-13 x 10<sup>6</sup> cells/mL dispersion for infusion (exagamglogene autotemcel) - gene therapy licensed for transfusion-dependent  $\beta$ -thalassemia and sickle cell disease in patients  $\geq 12$  years for whom haematopoietic stem cell transplantation is appropriate and a HLA matched related haematopoietic stem cell donor is not available
- Abrysvo (RSV vaccine; bivalent, recombinant) for passive protection against lower respiratory tract disease caused by RSV in infants from birth through 6 months of age following maternal immunisation during pregnancy, and also for active immunisation of individuals 60 years of age and older
- [New indications](#)
- Imfinzi (durvalumab) - for use in combination with tremelimumab for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma.
- Opdivo (nivolumab) - new indication of adjuvant treatment of adults with Stage IIB or IIC melanoma, or melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection

### European Medicines Agency (EMA)

- EU medicines agencies reflect on lessons learned from COVID-19 - [link](#)

### European Pharmaceutical Review

- European Commission authorises zilucoplan (Zilbrysq) for generalised myasthenia gravis in adults - [link](#)

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

- New Drug approvals
- nirogacestat (Ogsiveo) for adult patients with progressing desmoid tumours who require systemic treatment - [link](#)
- pirtobrutinib for Previously Treated CLL/SLL - [link](#)
- fabhalta ([lptacopan](#)) – a complement factor B inhibitor, indicated for adults with paroxysmal nocturnal hemoglobinuria

### **Health Services Safety Investigation Body**

- Investigation report: Continuity of care: delayed diagnosis in GP practices- [link](#)

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

- MHRA launches online eligibility checker tool via the International Recognition Procedure – [link](#) – [SPS commentary](#)

### **MIMS UK**

- New MIMS resource for ADHD prescribing – [link](#) – [SPS commentary](#)

### **NHS England**

- National guidance to support integrated care boards to commission acute mental health inpatient services for adults with a learning disability and autistic adults - [link](#)
- Shared workforce model for pharmacists: optional guidance for employers - [link](#)
- Medicines repurposing programme: annual highlights - [link](#)

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

- Foslevodopa–foscarnidopa for treating advanced Parkinson’s with motor symptoms ([TA934](#))
- Secukinumab for treating moderate to severe hidradenitis suppurativa – guidance ([TA935](#))
- COVID-19 rapid guideline: managing COVID-19 ([update](#))

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

- Antibiotics make little difference to children’s chest infections - [link](#)
- Pelvic floor and bladder problems can make people feel embarrassed, and have an impact on everyday life - [link](#)
- How can we improve partnerships between healthcare providers? - [link](#)
- New biological treatments for lupus do not increase the risk of serious infections – [link](#)

### **Reform Scholars**

- Smart Prescribing: Harnessing technology in the fight against AMR - [link](#)

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

- SPS Monthly Digest, [November 2023](#)
- Net Zero and Social Value requirements in NHSE medicines tenders – [link](#) – [SPS commentary](#)
- Understanding unlicensed medicines - [link](#)
- Governance principles for unlicensed medicines - [link](#)
- Making unlicensed medicines - [link](#)
- Purchasing Specials - [link](#)

### **UK Health Security Agency**

- Swine influenza: how to spot the disease - [link](#)
- UK One Health Report 2023: Joint report on antibiotic use, antibiotic sales and antibiotic resistance - [link](#)
- HIV Action Plan monitoring and evaluation framework 2023 report - [link](#)
- Tuberculosis (TB) notifications reported to enhanced TB surveillance systems: UK, 2000 to 2022 - [link](#)

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

- Antimicrobial Surveillance Assessment Tool - [link](#)
- Therapeutic patient education: an introductory guide- [link](#)

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## MEDICATION SAFETY

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### AIHI

- Health Innovation Series: e Medication Safety -[link](#)
- Is your administration documentation accurate? Check fields that auto-populate!
- A mix of prescribing systems may be a recipe for disaster
- Default first dose times can cause deadly double doses
- How free-text fields can lead to medication errors

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

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

- Tecentriq (atezolizumab) - haemophagocytic lymphohistiocytosis (HLH), including fatal cases, reported. For suspected HLH, discontinue permanently & refer patients to a specialist for further diagnosis & management
- Betacap (betamethasone valerate) Scalp Application - long term use of topical steroids can result in development of rebound flares after stopping treatment (withdrawal syndrome), which takes form of dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area
- Qutenza (capsaicin) patch - information regarding progressive response with repeated treatments
- Cefalexin products - reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy with cephalosporins. Most cases occurred in patients with renal impairment on doses above the recommended maximum and resolved following discontinuation
- Co-Amoxiclav - hypersensitivity reactions can progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Linear IgA disease, acute pancreatitis and drug-induced enterocolitis syndrome also added as adverse effects
- Vaxzevria (Covid-19 Vaccine AstraZeneca) - Section 4.4 updated to include a warning about acute disseminated encephalomyelitis
- Motilium (domperidone) - restless legs syndrome and urticaria included as ADRs; observed increase of plasma levodopa concentration (max 30-40%) when taken with domperidone; discussion of recommended dosing in severe renal impairment
- Imfinzi (durvalumab) - Additional warnings and adverse effects for use in combination with tremelimumab also included
- Actimorph (morphine sulfate) - addition of treatment goals and discontinuation included, special warnings for severe cutaneous adverse reactions and hepatobiliary disorders, and interaction with gabapentin resulting in respiratory depression, hypotension, profound sedation, or coma
- Tagrisso (osimertinib mesylate) - toxic epidermal necrolysis included as an ADR with information on dose modifications if this occurs (Table 1). Table 2 (ADRs reported in trials) updated to include decreased appetite, and increased blood creatine and phosphokinase
- Propofol - co-administration with midazolam likely to result in enhanced sedation and respiratory depression. Consider dose reduction of propofol when used concomitantly with midazolam
- Kisqali (ribociclib) - safety data included on carcinogenicity based on non-clinical studies
- Janumet (sitagliptin/metformin) - Metformin component can lead to vitamin B12 deficiency. Frequency of ADR changed from very rare (less than 1 in 10,000) to common (between 1 in 10 and 1 in 100)
- Adcortyl (triamcinolone acetonide) - central serous chorioretinopathy added as ADR of unknown frequency
- VFEND (voriconazole) - warning for the increased risk of skin toxicity with concomitant use of voriconazole and methotrexate, and potentially other drugs associated with ultraviolet reactivation
- Risk minimisation materials
- Caffeine Citrate 10mg/mL solution for injection and 10mg/mL oral solution - card contains important points to consider, including monitoring, dosing instructions (including to specify dose clearly as caffeine citrate), and to caution not to confuse with another available formulation of caffeine citrate solution, which is a different strength
- Tepkinly (epcoritamab) patient card - discusses risk and symptoms of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, which may be serious or fatal if not treated promptly. It should be carried at all times and shown to any healthcare professional who sees the patient

- Actiq (fentanyl) lozenges, Fentanyl (Effentora) 100 mcg Buccal Tablets - include a patient/carer guide, a pharmacist's guide for dispensing, and a physician's guide for prescribing, to support their safe and appropriate use for the treatment of cancer breakthrough pain
- Byooviz (ranibizumab) - separate patient booklets for each indication, providing an overview of how the treatment works, how it is administered and what to expect, the key signs and symptoms of potential adverse reactions and when to seek urgent medical attention
- Tyenne (tocilizumab) pre-filled pens - dosing guide (for both the IV and SC formulations), a healthcare professional brochure (both of which form part of the Risk Management Plan), and a patient brochure and alert card, to help patients understand treatment risks
- Rinvoq (upadacitinib hemihydrate) – GI perforation added as an uncommon ADR. The vaccination section of 4.4 and the vaccine studies section of 5.1 have also been updated

## EMA

- New measures to avoid topiramate exposure in pregnancy in Europe – [link](#) – [SPS commentary](#)
- GLP-1 receptor agonists' review: PRAC requests further clarifications from marketing authorisation holders - [link](#)
- PRAC recommends measures to minimise the risk of serious side effects with medicines containing pseudoephedrine – [link](#) – [SPS commentary](#)
- List of medicines under additional monitoring - [link](#)

## Food and Drug Administration (FDA) USA

- FDA Drug Safety Communication: Rare but serious drug reaction linked to use of levetiracetam or clobazam - [link](#)

## Health Canada – MedEffect Notice

- Health Product InfoWatch, [November 2023](#) includes: Melatonin and increased accidental ingestions in children - [link](#)

## Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! [November 30, 2023](#) includes: Patients with Low Health Literacy Make More Errors Interpreting Instructions and Warnings; Vitrakvi (larotrectinib)

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

- Nirmatrelvir, ritonavir (Paxlovid): be alert to the risk of drug interactions with ritonavir - [link](#)
- Ozempic (semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products – [link](#) – [SPS commentary](#)
- NPSA Alert - Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients – [link](#) - [SPS commentary](#)
- MHRA instructs health organisations to prepare now for new measures to reduce ongoing serious harms of valproate - [link](#)
- Valproate use by women and girls - [link](#)
- Valproate: review of safety data and expert advice on management of risks - [link](#)
- Valproate safety measures - [link](#)
- Drug Safety Update [November 2023](#)
- Letters to Healthcare Professionals
- Oral isotretinoin: New safety measures following review into sexual and psychiatric adverse reactions – [link](#) – [SPS commentary](#)
- Expected shortage of guanfacine hydrochloride (Intuniv) prolonged-release tablets - [link](#) – [SPS commentary](#)

## MIMS monthly updates

- New Contraindications
- Dexamethasone ([Dexamethasone](#)) is now contraindicated in bacteraemia
- Prochlorperazine maleate or mesilate ([Stemetil](#)) is now contraindicated in simultaneous administration with desferrioxamine. It is also contraindicated in children as an intramuscular injection, in paediatric surgery, and in conditions for which dosage has not been established
- Trimethoprim ([Triprim](#)) is now contraindicated in severe hepatic insufficiency
- Safety Related Changes



-- Alteplase ([Actilyse](#)) is no longer contraindicated in patients with known hypersensitivity to gentamicin

### Specialist Pharmacy Service

- Implementing pharmacogenomic testing for aminoglycosides - [link](#)
- Managing interactions between macrolides and statins - [link](#)
- Medication Restrictions for Patients Having CAR-T Cell Therapy (version 5) - [link](#)
- Medication Restrictions for Patients Having CAR T-cell Therapy: Pan-UK Pharmacy Working Group for ATMPs - [link](#)
- Deprescribing of antidepressants for depression and anxiety - [link](#)
- Medication Safety Update [November 2023](#)

### TGA

- [Safety alert](#): potential contamination of some saline products with *Ralstonia pickettii*
- [Safety alert](#): action following potential contamination of some saline products with *Ralstonia pickettii*
- Safety advisory: [Fluoxetine](#), [Duloxetine](#)
- [Sitagliptin](#) diabetes medicines safety advisory

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## PAPERS OF INTEREST

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### Annals of Internal Medicine

- Impact of Finerenone-Induced Albuminuria Reduction on Chronic Kidney Disease Outcomes in Type 2 Diabetes: A Mediation Analysis - [link](#)
- Second-Line Chimeric Antigen Receptor T-Cell Therapy in Diffuse Large B-Cell Lymphoma – [link](#) – [SPS commentary](#)

### Arthritis & Rheumatology

- Clinical Evaluation and Management of Thrombotic Microangiopathy (TMA) - [link](#)
- Weight Loss Induced by Antiobesity Medications and All-Cause Mortality Among Patients with Knee or Hip Osteoarthritis - [link](#)

### British Journal of Clinical Pharmacology

- Opioid-related deaths and their counterpart by occurrence-era, age-group and co-implicated drugs: Scotland versus England and Wales - [link](#)
- Proton pump inhibitors: Weighing the benefits and risks across various health conditions - [link](#)
- The correlation between four adherence measurements methods in patients with rheumatoid arthritis using methotrexate - [link](#)
- A Physiological Approach to Renal Clearance - from Premature Neonates to Adults - [link](#)

### British Journal of Psychiatry

- Treatment with psychostimulants and atomoxetine in people with psychotic disorders: reassessing the risk of clinical deterioration in a real-world setting - [link](#)

### British Medical Journal (BMJ)

- Covid-19 vaccine effectiveness against post-covid-19 condition among 589 722 individuals in Sweden: population based cohort study – [link](#) – [SPS commentary](#)
- Implementation of a high sensitivity cardiac troponin I assay and risk of myocardial infarction or death at five years: observational analysis of a stepped wedge, cluster randomised controlled trial – [link](#) – [SPS commentary](#)
- Social media use and health risk behaviours in young people: systematic review and meta-analysis - [link](#)
- Politicians, experts, and patient representatives call for the UK government to reverse the rate of antidepressant prescribing - [link](#)
- Advances in the management of chronic kidney disease - [link](#)

### BMJ Leader

- Reducing unwarranted variation- can a clinical dashboard be helpful for hospital executive boards and top-level leaders - [link](#)

## **BMJ Open**

- Paediatric hospitalisation related to medications administration errors of non-opioid analgesics, antipyretics and antirheumatics in England and Wales: a longitudinal ecological study - [link](#)
- Cognitive task analysis of clinicians' drug–drug interaction management during patient care and implications for alert - [link](#)

## **Circulation**

- An Aspirin-Free Versus Dual Antiplatelet Strategy for Coronary Stenting: STOPDAPT-3 Randomized Trial - [link](#)
- Evolving Contemporary Management of Atrial Fibrillation in Hypertrophic Cardiomyopathy - [link](#)
- Critical Care Management of Patients After Cardiac Arrest: A Scientific Statement from the American Heart Association and Neurocritical Care Society - [link](#)
- 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation - [link](#)
- Update on Cardiovascular Implantable Electronic Device Infections and Their Prevention, Diagnosis, and Management: A Scientific Statement from the American Heart Association - [link](#)

## **Cochrane**

- Adverse effects of immunotherapies for multiple sclerosis: a network meta-analysis - [link](#)
- Nirmatrelvir combined with ritonavir for preventing and treating COVID-19 - [link](#)
- HMG CoA reductase inhibitors (statins) for people with chronic kidney disease not requiring dialysis - [link](#)
- Oral dextrose gel to prevent hypoglycaemia in at-risk neonates - [link](#)
- Pharmacological treatments in panic disorder in adults: a network meta-analysis - [link](#)
- Special collection: Coronavirus (COVID-19): evidence relevant to acute and critical care - [updated](#)

## **Diabetes Care**

- Automated Insulin Delivery Systems in Children and Adolescents With Type 1 Diabetes: A Systematic Review and Meta-analysis of Outpatient Randomized Controlled Trials - [link](#)
- Diabetes and Multiple Long-term Conditions: A Review of Our Current Global Health Challenge - [link](#)
- Occurrence of Gastrointestinal Adverse Events Upon GLP-1 Receptor Agonist Initiation With Concomitant Metformin Use: A Post Hoc Analysis of LEADER, STEP 2, SUSTAIN 6, and PIONEER 6 - [link](#)
- Association of Continued Use of SGLT2 Inhibitors From the Ambulatory to Inpatient Setting With Hospital Outcomes in Patients With Diabetes: A Nationwide Cohort Study - [link](#)

## **Drug and Therapeutics Bulletin**

- DTB Select: Changes in primary endpoints in cancer trials - [link](#)
- DTB select: Safety update: statins and myasthenia gravis (MG) - [link](#)
- Changing the complexity of therapeutic monitoring - [link](#)
- Continuity of care: good for patients, good for prescribing - [link](#)

## **E Clinical Medicine**

- Alternate day versus consecutive day oral iron supplementation in iron-depleted women: a randomized double-blind placebo-controlled study - [link](#)

## **European Heart Journal**

- Stroke and bleeding risk in atrial fibrillation with CHA2DS2-VASC risk score of one: the Norwegian AFNOR study - [link](#)

## **European Journal of Hospital Pharmacy**

- Using machine learning or deep learning models in a hospital setting to detect inappropriate prescriptions: a systematic review - [link](#)

## **European Pharmaceutical Review**

- New 36-month follow-up data from Phase III study of gene therapy Adstiladrin (nadofaragene firadenovec-vncg) presented at conference – [link](#) – [SPS commentary](#)

## **Healthcare Quarterly -[link](#)**

- Was Virtual Care as Safe as In-Person Care?



- Inspiring Leadership: How a Community Hospital Is Tackling Healthcare's Most Difficult Problems

### **Heart**

- Management of arrhythmias during pregnancy - [link](#)
- Interaction of genetic risk and lifestyle on the incidence of atrial fibrillation - [link](#)

### **Internal Medicine Journal**

- ANZTCT consensus position statement on ruxolitinib in steroid-refractory acute and chronic graft-versus-host disease - [link](#)
- Comparative effectiveness of etanercept originator and biosimilar for treating rheumatoid arthritis: implications for cost-savings - [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**

- Toripalimab Plus Chemotherapy for Recurrent or Metastatic Nasopharyngeal Carcinoma: The JUPITER-02 Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Obesity Management in Adults: A Review - [link](#)
- Sintilimab Plus Chemotherapy for Unresectable Gastric or Gastroesophageal Junction Cancer: The ORIENT-16 Randomized Clinical Trial - [link](#)

### **JAMA Dermatology**

- Risk of Suicide and Psychiatric Disorders Among Isotretinoin Users: A Meta-Analysis - [link](#) – [SPS commentary](#)

### **JAMA Psychiatry**

- Attention-Deficit/Hyperactivity Disorder Medications and Long-Term Risk of Cardiovascular Diseases – [link](#) – [SPS commentary](#)
- Antipsychotic Medications and Mortality in Children and Young Adults - [link](#)

### **Joint Commission Journal on Quality and Patients Safety**

- Key Strategies to Publishing Your Quality Improvement Work - [link](#)

### **Lancet**

- HIV epidemiology, prevention, treatment, and implementation strategies for public health - [link](#)

### **Lancet Diabetes & Endocrinology**

- Estimating dose-response relationships for vitamin D with coronary heart disease, stroke, and all-cause mortality: observational and Mendelian randomisation analyses – [link](#) – [SPS commentary](#)
- Effects of empagliflozin on progression of chronic kidney disease: a prespecified secondary analysis from the empa-kidney trial – [link](#) – [SPS commentary](#)
- Efficacy and safety of bempedoic acid among patients with and without diabetes: prespecified analysis of the CLEAR Outcomes randomised trial – [link](#) – [SPS commentary](#)

### **Lancet Haematology**

- Addition of danicopan to ravulizumab or eculizumab in patients with paroxysmal nocturnal haemoglobinuria and clinically significant extravascular haemolysis (ALPHA): a double-blind, randomised, phase 3 trial - [link](#)

### **Lancet HIV**

- HIV pre-exposure prophylaxis and its implementation in the PrEP Impact Trial in England: a pragmatic health technology assessment – [link](#) – [SPS commentary](#)

### **Lancet Infectious Diseases**

- Oral VV116 versus placebo in patients with mild-to-moderate COVID-19 in China: a multicentre, double-blind, phase 3, randomised controlled study - [link](#)

- Effectiveness of bivalent mRNA vaccines against medically attended symptomatic SARS-CoV-2 infection and COVID-19-related hospital admission among SARS-CoV-2-naive and previously infected individuals: a retrospective cohort study - [link](#)
- The global burden of fracture-related infection: can we do better? - [link](#)

### **Lancet Psychiatry**

- ADHD medication discontinuation and persistence across the lifespan: a retrospective observational study using population-based databases - [link](#)
- Evaluating the epidemiology of clozapine-associated neutropenia among people on clozapine across Australia and Aotearoa New Zealand: a retrospective cohort study - [link](#)

### **Lancet Oncology**

- Treatment-related adverse events, including fatal toxicities, in patients with solid tumours receiving neoadjuvant and adjuvant immune checkpoint blockade: a systematic review and meta-analysis of randomised controlled trials – [link](#) - [SPS commentary](#)

### **Lancet Respiratory Medicine**

- Balanced crystalloids versus saline for critically ill patients (BEST-Living): a systematic review and individual patient data meta-analysis – [link](#) - [SPS commentary](#)
- GOLD COPD report: 2024 update - [link](#)

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

- Pharmacist-Led Interventions for Medication Adherence in Patients with Chronic Kidney Disease: A Scoping Review - [link](#)
- Uncovering the Hidden Burden of Pharmaceutical Poisoning in High-Income and Low-Middle-Income Countries: A Scoping Review - [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](#)
- Updated National Health and Medical Research Council statement on electronic cigarettes - [link](#)
- Advancing the Australian global health community's commitment to climate change and global health - [link](#)

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

- Digital Technology for Diabetes - [link](#)

### **Obstetrics and Gynecology**

- Vaginal micronised progesterone for the prevention of hypertensive disorders of pregnancy: A systematic review and meta-analysis – [link](#) – [SPS commentary](#)

### **Pharmacotherapy**

- Cardiovascular adverse events in patients with hepatocellular carcinoma receiving vascular endothelial growth factor inhibitors - [link](#)

### **Prescribe International – December 2023**

- Includes: Patient characteristics; Nirsevimab (Beyfortus) to prevent RSV infection in infants; Negative post-marketing trials: often ignored; Ustekinumab (Stelara): no live vaccines before 6 months of age for infants who have been exposed in utero; Zonisamide: as dangerous as topiramate during pregnancy?; Drugs to avoid: an analysis of Australia's pharmaceuticals market

### **Research in Health Services & Regions**

- Managing unwarranted variation in hospital care – findings from a regional audit in Norway- [link](#)

### **The American Journal of Surgery**

- Surgical leadership in a culture of safety: An inter-professional study of metrics and tools for improving clinical practice - [link](#)

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

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

- Flexible Diuretic Regime Clinical Practice Guide, closes 10 December 2023 - [link](#)
- Ear, Nose and Throat (ENT) State-wide Referral Criteria for Public Outpatient Services, closes 15 December 2023 - [link](#)
- Orthopaedics State-wide Referral Criteria for Public Outpatient Services, closes 15 December 2023 - [link](#)
- Post-consultation Gastroenterology State-wide Referral Criteria for Public Outpatient Services, closes 15 December 2023 - [link](#)
- Post-Consultation Ophthalmology State-wide Referral Criteria for Public Outpatient Services, closes 15 December 2023 - [link](#)

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

- Chronic Obstructive Pulmonary Disease Clinical Care Standard, closes 18 December 2023 - [link](#)

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## **WEBINARS & PODCASTS**

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### **Australian Prescriber Podcasts**

- [Episode 152](#): Therapeutic Guidelines Diabetes

### **MJA Podcasts**

- [Episode 34](#): iron deficiency in the general Australian population
- [Episode 35](#): iron deficiency in Aboriginal and Torres Strait Islander peoples

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## **Fortnightly TAG Mail – resources list      23 November 2023**

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A fortnightly newsletter for quality use of medicine healthcare practitioners



**NSW TAG is celebrating  
its 35-year anniversary**  
***Australia's longest-running independent QUM organisation***

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### **NSW TAG ACTIVITIES**

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Open email discussions Contact [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

#### **1. 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 **8<sup>th</sup> December 2023**.

## 2. IPU processes and required documentation

has made the following enquiry regarding IPU processes, noting this is an expanding and ever-complex area for their paediatric cohort. They also note the NSW Medicines Formulary has introduced some challenges that require local management.

As part of their assessment of IPU processes, they are seeking responses from other sites:

- Does the Drug and Therapeutics Committee document IPU outcomes (approval, non-approval) in the patient's medical record?
- If yes, is this for all IPU applications or a subset?
- If yes, where do you document the outcome so that it can be easily found?
- Is there a local policy or process for this that you would be happy to share?

Closes **27<sup>th</sup> November 2023**.

## 3. How are DTCs, particularly from hospitals with Familial Metabolic Health Services or similar, managing the usage of off-label GLP-1 analogues for the management of obesity?

- Are they on the local formulary?
- Is there a cap on the number of patients to receive off-label GLP-1 analogues?
- Is all usage via IPU/ or streamlined IPU/ restricted formulary?
- Are there any other strategies being used to manage usage/costs?

Closes **Monday 27<sup>th</sup> November 2023**

### Recently completed email discussions

- Local DTC management of andexanet alfa
- Burns from amiodarone *Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions.*

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## OTHER NEWS (new additions in bold)

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

- AURA 2023: Fifth Australian report on antimicrobial use and resistance in human health - [link](#)
- Antimicrobial use falls, but no room for complacency due to AMR - [link](#)
- It's time to weigh up harm from antibiotics: new report - [link](#)
- Launch of the first national Cosmetic Surgery Standards - [link](#)

### NSW Health

- Public health warning: Heroin overdoses after using drug suspected to be cocaine - [link](#)
- NSW residents urged to Beat the Heat this summer - [link](#)
- Isolated Patients Travel and Accommodation Assistance Scheme ([PD2023\\_038](#))

### TGA

- New medicine adverse event search for sponsors - [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](#)

- Pain Management Network: Positive language in pain consultations - [link](#)

### AHHA

- Health Advocate, [November 2023](#) includes
  - Re-thinking the prevention and treatment of heart disease
  - Patient-initiated follow-up as a low-carbon alternative for cancer surveillance
  - The carbon footprint of dialysis

### Australian Government Department of Health

- ATAGI recommendations on use of the Moderna and Pfizer monovalent Omicron XBB.1.5 COVID-19 vaccines - [link](#)

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

- Mesothelioma in Australia 2022 - [link](#)
- Suicide & self-harm monitoring - [link](#)
- Serving and ex-serving Australian Defence Force members who have served since 1985: suicide monitoring 1997 to 2021 - [link](#)
- Oral health and dental care in Australia - [link](#)
- GEN: Younger people in residential aged care - [link](#)
- GEN Aged Care Data: Residential Aged Care Quality Indicators Annual Report 2022–23 - [link](#)
- Head injuries in Australia 2020–21 - [link](#)
- The health of people in Australia's prisons 2022 - [link](#)
- Australia's mothers and babies – update (Stillbirths and neonatal deaths; Maternal deaths) - [link](#)
- Health of mothers and babies - [link](#)
- Environmental scan and assessment of the feasibility of developing a national neonatal hearing screening data collection - [link](#)

### **CATAG publication**

- Draft document: '*Facilitating the translation of evidence into best practice: andexanet alfa in life-threatening bleeds*' [link](#)

### **PBS**

- Outcome Statement from the September 2023 DUSC Meeting - [link](#)
- PBAC Public Summary Documents – July 2023 meeting - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - Mounjaro ([tirzepatide](#)) to treat adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
  - Jivi ([damoctocog alfa pegol](#)) for previously treated adults and adolescents with haemophilia A for the prevention or treatment of bleeding
  - Korsuva ([difelikefalin](#)) to treat moderate-to-severe pruritus associated with chronic kidney disease in adults on haemodialysis

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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

- Decarbonisation: inhaler prescribing, use and disposal 2023–2030. A national strategy for Wales - [link](#)

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

- Chief Medical Officer's annual report 2023: health in an ageing – [link](#)
- JCVI advice on the use of meningococcal B vaccination for the prevention of gonorrhoea – [link](#) – [SPS commentary](#)

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

- [New products](#)
  - Talvey (talquetamab) 40 mg/mL injection - for adults with relapsed/refractory multiple myeloma, who have received ≥3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, and have demonstrated disease progression on the last therapy

### **European Medicines Agency (EMA)**

- First electronic product information (ePI) published for selected human medicines - [link](#)
- European CHMP adopts positive opinion for:
  - [adagrasib](#) for advanced non-small cell lung cancer with KRAS G12C mutation (Krazati)
  - approval of new paediatric indication and pharmaceutical form and strength for patiomer ([Veltassa](#))

- azacitidine generic ([Azacitidine Kabi](#))
- extension to existing indication for [evinacumab](#) in homozygous familial hypercholesterolaemia
- extension to existing indication for [Fluad Tetra](#) (influenza vaccine) – prophylaxis in adults 50+
- extension to existing indication for [NexoBrid](#) (concentrate of proteolytic enzymes enriched in bromelain)
- extension to existing type 2 diabetes mellitus indication for [empagliflozin](#) to include use in children
- [momelotinib](#) for disease-related splenomegaly or symptoms in adults with moderate-to-severe anaemia and myelofibrosis
- new indication for [avapritinib](#) in indolent systemic mastocytosis
- new indication for [pembrolizumab](#) as first-line treatment of biliary tract carcinoma
- new indication for [talazoparib](#) for metastatic castration-resistant prostate cancer
- ranibizumab biosimilar ([Rimmyrah](#))
- [rozanolixizumab](#) for generalised Myasthenia Gravis
- [trametinib](#) for low- and high-grade glioma with a BRAF V600E mutation
- ustekinumab biosimilar ([Uzpruvo](#))
- recommending removal of pharmaceutical form of [dabigatran](#) and a change to existing indication for use in children
- Withdrawal of the EU marketing authorisation application for [alpelisib](#)
- Biosimilar medicines: Overview - [link](#)
- Biosimilars in the EU - Information guide for healthcare professionals - [link](#)

### European Pharmaceutical Review

- Quizartinib (Vanflyta) approved in EU for newly diagnosed FLT3-ITD positive acute myeloid leukaemia - [link](#)

### Food and Drug Administration (FDA) USA

- FDA amends [pembrolizumab](#)'s gastric cancer indication
- [enzalutamide](#) (Xtandi) new indication for non-metastatic castration-sensitive prostate cancer
- New approvals
- First Vaccine to Prevent Disease Caused by Chikungunya Virus - [link](#)
- First Treatment for Patients with Rare Inherited Blood Clotting Disorder - [link](#)
- New Medication for Chronic Weight Management - [link](#)
- [fruquintinib](#) ([Fruzaqla](#)) in refractory metastatic colorectal cancer
- [Defencath](#) (taurolidine, heparin) to reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter
- [Augtyro](#) (repotrectinib) to treat ROS1-positive non-small cell lung cancer
- [Ryzneuta](#) (efbemalenograstim alfa-vuxw) to treat neutropenia
- [Trugap](#) (capivasertib) to treat breast cancer that meets certain disease criteria

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

- MHRA authorises [tirzepatide](#) (Mounjaro) for weight management and weight loss – link – [SPS commentary](#)
- MHRA extends licence of cystic fibrosis drugs Kaftrio (ivacaftor, tezacaftor and elexacaftor) and Kalydeco (ivacaftor) to include patients aged two to five years old – [link](#)
- Dostarlimab in the treatment of endometrial cancer - [link](#)
- MHRA authorises world-first gene therapy that aims to cure sickle-cell disease and transfusion-dependent  $\beta$ -thalassaemia - [link](#)

### NHS Business Services Authority

- Prescribing Costs in Hospitals and the Community - England 2018/19 to 2022/23 - [link](#)

### NHS England

- Clinical commissioning policy:
- allogeneic haematopoietic stem cell transplantation (Allo-HSCT) for adult transfusion dependent thalassaemia - [link](#)
- infliximab for refractory sarcoidosis (excluding neurosarcoidosis) in adults [2204] – [link](#) - [SPS commentary](#)
- obinutuzumab for systemic lupus erythematosus with secondary non-response to rituximab (adults and post-pubescent children) – [link](#)



- siltuximab for idiopathic multicentric Castleman disease (adults) [2124] - [link](#)
- Improving lipid management to reduce cardiovascular disease and save lives - [link](#)
- Guidance note: virtual ward care for people with acute respiratory infection including chronic obstructive pulmonary disease - [link](#)
- Potential issues and challenges in evaluation of disease-modifying dementia treatments – [link](#) – [SPS commentary](#)
- Decision support tools: [enlarged prostate](#) (BPE), [gallstones](#), [inguinal hernia](#), [managing heavy periods](#), [varicose veins](#)
- Resource pack: Continuous positive airway pressure (CPAP) resources for healthcare professionals (in people with learning difficulties and autistic people) – [link](#) – [SPS commentary](#)

### **NHS Scotland**

- Accepted for use:
  - [Avacopan](#) (Tavneos®) in combination with a rituximab or cyclophosphamide regimen, for adults with severe, active granulomatosis with polyangiitis or microscopic polyangiitis
  - [Durvalumab](#) (Imfinzi®) in combination with gemcitabine and cisplatin for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer
  - [Risankizumab](#) (Skyrizi®) for patients ≥16 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if they are not advisable
  - [Tafamidis](#) (Vyndaqel®) for wild-type and hereditary transthyretin amyloidosis in adults with cardiomyopathy - in the context of an approved NHS Scotland Patient Access Scheme or a list price equivalent or lower
- Accepted for restricted use:
  - [Bimekizumab](#) (Bimzelx®) alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adults who have not responded adequately to two conventional DMARDs, given either alone or in combination
  - [Selpercatinib](#) (Retsevmo®) on an interim basis, in treatment-naïve adults with advanced RET fusion-positive non-small cell lung cancer not previously treated with a RET inhibitor or any other systemic treatments for their advanced stage of disease
- Not recommended:
  - [Efgartigimod alfa](#) (Vyvgart®) as an add-on to standard therapy for the treatment of adults with generalised Myasthenia Gravis who are anti-acetylcholine receptor antibody positive
  - Extended-release mercaptamine ([Procysbi®](#)) for the treatment of proven nephropathic cystinosis
  - [Pegunigalsidase alfa](#) (Elfabrio®) for long-term enzyme replacement therapy in adults with a confirmed diagnosis of Fabry Disease (deficiency of alpha-galactosidase)

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

- Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer - updated guidance ([CG164](#))
- Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments - guidance ([TA930](#))
- Hypertension in adults: diagnosis and management, updated ([NG136](#))
- Transient loss of consciousness ('blackouts') in over 16s, updated ([CG109](#))
- Zanubrutinib for treating chronic lymphocytic leukaemia ([TA931](#))
- Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management, updated [[NG237](#)]
- Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer, updated [[CG164](#)]

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

- NIHR alert: Pregnancy complications increase the risk of heart attacks and stroke in women with high blood pressure - [link](#)

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

- [SIGN 168](#): Assessment, diagnosis, care and support for people with dementia and their carers

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

- Annual planning advice for new medicines: Prescribing Outlook 2023 - [link](#)

- New Product Evaluations – [October 2023](#)

### **UK Health Security Agency**

- Diphtheria: public health control and management in England 2023 - updated [guidance](#)
- Hepatitis B immunoglobulin (issued November 2023) - post-exposure for non-responders [updated](#)
- English surveillance programme for antimicrobial utilisation and resistance (ESPAUR): Report 2022 to 2023 – [link](#) – [SPS commentary](#)

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

- Update to living WHO guideline on drugs for COVID-19 - [link](#) – [SPS commentary](#)
- WHO issues new and updated recommendations on treatment of mental, neurological and substance use conditions - [link](#)

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## **MEDICATION SAFETY**

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

- Corticosteroids in short supply - [link](#)

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

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

- Myozyme (alglucosidase alfa) - limited data suggest it is excreted in breast milk in very low concentrations; no clinical effect is expected in a breastfed infant. As a precaution, breast-feeding interruption for the first 24 hours after treatment [given every 2 wks] may be considered
- Augmentin Duo (amoxicillin trihydrate, clavulanic acid) - hypersensitivity reactions to penicillins can also progress to Kounis syndrome (very rare), a serious allergic reaction that can result in myocardial infarction
- Ondexxya (andexanet alfa) - posology is based upon PK/PD modelling & simulation exercises, and pharmacokinetics has not been studied in bleeding patients. Also dose recommendation updated when interval between last dose & bleeding episode is unknown for both apixaban & rivaroxaban
- Blincyto (blinatumomab) - CD19-negative B-precursor ALL, and lineage switch from ALL to AML reported in relapsed patients receiving blinatumomab
- Epidyolex (cannabidiol) - pneumonia events observed in controlled trials with cannabidiol in patients with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, including 6% of cannabidiol-treated patients compared with 1% of patients receiving placebo
- Cipramil (citalopram) - hyperprolactinaemia as an ADR (unknown frequency) that has been reported for the therapeutic class of SSRIs/SNRIs
- Cutaquig (human normal immunoglobulin) - Infusion rate information has been updated. For those already on immunoglobulin therapy, use previously used rates for the initial infusions. Then gradually increase rate by approx. 10ml/h/site every 2-4 weeks in adults (≥40kg) and up to 10mL/h/site every 4 weeks for paediatrics
- Dupixent (dupilumab) - license extension to include severe atopic dermatitis in children 6 months to 11 years old who are candidates for systemic therapy (previously 6-11 years for this indication) - study findings of use in atopic hand and foot dermatitis included, safety profile in these patients consistent with that from studies in adult/ paediatric patients with moderate-to-severe atopic dermatitis
- Imbruvica (ibrutinib) - acute kidney injury and pyogenic granuloma added as a common and uncommon ADR, respectively
- Revlimid (lenalidomide) Hard Capsules - anaemia added as a very common ADR
- Lutathera (lutetium (177Lu) oxodotreotide) - revisions to administration instructions, clarification of 1-week flexibility in the interval between each administration, and amendment of guidance regarding contraception (females should use for 7 months after end of treatment and males for 4 months)
- Magnaspartate (magnesium aspartate dihydrate) 243mg Powder for Oral Solution - administration instructions in following age groups: 4-18 years: 1 sachet daily dissolved in 50-200ml of water, tea, or orange juice. Alternatively for 4-10 years, for a half dosage, or in children age 2-4 years, use half volume of 1 sachet in 50-200ml of water
- Methocarbamol excipient soya lecithin removed and associated warning that it not be used in patients allergic to peanut or soya
- Movicol-Half (potassium chloride, sodium chloride, sodium bicarbonate, macrogol 3350) - other medicines should not be taken orally for one hour before, during and for one hour after

- Mysimba (naltrexone hydrochloride, bupropion hydrochloride) prolonged-release tablets - severe cutaneous ADRs such as Stevens-Johnson syndrome and acute generalised exanthematous pustulosis, which can be life-threatening or fatal, reported
- Zejula (niraparib) tablets should be taken without food (at least 1 hour before or 2 hours after a meal) or with a light meal. In clinical studies, the C<sub>max</sub> and AUC of niraparib increased by 11% and 28% respectively, when given following a high-fat meal vs fasting conditions
- Pegasys (peginterferon alfa-2a) - post-treatment recovery in growth observed in the majority of paediatric patients in short-term (81% up to 2 years) and long-term (82% up to 5 years) follow-up studies
- Fycompa (perampanel) - psychotic disorder added to SPC as an uncommon ADR
- Apexnar (Pneumococcal polysaccharide conjugate vaccine) - can be administered concomitantly with seasonal quadrivalent influenza vaccine but consider separating administration in those with underlying conditions associated with a high risk of developing life-threatening pneumococcal disease
- Skyrizi (risankizumab) 360 mg solution for injection cartridge may be stored out of the refrigerator (up to a maximum of 25°C) for up to 24 hours; 600 mg concentrate for solution for infusion - 0.9% saline as an additional diluent
- Okedi (risperidone) 75mg and 100mg powder and solvent for prolonged-release suspension for injection pre-filled syringes - Stevens-Johnson syndrome / toxic epidermal necrolysis added as an ADR (unknown frequency)
- Requip (ropinirole) - hiccups (uncommon), spontaneous penile erection (frequency unknown) ADRs
- Nexpovio (selinexor) – reversible covalent selective inhibitor of nuclear export (SINE) compound that specifically blocks exportin 1 licensed for use in combination with bortezomib & dexamethasone or in combination with dexamethasone, in pre-treated patients with multiple myeloma - [SPS commentary](#)
- Vyndaqel (tafamidis) - vaginal infection removed as an ADR
- Vemlidy (tenofovir alafenamide fumarate) - licence extension for treatment of chronic hepatitis B-infected children from age 6 years & weighing ≥25kg, based on interim results from week 24 clinical study report (CSR) for Cohort 1 & Cohort 2 Group 1, and supporting modular summaries for study GS-US-320-1092
- Lonsurf (tipiracil/trifluridine) - new indication of use with bevacizumab in adults with metastatic colorectal cancer who have received 2 prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies, anti-VEGF agents, and/or anti-EGFR agents – [SPS commentary](#)
- Mounjaro (tirzepatide) - licence extension as adjunct to a reduced-calorie diet and increased physical activity in weight management. It should not be used during pregnancy, and should be discontinued ≥1 month before a planned pregnancy due to its long half-life – [SPS commentary](#)
- Woodward's Gripe Water - hypersensitivity added as an adverse event of unknown frequency
- Xeljanz (tofacitinib citrate) - acne as a common side-effect
- Risk minimisation materials
- Talvey™ (talquetamab) - Booklet for HPs raises awareness of the risk of neurological toxicity and provides recommendations to minimise the risk, and to facilitate management and monitoring if it does occur. Patient card of symptoms that warrant immediate medical attention
- Treposuvi ([treprostinil](#)) - training for healthcare professionals, patient brochure, patient questionnaire - part of the additional measures implemented to reduce the risk of occurrence of catheter-related bloodstream infections

## EMA

- European Medicines Agency starts review of azithromycin-containing medicines - [link](#)
- Topiramate and topiramate/phentermine combination: New restrictions to prevent exposure during pregnancy - [link](#)

## FDA

- FDA warns consumers not to purchase or use Neptune's Fix or any tianeptine product due to serious risks - [link](#)

## Health Services Safety Investigation Body

- Investigation report: Risks to medication delivery using ambulatory infusion pumps – design and usability in inpatient settings - [link](#) – [SPS commentary](#)

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

- Medication Safety Alert! [November 16, 2023](#) includes:
  - Why “Benchmarking” Error Rates Is NEVER a Good Measure of Performance or Patient Safety - [link](#)

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

- Update - Interleukin inhibitors and the possible risk of pancreatitis - [link](#)

### **Specialist Pharmacy Service**

- Continuing management of the ADHD medicines shortage – [link](#) – [SPS commentary](#)
- Using duloxetine, mirtazapine, trazodone or venlafaxine during breastfeeding - [link](#)
- Using paracetamol during breastfeeding - [link](#)

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## **PAPERS OF INTEREST**

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

- Implementing services for pediatric cystic fibrosis treatment in a community hospital - [link](#)
- Use of remote patient monitoring kits to reduce hospitalization and mortality rates for patients with heart failure - [link](#)
- Translational research and implementation science: Accelerating the imperative - [link](#)
- Considerations and limitations of buprenorphine prescribing for opioid use disorder in the intensive care unit setting: A narrative review - [link](#)
- Antimicrobial resistance patterns and empiric antibiotic selections for patients admitted from post-acute care facilities - [link](#)

### **Annals of Internal Medicine**

- Relationship Between Clinician Language and the Success of Behavioral Weight Loss Interventions: A Mixed-Methods Cohort Study – [link](#) – [SPS commentary](#)
- SARS-CoV-2 Virologic Rebound With Nirmatrelvir–Ritonavir Therapy: An Observational Study – [link](#) – [SPS commentary](#)
- Prevalence of pharmacologic and nonpharmacologic pain management therapies among adults with chronic pain— United States, 2020 - [link](#)

### **Arthritis & Rheumatology**

- Towards the Lowest Efficacious Dose (ToLEDo): Results of a Multicenter Non-Inferiority Randomized Open-Label Controlled Trial Assessing Tocilizumab or Abatacept Injection Spacing in Rheumatoid Arthritis in Remission – [link](#) – [SPS commentary](#)
- Association Between Severe Nonadherence to Hydroxychloroquine and Systemic Lupus Erythematosus Flares, Damage, and Mortality in 660 Patients From the SLICC Inception Cohort - [link](#)
- Kidney Outcomes and Preservation of Kidney Function with Obinutuzumab in Patients with Lupus Nephritis: A Post Hoc Analysis of the NOBILITY Trial - [link](#)
- Expert Perspective on a Clinical Challenge: Lupus and Pregnancy - [link](#)

### **Australian Health Review, Journal of the Australian Healthcare & Hospitals Association**

- A conceptual framework to support hospitals to measure and realise financial benefits from process improvement programs: perspectives from Australia, USA and UK - [link](#)

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

- Clinical decision making in benzodiazepine deprescribing by HealthCare Providers vs AI-assisted approach - [link](#)
- Older adults’ adherence to medications and willingness to deprescribe: A sub-study of a randomized clinical trial - [link](#)
- Drug-drug interactions and the risk of adverse drug reaction-related hospital admissions in the older population – [link](#) – [SPS commentary](#)
- Assessing and further developing age-appropriate information for young people about reporting suspected adverse drug reactions - [link](#)
- Are opioids effective analgesics and is physiological opioid dependence benign? Revising current assumptions to effectively manage long-term opioid therapy and its deprescribing - [link](#)
- Clinical characteristics of acute lacosamide poisoning: Pavia Poison Control Centre experience - [link](#)

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

- Private prescribing of controlled opioids in England, 2014–2021: a retrospective observational study - [link](#)

### **British Journal of Psychiatry**

- How to classify antipsychotics: time to ditch dichotomies? - [link](#)

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

- Effectiveness of the live zoster vaccine during the 10 years following vaccination: real world cohort study using electronic health records – [link](#) – [SPS commentary](#)
- Covid-19: Is convalescent plasma still useful as a covid treatment? - [link](#)
- Otitis media with effusion in under 12s: summary of updated NICE guidance - [link](#)
- Is the US's Vaccine Adverse Event Reporting System broken? - [link](#)
- Practical Prescribing: Proton pump inhibitors – [link](#) – [SPS commentary](#)
- Practical Prescribing: Paracetamol use in adults – [link](#) – [SPS commentary](#)
- Chronic prostatitis (chronic pelvic pain syndrome) - [link](#)
- Practice: Vitamin B12 - [link](#)
- Advances in the understanding and management of alcohol-related liver disease - [link](#)

### **BMJ Open**

- Systematic literature review and network meta-analysis of therapies for psoriatic arthritis on patient-reported outcomes – [link](#) – [SPS commentary](#)
- Effectiveness of lipid-lowering therapy on mortality and major adverse cardiovascular event outcomes in patients undergoing percutaneous coronary intervention: a network meta-analysis of randomised controlled trials - [link](#)
- Digital health interventions to improve adherence to oral antipsychotics among patients with schizophrenia: a scoping review - [link](#)
- Medication prescription profile and hospital admission related to medication administration errors in England and Wales: an ecological study - [link](#)
- Pembrolizumab monotherapy for non-small cell lung cancer (NSCLC): can patient stratification be improved in the UK Tayside population? A retrospective cohort study - [link](#)
- WHY STOP? A prospective observational vignette-based study to determine the cognitive-behavioural effects of rapid diagnostic PCR-based point-of-care test results on antibiotic cessation in ICU infections - [link](#)

### **Circulation**

- 2023 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations: Summary From the Basic Life Support; Advanced Life Support; Pediatric Life Support; Neonatal Life Support; Education, Implementation, and Teams; and First Aid Task Forces - [link](#)
- Novel Prediction Equations for Absolute Risk Assessment of Total Cardiovascular Disease Incorporating Cardiovascular-Kidney-Metabolic Health: A Scientific Statement From the American Heart Association – [link](#) – [SPS commentary](#)
- Estimated Lifetime Cardiovascular, Kidney and Mortality Benefits of Combination Treatment With SGLT2 Inhibitors, GLP-1 Receptor Agonists, and Non-steroidal MRA Compared With Conventional Care in Patients With Type 2 Diabetes and Albuminuria - [link](#)
- Direct Oral Anticoagulants for Stroke Prevention in Patients with Device-Detected Atrial Fibrillation: A Study-Level Meta-Analysis of the NOAH-AFNET 6 and ARTESiA Trials - [link](#)
- A Multicenter, Single-Blind, Randomized, Warfarin-Controlled Trial of Edoxaban in Patients With Chronic Thromboembolic Pulmonary Hypertension: KABUKI Trial – [link](#) – [SPS commentary](#)
- A Synopsis of the Evidence for the Science and Clinical Management of Cardiovascular-Kidney-Metabolic (CKM) Syndrome: A Scientific Statement From the American Heart Association – [link](#) – [SPS commentary](#)

### **Cochrane**

- Infliximab for medical induction of remission in Crohn's disease - [link](#)
- Calcium channel blockers for preventing cardiomyopathy due to iron overload in people with transfusion-dependent beta thalassaemia - [link](#)



- Different antibiotic treatments for group A streptococcal pharyngitis - [link](#)
- Special collection: Coronavirus (COVID-19): evidence relevant to acute and critical care - [updated](#)

### **Diabetes Care**

- A Multicenter Prospective Evaluation of the Benefits of Two Advanced Hybrid Closed-Loop Systems in Glucose Control and Patient-Reported Outcomes in a Real-world Setting - [link](#)
- Metformin-Cimetidine Drug Interaction and Risk of Lactic Acidosis in Renal Failure: A Pharmacovigilance-Pharmacokinetic Appraisal – [link](#) – [SPS commentary](#)
- SGLT2 Inhibitor–Induced Ketoacidosis in a Patient Without Diabetes - [link](#)
- Euglycemic ketoacidosis in two patients without diabetes after introduction of sodium–glucose cotransporter 2 inhibitor for heart failure with reduced ejection fraction - [link](#)

### **European Heart Journal**

- Long COVID and its cardiovascular implications: a call to action - [link](#)
- Anticoagulation with edoxaban in patients with long Atrial High-Rate Episodes  $\geq 24$  hours - [link](#)
- The cardiovascular effects of novel weight loss therapies - [link](#)
- Fighting the pandemic of heart failure: better utilization of current treatments, new drugs, and new therapeutic targets - [link](#)

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

- Systematic review of room temperature stability of key beta-lactam antibiotics for extended infusions in inpatient settings - [link](#)

### **Heart**

- Eosinophilic myocarditis: systematic review - [link](#)
- Pulmonary arterial hypertension in congenital heart disease - [link](#)

### **Internal Medicine Journal**

- Editorial: Updated treatment options for immune thrombocytopenia - [link](#)
- Australian data on the utilisation and duration on treatment of ibrutinib with a proton pump inhibitor in patients with relapsed or refractory chronic lymphocytic leukaemia - [link](#)

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

- Managing delayed or missed pregabalin doses in patients with focal epilepsy: a Monte Carlo simulation study - [link](#)
- Cost-effectiveness analysis of nivolumab versus placebo for relapsed malignant mesothelioma - [link](#)
- Implementation of a national system for best practice delivery of paediatric infusions - [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**

- Long-Term Blood Pressure Control After Hypertensive Pregnancy Following Physician-Optimized Self-Management: The POP-HT Randomized Clinical Trial - [link](#)
- Higher-Dose Fluvoxamine and Time to Sustained Recovery in Outpatients With COVID-19: The ACTIV-6 Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Cardiology**

- Decline in Estimated Glomerular Filtration Rate After Dapagliflozin in Heart Failure With Mildly Reduced or Preserved Ejection Fraction: A Prespecified Secondary Analysis of the DELIVER Randomized Clinical Trial - [link](#)
- Torsemide vs Furosemide Among Patients With New-Onset vs Worsening Chronic Heart Failure: A Substudy of the TRANSFORM-HF Randomized Clinical Trial - [link](#)
- Effect of Tafamidis on Cardiac Function in Patients With Transthyretin Amyloid Cardiomyopathy: A Post Hoc Analysis of the ATTR-ACT Randomized Clinical Trial - [link](#)

### **JAMA Dermatology**



- Changes in Health Care Costs, Survival, and Time Toxicity in the Era of Immunotherapy and Targeted Systemic Therapy for Melanoma - [link](#)
- JAMA Dermatology Clinical Evidence Synopsis: The Best Psoriasis Medications Emerge - [link](#)
- Management of Adult Patients with Drug Reaction With Eosinophilia and Systemic Symptoms: A Delphi-Based International Consensus - [link](#)

### **JAMA Internal Medicine**

- Health Disinformation Use Case Highlighting the Urgent Need for Artificial Intelligence Vigilance: Weapons of Mass Disinformation - [link](#)
- Lepodisiran, an Extended-Duration Short Interfering RNA Targeting Lipoprotein(a): A Randomized Dose-Ascending Clinical Trial – [link](#) – [SPS commentary](#)
- Risk of Bleeding Following Non–Vitamin K Antagonist Oral Anticoagulant Use in Patients With Acute Ischemic Stroke Treated With Alteplase - [link](#)

### **JAMA Network Open**

- Aspirin and Hemocompatibility Events With a Left Ventricular Assist Device in Advanced Heart Failure: The ARIES-HM3 Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Neurology**

- Behavioral Outcomes and Neurodevelopmental Disorders Among Children of Women With Epilepsy – [link](#) – [SPS commentary](#)

### **JAMA Oncology**

- Implications of High Tumor Burden on Chimeric Antigen Receptor T-Cell Immunotherapy: A review - [link](#)
- Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs: The ROAD Study - [link](#)

### **Journal of Clinical Oncology**

- Soft Tissue Sarcomas in Adolescents and Young Adults - [link](#)

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

- Estimation of kidney function for medication dosing in adult patients with chronic kidney disease: a practice update - [link](#)
- Medication error reporting attitudes and practices in a regional Australian hospital: a qualitative study - [link](#)
- A case of extrapyramidal side effects due to possible paliperidone: voriconazole interaction - [link](#)

### **Lancet**

- Multiple sclerosis - [link](#)
- The 2023 report of the Lancet Countdown on health and climate change: the imperative for a health-centred response in a world facing irreversible harms – [link](#) – [SPS commentary](#)
- Complement in human disease: approved and up-and-coming therapeutics - [link](#)
- Cushing's syndrome - [link](#)

### **Lancet Diabetes & Endocrinology**

- Diabetes: knowing your risk matters - [link](#)
- The Lancet Diabetes & Endocrinology Commission on type 1 diabetes: looking back to move forward - [link](#)

### **Lancet HIV**

- Post-exposure prophylaxis to prevent HIV: new drugs, new approaches, and more questions - [link](#)

### **Lancet Oncology**

- The future of cancer care in the UK—time for a radical and sustainable National Cancer Plan - [link](#)

### **Lancet Respiratory Medicine**

- Efficacy and safety of baricitinib or ravulizumab in adult patients with severe COVID-19 (TACTIC-R): a randomised, parallel-arm, open-label, phase 4 trial – [link](#) – [SPS commentary](#)

### **Lancet Neurology**

- Classic ketogenic diet versus further antiseizure medicine in infants with drug-resistant epilepsy (KIWE): a UK, multicentre, open-label, randomised clinical trial - [link](#)
- Neurological adverse events related to immune-checkpoint inhibitors in Spain: a retrospective cohort study - [link](#)

### **Lancet Respiratory Medicine**

- Short oral regimens for pulmonary rifampicin-resistant tuberculosis (TB-PRACTECAL): an open-label, randomised, controlled, phase 2B-3, multi-arm, multicentre, non-inferiority trial - [link](#)

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

- The Association of Serotonin Toxicity with Combination Linezolid–Serotonergic Agent Therapy: A Systematic Review and Meta-Analysis - [link](#)
- The Potential Roles of Pharmacists in the Clinical Implementation of Pharmacogenomics - [link](#)
- An EMR-Based Approach to Determine Frequency, Prescribing Pattern, and Characteristics of Patients Receiving Drugs with Pharmacogenomic Guidelines - [link](#)
- Efficacy and Tolerance of Antipsychotics Used for the Treatment of Patients Newly Diagnosed with Schizophrenia: A Systematic Review and Meta-Analysis - [link](#)

### **Medical Journal of Australia**

- Editorial: Time to treat the climate and nature crisis as one indivisible global health emergency - [link](#)
- Glucocorticoid-induced adrenal suppression: physiological basis and strategies for glucocorticoid weaning - [link](#)

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

- Osimertinib with or without Chemotherapy in EGFR-Mutated Advanced NSCLC – [link](#) – [SPS commentary](#)
- Catatonia - [link](#)
- Severe Immune-Related Enteritis after In Utero Exposure to Pembrolizumab - [link](#)
- Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis - [link](#)
- Two Phase 3 Trials of Gantenerumab in Early Alzheimer’s Disease – [link](#) – [SPS commentary](#)
- Liver Transplantation - [link](#)

### **Nursing Standard**

- Prescribing medicines in people with renal impairment - [link](#)

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

- Measurement of Ambulatory Medication Errors in Children: A Scoping Review - [link](#)
- 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**

- Medicine suppliers must submit a sustainability assessment each year from 2024 - [link](#)

### **Pharmacotherapy**

- Pharmacokinetics/pharmacodynamics analysis and establishment of optimal dosing regimens using unbound cefmetazole concentration for patients infected with Extended-Spectrum  $\beta$ -lactamase Producing Enterobacterales (ESBL-E) - [link](#)
- Methenamine for Urinary Tract Infection Prophylaxis: A Systematic Review - [link](#)
- Urinary Biomarkers as Indicators of Acute Kidney Injury in Critically Ill Children Exposed to Vancomycin - [link](#)
- Comparison of different sustained-release opioids and acute respiratory conditions in patients with cancer and chronic kidney disease - [link](#)

### **Prescriber UK**

- Serotonin toxicity – a problem ignored? - [link](#)
- Communicating adverse drug events: serotonin toxicity - [link](#)

- Eptinezumab for the prophylaxis of migraine in adults - [link](#)

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## CONSULTATIONS (new additions in bold)

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

- Draft Chronic Obstructive Pulmonary Disease Clinical Care Standard, closing 18 December 2023 - [link](#)

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## WEBINARS & PODCASTS

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### Australian Prescriber Podcasts

- [Episode 151](#) – COVID-19 vaccines in 2023
- [Episode 150](#) – COVID-19 testing: a 2023 update

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

- FDA Drug Topics: An Overview of FDA's Project Facilitate Oncology Expanded Access Program - December 12, 2023 - [link](#) - [register](#)

### MJA Podcasts

- [Episode 32](#): new Australian guidelines for diabetes related foot disease
- [Episode 33](#): How clinicians can help improve the care of culturally and linguistically diverse patients

### Purple Pen Podcast

- [PPP 154](#) - Haemochromatosis

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## UPCOMING EVENTS

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

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

- Virtual Medication Safety Intensive Workshop, November 30 & December 1, 2023 07:30-16:30 ET – register [here](#) 48 hours before
- Symposia: Leveraging IV Robotics to Optimize Sterile Compounding Practices to Improve Safety, Anaheim, December 6, 2023 - 11:30-13:00 – register [here](#) (free)
- Improving Medication Safety, Costs, and Patient Outcomes, New York, December 9, 2023 - 12:00-13:00 – register [here](#) (free)

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## 9<sup>th</sup> November 2023- Fortnightly TAG Mail- Resources list

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### NSW TAG ACTIVITIES

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**Huge congratulations to Russell Levy, Director of Pharmacy, Royal Prince Alfred Hospital and NSW TAG Management Committee member who was awarded the 2023 SHPA Medal of Merit at the SHPA Medicines Management Conference on the weekend. So well-deserved!**

### New open email discussions

1. **Local DTC management of andexanet alfa:**
  - Will your hospital/district keep stock-on-hand?
  - How much stock?
  - Will you use a streamlined IPU process?
  - Are you planning to develop a guideline for safe use?
  - Will you plan to monitor use/outcomes?

Please respond by *COB Friday 10<sup>th</sup> November 2023* to [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

2. **Documentation of IPU outcomes:**

- Does your DTC document IPU outcomes (approval, non-approval) in the patient’s medical record?
- If yes, is this for all IPU applications or a subset?
- If yes, where do you document the outcome so that it can be easily found?
- Is there a local policy or process for this that you would be happy to share?

Please respond by *COB Monday 27<sup>th</sup> November 2023* to [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

**3. How are DTCs, particularly from hospitals with Familial Metabolic Health Services or similar, managing the usage of off-label GLP-1 analogues for the management of obesity?**

- Are they on the local formulary?
- Is there a cap on the number of patients to receive off-label GLP-1 analogues?
- Is all usage via IPU/ or streamlined IPU/ restricted formulary?
- Are there any other strategies being used to manage usage/costs?

Please respond by *COB Monday 27<sup>th</sup> November 2023* to [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

**4. ‘Burns’ from amiodarone:**

A NSW TAG member has reported notification by a senior nurse of a high incidence of “amiodarone burns” that could be associated with the new contracted brand of IV amiodarone (Juno). It was suggested that enquiries be made of ICUs and CCUs as they may not have been recognising the amiodarone ADRs as an unusual occurrence and have been putting them down to e.g. phlebitis. They may instead be as a result of a new brand and re-evaluation of any ADRs and the prevalence of amiodarone ADRs since the new brand was introduced in June 2023 be re-considered in light of this possible ADR.

Please respond by *COB Monday 16<sup>th</sup> November 2023* to [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

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

- Potential for inappropriate antiviral prescribing in COVID-19 infections.
- Ward storage of anaesthetic medicines. See also recent SHPA Discussion Board for interstate management.

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

**OTHER NEWS**

**NSW Health**

- Warning: Multiple types of high-dose MDMA tablets (ecstasy) circulating in NSW - [link](#)
- Voluntary Assisted Dying ([PD2023\\_037](#))
- My Personal Health Record (Blue Book) ([IB2023\\_044](#))

**REPORTS AND PUBLICATIONS – AUSTRALIA**

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

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

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

- Health checks and follow-ups for Aboriginal and Torres Strait Islander people - [link](#)
- Suicide & self-harm monitoring update: Cause of Death 2022 - [link](#)
- Aboriginal and Torres Strait Islander mothers and babies - [link](#)
- Medicare Benefits Scheme funded services: monthly data - [link](#)
- Alcohol, tobacco and other drugs in Australia - [link](#)
- Let’s talk about the weather: injuries related to extreme weather - [link](#)
- Health of refugees and humanitarian entrants in Australia - [link](#)
- GEN Aged Care Data - [link](#) - Aged care data snapshot—2023 – [second release](#)
- Injury in Australia - [link](#)
- Data opportunities in perinatal mental health screening - [link](#)

- Palliative care services in Australia - [link](#)

### **Commonwealth of Australia**

- Assessment and support services for people with ADHD- [link](#)

### **MIMS monthly updates**

#### - New Products

-- Andexanet alfa ([Andexxa](#)) powder for solution for injection, a recombinant form of human factor Xa (FXa) protein that has been modified to lack FXa enzymatic activity. It is a specific reversal agent for FXa inhibitors. Andexxa has provisional approval for adult patients treated with a direct FXa inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

-- [Andusomeran](#) (Spikevax XBB.1.5) injection is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19. Spikevax XBB.1.5 is indicated for active immunisation to prevent COVID-19 in individuals 12 years of age and older as per official recommendations. Spikevax XBB 1.5 is contraindicated in individuals with known severe allergic reactions to a previous dose of Spikevax in any form.

-- Mavacamten ([Camzyos](#)) capsules, a selective, allosteric, and reversible cardiac myosin inhibitor. In hypertrophic cardiomyopathy (HCM) patients, myosin inhibition with mavacamten normalizes contractility, reduces dynamic LV outflow tract obstruction, and improves cardiac filling pressures and biomarkers of cardiac stress, improving symptoms and exercise capacity. Camzyos is indicated for adults with symptomatic NYHA class II-III obstructive HCM. Contraindicated in concomitant use with moderate to strong CYP2C19 inhibitors and inducers, strong CYP3A4 inhibitors, and moderate to strong CYP3A4 inducers.

-- Rimegepant ([Nurtec ODT](#)) binds with high affinity to the human calcitonin gene-related peptide (CGRP) receptor and antagonises CGRP receptor function. It is indicated for acute treatment of migraine with or without aura in adults and as prophylactic treatment of episodic migraine in adults who have at least 4 migraine attacks per month. Nurtec ODT (orally disintegrating tablets) contain rimegepant 75 mg.

#### - New indications

-- Ivosidenib (Tibsovo) is now indicated for acute myeloid leukaemia (AML) that carries an IDH1 R132 mutation as monotherapy, or in combination with azacitidine, in newly diagnosed patients who are not eligible to receive intensive induction chemotherapy; or as monotherapy in patients whose AML is relapsed and/or refractory to prior therapy

-- Secukinumab (Cosentyx) is now indicated for active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic hidradenitis suppurativa therapy

### **TGA**

- Global event promotes side effect reporting, 6-12 November - [link](#)
- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - [Nuvaxovid](#) (SARS-CoV-2-rS) - prevention of coronavirus disease 2019 (COVID-19)
  - Intrarosa ([prasterone](#)) - vulvar and vaginal atrophy
  - [Flucelvax Quad](#) (Influenza virus haemagglutinin) - prevention of influenza (Types A and B)

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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

- Data Spotlight: Patterns of Fall Interventions, 2023 - [link](#)

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

- All Wales COPD management and prescribing guideline, updated - [link](#)

### **BBC**

- Nitrous oxide: Laughing gas possession becomes illegal - [link](#)

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

- Intrathecal Drug Delivery Systems for Cancer Pain, updated - [link](#)
- Buprenorphine Naloxone Film versus Tablets for Opioid Use Disorder, updated - [link](#)
- Anti-Vascular Endothelial Growth Factor Drugs for Age-Related Macular Degeneration, updated - [link](#)
- Biologic Drugs for Severe Asthma - [link](#)
- Safe Handling of Cytotoxic Drugs and Medications, updated – [link](#)

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

- [New products](#)
- Inaqovi (cedazuridine and decitabine)- oral hypomethylating product licensed as monotherapy for adults with newly diagnosed acute myeloid leukaemia ineligible for standard induction chemotherapy
- Vyvgart (efgartigimod) - Fc receptor antagonist for add-on therapy for adults with generalised myasthenia gravis who are anti-acetylcholine receptor antibody +ve. It is given as a 4 week cycle of once weekly infusions. Subsequent cycles are given according to clinical evaluation.
- Lipidem 200 mg/ml emulsion for infusion - parenteral nutrition, for adults and children (all ages)
- Omeflex emulsion for infusion, Omeflex peri, Omeflex plus, Omeflex special and Omeflex special without electrolytes are licensed for parenteral nutrition of patients in states of moderate to severe catabolism when oral or enteral nutrition is impossible, insufficient or contraindicated
- Litfulo (ritlecitinib)- JAK3 and TEC kinases inhibitor licensed for severe alopecia areata in adults and adolescents 12 years of age and older
- Spevigo (spesolimab)- humanised antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signalling licensed for flares in adults with generalised pustular psoriasis as monotherapy.
- Tyenne- tocilizumab biosimilar licensed, in combination with methotrexate or as monotherapy, for adult rheumatoid arthritis, juvenile idiopathic (JI) arthritis in patients aged ≥1 year, JI polyarthritis in patients aged ≥2 years, and giant cell arteritis in adults

### **European Medicines Agency (EMA)**

- EMA's human medicines committee (CHMP) recommends authorising an adapted Nuvaxovid vaccine targeting the Omicron XBB.1.5 subvariant of the SARS-CoV-2 virus - [link](#)

### **European Pharmaceutical Review**

- Conference report: Metformin may help manage weight gain side effects associated with second-generation antipsychotics (SGAs) - [link](#)

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

- New Drug approvals
- Omvoh ([mirikizumab-mrkz](#)) for ulcerative colitis
- Loqtorzi ([toripalimab-tpzi](#)) for recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies
- FDA approves interchangeable biosimilar for multiple inflammatory diseases (Wezlana, [ustekinumab](#)) – [link](#) – [SPS commentary](#)
- Agamree ([vamorolone](#)) for Duchenne muscular dystrophy
- [vonoprazan](#) (Voquezna) potassium-competitive acid blocker for erosive esophagitis
- New indications
- [abatacept](#) (Orencia) - Indication for psoriatic arthritis expanded to include pediatric patients
- [entrectinib](#) (Rozlytrek) approved for NTRK gene fusion solid tumours in patients 1 month or older
- [pembrolizumab](#): for biliary tract cancer
- [secukinumab](#) (Cosentyx) approved for hidradenitis suppurativa

### **Health Services Safety Investigation Body, UK**

- Investigation report: Caring for adults with a learning disability in acute hospitals - [link](#)

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

- Treatment with isotretinoin for patients under 18 must be approved by two prescribers, under new MHRA rules - [link](#)
- Approves ritlecitinib (Litfulo) as a treatment for severe alopecia areata in adults and adolescents 12 years and older - [link](#)



- Approves adagrasib (Krazati) as a treatment for non-small cell lung cancer in adults - [link](#)
- Approves enzyme inhibitor, anastrozole, to prevent breast cancer in post-menopausal women - [link](#)

### **Neonatal & Paediatric Pharmacists Group, UK**

- Position statement 2023-03: Use of injection solutions to administer analgesics or sedatives via the intranasal route - [link](#)

### **NHS England**

- Commissioning recommendations following the national assessment of blood glucose and ketone meters, testing strips and lancets - update - [link](#)
- Clinical commissioning statement: parenteral nutrition for the treatment of adults and children with type 2 and type 3 intestinal failure requiring home parenteral nutrition - [link](#)
- National paediatric early warning system (PEWS) observation and escalation charts – [link](#) – [SPS commentary](#)
- Clinical commissioning policies
- Allogeneic haematopoietic stem cell transplant for patients with X-linked cerebral adrenoleukodystrophy (adults) - [link](#)
- Obinutuzumab elective therapy to prevent immune Thrombotic Thrombocytopenic Purpura (TTP) relapse in patients who are refractory or intolerant to rituximab (adults) - [link](#)
- Sorafenib maintenance for adults with FLT3-internal tandem duplication (FLT3-ITD) acute myeloid leukaemia (AML) undergoing allogeneic haematopoietic stem cell transplantation (allo-HSCT) - [link](#)
- Subcutaneous copper histidinate injections for presymptomatic neonates with classical Menkes disease - [link](#)
- Trametinib in recurrent or progressive low grade serous ovarian cancer (adults) - [link](#)

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

- Digital technologies for delivering specialist weight-management services to manage weight-management medicine: early value assessment – [link](#) – [SPS commentary](#)
- Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine ([TA928](#))
- Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction ([TA929](#))
- Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management, updated ([NG237](#))
- Acute respiratory infection in over 16s: initial assessment and management including virtual wards (hospital at home) - quality standard ([QS210](#))
- Pneumonia in adults: diagnosis and management, updated ([CG191](#))
- Jaundice in newborn babies under 28 days, updated ([CG98](#))
- Ranibizumab for treating diabetic macular oedema, updated ([TA274](#))
- Flow transcranial direct current stimulation for treating depression - Medtech Innovation Briefing ([MIB324](#))

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

- A pragmatic, multicentre, double-blind, placebo-controlled randomised trial to assess the safety, clinical and cost-effectiveness of mirtazapine and carbamazepine in people with Alzheimer's disease and agitated behaviours: the HTA-SYMBAD trial - [link](#)
- Why we need to understand breast cancer risk - [link](#)
- NIHR alert: What could reduce aggressive behaviour in adults with learning disabilities? - [link](#)

### **Royal Pharmaceutical Society**

- Royal Pharmaceutical Society calls for legislative ban on multi-buy deals of paracetamol - [link](#)

### **The Health Foundation**

- Nine major challenges facing health and care in England - [link](#)

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

- What is compassionate leadership? - [link](#)
- [Audio](#): Joy Warmington on anti-racism, leadership and the courage to speak out (in the context of healthcare)

- Can the NHS manage without AI? - [link](#)

### **UK Health Security Agency**

- MenACWY vaccine: information for young people - [link](#)

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

- Global tuberculosis report 2023 - [link](#) - [factsheet](#)

- WHO releases updated Target Regimen Profiles for tuberculosis treatment and new Target Product Profiles for tuberculosis treatment monitoring and optimization - [link](#)

- WHO releases special journal issue on measuring healthy ageing - [link](#)

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## **MEDICATION SAFETY**

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### **PBS**

- PBS arrangements during shortage of amoxicillin and clavulanate potassium 400 mg/57 mg per 5 mL oral suspension effective 1 November 2023 - [link](#)

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

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

-- Sinemet (carbidopa, levodopa) – urinary tract infection added as a very frequent ADR. Also scoreline removed from Sinemet 12.5 mg/50 mg and Sinemet Plus 25 mg/100 mg tablets

-- Duodopa (levodopa/carbidopa) intestinal gel - urinary tract infections added as a very common possible ADR (frequency  $\geq 1/10$ )

-- Flucloxacillin products (CYP450 inducer) reported to significantly decrease plasma voriconazole concentrations. Monitor for potential loss of voriconazole effectiveness (e.g. therapeutic drug monitoring) and increase dose if required

-- Strefen (flurbiprofen) lozenges – systemic NSAIDs can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment. Manufacturers state that when Strefen is administered in a patient with fever or pain in relation to infection, monitor for infection.

-- Octagam (human normal immunoglobulin) – Use immediately after first opening

-- Roaccutane (isotretinoin) – In patients <18 years, 2 independent prescribers must agree there is no other appropriate effective treatment before initiating isotretinoin. Additional guidance on pregnancy risk, counselling for psychiatric adverse events & mental health assessment prior to initiation

-- Jylamvo (methotrexate) - potential for photosensitivity and that exposure to intense sunlight or UV rays should be avoided. Use a sun-protection product with a high protection factor

-- Lamictal (lamotrigine) - presence of the HLA B\*1502 allele in individuals of Asian (primarily Han Chinese & Thai) origin is associated with a risk of Stevens Johnson Syndrome with lamotrigine treatment. Potential use of lamotrigine should be carefully considered in such patients

-- Phenobarbital – Do not use in women of childbearing potential unless clinical benefit is judged to outweigh the potential risk of increasing the risk of congenital malformations by a factor of 2-3

-- Lynparza (Olaparib) - risk of liver injury (incidence unknown) after it was observed in post-marketing studies. If symptoms or signs suggestive of hepatotoxicity develop, prompt clinical evaluation is advised. If suspected, stop/interrupt Olaparib.

-- Keytruda (pembrolizumab) - license extension to include first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS  $\geq 1$

-- Rekambys (rilpivirine) - "In order to avoid transmission of HIV to the infant it is recommended that women living with HIV do not breast-feed."

-- Prometax (rivastigmine) patch - electrocardiogram QT prolongation may occur in patients treated with certain cholinesterase inhibitor products including rivastigmine

-- Cosentyx (secukinumab) pyoderma gangrenosum included as an ADR (unknown frequency)

-- Trelegy Ellipta (fluticasone furoate, vilanterol trifenate, umeclidinium bromide) - hyperglycaemia, anxiety, tremor, palpitations and muscle spasms included as ADRs

-- Minjuvi (tafasitamab) - progressive multifocal leukoencephalopathy (PML) reported during combination therapy with tafasitamab. Monitor for new/worsening neurological symptoms suggestive of PML (e.g. altered mental status). If suspected, stop treatment immediately

-- Vantobra (tobramycin) nebuliser - increased risk of ototoxicity in patients with mitochondrial DNA mutations (nucleotide 1555 A to G substitution in the 12S rRNA gene) even if aminoglycoside serum levels are within range during treatment. Consider alternative options in these patients

- Brukinsa (zanubrutinib) – consider risks and benefits of co-administration with anticoagulant or antiplatelet therapy, including benefit-risk of withholding zanubrutinib for 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding
- Risk minimisation materials
- Produodopa (foslevodopa/foscarbidopa) patient guide- on preventing and managing the risk of infusion site skin infection and skin reactions, which are very common side-effects
- Libtayo (cemiplimab) -important safety information to minimise complications from immune-mediated adverse reactions include a patient guide and alert card, to help patients identify and report side effects
- Columvi (glofitamab) patient card - discusses cytokine release syndrome and symptoms for which immediate medical attention should be sought. Also includes information for other healthcare professionals and space for details of treatment schedule and prescribing haematologist to be added

## EMA

- GLP-1 receptor agonists: available evidence not supporting link with thyroid cancer - [link](#)

## Food and Drug Administration (FDA) USA

- FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions - [link](#)
- FDA Raises Concerns About Probiotic Products Sold for Use in Hospitalized Preterm Infants - [link](#)

## Formulary Watch

- Safety labelling for esketamine (Spravato) updated in the US to include risk of respiratory depression and arrest – [link](#) – [SPS commentary](#)

## Health Canada – MedEffect Notice

- Health Product InfoWatch [October 2023](#) includes: Use of probiotics in preterm infants; Omnipod Insulin Management Systems and the risks of Pod detachment and needle deformation

## Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! [November 2, 2023](#) includes:
- Intravenous (IV) Push Medications – Bridging the Gap Between Education and Clinical Practice - [link](#)
- Moderna COVID-19 vaccine overfill leads to a double dose

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

- Isotretinoin: an expert review of suspected psychiatric and sexual side effects - [link](#)
- MHRA warns of unsafe fake weight loss pens - [link](#)
- Drug Safety Update [October 2023](#)
- Isotretinoin (Roaccutane ▼): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age - [link](#)
- Valproate: dispense full packs of valproate-containing medicines - [link](#)

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

- Reclassification of methenamine hippurate - [link](#)

## MIMS monthly updates [November 2023](#)

- New Contraindications
- Midodrine HCl (Vasodrine) - in obliterative blood vessel disease of any severity, acute nephritis, hypertrophy of the prostate gland with residual urine volume increased, and vasovagal hypotension

## Pharma

- Columvi ([glofitamab](#)) Healthcare Professional Guide (Roche) – with patient card to help minimise risk of cytokine release syndrome when used to treat relapsed or refractory diffuse large B-cell lymphoma

## Specialist Pharmacy Service

- Using laxatives during breastfeeding - [link](#)
- Giving vaccines during breastfeeding - [link](#)

- Considering drug interactions with smoking - [link](#)
- Managing specific interactions with smoking - [link](#)
- Managing the risks of using liquid oral phenobarbital preparations - [link](#)
- Medication Safety Update [October 2023](#)

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## PAPERS OF INTEREST

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### Age and Ageing

- Antiplatelet therapy and incident cognitive impairment or dementia—a systematic review and meta-analysis of randomised clinical trials - [link](#)

### American Journal of Gastroenterology

- Long-Term Treatment With Tenofovir Alafenamide for Chronic Hepatitis B Results in High Rates of Viral Suppression and Favorable Renal and Bone Safety - [link](#)

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

- Long-term outcomes and adverse effects of teduglutide in patients with short bowel syndrome: Highlighting hyperamylasemia and hyperlipasemia - [link](#)
- A pharmacist-driven deprescribing protocol for negative urine and sexually transmitted infection cultures in the emergency department increases antibiotic-free days - [link](#)
- Assessment of technology-assisted technician verification of compounded intravenous sterile preparations versus pharmacist verification - [link](#)
- Variability in opioid conversion calculators in critically ill children transitioned from fentanyl to hydromorphone - [link](#)
- Nebulized medications in the emergency department: A narrative review of non-traditional agents - [link](#)

### Annals of Internal Medicine

- Inappropriate Prescribing to Older Patients by Nurse Practitioners and Primary Care Physicians – [link](#) – [SPS commentary](#)
- Effectiveness of Nirmatrelvir–Ritonavir Against the Development of Post–COVID-19 Conditions Among U.S. Veterans - A Target Trial Emulation - [link](#)
- Effects of Remote Patient Monitoring Use on Care Outcomes Among Medicare Patients With Hypertension – [link](#) – [SPS commentary](#)
- Accurate Measurements of Gastric Emptying and Gastrointestinal Symptoms in the Evaluation of Glucagon-like Peptide-1 Receptor Agonists - [link](#)

### Arthritis & Rheumatology

- Association Between Plasma Rituximab Concentration and the Risk of Major Relapse in Antineutrophil Cytoplasmic Antibody–Associated Vasculitides During Rituximab Maintenance Therapy - [link](#)
- Identification of Covariates Modulating B-Cell Repopulation Kinetics in Subjects Receiving Rituximab Treatment - [link](#)

### British Journal of Clinical Pharmacology

- Identification and comparison of sex-specific serious adverse drug reactions in spontaneous reports and systematically collected reports (ADRED) - [link](#)
- Effect of Oral Clonidine on Pain Reduction in Patients with Opioid Use Disorder in the Emergency Department: A Randomized Clinical Trial - [link](#)
- Implementation of pre-emptive testing of a pharmacogenomic panel in clinical practice: Where do we stand? - [link](#)
- Development and validation of a predictive tool for Adverse Drug Reactions in neonates under intensive care - [link](#)
- Development of a predictive model for nephrotoxicity during tacrolimus treatment using machine learning methods - [link](#)
- Anastrozole as a therapeutic option for gynecomastia in a person receiving anti-retroviral therapy: case report - [link](#)
- Effect of Oral Clonidine on Pain Reduction in Patients with Opioid Use Disorder in the Emergency Department: A Randomized Clinical Trial - [link](#)

- Dapagliflozin pharmacokinetics is similar between patients with heart failure with reduced ejection fraction and patients with type 2 diabetes mellitus - [link](#)
- Should we abandon therapeutic drug monitoring of tacrolimus in whole blood and move to intracellular concentration measurements? - [link](#)
- Identification and comparison of sex-specific serious adverse drug reactions in spontaneous reports and systematically collected reports (ADRED) - [link](#)
- Implementation of pre-emptive testing of a pharmacogenomic panel in clinical practice: Where do we stand? - [link](#)

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

- Sleep disturbance in dementia or mild cognitive impairment: a realist review of general practice - [link](#)

### **British Journal of Psychiatry**

- Severe mental illness, race/ethnicity, multimorbidity and mortality following COVID-19 infection: nationally representative cohort study - [link](#)
- Artificial intelligence and increasing misinformation - [link](#)

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

- Pharmaceutical industry payments and delivery of non-recommended and low value cancer drugs: population based cohort study – [link](#) – [SPS commentary](#)
- Enhancing reporting quality and impact of early phase dose-finding clinical trials: CONSORT Dose-finding Extension (CONSORT-DEFINE) guidance – [link](#) – [SPS commentary](#)
- What do we know about covid in immunocompromised people? - [link](#)
- Advances in the management of systemic lupus erythematosus - [link](#)
- Advances in molecular pathology, diagnosis, and treatment of amyotrophic lateral sclerosis - [link](#)
- Practice Pointer: Anti-tuberculosis drug-induced liver injury - [link](#)
- Pyrotinib versus placebo in combination with trastuzumab and docetaxel as first line treatment in patients with HER2 positive metastatic breast cancer (PHILA): randomised, double blind, multicentre, phase 3 trial - [link](#)
- Sustainable practice: what can I do? – [link](#) – [SPS commentary](#)
- Anastrozole: repurposed drug could prevent thousands of breast cancer cases – [link](#) – [SPS commentary](#)

### **BMJ Open**

- What happens when pharmacist independent prescribers lead on medicine management in older people's care homes: a qualitative study - [link](#)
- Associations of anaemia with bleeding and thrombotic complications in patients with atrial fibrillation treated with warfarin: a registry-based nested case-control study - [link](#)

### **Canadian Medical Association Journal**

- Predictors of fatal and nonfatal overdose after prescription of opioids for chronic pain: a systematic review and meta-analysis of observational studies - [link](#)

### **Circulation**

- Stopping Aspirin Within 1 Month After Stenting for Ticagrelor Monotherapy in Acute Coronary Syndrome: The T-PASS Randomized Noninferiority Trial - [link](#)
- Next Generation, Modifiable Cardiometabolic Biomarkers: Mitochondrial Adaptation and Metabolic Resilience: A Scientific Statement From the American Heart Association - [link](#)
- ChaMP-CMD: A Phenotype-Blinded, Randomized Controlled, Cross-Over Trial – [link](#) – [SPS commentary](#)
- Inflammation and Cholesterol as Predictors of Cardiovascular Events Among 13970 Contemporary High-Risk Patients with Statin Intolerance - [link](#)

### **Cochrane**

- Phosphodiesterase 5 inhibitors (PDE5i) for the treatment of Raynaud's phenomenon - [link](#)
- Antioxidants for adults with chronic kidney disease - [link](#)
- Methylxanthine for the prevention and treatment of apnea in preterm infants - [link](#)
- Surfactant therapy guided by tests for lung maturity in preterm infants at risk of respiratory distress syndrome - [link](#)

- Tranexamic acid for percutaneous nephrolithotomy - [link](#)
- Doxapram for the prevention and treatment of apnea in preterm infants - [link](#)

### **Drug and Therapeutics Bulletin**

- Semaglutide: a new drug for the treatment of obesity – [link](#) – [SPS commentary](#)
- Hydrocortisone for severe community acquired pneumonia in ICU - [link](#)
- Time to treat the climate and nature crisis as one indivisible global health emergency - [link](#)
- A deprescribing intervention from hospital to post acute community care - [link](#)
- Hydrocortisone for severe community acquired pneumonia in ICU - [link](#)

### **European Heart Journal**

- Clinical implementation of partial oral treatment in infective endocarditis: the Danish POETry study – [link](#) – [SPS commentary](#)
- Amiodarone and pulmonary toxicity in atrial fibrillation: a nationwide Israeli study - [link](#)
- Discontinuation vs. continuation of renin–angiotensin system inhibition before non-cardiac surgery: the SPACE trial - [link](#)
- Potassium intake: the Cinderella electrolyte - [link](#)

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

- Primary care electronic medication record discrepancies in patients starting treatment at a hospital-based ambulatory care pharmacy and impact on prevalence of potential drug–drug interactions – [link](#) – [SPS commentary](#)
- Specific features of rational pharmacotherapy in elderly patients - [link](#)
- Budget impact analysis: comparing the costs of nusinersen and risdiplam in the treatment of type 3 spinal muscular atrophy patients - [link](#)
- Quality assurance standards and their use in the preparation of parenteral systemic anticancer therapy products in healthcare establishments: a scoping review - [link](#)
- In-use stability of ready-to-administer daratumumab subcutaneous injection solution in plastic syringes - [link](#)

### **Heart**

- Triple vasodilator therapy in pulmonary arterial hypertension associated with congenital heart disease – [link](#) – [SPS commentary](#)
- Atherosclerotic cardiovascular disease risk prediction: current state-of-the-art - [link](#)
- New National Institute for Health and Care Excellence guidance for hypertension: a review and comparison with the US and European guidelines - [link](#)

### **Internal Medicine Journal**

- Viewpoint: Adrenaline autoinjectors for Australian out-of-hospital anaphylaxis: where to from here? - [link](#)

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

- How to manage the dose of drugs in cancer patients with acute kidney injury, practical recommendations - [link](#)

### **JAMA**

- Intravenous Vitamin C for Patients Hospitalized With COVID-19: Two Harmonized Randomized Clinical Trials – [link](#) – [SPS commentary](#)
- Landiolol and Organ Failure in Patients With Septic Shock: The STRESS-L Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Topical Nonprescription Pain Medications for Adults - [link](#)

### **JAMA Dermatology**

- Cardiovascular and Venous Thromboembolic Risk With JAK Inhibitors in Immune-Mediated Inflammatory Skin Diseases: A Systematic Review and Meta-Analysis - [link](#)

### **JAMA Network Open**

- Pharmacotherapy for alcohol use disorder: A systematic review and meta-analysis - [link](#)



- Efficacy of testosterone replacement therapy in correcting anemia in men with hypogonadism: A Randomized Clinical Trial - [link](#)
- APOE genotype in the era of disease-modifying treatment with monoclonal antibodies against amyloid- $\beta$  - [link](#)

### **JAMA Neurology**

- Antiplatelets Are Enough for Nondisabling Strokes - [link](#)
- Brexpiprazole for the Treatment of Agitation in Alzheimer Dementia – [link](#) – [SPS commentary](#)

### **JAMA Psychiatry**

- Treatment Outcomes With Licensed and Unlicensed Stimulant Doses for Adults With Attention-Deficit/Hyperactivity Disorder: A Systematic Review and Meta-Analysis - [link](#)
- Choosing Between Ketamine and Electroconvulsive Therapy for Outpatients with Treatment-Resistant Depression—Advantage Ketamine? – [link](#) – [SPS commentary](#)

### **The Joint Commission Journal on Quality and Patient Safety**

- Factors Associated with Acute Injurious Falls in Elderly Hospitalized Patients: A Multicenter Descriptive Study – [link](#)
- A Data-Driven Approach to Evaluate Barcode-Assisted Medication Preparation Alerts at a Large Academic Medical Center – [link](#)
- Improving Judicious Use of Heparin-Induced Thrombocytopenia Testing Through Electronic Health Record–Based Intervention - [link](#)

### **Lancet**

- Rheumatoid arthritis - [link](#)
- Pembrolizumab plus chemotherapy versus chemotherapy in untreated advanced pleural mesothelioma in Canada, Italy, and France: a phase 3, open-label, randomised controlled trial - [link](#)

### **Lancet Diabetes & Endocrinology**

- Catecholamine-induced hypertensive crises: current insights and management - [link](#)

### **Lancet Gastroenterology and Hepatology**

- Genetic predisposition to gastrointestinal polyposis: syndromes, tumour features, genetic testing, and clinical management - [link](#)

### **Lancet HIV**

- Integrase strand-transfer inhibitor use and cardiovascular events in adults with HIV: an emulation of target trials in the HIV-CAUSAL Collaboration and the Antiretroviral Therapy Cohort Collaboration - [link](#)

### **Lancet Infectious Diseases**

- Efficacy and safety of moxidectin vs. ivermectin against *Strongyloides stercoralis* infection in adults in Laos and Cambodia: a randomised, double-blind, non-inferiority, phase 2b/3 trial - [link](#)

### **Lancet Respiratory Medicine**

- COPD and multimorbidity: recognising and addressing a syndemic occurrence - [link](#)

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

- Phase 3 Trial of Nemolizumab in Patients with Prurigo Nodularis – [link](#) – [SPS commentary](#)
- Simvastatin in Critically Ill Patients with Covid-19 - [link](#)
- Cystic Fibrosis - [link](#)
- Sparsentan versus Irbesartan in Focal Segmental Glomerulosclerosis – [link](#) – [SPS commentary](#)

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

- Innovations in Cancer Treatment of Children - [link](#)

### **Pharmaceutical Journal**

- MHRA to consider European Medicines Agency recommendation to avoid topiramate in pregnancy - [link](#)

- Electronic Prescription Service (EPS) rolled out in six NHS hospital trusts – [link](#) - [SPS commentary](#)

### Pharmacotherapy

- Efficacy and Safety of Factor Xa Inhibitors in Low Body Weight Patients - [link](#)
- Development and Validation of a Model to Predict Acute Kidney Injury following High-Dose Methotrexate in Patients with Lymphoma - [link](#)
- Impact of medication intensification on 30-day hospital readmissions in a geriatric trauma population: A multicenter cohort study - [link](#)
- Precision medicine in the ICU: One size fits one patient - [link](#)
- A systematic review of clozapine-associated inflammation and related monitoring - [link](#)

**Prescribe – French Medical Journal** – [November 2023](#) includes:

- Diclofenac: also harmful for the environment - [link](#)

### Thrombosis Research

- Anticoagulation in chronic thromboembolic pulmonary hypertension: A systematic review and meta-analysis - [link](#)

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## CONSULTATIONS (new additions in bold)

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

- Draft Chronic Obstructive Pulmonary Disease Clinical Care Standard, closing 18 December 2023 - [link](#)

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## WEBINARS & PODCASTS

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

- FDA Drug Topics: Advancing Transparency and Regulatory Science Activities on the Risk Evaluation and Mitigation Strategy (REMS) - November 28, 2023 - [link](#)

### **MJA Podcasts**

- [Episode 31](#): the new Australian Cancer Plan

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## UPCOMING EVENTS

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

### **AHHA**

- Strategies to Manage Vicarious Trauma & Compassion Fatigue: Online Seminar, 5 Dec 2023 9-1 - [register](#)

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## 26 October 2023 - Fortnightly TAG Mail – resources list

A fortnightly newsletter for quality use of medicine healthcare practitioners

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## NSW TAG ACTIVITIES

### **New open email discussions**

- Do hospitals record Epoetins in the S4D books at the pharmacy and wards?' Closes COB 3 November 2023.
- NSW TAG has received a few enquiries about how NSW Drug and Therapeutics Committee plan to manage this andexanet alfa. In particular:
  - will your hospital/district keep stock-on-hand?
  - how much stock?
  - will you use a streamlined IPU process?
  - are you planning to develop a guideline for safe use?
  - will you plan to monitor use/outcomes?

Closes COB Friday 10th November 2023.

### **Recently completed email discussions**

- Potential for inappropriate antiviral prescribing in COVID-19 infections. Closes 16th October
- Ward storage of anaesthetic medicines. Closes 16th October
- Access to miglustat: need for advocacy?
- Problematic access to gemtuzumab: need for advocacy?
- DTC consideration of cenobamate.

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions. They will be on the agenda at TAG General Meetings.

#### Updated TAG publications

- Off-Label Rituximab Patient Fact Sheet and Consent Form Sept 2023 <https://www.nswtag.org.au/off-label-use-of-medicines-2/>
- Transitioning Young People on Complex or High Cost Medicines from Paediatric to Adult Care Services: Guiding Principles and Supporting Resources Sept 2023. (hyperlinks and contact list updated. <https://www.nswtag.org.au/practical-guidance/>)

#### Job advertisements and Expressions of Interest (Eols)

The NSW Editorial Committee is seeking Eols from senior frontline clinical pharmacists to join. Applications close 3<sup>rd</sup> November 2023. Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information.

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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](#)

#### Australian Government Department of Health

- AHPPC statement – End of COVID-19 emergency response - [link](#)

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

- Apparent consumption of alcohol in Australia - [link](#)
- Transitions to residential aged care after hospital for people living with dementia - [link](#)
- Practice Incentives Program Quality Improvement Measures: annual data update 2022-23 - [link](#)
- GEN Aged Care Data: Residential Aged Care Quality Indicators April-June 2023 - [link](#)
- Health expenditure Australia 2021-22 - [link](#)

#### TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- [AusPARs](#): [Gavreto](#) (pralsetinib)
- Australian prescription medicine decision summaries: [Vafseo](#) (vadadustat)

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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

- Cost-Effectiveness of Nirsevimab for Prevention of Respiratory Syncytial Virus Outcomes in Infants - [link](#)
- Alemtuzumab, Cladribine, Fingolimod, and Natalizumab as First-Line Treatments in Adult Patients With Highly Active Relapsing Multiple Sclerosis - [link](#)
- Semaglutide 2 mg for Type 2 Diabetes - [link](#)

#### Canadian Pharmacists Association

- Natural Disasters and Pharmacy Practice - toolkit - [link](#)

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

- [New products](#)
- Estriol 0.5 mg pessary for symptoms of vaginal atrophy due to oestrogen deficiency in post-menopausal women, and as pre-surgery therapy for vaginal operations and during subsequent convalescence

- Columvi (glofitamab), bispecific monoclonal antibody that binds to CD20 on B cell and CD3 on T cell; Early Access Medicines Scheme; for adults with relapsed or refractory diffuse large B-cell lymphoma
- Violite (levonorgestrel and ethinylestradiol) 100/20 micrograms tablets for oral contraception
- Xyquila (olanzapine) IM injection for rapid control of agitation and disturbed behaviour in patients with schizophrenia or manic episodes, when oral therapy is not appropriate, then discontinue and initiate oral olanzapine as soon as clinically appropriate
- Adtralza (tralokinumab) pre-filled pen - new formulation (alternative to the pre-filled syringes), for moderate-to-severe atopic dermatitis in adult and adolescent patients 12 years and older who are candidates for systemic therapy
- [Revised SPCs](#)
- Refixia (nonacog beta pegol) - license extension for the treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency) of any age
- Renvela (sevelamer) - as an alternative to water, the powder for oral suspension may be pre-mixed with a small amount of beverage or food (eg 100 grams/120 ml) and consumed within 30 minutes. Do not heat the powder (eg microwave) or add to heated foods or liquids

### European Medicines Agency (EMA)

- CHMP positive opinions for new indications
- [elranatamab](#) ([Elrexfio](#)) for relapsed and refractory multiple myeloma (conditional)
- [fezolinetant](#) ([Veoza](#)) for moderate to severe vasomotor symptoms associated with menopause
- [gadopiclenol](#) ([Elucirem](#)) diagnostic medicine
- [pegzilarginase](#) ([Loargys](#)) for arginase 1 deficiency under exceptional circumstances
- [rezafungin](#) ([Rezzayo](#)) for invasive candidiasis
- [vamorolone](#) ([Agamree](#)) for Duchenne muscular dystrophy in patients aged  $\geq 4$  years
- CHMP extensions of therapeutic indication
- [durvalumab](#) ([Imfinzi](#)) for advanced or unresectable hepatocellular carcinoma
- [leteirmovir](#) ([Prevymis](#)) for prophylaxis of CMV disease
- [pembrolizumab](#) ([Keytruda](#)) for HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma
- [rucaparib](#) ([Rubraca](#)) for maintenance treatment of high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer
- [zanubrutinib](#) ([Brukinsa](#)) for refractory or relapsed follicular lymphoma
- CHMP positive opinions for extended indications or other
- [alirocumab](#) ([Praluent](#)) for heterozygous familial hypercholesterolaemia in patients  $\geq 8$  years
- [vonicog alfa](#) ([Veyvondi](#)) in von Willebrand disease (VWD)
- CHMP negative opinions
- [Albrioza](#) (sodium phenylbutyrate / ursodoxicoltaurine) for amyotrophic lateral sclerosis
- [Jivadc](#) (trastuzumab duocarmazine): withdrawal of the marketing authorisation application

### Food and Drug Administration (FDA) USA

- New Drug approvals
- adapalene/benzoyl peroxide/clindamycin topical ([Cabtreo](#)) - new topical gel approved for acne vulgaris in patients aged 12 years and older
- [bimekizumab](#) ([Bimzelx](#)) for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- [encorafenib with binimetinib](#) for metastatic non-small cell lung cancer with a BRAF V600E mutation
- pediatric indication for [entrectinib](#) expanded and approved new pellet formulation
- [Etrasimod](#) ([Velsipity](#)), the second oral sphingosine-1-phosphate (S1P) receptor, for moderate to severe active ulcerative colitis in adults
- [infliximab](#) ([Zymfentra](#)) - first SC dosage form approved for maintenance treatment of adults with ulcerative colitis or Crohn's disease
- [Nivolumab](#) for resected Stage IIB/C Melanoma, earlier-stage disease
- Tibsovo ([ivosidenib](#)) for myelodysplastic syndromes
- meningococcal ABCWY pentavalent vaccine ([Penbraya](#)) - first pentavalent vaccine for prevention of most common serogroups causing meningococcal disease
- neoadjuvant/adjuvant [pembrolizumab](#) for resectable non-small cell lung cancer
- [zilucoplan](#) ([Zilbrysq](#)) complement inhibitor for generalized myasthenia gravis
- [vosoritide](#) ([Voxzogo](#)) for achondroplasia expanded to include all children with open epiphyses

### **Health Services Safety Investigation Body**

- Investigation report: Safety management systems - an introduction for healthcare – [link](#) – [SPS commentary](#)

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

- MHRA authorises epcoritamab (Tepkinly) as a treatment for diffuse large B-cell lymphoma in adults - [link](#)

### **NHS England**

- New awareness campaign to help reduce hospital admissions for urinary tract infections - [link](#)
- Commissioning statement: imlifidase-enabled deceased donor kidney transplantation - [link](#)
- Guidance note: virtual ward care for people with heart failure - [link](#)

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

- Thyroid disease: assessment and management, updated ([NG145](#))
- Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments ([TA927](#))
- Baricitinib for treating severe alopecia areata ([TA926](#))
- Mirikizumab for treating moderately to severely active ulcerative colitis ([TA925](#))
- Tirzepatide for treating type 2 diabetes ([TA924](#))
- Daridorexant for treating long-term insomnia ([TA922](#))
- Ruxolitinib for treating polycythaemia vera ([TA921](#))
- Tofacitinib for treating active ankylosing spondylitis ([TA920](#))
- Rimegepant for treating migraine ([TA919](#))
- Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable ([TA917](#))
- Stroke rehabilitation in adults ([NG236](#))
- Diagnosis of venous thromboembolic diseases in people with covid-19: summary of updated NICE guidance - [link](#)

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

- Comparison of lotions, creams, gels and ointments for the treatment of childhood eczema: the BEE RCT - [link](#)

### **Royal College of Physicians, British Pharmacological Society**

- Personalised prescribing: using pharmacogenomics to improve patient outcomes - [link](#)

### **Royal College of Psychiatrists**

- Infant and early childhood mental health: the case for action - [link](#)

### **Royal Pharmaceutical Society**

- New RPS interim professional standards for virtual wards (and 'hospital at home' setting) - [link](#)

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

- Azithromycin (oral) for use within sexual health services- updated PGD template - [link](#)
- Combined oral hormonal contraceptive (COC) in reproductive health - updated PGD template - [link](#)
- Copper Intrauterine Device (Cu-IUD) - PGD template - [link](#)
- Metronidazole (oral) for use within sexual health services - updated PGD template – [link](#)
- Podophyllotoxin (topical) for external anogenital warts - updated PGD template - [link](#)

### **UK Health Security Agency**

- Antimicrobial resistance awareness: toolkit for healthcare providers (update)

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

- 13 critical interventions that support countries to address antimicrobial resistance in human health - [link](#)

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## **MEDICATION SAFETY**

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## Agency for Healthcare Research and Quality AHRQ

- Insulin Administration: Pen vs Vial – Similar, but Not Interchangeable - [link](#)

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

- Glycine toxicity and TURP syndrome – [link](#)

- Tranexamic acid labelling deaths - [link](#)

## electronic Medicines Compendium (eMC) (UK)

- [Revised SPCs](#)

-- Calquence (acalabrutinib) – hypertension added as ADR with monotherapy (common), and combination therapy (very common).

-- Vipidia (alogliptin) - paediatric population information added to 'posology', 'undesirable effects', 'pharmacodynamic and pharmacokinetic properties' sections.

- Arikayce (amikacin) nebulised - increased risk of ototoxicity in patients with mitochondrial DNA mutations (particularly nucleotide 1555 A to G substitution in 12S rRNA gene), even if concentrations in recommended range. Alternative options should be considered in such patients.

-- Evotaz (atazanavir and cobicistat) - concomitant use with ticagrelor and clopidogrel not recommended due to increased and decreased antiplatelet activity respectively, through CYP3A or P-gp inhibition by atazanavir and cobicistat. Prasugrel is recommended as an alternative antiplatelet.

-- Tecentriq (atezolizumab) - haemophagocytic lymphohistiocytosis (HLH) added as rare ADR and should be considered when presentation of cytokine release syndrome is atypical/ prolonged. Monitor patients for clinical signs and symptoms of HLH and treatment discontinued if suspected.

-- Libmeldy (atidarsagene autotemcel)-the removal of bone marrow as an option to collect CD34+ cells removed from the SPC and peripheral blood is now the only permitted cellular source.

-- Invokana (canagliflozin) - concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. Monitor lithium levels more closely during treatment with canagliflozin, especially during initiation and dosage changes

-- Celectol (celiprolol) - alopecia added as a potential ADR (frequency unknown)

-- Pfizer/BioNTech bivalent vaccine - BA.4-5 for age 6 months to 4 years - updated following approval of the Comirnaty Omicron XBB.1.5 vaccines and to update information on myocarditis

-- Cabometyx (cabozantinib) - rare instances of vanishing bile duct syndrome reported; all occurred in patients who have also received immune checkpoint inhibitors. Arterial embolism (uncommon) also added as an ADR.

-- Flolan (epoprostenol) - maximum in-use period for reconstituted solution, when used to treat pulmonary arterial hypertension, amended (with changes to sections 4.2 and 6.3), following ongoing monitoring of the reconstituted solution and review of the potency data.

-- Azocan-P (fluconazole) - washout period of ~ 1 week (5-6 half-lives) before becoming pregnant. Fluconazole increases exposure of abrocitinib active moiety by 155%, so if co-administered, the dose of abrocitinib needs to be adjusted in line with its prescribing information.

-- Bemfola (follitropin alfa) - injection site should be alternated daily. Additional independent risk factors for ovarian hyperstimulation syndrome (OHSS) added: young age, lean body mass, higher doses exogenous gonadotropins, previous episodes of OHSS, and large number of oocytes retrieved.

-- Fybogel Mebeverine - mebeverine should be used with care in patients with hepatic or renal impairment, and those with cardiac disorders such as heart block.

-- Iloprost - apathy, pulsatile sensation, nervousness and a generalised feeling of heat/discomfort and asthenia added to ADR section.

-- Glivec (imatinib) - pemphigus (rare) and osteonecrosis (uncommon) added as potential ADRs.

-- Iomeron (iomeprol) - the small amount of free inorganic iodide that may be present in contrast media might have some effects on thyroid function. These effects appear more evident in patients with latent or overt hyperthyroidism or goitre. Thyroid storm has been reported.

-- COVID-19 Vaccine Janssen - warning added about myocarditis and pericarditis, a possible ADR.

-- Saxenda (liraglutide) injection – rash added as common adverse reaction in adults

-- Victoza (liraglutide) injection - dysgeusia added as potential ADR (frequency uncommon)

-- Rydapt (midostaurin) - interaction with BCRP transporter substrates. In a pharmacokinetic study, rosuvastatin C<sub>max</sub> levels doubled on administration of a single dose of midostaurin 100mg. Caution should be used when administering midostaurin concomitantly with BCRP substrates

-- Numeta G19%E, G13%E Preterm (parenteral nutrition) - use of 1.2 micron filter recommended for administration



- Tagrisso (osimertinib mesylate) - myositis (rare) and increased blood creatine phosphokinase (common) added as ADRs
- Utrogestan (progesterone) - emergency contraceptives section added to warn that the concomitant use of ulipristal acetate with progesterone is expected to result in reduced efficacy of progesterone
- Rifadin (rifampicin) –thrombotic microangiopathy including thrombotic thrombocytopenic purpura/haemolytic uremic syndrome (including fatal cases) and drug-induced liver injury (including fatal cases) added as ADRs
- Ritonavir containing preparations - serum levels of both dabigatran and edoxaban may be increased with concomitant use, owing to P-gp inhibition by ritonavir. Clinical monitoring and/or dose reduction of dabigatran and edoxaban should be considered when co-administered with ritonavir
- Spikevax and Spikevax bivalent Original/Omicron booster vaccines - information on myocarditis and pericarditis and use in immunocompromised individuals updated, and mechanical urticaria (ie triggered by exogenous mechanical stimuli) added as an ADR
- Decapeptyl (triptorelin pamoate) - idiopathic intracranial hypertension (pseudotumor cerebri) added as possible ADR of treatment for central precocious puberty
- Risk minimisation materials
- Patient Alert Card (Pharma): [Pradaxa](#) (dabigatran) granules - for carers of children taking the product. This is intended to alert other healthcare providers that the person is taking an anticoagulant

#### EMA

- reviewing benefits and risks of [obeticholic acid](#) used to treat adults with primary biliary cholangitis
- EMA alerts EU patients and healthcare professionals to reports of falsified [Ozempic pens](#)
- EMA takes further steps to address critical shortages of medicines in the EU – [link](#) - [toolkit](#)

#### FDA

- Warns of Hidden Ingredients in Arthritis, Pain Products - [link](#)

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

- Medication Safety Alert! [October 19, 2023](#) includes:
- Temporarily Holding Medication Orders Safely in Order to Prevent Patient Harm - [link](#)

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

- Reclassification of low-dose cannabidiol - [link](#)
- Oral lidocaine containing products and risks of toxicity in younger children and infants - [link](#)
- DPP-4 inhibitors and GLP-1 receptor agonists and the risk of intestinal obstruction - [link](#)
- Acetylcholinesterase inhibitors and the risk QT prolongation and Torsades de Pointes - [link](#)
- Isotretinoin – psychiatric disorders and sexual dysfunction - [link](#)

#### Specialist Pharmacy Service (SPS)

- Using oseltamivir and zanamivir during breastfeeding - [link](#)
- SPS launches new refrigerated stability tool - [link](#)

#### TGA

- Be alert if you are taking baclofen in high doses - [link](#)
- Warnings on supply and advertising of 'Haytox' - [link](#)

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### PAPERS OF INTEREST

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

- Severe cutaneous adverse reaction to drug excipient following brand-to-generic switch of levetiracetam - [link](#)
- Understanding pathways to health-system pharmacy administration: A journey mapping study - [link](#)

#### Annals of Internal Medicine

- Risk for Congenital Anomalies in Children Conceived with Medically Assisted Fertility Treatment: A Population-Based Cohort Study - [link](#)

#### Annals of Rheumatic Diseases

- Safety of colchicine and NSAID prophylaxis when initiating urate-lowering therapy for gout: propensity score-matched cohort studies in the UK Clinical Practice Research Datalink – [link](#) – [SPS commentary](#)

### **Arthritis & Rheumatology**

- Determinants of Achieving Serum Urate Goal with Treat-to-Target Urate-Lowering Therapy in Gout - [link](#)
- 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis - [link](#)
- Methotrexate safety and efficacy in combination therapies in patients with early rheumatoid arthritis: a post-hoc analysis of a randomized controlled trial (NORD-STAR) - [link](#)

### **Australian Health Review, Journal of the Australian Healthcare & Hospitals Association**

- The unfulfilled promises of electronic health records - [link](#)
- Making good on the promise of genomics in healthcare: the NSW Health perspective - [link](#)

### **Australian Prescriber**

- Management of menopause - [link](#)
- Blood glucose monitoring devices: current considerations - [link](#)
- COVID-19 vaccines in 2023 - [link](#)
- Editorial: Digital health and prescribing: declare the past, diagnose the present, foretell the future - [link](#)
- Update on changing Australian medicine names - [link](#)
- New drugs: [Elasomeran+davesomeran](#) and [Tozinameran+riltozinameran and tozinameran+famtozinameran](#) for prevention of COVID-19; [Finerenone](#) for chronic kidney disease associated with type 2 diabetes with albuminuria

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

- Is Imiquimod a promising drug to treat oral mucosa diseases? A scoping review and new perspectives - [link](#)
- Pharmacokinetics of oral ciprofloxacin in adult patients: a scoping review - [link](#)
- Documentation and Classification of Hospital Pharmacist Interventions: A Scoping Review - [link](#)
- Posaconazole-ibrutinib interaction cannot be avoided by staggered dosing: How to optimize ibrutinib dose during posaconazole treatment - [link](#)
- Exploring the challenges faced by foundation doctors when prescribing high risk medicines safely during the on-call period: a qualitative study - [link](#)
- Venetoclax Pharmacokinetics in Participants with End-stage Renal Disease Undergoing Hemodialysis - [link](#)

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

- Understanding non-recreational prescription medication sharing behaviours: A systematic review - [link](#) – [SPS commentary](#)
- Optimising prediction of mortality, stroke, and major bleeding for patients with atrial fibrillation: validation of the GARFIELD-AF tool in UK primary care electronic records - [link](#)

### **British Journal of Psychiatry**

- Measuring the impact of therapy on medication use: data-linkage study – [link](#)

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

- GLP-1 agonists linked to adverse gastrointestinal events in weight loss patients – [link](#) – [SPS commentary](#)
- Public health expert calls for action across Europe to reduce use of carbon emitting anaesthetic, desflurane - [link](#)

### **BMJ Open**

- Placebo and nocebo effects and mechanisms associated with pharmacological interventions: an umbrella review - [link](#)
- Evaluation of US oncology electronic health record real-world data to reduce uncertainty in health technology appraisals: a retrospective cohort study - [link](#)

### **Canadian Pharmacists Journal**

- Antidepressant discontinuation and the role of the pharmacist - [link](#)

### **Circulation**

- Efficacy, Safety, and Tolerability of Inclisiran in Patients With Homozygous Familial Hypercholesterolemia: Results From the ORION-5 Randomized Clinical Trial - [link](#)
- Rivaroxaban Plus Aspirin Versus Aspirin Alone After Endovascular Revascularization for Symptomatic PAD: Insights From VOYAGER PAD - [link](#)
- Evinacumab for Pediatric Patients with Homozygous Familial Hypercholesterolemia - [link](#)
- Safety and Efficacy of Ticagrelor Monotherapy in Patients With Acute Coronary Syndromes Undergoing Percutaneous Coronary Intervention: an Individual Patient Data Meta-analysis of TWILIGHT and TICO Randomized Trials - [link](#)

### **Clinical Journal of Pain**

- Evaluating the Effect of Pregabalin in the Treatment of Carpal Tunnel Syndrome: A Prospective, Randomized, Triple-Blinded, Placebo-controlled Trial - [link](#)

### **Cochrane**

- Anti-seizure medications for neonates with seizures - [link](#)
- Haemostatic therapies for stroke due to acute, spontaneous intracerebral haemorrhage - [link](#)
- Synbiotics, prebiotics and probiotics for people with chronic kidney disease - [link](#)
- Immunomodulatory interventions for focal epilepsy - [link](#)
- Immunoglobulin treatment for hospitalised infants and young children with respiratory syncytial virus infection - [link](#)
- Interventions to improve the appropriate use of polypharmacy for older people - [link](#)
- Special Collections: Cochrane at 30: what our 30th year can tell us about the future - [link](#)

### **Diabetes Care**

- Dasiglucagon Treatment for Postprandial Hypoglycemia After Gastric Bypass: A Randomized, Double-Blind, Placebo-Controlled Trial - [link](#)
- A Randomized Trial of Closed-Loop Insulin Delivery Postpartum in Type 1 Diabetes - [link](#)
- Predictors of  $\geq 15\%$  Weight Reduction and Associated Changes in Cardiometabolic Risk Factors with Tirzepatide in Adults with Type 2 Diabetes in SURPASS 1–4 - [link](#)
- Association Between Atrial Fibrillation and Diabetes-Related Complications: A Nationwide Cohort Study - [link](#)
- COVID-19 Vaccination Prior to SARS-CoV-2 Infection Reduced Risk of Subsequent Diabetes Mellitus: A Real-World Investigation Using U.S. Electronic Health Record - [link](#)
- Impact of Guideline-Directed Statin Intervention for Primary Prevention in Patients With Diabetes – [link](#) – [SPS commentary](#)
- An Update to the Overview of Reviews: Risks of and From SARS-COV-2 Infection and COVID-19 in People With Diabetes - [link](#)

### **Drug Safety**

- A multi-method exploratory evaluation of a service designed to improve medication safety for patients with monitored dosage systems following hospital discharge - [link](#)

### **Drug and Therapeutics Bulletin**

- Bempedoic acid and cardiovascular outcomes - [link](#)
- Safety update: methotrexate and photosensitivity reactions - [link](#)

### **European Heart Journal**

- Acute heart failure: current pharmacological treatment and perspectives - [link](#)

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

- Systematic review of room temperature stability of key beta-lactam antibiotics for extended infusions in inpatient settings - [link](#)

### **Gastroenterology**

- Efficacy of Probiotics in Irritable Bowel Syndrome: Systematic Review and Meta-analysis – [link](#) – [SPS commentary](#)

#### **Internal Medicine Journal**

- The use of belimumab in three cases of refractory lupus nephritis - [link](#)

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

- Comparing patient reported and medical record data of adverse drug reactions to anti-seizure drugs - [link](#)

#### **JAMA**

- Nasal Iodophor Antiseptic vs Nasal Mupirocin Antibiotic in the Setting of Chlorhexidine Bathing to Prevent Infections in Adult ICUs: A Randomized Clinical Trial - [link](#) – [SPS commentary](#)
- Diagnosis and Treatment of Bipolar Disorder: A Review - [link](#)
- Orthostatic Hypotension, Hypertension Treatment, and Cardiovascular Disease: An Individual Participant Meta-Analysis – [link](#) - [SPS commentary](#)
- Hyperthyroidism: A Review - [link](#)
- The Use of Historical Controls in Clinical Trials - [link](#)
- Traditional Chinese Medicine Compound (Tongxinluo) and Clinical Outcomes of Patients With Acute Myocardial Infarction: The CTS-AMI Randomized Clinical Trial – [link](#) – [SPS commentary](#)

#### **JAMA Dermatology**

- Janus Kinase Inhibitors and Adverse Events of Acne: A Systematic Review and Meta-Analysis - [link](#)
- Dupilumab-Associated Lymphoid Reactions in Patients With Atopic Dermatitis - [link](#) – [SPS commentary](#)

#### **JAMA Internal Medicine**

- Nirmatrelvir and Molnupiravir and Post–COVID-19 Condition in Older Patients - [link](#)
- Endogenous and Exogenous Thyrotoxicosis and Risk of Incident Cognitive Disorders in Older Adults – [link](#) – [SPS commentary](#)

#### **JAMA Oncology**

- Systemic Anticancer Therapy and Thromboembolic Outcomes in Hospitalized Patients With Cancer and COVID-19 - [link](#)

#### **JAMA Psychiatry**

- Psychotherapies for Generalized Anxiety Disorder in Adults: A Systematic Review and Network Meta-Analysis of Randomized Clinical Trials - [link](#)

#### **Journal of Clinical Oncology**

- Adolescent and Young Adult Germ Cell Tumors: Epidemiology, Genomics, Treatment, and Survivorship - [link](#)
- Systemic Therapy for Small-Cell Lung Cancer: ASCO-Ontario Health (Cancer Care Ontario) Guideline - [link](#)
- Review: Poly(ADP-ribose) Polymerase Inhibitor Combinations in First-Line Metastatic Castration-Resistant Prostate Cancer: Increasing Toxicity With Unclear Benefits - [link](#)
- Evidence-Based Care of Older Adults with Metastatic Colorectal Cancer: Insights From Landmark Clinical Trials - [link](#)
- Palliative Care in Adolescents and Young Adults With Cancer - [link](#)
- Recent Bendamustine Treatment Before Apheresis Has a Negative Impact on Outcomes in Patients With Large B-Cell Lymphoma Receiving Chimeric Antigen Receptor T-Cell Therapy - [link](#)

#### **Journal of General Internal Medicine**

- Medication safety amid technological change: usability evaluation to inform inpatient nurses' electronic health record system transition - [link](#)

#### **Lancet**

- Methotrexate to treat hand osteoarthritis with synovitis (METHODS): an Australian, multisite, parallel-group, double-blind, randomised, placebo-controlled trial - [link](#)

- Anticoagulation in patients with cerebral amyloid angiopathy - [link](#)
- Viewpoint:  $\beta$  blockers switched to first-line therapy in hypertension - [link](#)
- Amitriptyline at Low-Dose and Titrated for Irritable Bowel Syndrome as Second-Line Treatment in primary care (ATLANTIS): a randomised, double-blind, placebo-controlled, phase 3 trial – [link](#) – [SPS commentary](#)
- Review: Polymyalgia rheumatica - [link](#)

### **Lancet Diabetes & Endocrinology**

- Empagliflozin in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial – [link](#) – [SPS commentary](#)

### **Lancet Gastroenterology and Hepatology**

- Diagnosis and management of ectopic varices in portal hypertension - [link](#)
- The immunological landscape in pancreatic ductal adenocarcinoma and overcoming resistance to immunotherapy - [link](#)

### **Lancet Haematology**

- Acquired plasminogen deficiency and ligneous conjunctivitis associated with chronic tranexamic acid use - [link](#)

### **Lancet HIV**

- HIV-1 drug resistance in people on dolutegravir-based antiretroviral therapy: a collaborative cohort analysis – [link](#) – [SPS commentary](#)

### **Lancet Infectious Diseases**

- Overcoming publication and dissemination bias in infectious diseases clinical trials - [link](#)
- Understanding vancomycin nephrotoxicity augmented by  $\beta$ -lactams: a synthesis of endosymbiosis, proximal renal tubule mitochondrial metabolism, and  $\beta$ -lactam chemistry - [link](#)

### **Lancet Neurology**

- Effect of blood pressure-lowering agents on microvascular function in people with small vessel diseases (TREAT-SVDs): a multicentre, open-label, randomised, crossover trial – [link](#) – [SPS commentary](#)
- Stimulation of TREM2 with agonistic antibodies—an emerging therapeutic option for Alzheimer's disease - [link](#)

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

- Application of Precision Medicine Concepts in Ambulatory Antibiotic Management of Acute Pyelonephritis - [link](#)
- Medication Reviews and Clinical Outcomes in Persons with Dementia: A Scoping Review - [link](#)
- Adult Patients with Difficulty Swallowing Oral Dosage Forms: A Systematic Review of the Quantitative Literature - [link](#)
- Identifying Prescription-Opioid-Related Risks Using Prescription Drug Monitoring Programs' Algorithms and Clinical Screening Tools - [link](#)

### **Nature Medicine**

- Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial - [link](#)

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

- Decolonization in Nursing Homes to Prevent Infection and Hospitalization – [link](#) – [SPS commentary](#)
- Adjunctive Dexamethasone for Tuberculous Meningitis in HIV-Positive Adults – [link](#) – [SPS commentary](#)
- Shiga Toxin–Producing Escherichia coli and the Hemolytic–Uremic Syndrome - [link](#)
- Improved Outcomes with Enzalutamide in Biochemically Recurrent Prostate Cancer – [link](#) – [SPS commentary](#)
- Review: The Syndrome of Inappropriate Antidiuresis - [link](#)

### **Pharmacotherapy**

- A systematic review of clozapine-associated inflammation and related monitoring - [link](#)

#### **Prescriber UK**

- Novel approaches to the management of hyperlipidaemia - [link](#)  
- Raising awareness of drug-micronutrient interactions - [link](#)

#### **Public Library of Science (PLOS) One**

- Safety outcomes when switching between biosimilars and reference biologics: A systematic review and meta-analysis - [link](#)

#### **Stroke**

- Effect of Individualized Versus Standardized Blood Pressure Management During Endovascular Stroke Treatment on Clinical Outcome: A Randomized Clinical Trial - [link](#)

#### **Thorax**

- Immediate smoking cessation support during lung cancer screening: long-term outcomes from two randomised controlled trials - [link](#)

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### **WEBINARS & PODCASTS**

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#### **Australian Prescriber Podcasts**

- [Episode 149](#) – Treatments for atopic dermatitis

#### **MJA Podcasts**

- [Episode 28](#): Kidney health of Aboriginal and Torres Strait Islander peoples

#### **Purple Pen Podcast**

- [PPP 153](#) - Human Papillomavirus (HPV)

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## **Fortnightly TAG Mail – resources list 12<sup>th</sup> October 2023**

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<https://www.nswtag.org.au/tag-mail/>

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### **NSW TAG ACTIVITIES**

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*Don't forget NSW TAG also provides a cumulative listing of TAG Mails at <https://www.nswtag.org.au/tag-mail/>.*

*Use 'control F' to find recent information on medicines or topics of interest.*

#### **Email discussion**

##### **Open email discussions**

Potential for inappropriate antiviral prescribing in COVID-19 infections. Closes 16th October

Ward storage of anaesthetic medicines. Closes 16th October

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

Access to miglustat: need for advocacy?

Problematic access to gemtuzumab: need for advocacy?

DTC consideration of cenobamate.

Contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about any email discussions. They will be on the agenda at TAG General Meetings.

#### **Upcoming TAG meeting dates**

- Annual General Meeting 19th October 2023 4.30pm at Level 7 Board Room, Kolling Building at Royal North Shore Hospital or via Teams

- General Meeting 19th October 2023 3-4.30pm at Level 7 Board Room, Kolling Building at Royal North Shore Hospital or via Teams

#### **Updated TAG [publications](#)**



Off-Label Rituximab Patient Fact Sheet and Consent Form Sept 2023 <https://www.nswtag.org.au/off-label-use-of-medicines-2/>

Transitioning Young People on Complex or High Cost Medicines from Paediatric to Adult Care Services: Guiding Principles and Supporting Resources Sept 2023. (hyperlinks and contact list updated. <https://www.nswtag.org.au/practical-guidance/>)

## **CATAG**

- Next CATAG meeting 25<sup>th</sup> October 12 noon.

## **Job advertisements and Expressions of Interest (Eols)**

1. The NSW Editorial Committee is seeking Eols from senior frontline clinical pharmacists to join. Applications close 13<sup>th</sup> October 2023. Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information.
2. NSW TAG is seeking input from accredited pharmacists working in Residential Aged Care Facilities who are experienced with the activity of Medication Advisory Committees and QUM activities. Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information.
3. CATAG QUM Project Officer Part-Time Position advertised. See <https://www.seek.com.au/job/70331840>

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

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

- Expression of Interest for a mid-career clinician / academic to become an Observer to Medication Safety Oversight Committee through until the end of its current term which ends on 30 June 2024 – closes midnight Thursday 19 October 2023. Applications to [medsafety@safetyandquality.gov.au](mailto:medsafety@safetyandquality.gov.au) - link Contact Sasha Bennett for more information: [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au)

### **NSW Health**

- Measles alert for international flight passengers - [link](#)
- Syphilis in Pregnancy and Newborns ([PD2023\\_029](#)) [06 October 2023]
- Framework for the Specialist Trans and Gender Diverse Health Service for People Under 25 Years ([IB2023\\_043](#)) [06 October 2023]
- NSW Health Procurement (Goods and Services) Policy ([PD2023\\_028](#)) [04 October 2023]
- Public Interest Disclosures ([PD2023\\_026](#)) [03 October 2023]

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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](#)

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

- Suicide & self-harm monitoring - [link](#)
- GEN Aged Care Data - [link](#)
- BreastScreen Australia monitoring report 2023 – [link](#)
- Australia's Disability Strategy - [link](#)
- MyHospitals: Hospital resources 2021–22 - [link](#)
- Maternity models of care in Australia, 2023 - [link](#)
- National Perinatal Data Collection Data Availability Resource - [link](#)

### **MIMS monthly updates, [October 2023](#)**

- New Products
- Enfortumab vedotin ([Padcev](#)) an ADC targeting Nectin-4, monotherapy for adult locally advanced or metastatic urothelial cancer in patients who previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand-1 inhibitor

- Tirzepatide ([Mounjaro](#)) a long-acting dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist for treatment of insufficiently controlled adult type 2 diabetes mellitus as an adjunct to diet and exercise either as monotherapy when metformin is not tolerated or contraindicated, or in addition to other medicinal products for the treatment of type 2 diabetes
- New Indications
- Apremilast ([Otezla](#)) for plaque psoriasis (any severity) in adults, who are candidates for phototherapy or systemic therapy and adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy
- Dupilumab ([Dupixent](#)) for moderate to severe prurigo nodularis in adults, who are candidates for systemic therapy
- Glecaprevir and pibrentasvir ([Maviret](#)) (granules) for children 3 years and older

### **Society of Hospital Pharmacists of Australia (SHPA)**

- Pharmacy Forecast Australia 2023 - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
  - AusPAR: Tavneos ([avacopan](#)) in combination with a rituximab or cyclophosphamide based regimen for anti-neutrophil cytoplasmic autoantibody-associated vasculitis
- Australian prescription medicine decision summaries for approvals:
  - Tibsovo ([ivosidenib](#)) for acute myeloid leukaemia that carries an IDH1 R132 mutation
  - Alhemo ([concizumab](#)) to prevent haemophilia

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

- Clinical Communiqué [Episode #11](#): First Nations - A lack of cultural safety is a contributing factor in preventable hospital deaths - [link](#)

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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

- IV Acetaminophen for Acute Pain in Emergency Departments, updated - [link](#)
- Treatment of Chronic Pain in Patients on Opioid Agonist Therapy or with Opioid Use Disorder, updated, - [link](#)
- The Safety of Niraparib in Ovarian Cancer, updated - [link](#)

### **Centre for Mental Health**

- A mentally healthier nation. Towards a ten-year, cross-government plan for better prevention, equality and support - [link](#)

### **Community Pharmacy England**

- All valproate containing products reclassified as special containers from 1st October 2023 – [SPS commentary](#)

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

- Disclosure of industry payments to the healthcare sector: consultation – [link](#) – [SPS commentary](#)

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

- [New products](#)
- Sogroya (somapacitan)- long-acting recombinant human growth hormone derivative licensed for replacement of endogenous growth hormone in children aged  $\geq 3$  years, and adolescents with growth failure due to growth hormone deficiency, and in adults with growth hormone deficiency
- Pradaxa (dabigatran) coated granules (various strengths) - new formulation licensed for the treatment of venous thromboembolic events (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age

### **European Medicines Agency (EMA)**

- EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna - [link](#)
- EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep - [link](#)

### Food and Drug Administration (FDA) USA

- grants first marketing authorization for a DNA test to assess predisposition for dozens of cancer types - [link](#)
- Final Guidance: Human Prescription Drug and Biological Products--Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers--"Dose Banding" - [link](#)
- New Drug approvals
  - Rivfloza ([nedosiran](#)) for lowering urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function
  - Pombiliti ([cipaglucosidase alfa-atga](#)) for late-onset Pompe disease
  - [miqlustat](#) (Opfolda) stabilizes and reduces inactivation of cipaglucosidase alfa when used for Pompe disease
  - [roflumilast](#) topical (Zoryve) for plaque psoriasis to include children aged 6 years and older
  - [phentolamine](#) ophthalmic (Ryzumvi) nonselective alpha-1 and alpha-2 agonist for pharmacologically induced mydriasis

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

- authorises [dostarlimab](#) (Jemperli) in combination with chemotherapy for first-line treatment of primary advanced or metastatic endometrial cancer

### NHS England

- Inclusive digital healthcare: a framework for NHS action on digital inclusion - [link](#)

### NHS Scotland

- Accepted for use:
  - [Belzutifan](#) (Welireg®) for adult von Hippel-Lindau (VHL) disease in those who require therapy for VHL-associated renal cell carcinoma, CNS hemangioblastomas, or pancreatic neuroendocrine tumours, and for whom localised procedures are unsuitable or undesirable
  - [Brexucabtagene autoleucel](#) (Tecartus®) under end-of-life and orphan equivalent medicine process, for adults aged  $\geq 26$  years with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia
  - [Darolutamide](#) (Nubeqa®) under orphan medicine process, in combination with docetaxel for adults with metastatic hormone-sensitive prostate cancer
  - [Fenfluramine](#) (Fintepla®) for seizures associated with Dravet syndrome as an add-on to other anti-epileptic medicines for patients 2 years of age and older
  - Kaletra (ritonavir/lopinavir) - interaction with edoxaban resulting in increased serum edoxaban concentration added. Clinical monitoring and/or dose reduction of the DOAC should be considered when co-administered with ritonavir containing products
  - [Maribavir](#) (Livtencity®) for cytomegalovirus infection and/or disease refractory to  $\geq 1$  prior therapies, including ganciclovir, valganciclovir, cidofovir or foscarnet in adults who have undergone a haematopoietic stem cell transplant or solid organ transplant
  - [Olaparib](#) (Lynparza®) as monotherapy or in combination with endocrine therapy for adjuvant treatment of adults with germline BRCA1/2-mutations who have HER2-negative, high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy
  - [Regorafenib](#) (Stivarga®) as monotherapy for adults with metastatic colorectal cancer who have been previously treated with, or are unsuitable for, available therapies (including fluoropyrimidine-based chemotherapy, anti-VEGF therapy and anti-EGFR therapy)
  - [Voclosporin](#) (Lupkynis®) in combination with mycophenolate mofetil for the treatment of adult patients with active class III, IV or V (including mixed class III/V and IV/V) lupus nephritis
- Accepted for restricted use:
  - [Atogepant](#) (Aquipta®) for migraine prophylaxis in adults who have  $\geq 4$  migraine days per month. Use is restricted to those with chronic and episodic migraine who have had prior failure on  $\geq 3$  three migraine preventive treatments
  - [Semaglutide](#) (Wegovy®) as an adjunct to a reduced calorie diet and increased physical activity for weight management, in adults with a BMI of  $\geq 30\text{kg/m}^2$  in the presence of at least one weight-related comorbidity

- [Zanubrutinib](#) (Brukinsa®) as monotherapy for adults with chronic lymphocytic leukaemia. Use is restricted to those in whom chemo-immunotherapy is unsuitable
- Not recommended:
- [Lutetium](#) (177Lu) vipivotide tetraxetan (Pluvicto®) for adults with PSMA-positive metastatic castration-resistant prostate cancer, who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy or who are not medically suitable for taxanes

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

- Acute kidney injury: prevention, detection and management, updated ([NG148](#))
- COVID-19 rapid guideline: haematopoietic stem cell transplantation, updated ([NG164](#))
- Intrapartum care ([NG235](#))
- Hearing loss in adults: assessment and management, updated ([NG98](#))
- Suspected neurological conditions: recognition and referral, updated ([NG127](#))
- Suspected cancer: recognition and referral, updated ([NG12](#))
- Ovarian cancer: recognition and initial management, updated ([CG122](#))
- Urinary incontinence in neurological disease: assessment and management, updated ([CG148](#))
- Bimekizumab for treating active psoriatic arthritis ([TA916](#))
- Bimekizumab for treating axial spondyloarthritis ([TA918](#))
- Pegunigalsidase alfa for treating Fabry disease ([TA915](#))

### **Royal Pharmaceutical Society**

- Use of Patient Group Directions by Pharmacy Technicians – [link](#) – [SPS commentary](#)

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

- Managing COVID-19 and breastfeeding - [link](#)
- Medroxyprogesterone acetate (DMPA) IM injection for contraception - updated PGD – [link](#) – [SPS commentary](#)
- Medroxyprogesterone acetate (SC-DMPA) injection for contraception – updated PGD – [link](#) – [SPS commentary](#)
- Progestogen-Only Intra-Uterine Device (LNG-IUD) for contraception – updated PGD - [link](#)
- Ulipristal acetate 30mg tablets for emergency contraception – updated PGD - [link](#)

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

- recommends R21/Matrix-M vaccine for malaria prevention in updated advice on immunization - [link](#)

## **MEDICATION SAFETY**

### **Allergy UK**

- Reducing the risk of your child having a serious allergic reaction: guidance for parents & carers - [link](#)

### **Department of Health and Social Care - National Patient Safety Alert**

- Shortage of methylphenidate prolonged-release capsules and tablets, lisdexamfetamine capsules, and guanfacine prolonged-release tablets - [link](#)
- Shortage of verteporfin 15mg powder for solution for injection - [link](#)

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

- [Revised SPCs](#)
- Eliquis (apixaban) - available data on paediatric thromboembolism prevention included (studies CV185155 and CV185362) but no recommendation on a posology in this group made
- Aqueous Cream BP, Eczemol/Cetraben (chlorhexidine) cream - can make skin and surfaces slippery after use. Advise patients to take care following use, especially when entering or leaving the bath/shower
- Comirnaty Original/Omicron BA.1 COVID-19 mRNA Vaccine (nucleoside modified) - individuals may not be fully protected until 7 days after their vaccination
- COVID-19 Vaccine Janssen - increased risk of myocarditis and pericarditis following vaccination- can develop within a few days, primarily within 14 days, and more often in males <40 years
- Jemperli (dostarlimab) - recent licence extension, for use in combination with platinum-containing chemotherapy for mismatch repair deficient (dMMR)/ microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer in candidates suitable for systemic therapy

- Lixiana (edoxaban) – correction -anticoagulant-related nephropathy (not neuropathy) (frequency unknown) added as ADR
- Elleste Duet (estradiol hemihydrate, norethisterone acetate) - although the potential interaction between HRT and lamotrigine has not been studied, a similar interaction to that seen with oestrogen-containing contraceptives (decreased lamotrigine concentrations) is likely- may reduce seizure control
- Benepali (etanercept) pre-filled syringe may be stored at temperatures up to a maximum of 30°C (previously 25°C) for a single period of up to 31 days (previously 4 weeks); after which, it should not be refrigerated again. It should be discarded if not used within 31 days of removal from refrigeration
- Enbrel (etanercept) – breastfeeding guidance updated and the possibility of administration of live vaccines to infants exposed to etanercept during breastfeeding
- Kaolin and Morphine Mixture BP - warnings regarding sleep-related breathing disorders, acute generalised exanthematous pustulosis, hepatobiliary disorders (dysfunction and spasm of the sphincter of Oddi), and to note repeated use can lead to drug dependence, even at therapeutic doses
- Vitrakvi (larotrectinib) – updated dosing recommendations in patients with liver function abnormalities, existing warning on hepatotoxicity, drug interaction information linked to CYP3A, P-gp and BCRP inhibitors and CYP3A and P-gp inducers
- Isturisa (osilodrostat phosphate) - myalgia and arthralgia added as very common potential ADR
- Adempas (riociguat) - license extension for treatment of pulmonary arterial hypertension in paediatric patients aged <18 years and body weight ≥ 50 kg with WHO Functional Class II to III in combination with endothelin receptor antagonists – [SPS commentary](#)
- MabThera (rituximab) – enteroviral meningoencephalitis included as an ADR (frequency unknown), and to advise that due to risk of false negative serologic testing of infections, consider alternative diagnostic tools in patients presenting with symptoms of rare infectious disease

#### **EMA**

- New safety information for Omega-3-acid ethyl esters - [link](#)

#### **FDA**

- FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders - [link](#)

#### **Health Canada – MedEffect Notice**

- Health Product InfoWatch, [September 2023](#)

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

- Medication Safety Alert! [October 5, 2023](#)
- Minimizing Distractions and Interruptions During Medication Safety Tasks - [link](#)

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

- Safety warnings to be provided to all patients with every valproate-containing medicine they receive under new law - [link](#)
- Guidance: Full pack dispensing of valproate-containing medicines - [link](#)
- Medicines that you cannot export from the UK or hoard - [link](#)

#### **MIMS monthly updates, [October 2023](#)**

- New Contraindications
- Arsenic trioxide ([Phenasen](#)) contraindicated in pregnancy/when there is a possibility of pregnancy

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

- Antidepressants in pregnancy: applying causal epidemiological methods to understand service-use outcomes in women and long-term neurodevelopmental outcomes in exposed children - [link](#)

#### **Pharma**

- Simponi ([golimumab](#)) 50 mg and 100 mg SmartJect Pre-filled Pen (MSD): Instructions for use for this product have been revised, as accidental needle stick injuries, bent or hooked needles, and device actuation failure have been reported; in some cases, these have prevented patients from receiving the scheduled dose or caused injury
- Xalkori ([crizotinib](#)) (Pfizer): Vision disorders, including risk of severe visual loss, need for monitoring in paediatric patients

### **Royal Pharmaceutical Society**

- Penicillin allergy checklist – [link](#) – [SPS commentary](#)

### **Specialist Pharmacy Service**

- Medically terminating a pregnancy during breastfeeding - [link](#)
- Preparing Comirnaty 10 (XBB.1.5) ready to use vaccine – [preparing](#) – [understanding characteristics](#)
- Understanding the characteristics of Comirnaty 3 (THREE) (XBB.1.5) concentrate vaccine - [link](#)
- Prescribing available medicines to treat ADHD - [link](#)
- Switching between oral prednisolone and IV hydrocortisone - [link](#)
- Using lithium and valproate for bipolar disorder during breastfeeding - [link](#)
- Medication Safety Update [September 2023](#)
- Using emergency contraception during breastfeeding - [link](#)

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## **PAPERS OF INTEREST**

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### **Academic Emergency Medicine**

- Phenobarbital for alcohol withdrawal management in the emergency department: A systematic review of direct evidence for the SAEM GRACE initiative – [link](#) – [SPS commentary](#)

### **Age and Ageing**

- Risk of adverse events following the initiation of antihypertensives in older people with complex health needs: a self-controlled case series in the United Kingdom - [link](#) – [EvidenceAlert](#)

### **American Journal of Cardiology**

- An Evidence-Based Approach to Anticoagulation Therapy Comparing Direct Oral Anticoagulants and Vitamin K Antagonists in Patients With Atrial Fibrillation and Bioprosthetic Valves: A Systematic Review, Meta-Analysis, and Network Meta-Analysis – [link](#) – [SPS commentary](#) - [EvidenceAlert](#)
- Ticagrelor Versus Prasugrel in Patients With Acute Coronary Syndrome: A Systematic Review and Meta-Analysis - [link](#)

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

- Prevented harm and cost avoidance with pharmacist intervention while utilizing a discharge medication reconciliation tool - [link](#)
- Data-based program management of system-wide IV smart pump integration - [link](#)
- The expanding universe of gene and cell therapy - [link](#)
- Precipitation of hyponatremia and seizures by esmolol in sterile water formulation - [link](#)
- Integrating professional identity formation into experiential pharmacy education and training - [link](#)
- Admission medication history quality: Considering non-prescription medications, limited English proficiency, and medication history sources - [link](#)
- The evolution of multiple sclerosis disease-modifying therapies: An update for pharmacists - [link](#)
- Diabetes distress among people with type 2 diabetes in a pharmacist-run community care clinic - [link](#)
- Direct transition from rapid-infusion originator to rapid-infusion biosimilar tumor necrosis factor inhibitor in children with inflammatory bowel disease: A case series - [link](#)

### **Annals of Internal Medicine**

- Atrial Fibrillation Recurrence in Patients with Transient New-Onset Atrial Fibrillation Detected During Hospitalization for Noncardiac Surgery or Medical Illness: A Matched Cohort Study - [link](#)
- Xylazine Adulteration of the Heroin–Fentanyl Drug Supply – [link](#) – [SPS commentary](#)

### **Annals of Rheumatic Diseases**

- Anti-GM-CSF otilimab versus tofacitinib or placebo in patients with active rheumatoid arthritis and an inadequate response to conventional or biologic DMARDs: two phase 3 randomised trials (contRAst 1 and contRAst 2) - [link](#)

### **Arthritis & Rheumatology**

- Identification, Monitoring, and Management of Rheumatoid Arthritis–Associated Interstitial Lung Disease - [link](#)



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

- UK Prescribing Safety Assessment (PSA): The development, implementation and outcomes of a national online prescribing assessment - [link](#)
- Call to Action: Harmonisation of Pharmacovigilance Regulations for Post-marketing Pregnancy and Breastfeeding Safety Studies - [link](#)
- Cost-effectiveness Analysis of CYP2C19 Genotype-guided Antiplatelet Therapy for Patients with Acute Minor Ischemic Stroke and High-risk Transient Ischemic Attack in China - [link](#)
- Results of the first international quality control programme for oral targeted oncolytics - [link](#)

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

- Comparing dietary strategies to manage cardiovascular risk in primary care: Narrative review of systematic reviews - [link](#)
- Long-term cardiovascular risks and statin treatment impact on socioeconomic inequalities: microsimulation model - [link](#)
- Post-hospitalisation asthma management in primary care: a retrospective cohort study - [link](#) – [SPS commentary](#)

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

- Association between recently raised anticholinergic burden and risk of acute cardiovascular events: nationwide case-case-time-control study – [link](#) – [SPS commentary](#)
- Tackling climate change: the pivotal role of clinicians - [link](#)
- Association between changes in carbohydrate intake and long term weight changes: prospective cohort study - [link](#)
- Struggling in the heat: what I need to know about my medication - [link](#)
- When I use a word . . . Dinitrophenol? Don't take it - [link](#)
- Early versus delayed antihypertensive treatment in patients with acute ischaemic stroke: multicentre, open label, randomised, controlled trial - [link](#)
- Evidence for clinical interventions targeting the gut microbiome in cardiometabolic disease - [link](#)

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

- Intrapartum azithromycin to prevent maternal and neonatal sepsis and deaths: A systematic review with meta-analysis - [link](#)

### **BMJ Open**

- Statins exposure and acute pancreatitis: a retrospective cohort study using a large national insurance database - [link](#)
- Early use of oral semaglutide in the UK: A cost-effectiveness analysis versus continuing metformin and SGLT-2 inhibitor therapy - [link](#)

### **BMJ Quality and Safety**

- Informing understanding of coordination of care for patients with heart failure with preserved ejection fraction: a secondary qualitative analysis - [link](#)
- Quality of care for secondary cardiovascular disease prevention in 2009–2017: population-wide cohort study of antiplatelet therapy use in Scotland - [link](#)

### **Circulation**

- Association Between Mental Health Burden, Clinical Presentation, and Outcomes in Individuals With Symptomatic Peripheral Artery Disease: A Scientific Statement From the American Heart Association - [link](#)
- Nondental Invasive Procedures and Risk of Infective Endocarditis: Time for a Revisit: A Science Advisory From the American Heart Association - [link](#)

### **Clinical Journal of Pain**

- Comparative Efficacy and Safety of Five Anti-calcitonin Gene-related Peptide Agents for Migraine Prevention: A Network Meta-analysis - [link](#)

### **Cochrane**

- Immunotherapy for advanced or metastatic urothelial carcinoma - [link](#)
- Vitamin D for the treatment of inflammatory bowel disease - [link](#)

- Special collection: Coronavirus (COVID-19): infection control and prevention measures - [link](#)

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

- Effect of tirzepatide on blood pressure and lipids: A meta-analysis of randomized controlled trials - [link](#)

### **European Heart Journal**

- Acquired cardiovascular disease in adults with congenital heart disease: A call to action for timely preventive measures – a European clinical consensus statement - [link](#)

- Mavacamten: a first-in-class myosin inhibitor for obstructive hypertrophic cardiomyopathy - [link](#)

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

- Older people, medication usage and long-term care pharmacists: a retrospective cohort study - [link](#)

- Assessment of the accuracy of estimated free phenytoin concentrations in a mixed patient population - [link](#)

- Case report: Successful desensitisation to paclitaxel with omalizumab - [link](#)

### **Internal Medicine Journal**

- Improving palliative and supportive care in advanced cirrhosis: the HepatoCare model of integrated collaborative care - [link](#)

- P101: Health care pathways for anaphylaxis: identified from linked ambulance, emergency and hospitalisations data - [link](#)

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

- A novel machine learning model to predict high on-treatment platelet reactivity on clopidogrel in Asian patients after percutaneous coronary intervention - [link](#)

- Environmental scan of current strategies to decrease sedative-hypnotic drug use and promote sleep in hospital patients - [link](#)

### **JAMA**

- Eplontersen for Hereditary Transthyretin Amyloidosis With Polyneuropathy – [link](#) – [SPS commentary](#)

- Adherence to CPAP Treatment and the Risk of Recurrent Cardiovascular Events: A Meta-Analysis – [link](#) – [SPS commentary](#)

- Estimated Glomerular Filtration Rate, Albuminuria, and Adverse Outcomes: An Individual-Participant Data Meta-Analysis – [link](#) – [SPS commentary](#)

### **JAMA Cardiology**

- Effectiveness and Safety of Enteric-Coated vs Uncoated Aspirin in Patients With Cardiovascular Disease: A Secondary Analysis of the ADAPTABLE Randomized Clinical Trial - [link](#)

### **JAMA Dermatology**

- Outcome Measures for the Evaluation of Treatment Response in Hidradenitis Suppurativa for Clinical Practice: A HISTORIC Consensus Statement - [link](#)

### **JAMA Neurology**

- Loneliness and Risk of Parkinson Disease - [link](#)

- Underlying Causes of TIA and Minor Ischemic Stroke and Risk of Major Vascular Events - [link](#)

### **JAMA Oncology**

- Heterogeneity and Utility of Pharmaceutical Company Sharing of Individual-Participant Data Packages - [link](#)

- Tislelizumab vs Sorafenib as First-Line Treatment for Unresectable Hepatocellular Carcinoma: A Phase 3 Randomized Clinical Trial - [link](#)

### **JAMA Psychiatry**

- Antidepressant Use and Risk of Manic Episodes in Children and Adolescents With Unipolar Depression – [link](#) – [SPS commentary](#)

- Individual-Level Risk Prediction of Return to Use During Opioid Use Disorder Treatment - [link](#)

### **Journal of Clinical Oncology**

- Systemic Therapy for Tumor Control in Metastatic Well-Differentiated Gastroenteropancreatic Neuroendocrine Tumors: ASCO Guideline - [link](#)
- Canakinumab as Adjuvant Therapy in Patients with Completely Resected Non–Small-Cell Lung Cancer: Results From the CANOPY-A Double-Blind, Randomized Clinical Trial - [link](#)
- Redefining the Position of Hormonal Therapy in Endometrial Cancer in the Era of Molecular Classification - [link](#)
- Importance of Low- and Moderate-Grade Adverse Events in Patients' Treatment Experience and Treatment Discontinuation: An Analysis of the E1912 Trial - [link](#)

### **Journal of Health Services Research & Policy**

- Optimising the prescribing of drugs that may cause dependency: An evidence and gap map of systematic reviews - [link](#)

### **Journal of Patient Safety**

- Reduced post discharge incidents after implementation of a hospital-to-home transition intervention for children with medical complexity - [link](#)

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

- Evaluation of local guideline introduction on surgical antimicrobial prophylaxis prescribing for open reduction internal fixations at an Australian tertiary hospital - [link](#)
- Safety and efficacy comparisons of intravenous trastuzumab biosimilars to the reference product medicine in treatment-naïve and switch-over patients with breast cancer: a systematic and meta-analysis - [link](#)

### **Lancet**

- Efficacy and safety of the neonatal Fc receptor inhibitor efgartigimod in adults with primary immune thrombocytopenia (ADVANCE IV): a multicentre, randomised, placebo-controlled, phase 3 trial – [link](#) – [SPS commentary](#)

### **Lancet Diabetes & Endocrinology**

- Precision medicine of obesity as an integral part of type 2 diabetes management – past, present, and future - [link](#) – [SPS commentary](#)

### **Lancet Gastroenterology and Hepatology**

- Bivalent mRNA SARS-CoV-2 vaccination in patients with inflammatory bowel disease - [link](#)

### **Lancet HIV**

- Checklist for studies of HIV drug resistance prevalence or incidence: rationale and recommended use - [link](#)

### **Lancet Infectious Diseases**

- Antiviral efficacy of molnupiravir versus ritonavir-boosted nirmatrelvir in patients with early symptomatic COVID-19 (PLATCOV): an open-label, phase 2, randomised, controlled, adaptive trial – [link](#) – [SPS commentary](#)

### **Lancet Neurology**

- Pragmatic solutions to reduce the global burden of stroke: a World Stroke Organization–Lancet Neurology Commission – [link](#) – [SPS commentary](#)

### **Lancet Psychiatry**

- Antidepressant and antipsychotic side-effects and personalised prescribing: a systematic review and digital tool development – [link](#) – [SPS commentary](#)
- Antipsychotic dose reduction and discontinuation versus maintenance treatment in people with schizophrenia and other recurrent psychotic disorders in England (the RADAR trial): an open, parallel-group, randomised controlled trial – [link](#) – [SPS commentary](#)

### **Lancet Public Health**

- The need to promote sleep health in public health agendas across the globe - [link](#)

### Medical Journal of Australia

- Diabetes mellitus and the progression of non-alcoholic fatty liver disease to decompensated cirrhosis: a retrospective cohort study - [link](#)
- Carbapenemase-producing Enterobacterales: a profound threat to Australian public health - [link](#)
- Sodium glucose cotransporter 2 inhibitor-induced ketoacidosis is unlikely in patients without diabetes - [link](#)
- Activating pharmacists to reduce the frequency of medication-related problems (ACTMed): a stepped wedge cluster randomised trial - [link](#)

### New England Journal of Medicine

- Ceftobiprole for Treatment of Complicated Staphylococcus aureus Bacteremia - [link](#)
- Tight Blood-Glucose Control without Early Parenteral Nutrition in the ICU – [link](#) – [SPS commentary](#)
- Esketamine Nasal Spray versus Quetiapine for Treatment-Resistant Depression - [link](#) – [SPS commentary](#)
- Global Effect of Modifiable Risk Factors on Cardiovascular Disease and Mortality – [link](#) – [SPS commentary](#)
- Sarilumab for Relapse of Polymyalgia Rheumatica during Glucocorticoid Taper – [link](#) – [SPS commentary](#)
- Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes – [link](#) – [SPS commentary](#)

### Pharmacotherapy

- Vancomycin Removal and Pharmacokinetics During Accelerated Venovenous Hemofiltration - [link](#)
- Developing precision-based multidisciplinary pharmacotherapy management plans in the critically ill - [link](#)
- Kidney Function as a Key Driver of the Pharmacokinetic Response to High-Dose L-Carnitine in Septic Shock - [link](#)
- Modifiable statin characteristics associated with potential statin-related prescribing cascades - [link](#)
- Metabolomic analysis of serum samples from a clinical study on ipragliflozin and metformin treatment in Japanese patients with type 2 diabetes: Exploring human metabolites associated with visceral fat reduction - [link](#)

### Prescrire International Journal – [October 2023](#)

- Includes: Rimegepant (Vyndura<sup>®</sup>) in migraine; Lenacapavir (Sunlenca<sup>®</sup>) in multidrug-resistant HIV-1 infection; Cannabidiol: sometimes serious adverse effects, and multiple drug interactions

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## CONSULTATIONS (new additions in bold)

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

- Consultation on the draft NSQHS Standards Guide for Ambulance Health Services, Closing 10 November 2023 - [link](#)

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## WEBINARS & PODCASTS

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### Australian Prescriber Podcasts

- [Episode 148](#) – Medicines Stewardship

### AHPRA Taking care podcast

- [Taking care](#): A podcast of conversations about public safety and healthcare

### Health Quality & Safety Commission New Zealand

- Launch of the 2023 Frailty Care Guides - [link](#)

### MJA Podcasts

- [Episode 27](#): New cardiovascular disease (CVD) risk guidelines and calculator
- [Episode 26](#): Improving the health of Aboriginal and Torres Strait Islander children

### Purple Pen Podcast

- [PPP 152](#) - International Pharmaceutical Federation (FIP) World Congress 2023 Wrap Up

### Specialist Pharmacy Service - [podcasts](#)

- MSATS: Language barriers and medication safety inequalities  
- Supporting people with mental health conditions in primary care

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## UPCOMING EVENTS

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

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### ACI

- Hypothetical debate Frailty is reversible... or is it? 9 November 2023 14:00-15:00 – [register](#) - [flyer](#)

### FDA

- Drug Topics: Naltrexone Injection for Opioid Use Disorder - FDA's Efforts to Reduce Medication Errors - October 24, 2023 – [register](#) - [info](#)

### Society of Hospital Pharmacists (SHPA)

- Medicines Management 2023, 47th SHPA National Conference, 2-4 November 2023, Cairns – register [here](#) – now CPD [accredited](#)

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## 28 September 2023 | Fortnightly TAG Mail – resources list

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See <https://www.nswtag.org.au/tag-mail/> for previous TAGMails and cumulative listing

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### NSW TAG ACTIVITIES

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#### New [open](#) email discussions

Potential for inappropriate antiviral prescribing in COVID-19 infections? Closes 4<sup>th</sup> October  
DTC consideration of cenobamate. Closes 4<sup>th</sup> October  
Ward storage of anaesthetic medicines Closes 29<sup>th</sup> September  
Access to miglustat: need for advocacy? Closes 29<sup>th</sup> September  
Problematic access to gemtuzumab: need for advocacy? Closes 29<sup>th</sup> September  
Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information about these email discussions.

#### Upcoming TAG meeting dates

- Annual General Meeting 19th October 2023 4.30pm at Royal North Shore Hospital or via Teams  
- General Meeting 19th October 2023 3-4.30pm at Royal North Shore Hospital or via Teams

#### NSW TAG publications

Coming soon: updated Off-Label Rituximab Patient Fact Sheet and Consent Form  
Coming soon: updated Transitioning Young People on Complex or High Cost Medicines from Paediatric to Adult Care Services: Guiding Principles and Supporting Resources.

#### Job advertisements and Expressions of Interest (Eols)

1. The NSW Editorial Committee is seeking Eols from senior frontline clinical pharmacists to join. Applications close 13<sup>th</sup> October 2023. Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information.
2. NSW TAG is seeking input from accredited pharmacists working in Residential Aged Care Facilities who are experienced with the activity of Medication Advisory Committees and QUM activities. Please contact Sasha Bennett at [sasha.bennett@svha.org.au](mailto:sasha.bennett@svha.org.au) for further information.
3. CATAG QUM Project Officer Part-Time Position advertised. See <https://www.seek.com.au/job/70331840>

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## OTHER NEWS (new additions in bold)

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## NSW Health

- Infection Prevention and Control in Healthcare Settings ([PD2023\\_025](#))
- Women set to benefit from increased access to the pill - [link](#)
- Bushfire response and recovery - [link](#)
- [Following the detection of a high dose MDMA \(ecstasy\) tablet in NSW, a public drug warning](#) has been published on the NSW Ministry of Health website

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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](#)

### Australian Government Department of Health

- Medicines just got cheaper - [link](#)

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

- Endometriosis - [link](#)
- Dementia in Australia - [update](#)

### TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages  
Lithium carbonate ER 450mg (USP) tablets, Hydromorphone hydrochloride (USP) oral solution  
1mg/mL 473mL, Vyvanse lisdexamfetamine dimesylate capsules 30mg (USA)

- AusPARs:

- [Nuceiva](#) (prabotulinum toxin A) for temporary improvement in appearance of glabellar lines

- Australian prescription medicine decision summaries:

- [Vaxchora](#) (vibrio cholerae) is approved to prevent disease caused by Vibrio cholerae serogroup O1 in those travelling to cholera-affected countries
- [Vegzelma](#) (bevacizumab) is approved to treat cancer

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Academy of Medical Royal Colleges

- Securing our healthy future: Prevention is better than cure - [link](#)

### Agency for Drugs and Technologies in Health

- Direct-Acting Antivirals for Pediatric Chronic Hepatitis C Virus Infection, updated - [link](#)
- Somatropin for Short Stature, updated - [link](#)

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

- [New products](#)

- Spikevax XBB.1.5 0.1 mg/mL (andusomeran) dispersion for injection (MDV) (multidose) for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older
- Levocarnitine Paediatric 30% oral solution and 30% oral solution sugar free for primary and secondary carnitine deficiency in newborns, infants, and children aged under 12 years
- LoviOne (levonorgestrel) 1.5 mg tablet for emergency contraception for use within 72 hours
- Wakix (pitolisant) 4.5mg and 18 mg film-coated tablets licence extension covering improvement of wakefulness and reduction of excessive daytime sleepiness (EDS) in adults with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy (e.g. CPAP)
- Sapropterin dihydrochloride 100 mg soluble tablets for hyperphenylalaninaemia in patients of all ages with phenylketonuria or tetrahydrobiopterin deficiency, who have been shown to be responsive to such treatment. A powder for oral solution (100mg and 500mg) also available.

### European Medicines Agency (EMA)



- European CHMP recommends
- approval of [pembrolizumab](#) (Keytruda) for adjuvant monotherapy in non-small cell lung carcinoma
- change to the existing indication for [melphalan flufenamide](#) (Pepaxti) for multiple myeloma
- extension to the current indication for [vosoritide](#) (Voxzogo)
- approval of a new indication for Kalydeco ([ivacaftor](#)) granules
- approval of [brentuximab vedotin](#) (Adcetris) for stage III Hodgkin lymphoma
- approval of [dabrafenib](#) (Finlee) for paediatric patients with glioma and a BRAF V600E mutation
- approval of [lanadelumab](#) (Takhzyro) for use in younger patients
- approval of [lebrikizumab](#) (Ebglyss) for atopic dermatitis
- approval of [methotrexate](#) (Nordimet) for psoriasis
- approval of [quizartinib](#) (Vanflyta) for acute myeloid leukaemia (AML)
- approval of relugolix / estradiol / norethisterone acetate ([Ryeqo](#)) for endometriosis
- approval of [trastuzumab](#) deruxtecan (Enhertu) for advanced HER2-mutant non-small cell lung cancer
- approval of two new presentations of [Kaftrio](#) (ivacaftor / tezacaftor / elexacaftor)
- approval of [zilucoplan](#) (Zilbrysq) for generalised myasthenia gravis in adults
- approval of Zoonotic Influenza Vaccine [Seqirus](#) for active immunisation against H5N1 subtype of Influenza A virus
- extension of [baricitinib](#) (Olumiant) atopic dermatitis indication to include paediatric patients
- granting of a Paediatric Use Marketing Authorisation for [enalapril](#) (Aqumeldi) for heart failure
- non-renewal of authorisation of [ataluren](#) (Translarna) for Duchenne muscular dystrophy
- non-renewal of authorisation of [belantamab mafodotin](#) (Blenrep) for refractory multiple myeloma

### Food and Drug Administration (FDA) USA

- New Drug approvals
- [Momelotinib](#) (Ojjaara) to treat intermediate or high-risk myelofibrosis in adults with anemia
- [Gepirone](#) (Exxua) to treat major depressive disorder
- Expanded drug approvals
- [trametinib](#) (Mekinist) for children aged 1 year and older for BRAF V600E-positive solid tumors
- [dabrafenib](#) (Tafinlar) for BRAF V600E-positive solid tumors expanded to include children aged 1 year and older

### Healthwatch England

- Why meeting patients' communication needs is crucial - [link](#)

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

- MHRA approves adapted [Spikevax](#) (formerly COVID-19 Vaccine Moderna) XBB.1.5 vaccine plus [SPS Commentary](#): Understanding the characteristics of Comirnaty 30 (XBB.1.5) vaccine -

### NHS England

- Rapid evaluation report: chronic obstructive pulmonary disease virtual ward enabled by technology: South and West Hertfordshire Health and Care Partnership - [link](#)

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

- Final appraisal document: Rimegepant for treating migraine – [link](#) and [SPS commentary](#)
- Birch bark extract for treating epidermolysis bullosa – guidance ([HST28](#))
- Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency ([TA914](#)) – [SPS commentary](#)
- Removal, preservation and reimplantation of ovarian tissue for restoring fertility after gonadotoxic treatment- interventional procedures guidance ([IPG772](#))
- Chronic obstructive pulmonary disease in adults, updated ([QS10](#))

### National Institute for Health Research (NIHR)

- Alert: NEWS2 patient score can predict worsening condition in care home residents – [link](#)

### Parkinson's UK

- Every minute counts: Time critical Parkinson's medication on time, every time – [link](#) - [SPS commentary](#)

### **Royal Pharmaceutical Society**

- Welsh Government accepts Royal Pharmaceutical Society (RPS) recommendations for hospital pharmacy transformation - [link](#)

### **UK Health Security Agency**

- Tetanus: advice for health professionals - [link](#)

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

- Paediatric Abacavir/Lamivudine/Dolutegravir (pALD) fixed-dose combination - [link](#)

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## **MEDICATION SAFETY**

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

- [Revised SPCs](#)

- Alecensa (alectinib) - haemolytic anaemia (HA) reported. If haemoglobin is <10 g/dL and HA suspected, withhold treatment and initiate appropriate lab testing. If HA confirmed, resume at reduced dose upon resolution as per dosing in table 2 in SPC. Oedema added as common ADR
- Xofluzza (baloxavir marboxil) license extension includes uncomplicated influenza and post-exposure prophylaxis of influenza in individuals aged 1 year and above (previously for ≥12 years)
- Jardiance (empagliflozin) license extension update for adult chronic kidney disease. Renal impairment wording updated and the ketoacidosis warning revised
- Sirturo (bedaquiline) excreted in human milk. Infant levels similar to those in breastfeeding mothers on bedaquiline, the clinical consequence of which is unknown, thus women should not breastfeed
- Comirnaty mRNA Vaccine 30 micrograms/dose concentrate for dispersion for injection (for 5-11, 12+ years) - statement on myocarditis updated to highlight that available data indicate most cases recovered, but some required intensive care support and fatal cases were observed
- -- Dupixent (dupilumab) – updated with clinical trial safety data. In study AD-1539, treatment-emergent eosinophilia (≥5,000 cells/mcL) was reported in 8.4 % on dupilumab-vs. 0 % on placebo with median eosinophil counts declining below baseline at end of treatment period – [SPS commentary](#)
- Ponvory (ponesimod) updated to include 'seizure' as a common adverse reaction
- Ultomiris (ravulizumab) licence extension update for adults with neuromyelitis optica spectrum disorder who are anti-aquaporin 4 antibody-positive
- Ruxience (rituximab) post-marketing cases of enteroviral meningoencephalitis including fatalities reported (frequency unknown)
- Rocuronium updated to include mydriasis and fixed pupils as adverse effects (unknown frequency)
- Entresto (sacubitril, valsartan) licence extension covering treatment of children and adolescents aged one year or older with symptomatic chronic heart failure and left ventricular systolic dysfunction
- Wegovy (semaglutide) 'delayed gastric emptying' an uncommon side-effect
- Retsevmo (selpercatinib) Interstitial lung disease (ILD)/pneumonitis, chylothorax and chylous ascites added as common ADRs. Monitored patients for pulmonary symptoms (cough and fever) and withhold selpercatinib if suspected
- Cialis (tadalafil) updated to include central serous chorioretinopathy as a visual defect (frequency unknown) reported with intake of PDE5 inhibitors. Most cases resolved spontaneously after stopping
- Kenalog (triamcinolone acetonide) - central serous chorioretinopathy (frequency unknown) reported after use of systemic and topical corticosteroids including triamcinolone acetonide
- Risk minimisation materials
- Pombiliti (cipaglucosidase alfa) and Opfolda (miglustat): Prescriber guide on pregnancy and home infusion – [SPS commentary](#)
- Pharmacist's guide to dispensing PecFent® (fentanyl citrate) - specific information on safe prescribing and a pharmacist's checklist
- Important safety information for patients taking Zynlonta (loncastuximab tesirine) - patient alert card on risk of photosensitivity reactions and the need to protect skin from exposure

### **EMA**

- EMA starts review of [Mysimba](#) (naltrexone / bupropion)

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

- Picking Up a Prescription? 6 Tips to Avoid Dangerous Pharmacy Errors - [link](#)

- Medication Safety Alert! [September 21, 2023](#) including
- Worth repeating... FLUZONE packaging leads to a double dose
- Fatal N-acetylcysteine overdose due to pump programming errors
- Patient Death Tied to Lack of Proper Escalation Process for Barcode Scanning Failures - [link](#)

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

- Drug Safety Update [September 2023](#)
- Statins: very infrequent reports of myasthenia gravis - [link](#)
- Fluoroquinolone antibiotics: suicidal thoughts and behaviour - [link](#)
- Letters to Healthcare Professionals August 2023
- Xalkori ([crizotinib](#)): Vision disorders, including risk of severe visual loss, need for monitoring in paediatric patients

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

- Consent to distribute pholcodine-containing medicines will be revoked on 12 January 2024 - [link](#)
- Reclassification of paracetamol (liquid formulations) – [link](#)
- Reclassification of naproxen - [link](#)

### **SPS (Specialist Pharmacy Service) UK**

- Developing Medication Safety Across The System (MSATS) - [link](#)
- Using intramuscular injections in people on oral anticoagulants - [link](#)

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## **PAPERS OF INTEREST**

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### **Academic Emergency Medicine**

- Efficacy of prescribed opioids for acute pain after being discharged from the emergency department: A systematic review and meta-analysis - [link](#)

### **American Journal of Cardiology**

- Aspirin Versus Warfarin after Transcatheter Aortic Valve Replacement in Low-Risk Patients: 2-Year Follow-Up - [link](#)

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

- National Hospital and Health-System Controlled Substances Drug Diversion Prevention & Surveillance Program Assessment Survey–2021 - [link](#)
- Screening for quality with process analytical technology in a health-system pharmacy: A primer - [link](#)
- ASHP Survey of Health-System Specialty Pharmacy Practice: Practice Models, Operations, and Workforce–2022 - [link](#)
- Physical compatibility of sulbactam/durlobactam with select intravenous drugs during simulated Y-site administration - [link](#)
- The effect of plasma exchange on serum levels of lacosamide: A case report - [link](#)

### **American Journal of Obstetrics and Gynecology**

- The effect of valacyclovir on secondary prevention of congenital cytomegalovirus infection, following primary maternal infection acquired periconceptionally or in the first trimester of pregnancy. An individual patient data meta-analysis - [link](#)

### **Annals of Internal Medicine**

- Outpatient Treatment of Confirmed COVID-19: A Living, Rapid Evidence Review for the American College of Physicians (Version 2) – [link](#) - [SPS commentary](#)
- Once-Weekly Insulin Icodec With Dosing Guide App Versus Once-Daily Basal Insulin Analogues in Insulin-Naive Type 2 Diabetes (ONWARDS 5): A Randomized Trial - [link](#)
- Multicenter, Prospective, Randomized Controlled Trial of High-Sensitivity Cardiac Troponin I–Guided Combination Angiotensin Receptor Blockade and Beta-Blocker Therapy to Prevent Anthracycline Cardiotoxicity: The Cardiac CARE Trial – [link](#) – [SPS commentary](#)

### **Annals of Rheumatic Diseases**

- Anti-GM-CSF otilimab versus sarilumab or placebo in patients with rheumatoid arthritis and inadequate response to targeted therapies: a phase III randomised trial (contRAst 3) - [link](#)

### **Australian Health Review, Journal of the Australian Healthcare & Hospitals Association**

- Addressing the end-of-life actions in the National Safety and Quality Health Service Standards (2nd edn): a national survey - [link](#)

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

- No action is without its side effects: adverse drug reactions and missed doses of anti-tuberculosis therapy, a scoping review - [link](#)  
- Model-based dosing optimization and therapeutic drug monitoring practices of teicoplanin in patients with complicated or non-complicated MRSA infection - [link](#)  
- Administration of oxathridine, a first-in-class histamine-3 receptor partial agonist in healthy male volunteers: central nervous system depression and pseudo-hallucinations - [link](#)  
- Population Pharmacokinetic Models of Tacrolimus in Pediatric Solid Organ Transplant Recipients: A Systematic Review - [link](#)

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

- Trends in consultations and prescribing for rheumatic and musculoskeletal diseases: an electronic primary care records study - [link](#)

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

- Comparing letrozole and mifepristone pre-treatment in medical management of first trimester missed miscarriage: a prospective open-label non-inferiority randomised controlled trial - [link](#)

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

- Advances in the care of breast cancer survivors - [link](#)  
- FDA reports decongestant phenylephrine used in over-the-counter cold, flu, and allergy remedies is not effective - [link](#)  
- Unethical pharmaceutical marketing: a common problem requiring collective responsibility - [link](#)  
- Efficacy and safety of an inactivated virus-particle vaccine for SARS-CoV-2, BIV1-CovIran: randomised, placebo controlled, double blind, multicentre, phase 3 clinical trial - [link](#)

### **BMJ Open**

- Does inclusion of bioactive n-3 PUFAs in parenteral nutrition benefit postoperative patients undergoing liver surgery? A systematic review and meta-analysis of randomised control trials - [link](#)  
- Development of a patient-centred medication management model for polymedicated home-dwelling older adults after hospital discharge: results of a mixed methods study – [link](#) – [SPS commentary](#)  
- Antenatal corticosteroids in specific groups at risk of preterm birth: a systematic review - [link](#)

### **Circulation**

- 2023 American Heart Association Focused Update on the Management of Patients with Cardiac Arrest or Life-Threatening Toxicity Due to Poisoning - [link](#)  
- Bivalirudin Versus Heparin During PCI in NSTEMI: Individual Patient Data Meta-Analysis of Large Randomized Trials - [link](#)  
- Expanding the Paradigm for Cardiovascular Palliative Care - [link](#)

### **Cochrane**

- Pharmacological and electronic cigarette interventions for smoking cessation in adults: component network meta-analyses – [link](#) and [SPS commentary](#)  
- Pravastatin for lowering lipids - [link](#)

### **Diabetes Care**

- Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease and Diabetes Mellitus: A Subgroup Analysis of the ADAPTABLE Trial - [link](#)  
- Effect of Postmenopausal Hormone Therapy on Glucose Regulation in Women With Type 1 or Type 2 Diabetes: A Systematic Review and Meta-analysis - [link](#)  
- Genetic Evidence Strongly Supports Managing Weight and Blood Pressure in Addition to Glycemic Control in Preventing Vascular Complications in People With Type 2 Diabetes - [link](#)  
- Hybrid Closed-Loop Therapy in Adults With Type 1 Diabetes and Above-Target HbA1c: A Real-world Observational Study – [link](#) – [SPS commentary](#)

- Safety and Efficacy of Sustained Automated Insulin Delivery Compared With Sensor and Pump Therapy in Adults With Type 1 Diabetes at High Risk for Hypoglycemia: A Randomized Controlled Trial - [link](#)

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

- The effects of canagliflozin in type 2 diabetes in subgroups defined by population-specific body mass index: Insights from the CANVAS Program and CREDENCE trial - [link](#)

### **Diabetes & Metabolic Syndrome: Clinical Research & Reviews**

- Efficacy and safety of once-weekly versus once-daily basal insulin analogues in the treatment of type 2 diabetes mellitus: A systematic review and meta-analysis - [link](#)

### **European Heart Journal**

- [Acquired risk factors and incident atrial fibrillation according to age and genetic predisposition - link](#)

- [Lack of association between fluoroquinolone and aortic aneurysm or dissection - link](#)

- [Placing patient-reported outcomes at the centre of cardiovascular clinical practice: implications for quality of care and management - link](#)

- Dapagliflozin vs. metolazone in heart failure resistant to loop diuretics – [link](#) - [summary](#)

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

- [Factors influencing accuracy when preparing injectable drug concentrations in appliance with clinical practice: a norepinephrine case study - link](#)

- [Development of a quality assessment tool for pharmacy and therapeutics committees and subsequent pilot testing - link](#)

- [Comparison of outcomes for fixed and weight-based four-factor prothrombin complex concentrate dosing regimens - link](#)

- [Analysing electronic prescribing data to detect potential undocumented adverse reactions to medications - link](#)

### **Internal Medicine Journal**

- Chronic lymphocytic leukaemia Australasian consensus practice statement - [link](#)

- Efficacy and safety of prophylactic anticoagulation in patients with primary nephrotic syndrome: a systematic review and meta-analysis - [link](#)

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

- Association of silodosin, tamsulosin, and naftopidil with delirium: analysis of the pharmacovigilance database in Japan - [link](#)

- Pharmacists' contribution to benzodiazepine deprescribing in older outpatients: a systematic review and meta-analysis - [link](#)

### **International Journal for Quality in Health Care**

- EPERCAS Study. Strategies for Preventing Medication Administration Errors in Nursing Homes - [link](#)

### **JAMA**

- Patient Page: What Is Huntington Disease? - [link](#)

- Reported Risky Alcohol Use Among US Adults Prescribed 3 Classes of Chronic Alcohol-Interactive Medications - [link](#)

- Receipt of BNT162b2 Vaccine and COVID-19 Ambulatory Visits in US Children Younger Than 5 Years - [link](#)

- Nonhormonal Therapies for Menopausal Vasomotor Symptoms - [link](#)

- Treatment Failure and Adverse Events After Amoxicillin-Clavulanate vs Amoxicillin for Pediatric Acute Sinusitis - [link](#)

- Two-Year Outcomes After Minimally Invasive Surfactant Therapy in Preterm Infants: Follow-Up of the OPTIMIST: A Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Cardiology**

- Longer-Term Efficacy and Safety of Evinacumab in Patients With Refractory Hypercholesterolemia – [link](#) and [SPS commentary](#)

### **JAMA Dermatology**

- Clinical Management of Neuropathic Itch - [link](#)

### **JAMA Network Open**

- Chatbot-Delivered Online Intervention to Promote Seasonal Influenza Vaccination During the COVID-19 Pandemic: A Randomized Clinical Trial – [link](#) and [SPS commentary](#)

### **JAMA Oncology**

- Risk-Directed Ambulatory Thromboprophylaxis in Lung and Gastrointestinal Cancers: The TARGET-TP Randomized Clinical Trial - [link](#)

### **JAMA Psychiatry**

- Sexual Dysfunction in Schizophrenia: A Systematic Review and Meta-Analysis – [link](#) and [SPS commentary](#)

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

- Drug-related readmissions in older hospitalized adults: External validation and updating of OPERAM DRA prediction tool – [link](#) - [summary](#)

### **Journal of Clinical Oncology**

- Nine-Week Versus One-Year Trastuzumab for Early Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: 10-Year Update of the ShortHER Phase III Randomized Trial - [link](#)

### **Journal of Pain and Symptom Management**

- Efficacy and Safety of Naloxegol in Patients with Chronic Non-Cancer Pain Who Experience Opioid-Induced Constipation: A Pooled Analysis of Two Global, Randomized Controlled Studies - [link](#)

### **Lancet**

- Scientific advances and the end of tuberculosis: a report from the Lancet Commission on Tuberculosis - [link](#)

- Dilated cardiomyopathy: causes, mechanisms, and current and future treatment approaches - [link](#)

- Efficacy and safety of subcutaneous spesolimab for the prevention of generalised pustular psoriasis flares (Effisayil 2): an international, multicentre, randomised, placebo-controlled trial – [link](#) – [SPS commentary](#)

- Primary brain tumours in adults - [link](#)

- Glaucoma: now and beyond - [link](#)

- Hepatitis C - [link](#)

### **Lancet Diabetes & Endocrinology**

- Life expectancy associated with different ages at diagnosis of type 2 diabetes in high-income countries: 23 million person-years of observation – [link](#) and [SPS commentary](#)

### **Lancet Gastroenterology and Hepatology**

- Trimodality therapy versus perioperative chemotherapy in the management of locally advanced adenocarcinoma of the oesophagus and oesophagogastric junction (Neo-AEGIS): an open-label, randomised, phase 3 trial – [link](#) – [SPS commentary](#)

- Joint statement in support of hepatitis C human challenge studies - [link](#)

### **Lancet Neurology**

- Migraine in older adults - [link](#)

- Safety and efficacy of arimoclomol for inclusion body myositis: a multicentre, randomised, double-blind, placebo-controlled trial – [link](#) – [SPS commentary](#)

- Safety and efficacy of tamoxifen in boys with Duchenne muscular dystrophy (TAMDMD): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial – [link](#) – [SPS commentary](#)

### **Lancet Respiratory Medicine**

- Efficacy of a bivalent (D614 + B.1.351) SARS-CoV-2 recombinant protein vaccine with AS03 adjuvant in adults: a phase 3, parallel, randomised, modified double-blind, placebo-controlled trial – [link](#) and [SPS commentary](#)



- COVID-19 boosters versus primary series: update to a living review - [link](#)

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

- Asthma in Adults - [link](#)
- Dabrafenib plus Trametinib in Pediatric Glioma with BRAF V600 Mutations - [link](#)
- Inhaled Fluticasone Furoate for Outpatient Treatment of Covid-19 - [link](#)

### **Pharmaceutical Journal**

- Blanket switch' to greener inhalers not recommended in draft Scottish prescribing guidance - [link](#)
- Charting the course to advancing pharmacist prescribing – [link](#) and [SPS commentary](#)
- Filling the gap in smoking cessation therapies: a race to a smoke-free 2030 – [link](#) and [SPS commentary](#)
- Rapid-acting antidepressants face a slow journey to wider use – [link](#) – [SPS commentary](#)

### **Pharmacotherapy**

- Anticoagulant Drug-Drug Interactions with Cannabinoids: A Systematic Review - [link](#)
- Morphomics-Informed Population Pharmacokinetic and Physiologically-Based Pharmacokinetic Modeling to Optimize Cefazolin Surgical Prophylaxis - [link](#)

### **Prescriber UK**

- Cutaneous reactions secondary to COVID-19 vaccination - [link](#)

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

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

- Induction of Labour Clinical Practice Guide Consultation, closes 10 October 2023 - [link](#)

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

- Consultation on the draft NSQHS Standards Guide for Ambulance Health Services, closes 10 November 2023 - [link](#)

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## **WEBINARS & PODCASTS**

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### **AHHA**

- Understanding variation in health care: using data to identify and address low value care Wednesday 18 October 12pm – 1pm AEDT – [register](#) free online
- [S2E9](#) – Empowering primary health to deliver palliative care
- [Episode 29](#) – The 2022 John Deeble Lecture: panel discussion (on the complexities of the health workforce and the ways we deliver health workforce policy in Australia)

### **Australian Prescriber Podcasts**

- [Episode 147](#) – Therapeutic Guidelines Addiction

### **Health Literacy Hub**

- Health Literacy, Disability, and Digital Health Communication ([Webinar 2 of 3](#))
- Health Literacy, Disability, and Face-to-Face Health Communication (Webinar 3 of 3), 10th October 13:00-14:00 – register [here](#)

### **MIMS Learning**

- Podcast: climate change, CKD, and scarlet fever – register [here](#)

### **MJA Podcasts**

- [Episode 25](#): New research into breast cancer and rare cancers
- [Episode 24](#): Improving Aboriginal and Torres Strait Islander outcomes

### **Purple Pen Podcast**

- [PPP151](#) - Special Edition: World Pharmacist Day 2023

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## UPCOMING EVENTS

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

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### AHHA

- Getting more value from mental healthcare funding and investment workshop, online, Tue, 26 Sep 2023 10:30 AM AEST or Wed, 11 Oct 2023 10:30 AM AEDT – register [here](#)

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## TAG Mail

**14 September 2023**

A fortnightly newsletter for quality use of medicine healthcare practitioners

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### NSW TAG ACTIVITIES

Thank you to members who provided feedback regarding TGA Review of Medicines Labelling Rules and CATAG enquiry regarding re-purposing of medicines. Discussion of responses will occur at the NSW TAG General meeting 19<sup>th</sup> October.

#### Upcoming TAG meeting dates

NSW TAG General Meeting 19<sup>th</sup> October 3-4.30pm

NSW Annual General Meeting 19<sup>th</sup> October 4.30pm

#### Upcoming CATAG meetings

CATAG Members meeting 25<sup>th</sup> October 2023

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### OTHER NEWS

#### NSW Health

- Opioid Treatment Program - Transition to Section 100 Highly Specialised Drugs Program - [link](#)

#### TGA

- Changes to choline salicylate access to start from 1 October 2023 - [link](#)

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### REPORTS AND PUBLICATIONS – AUSTRALIA

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

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

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

- Australia's welfare 2023 - [link](#)

- Rural and remote health - [link](#)

- Health of young people - [link](#)

- Health of children - [link](#)

- Burden of avoidable deaths among Aboriginal and Torres Strait Islander people 2018 - [link](#)

#### MIMS monthly updates, [September 2023](#)

- New indications

-- Dapagliflozin (propanediol monohydrate) ([Forxiga](#)) – adult symptomatic heart failure independent of left ventricular ejection fraction, as an adjunct to standard of care therapy

-- Dupilumab ([Dupixent](#)) - severe atopic dermatitis in patients aged 6 months to 11 years old who are candidates for chronic systemic therapy

-- Ferric carboxymaltose ([Ferinject](#)) - iron deficiency anaemia in children aged 1 to 13 years when oral iron preparations are ineffective or cannot be used

-- Finerenone ([Kerendia](#)) - to reduce the risk of adult cardiovascular mortality and morbidity in chronic kidney disease (with albuminuria) associated with Type 2 diabetes, in addition to standard of care

-- Influenza virus vaccine, surface antigen, quadrivalent (inactivated) ([Flucelvax](#) Quad) - children from 6 months of age and older to help prevent influenza virus types A and B

-- Upadacitinib ([Rinvoq](#)) - moderate to severe active adult Crohn's disease, who have had inadequate response, lost response or were intolerant to either conventional therapy or a biological medicine

-- Sacituzumab govitecan ([Trodelvy](#)) – adults with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received endocrine-based therapy (including a CDK4/6 inhibitor) and at least two additional systemic therapies in the locally advanced or metastatic setting

### **PBS**

- Information regarding brands availability of colestyramine with changes to PBS listing of s19A JAMP CHOLESTYRAMINE effective 1 September 2023 - [link](#)

### **TGA**

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages  
-- [Bendarabine](#) fludarabine 50mg powder for injection or infusion (Germany) - until 30/04/  
-- [Ampicillin](#) for injection, USP 1g/vial (Mylan, USA) - until 30/11/2023

- AusPARs:

-- [Gardasil 9](#) (HPV 9-valent vaccine, recombinant) – extension of indications - prevention of anal cancer, precancerous or dysplastic lesions, external genital lesions, infection caused by HPV in males  
-- [Spikevax](#) Bivalent Original/Omicron BA.4 - 5 (Elasomeran/davesomeran) – full registration for the prevention of coronavirus disease 2019 caused by SARS-CoV-2  
-- [Vaxneuvance](#) (Pneumococcal 15-valent conjugate vaccine (CRM197 protein), adsorbed) for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes  
-- [Comirnaty](#) (tozinameran) – dose change – for prevention of coronavirus disease 2019 (COVID-19)  
-- [Vazkepa](#) (icosapent ethyl) to reduce the risk of cardiovascular events

- Australian prescription medicine decision summaries:

-- [Xenpozyme](#) (olipudase alfa) - non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD)

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## **REPORTS AND PUBLICATIONS – INTERNATIONAL**

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### **Academic Health Science Network (ASHN)**

- Polypharmacy Programme Interim Evaluation: Executive Summary and Year 1 Impact - [link](#)

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

- Nitrous oxide: legitimate uses and appropriate controls - [link](#)

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

- [New products](#)

-- Aquipta (atogepant) 10 and 30 mg tablets - CGRP receptor antagonist licensed for migraine prophylaxis in adults who have at least 4 migraine days per month. Dose is 60 mg once daily, which should be reduced to 10mg once daily if there is concomitant use of strong CYP3A4 inhibitors or strong OATP inhibitors  
-- Combogesic IV 10 mg/ml + 3 mg/ml [1000mg / 300mg in 100ml] solution for infusion (paracetamol / ibuprofen) licensed for use in adults for the short-term symptomatic treatment of acute moderate pain and the reduction of fever, where an IV route of administration is considered clinically necessary and/or when other routes of administration are not possible  
-- Gadobutrol 1.0 mmol/mL solution for injection in prefilled syringe licensed for contrast enhancement in cranial, spinal, liver, kidneys, angiography MRI, and whole body pathologies  
-- Macimorelin 60 mg granules for oral suspension in sachet, a peptidomimetic with growth hormone (GH) secretagogue activity licensed for adult GH deficiency  
-- Ceyesto (melatonin) 1mg/ml Oral Solution - licensed for: delayed sleep wake phase disorder in patients age 6-25 years, short-term treatment of jet lag in adults, insomnia in patients age 6-17 years with ADHD, and as single dose for sedation for electroencephalograms in patients age 1-18 years  
-- Comirnaty (raxtozinameran) Omicron XBB.1.5 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) licensed for active SARS-CoV-2 COVID-19 immunisation in individuals in various age groups

-- Byfavo (remimazolam) 50 mg powder for concentrate solution for injection/infusion - new formulation, an ultra-short acting benzodiazepine sedative/hypnotic, licensed for intravenous induction and maintenance of general anaesthesia in adults

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

- New Drug approvals

-- [Aphexda](#) (motixafortide) - with filgrastim (G-CSF) to mobilize hematopoietic stem cells to peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma

- Applications

-- [dabrafenib](#) (Tafinlar) - for BRAF V600E-positive solid tumors expanded to include children aged 1 year and older

-- [trametinib](#) (Mekinist) - indication expanded to children aged 1 year and older for BRAF V600E-positive solid tumors

-- [canakinumab](#) (Ilaris) - new indication approved for treatment of gout flares

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

- Guidance published on the new international regulatory recognition routes for medicines approvals - [link](#)

### **MIMS, UK**

- New twice-weekly rivastigmine patch for Alzheimer's disease - [link](#)

### **NHS England**

- Addressing palliative and end of life care needs for people living with heart failure: a revised framework for integrated care systems - [link](#)

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

- NICE committee recommends [tirzepatide](#) as new treatment option for people with type 2 diabetes

- Semaglutide for managing overweight and obesity, updated ([TA875](#)) – [SPS Commentary](#)

- Caesarean birth – guidance ([NG192](#)) – update

- Mavacamten for treating symptomatic obstructive hypertrophic cardiomyopathy ([TA913](#))

- Spinal metastases and metastatic spinal cord compression ([NG234](#)) – [SPS commentary](#)

- Cirrhosis in over 16s: assessment and management, updated ([NG50](#))

- Final draft guidance

-- Bimekizumab for treating active psoriatic arthritis [[ID4009](#)]

-- Bimekizumab for treating axial spondyloarthritis [[ID6245](#)]

-- Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments [[ID3970](#)]

### **Pharma**

- Retinopathy of prematurity (ROP) and EYLEA® ([aflibercept](#)): Information for parents and caregivers

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

- [SIGN146](#): Cutaneous melanoma

### **Scottish Medicines Consortium**

- Accepted for use in NHS Scotland

-- [daratumumab](#) (Darzalex) with lenalidomide and dexamethasone for adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

-- [ibrutinib](#) (Imbruvica) with venetoclax for the treatment of adults with previously untreated chronic lymphocytic leukaemia

-- [Vutrisiran](#) (Amvuttra), double-stranded small interfering ribonucleic acid (siRNA) for use in hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adults with stage 1 or stage 2 polyneuropathy

- Accepted for restricted use: [Rimegepant](#) (Vydura®) for episodic migraine prevention in adults who have ≥4 migraine attacks per month, but <15 headache days per month and who have had prior failure on ≤3 migraine preventive treatments

- Not accepted for use: [mosunetuzumab](#) (Lunsumio) as monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies

- Completes initial assessment of the evidence for eladocagene exuparvovec (Upstaza) for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency with a severe phenotype – [link](#) and [SPS commentary](#)
- Completes initial assessment of the evidence for olipudase alfa (Xenpozyme) for the treatment of non-Central Nervous System manifestations of Acid Sphingomyelinase Deficiency (ASMD) – [link](#) and [SPS commentary](#)

### UK Health Security Agency

- National protocol for COVID-19 vaccine (adults) – [update](#) and [SPS commentary](#)

### World Health Organisation (WHO) - World Patient Safety Day - 17 September 2023

- WHO Special Initiative for Mental Health - [link](#)
- WHO's operational handbook on tuberculosis infection prevention and control - [link](#)

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## MEDICATION SAFETY

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

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

- Benadryl (cetirizine dihydrochloride) - drug-induced liver injury and other types of non-infectious hepatitis possible adverse reactions (frequency not known)
- Bimzelx (bimekizumab) - new indication of adult psoriatic arthritis with inadequate response/intolerance to  $\geq 1$  DMARDs. Treatment should be stopped in the case of infection that becomes serious/unresponsive to standard therapy
- Vocabria (cabotegravir) – data added from retrospective analysis of 3 studies in 29 subjects who received oral bridging for median duration of 59 days with ART other than Vocabria plus rilpivirine (alternative oral bridging) during treatment with Vocabria plus rilpivirine LA IM injections
- Ruconest (conestat alfa) - serious arterial and venous thromboembolic events have been reported at recommended dose of plasma derived C1 esterase inhibitor products in patients with known risk factors: monitor these patients closely
- Comirnaty (COVID-19 mRNA Vaccine) - updated to state individuals may not be fully protected until 7 days after their vaccination, new posology for primary immunisation; lymphadenopathy now a common adverse effect; shelf life extended from 18 months to 2 years
- Lixiana (edoxaban) - clarithromycin (500 mg twice daily) for 10 days with a single concomitant dose of edoxaban 60mg on day 9 increased the edoxaban AUC and C<sub>max</sub> by approximately 53% and 27%, respectively. Anticoagulant-related neuropathy added as an ADR.
- Ergometrine Injection - can be stored outside of the refrigerator at a temperature of up to 25°C for a maximum 12 weeks, after which it should be discarded. (Do not place back into refrigerator, once it has been kept outside)
- Yasmin (ethinylestradiol, drospirenone) - ALT elevations reported when used with ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin and glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir. Now contraindicated with concomitant use of sofosbuvir/velpatasvir/voxilaprevir
- Nurofen (ibuprofen) - renal tubular acidosis and hypokalaemia may occur following acute overdose and use over long periods at high doses; from the 20th week of pregnancy, ibuprofen use may cause oligohydramnios resulting from foetal renal dysfunction
- Oruvail (ketoprofen) - increased risk for arterial thrombotic events reported in patients on non-aspirin NSAIDs (e.g. parecoxib & valdecoxib) for perioperative pain in setting of coronary artery bypass surgery has not been observed with ketoprofen
- Lenvima and Kisplyx (lenvatinib) - details added on preparing and administering a suspension from the hard capsules
- Camzyos (mavacamten) - selective, allosteric, and reversible cardiac myosin inhibitor for symptomatic (NYHA, class II-III) obstructive adult hypertrophic cardiomyopathy
- Hypnovel (midazolam) - Kounis syndrome (cardiovascular symptoms secondary to allergic or hypersensitivity insults) added as a potential ADR (frequency unknown)
- Rydapt - 'acute febrile neutrophilic dermatosis' included as an ADR (frequency not known).
- Losec (omeprazole) - no or negligible influence on the ability to drive and use machines. However, if ADRs such as dizziness and visual disturbances occur, patients should not drive or use machines
- Pemazyre (pemigatinib) - cutaneous calcification as a possible uncommon ADR.

- Gavreto (pralsetinib) - TB, mostly extrapulmonary, reported as an uncommon ADR. Antimycobacterial therapy needs to be started in those with active/latent TB before Gavreto initiation
- Ropivacaine hydrochloride - Horner's syndrome (a condition that results from an interruption of the sympathetic nerve supply to the eye) added as .ADR
- Buccastem (prochlorperazine) - updated to note it may potentiate QT interval prolongation which increases the risk of serious ventricular arrhythmias. Use with caution in patients with, or have risk factors for, QT prolongation
- Adynovi (rurioctocog alfa pegol) - anaphylaxis added as ADR (frequency unknown)
- Retsevmo (selpercatinib) - hypothyroidism reported. Also, can inhibit D2 deiodinase & thereby decrease conversion of levothyroxine (T4) to liothyronine (T3) so patients may have insufficient response to T4 and may require supplementation with T3
- Risk minimisation materials
- Camzyos (mavacamten) – HP checklist for HP including embryo-foetal toxicity risks, heart failure due to systolic dysfunction, and adverse events due to overexposure (drug interactions)

### EMA

- PRAC recommends new measures to avoid topiramate exposure in pregnancy - [link](#)

### Health Canada – MedEffect Notice

- Health Product InfoWatch: [August 2023](#)
- Domperidone and psychiatric withdrawal events when used off-label for lactation stimulation
- Medication errors with specific mineral supplements: calcium, iron, magnesium, and zinc

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

- Medication Safety Alert! [September 7, 2023](#)
- Drug, Supply, and Equipment Shortages Continue to Compromise Patient Care – [link](#)
- Limitations of the most recent posaconazole formulation
- Confusing FLUZONE high-dose packaging

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

- Prescriber Update 44(3) [September 2023](#) includes
- Spotlight on clonidine - [link](#)
- Reports of persisting serious adverse reactions to fluoroquinolones - [link](#)
- Antidepressant withdrawal: taper antidepressants slowly - [link](#)
- Recent data sheet updates: important new safety information - [link](#)
- Vanishing bile duct syndrome – a complication of drug-induced liver injury - [link](#)
- Infusion-related reactions – not all allergy related - [link](#)

### MIMS monthly updates

- New Contraindications
- Ravulizumab ([Ultomiris](#) 100 mg/mL) - in patients who are not currently vaccinated against Neisseria meningitidis, unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination

### Specialist Pharmacy Services NHS UK

- Managing pharmaceutical waste - [link](#) and [SPS commentary](#)
- Considerations when switching between solid doses and liquids – [link](#) and [SPS commentary](#)
- Specific medicine switches for solid dose and liquid formulations – [link](#) and [SPS commentary](#)

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## PAPERS OF INTEREST

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### American Journal of Cardiology

- CYP2C19 Genotype Prevalence and Association With Recurrent Myocardial Infarction in British–South Asians Treated With Clopidogrel - [link](#)
- Angiotensin Receptor–Neprilysin Inhibitor Effects on Atherosclerotic Cardiovascular Disease Events: A Meta-Analysis of Randomized Controlled Trials - [link](#)
- Effect of furosemide versus torsemide on hospitalizations and mortality in patients with heart failure: a meta-analysis of randomized controlled trials - [link](#)



### **American Journal of Gastroenterology**

- Systematic Review With Meta-Analysis: Chronic Opioid Use Is Associated With Esophageal Dysmotility in Symptomatic Patients - [link](#)

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

- Implementation of a pharmacy-driven rapid bacteremia response program - [link](#)
- The Pharmacy 5.0 framework: A new paradigm to accelerate innovation for large-scale personalized pharmacy care - [link](#)
- Nirsevimab-alip - [link](#)
- Infectious complications among patients receiving ibrutinib for the treatment of hematological malignancies - [link](#)
- Cold chain management in health systems: Navigating a complex and evolving landscape - [link](#)
- Administration of andexanet alfa for traumatic intracranial hemorrhage in the setting of massive apixaban overdose: A case report - [link](#)
- An interrupted time series study of electronic health record clinical decision support for providers caring for patients with atrial fibrillation at increased stroke risk - [link](#)

### **American Journal of Kidney Disease**

- Vitamin D Therapy in Adults With CKD: A Systematic Review and Meta-analysis – [link](#) - [commentary](#)

### **Annals of Internal Medicine**

- Comparative Safety Analysis of Oral Antipsychotics for In-Hospital Adverse Clinical Events in Older Adults After Major Surgery: A Nationwide Cohort Study - [link](#)
- In the clinic: Travel Medicine - [link](#)

### **Annals of Rheumatic Diseases**

- Is colchicine prophylaxis required with start-low go-slow allopurinol dose escalation in gout? A non-inferiority randomised double-blind placebo-controlled trial – [link](#) – [SPS commentary](#)

### **Arthritis & Rheumatology**

- Long-term efficacy/safety of canakinumab in patients with tumor necrosis factor receptor-associated periodic syndrome: results from a phase III trial - [link](#)

### **Australian Health Review, Journal of the Australian Healthcare & Hospitals Association**

- Emerging health and social policy considerations for safe and quality end-of-life care in Australia – the evidence, gaps and challenges - [link](#)

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

- Evaluating the performance of ChatGPT in clinical pharmacy: A comparative study of ChatGPT and clinical pharmacists - [link](#)
- ChatGPT in pharmacometrics? Potential opportunities and limitations - [link](#)
- Considerations on implementation of the newest treatment for symptomatic uterine fibroids: oral GnRH antagonists - [link](#)
- Implementation of a clinical decision support system for the optimization of antidiabetic drug orders by pharmacists - [link](#)
- Review: Paracetamol (acetaminophen) poisoning: The early years – [link](#) – [SPS commentary](#)
- Tools and guidelines to assess the appropriateness of medication and aid the deprescribing: an umbrella review - [link](#)
- Letter: Meloxicam-induced capillaritis with positive rechallenge - [link](#)
- Key factors associated with 6-thioguanine and 6-methylmercaptapurine nucleotide concentrations in children treated by thiopurine for acute leukaemia and inflammatory bowel disease - [link](#)
- Continuous infusion of cefiderocol in a critically ill patient with continuous venovenous haemofiltration - [link](#)
- A case of acute pulmonary complication due to botulinum toxin: Patient with central pontine myelinolysis developed acute respiratory distress syndrome after botulinum neurotoxin type A injection into spastic lower extremity muscles - [link](#)

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

- Adherence to 5-aminosalicylic acid maintenance treatment in young people with ulcerative colitis: a retrospective cohort study in primary care - [link](#)
- Pre-diagnostic prescription patterns in bladder and renal cancer: a longitudinal linked data study - [link](#)

### **British Journal of Psychiatry**

- Drug-related deaths among housed and homeless individuals in the UK and the USA: comparative retrospective cohort study - [link](#)

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

- Balancing risks and benefits of cannabis use: umbrella review of meta-analyses of randomised controlled trials and observational studies - [link](#)
- Two-drug antiretroviral regimens for HIV - [link](#)
- Personality disorder - [link](#)
- Effect of tapered versus stable treatment with tumour necrosis factor inhibitors on disease flares in patients with rheumatoid arthritis in remission: a randomised, open label, non-inferiority trial - [link](#)
- Essential medicines lists are for high income countries too - [link](#)
- Pyoderma gangrenosum - [link](#)
- Food additive emulsifiers and risk of cardiovascular disease in the NutriNet-Santé cohort: prospective cohort study - [link](#)
- Venous thromboembolism with use of hormonal contraception and non-steroidal anti-inflammatory drugs: nationwide cohort study – [link](#) – [SPS commentary](#)
- Management of epilepsy during pregnancy and lactation - [link](#)
- Prevent TB to end TB - [link](#)
- Glucose monitoring and glucose lowering agents for children and young people with type 2 diabetes: summary of updated NICE guidance – [link](#) - [SPS commentary](#)

### **BMC Medicine**

- Healthcare fragmentation, multimorbidity, potentially inappropriate medication, and mortality: a Danish nationwide cohort study - [link](#)

### **BMJ Open**

- Safety of influenza vaccination during pregnancy: a systematic review - [link](#)

### **Circulation**

- Associations of Apixaban Dose With Safety and Effectiveness Outcomes in Patients With Atrial Fibrillation and Severe Chronic Kidney Disease – [link](#) – [SPS commentary](#)

### **Cochrane**

- Platinum-based chemotherapy for early triple-negative breast cancer - [link](#)

### **Diabetes Care**

- Comparative Cardiovascular Effectiveness and Safety of SGLT-2 Inhibitors, GLP-1 Receptor Agonists, and DPP-4 Inhibitors According to Frailty in Type 2 Diabetes - [link](#)

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

- Cardiovascular efficacy and safety of antidiabetic agents: A network meta-analysis of randomized controlled trials – [link](#) – [SPS commentary](#)

### **Drug and Therapeutics Bulletin**

- Managing drugs with anticholinergic activity - [link](#)

### **Emergency Medicine Journal**

- Comparison of intravenous paracetamol (acetaminophen) to intravenously or intramuscularly administered non-steroidal anti-inflammatory drugs (NSAIDs) or opioids for patients presenting with moderate to severe acute pain conditions to the ED: systematic review and meta-analysis – [link](#) - [commentary](#)

### **European Heart Journal**

- [2023 ACR/EULAR Antiphospholipid Syndrome Classification Criteria - link – SPS commentary](#)
- [Electronic health record alerts for management of heart failure with reduced ejection fraction in hospitalized patients: the PROMPT-AHF trial - link](#)
- [Beta-blockers in non-obstructive hypertrophic cardiomyopathy: time to ease the heart rate restriction? - link](#)
- [Mechanisms of benefits of sodium-glucose cotransporter 2 inhibitors in heart failure with preserved ejection fraction - link](#)

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

- [Do junior doctors make more prescribing errors than experienced doctors when prescribing electronically using a computerised physician order entry system combined with a clinical decision support system? A cross-sectional study - link](#)
- [European Association of Hospital Pharmacists \(EAHP\) position paper: Digital health - link](#)
- [European Association of Hospital Pharmacists \(EAHP\) position paper: Infectious diseases and antimicrobial resistance - link](#)

### **Heart**

- [Optimal antiplatelet strategy following coronary artery bypass grafting: a meta-analysis - link](#)
- [Beta-blockers and renin-angiotensin system inhibitors for Takotsubo syndrome recurrence: a network meta-analysis – link – SPS commentary](#)

### **Internal Medicine Journal**

- Provision of continuous subcutaneous insulin infusion to type 1 diabetes ‘frequent flyers’ - [link](#)

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

- Look-alike medications in the perioperative setting: scoping review of medication incidents and risk reduction interventions - [link](#)
- Prevalence, contributing factors, and interventions to reduce medication errors in outpatient and ambulatory settings: a systematic review - [link](#)
- Development and partial validation of Be-CLIPSS: a classification system for hospital clinical pharmacy activities - [link](#)

### **JAMA**

- Blood Pressure Management After Endovascular Therapy for Acute Ischemic Stroke: The BEST-II Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Intensive vs Conventional Blood Pressure Lowering After Endovascular Thrombectomy in Acute Ischemic Stroke: The OPTIMAL-BP Randomized Clinical Trial – [link](#) – [SPS commentary](#)
- Intensive Statin Therapy Versus Upfront Combination Therapy of Statin and Ezetimibe in Patients With Acute Coronary Syndrome: A Propensity Score Matching Analysis Based on the PL-ACS Data – [link](#) – [SPS commentary](#)
- Aldosterone Synthase Inhibition With Lorundrostat for Uncontrolled Hypertension: The Target-HTN Randomized Clinical Trial - [link](#)
- Efficacy and tolerability of gefapixant for treatment of refractory or unexplained chronic cough: A Systematic Review and Dose-Response Meta-Analysis – [link](#) – [SPS commentary](#)
- Ulcerative Colitis in Adults: A Review - [link](#)

### **JAMA Cardiology**

- Mavacamten in Patients With Hypertrophic Cardiomyopathy Referred for Septal Reduction: Week 56 Results From the VALOR-HCM Randomized Clinical Trial – [link](#) – [SPS commentary](#)

### **JAMA Dermatology**

- Cutaneous Adverse Events and Cancer Survival Prognosis With Immune Checkpoint Inhibitor Treatment: A Systematic Review and Meta-Analysis - [link](#)

### **JAMA Internal Medicine**

- Estimated Lifetime Gained With Cancer Screening Tests: A Meta-Analysis of Randomized Clinical Trials – [link](#) – [SPS commentary](#)

### **JAMA Neurology**

- Vaccines and the Risk of Hospitalization for Multiple Sclerosis Flare-Ups - [link](#)
- Efficacy and safety of ravulizumab, a complement C5 inhibitor, in adults with amyotrophic lateral sclerosis - [link](#)

### **JAMA Oncology**

- Use of Artificial Intelligence Chatbots for Cancer Treatment Information – [link](#) – [SPS commentary](#)
- Nivolumab Plus Ipilimumab vs Nivolumab Alone in Advanced Cancers Other Than Melanoma: A Meta-Analysis - [link](#)
- Project Optimus: Is the US Food and Drug Administration Waiving Dose Optimization for Orphan Drugs? - [link](#)
- Neoadjuvant Immune Checkpoint Inhibitor Therapy for Localized Deficient Mismatch Repair Colorectal Cancer (dMMR CRC) - [link](#)

### **JAMA Psychiatry**

- Prenatal Antidepressant Exposure and Offspring Brain Morphologic Trajectory - [link](#)
- Efficacy and Safety of Antidepressants in Patients With Comorbid Depression and Medical Diseases: An Umbrella Systematic Review and Meta-Analysis – [link](#) – [SPS commentary](#)
- Association Between Stimulant Treatment and Substance Use Through Adolescence Into Early Adulthood - [link](#)
- Gabapentin Use Among Individuals Initiating Buprenorphine Treatment for Opioid Use Disorder - [link](#)

### **Journal of Clinical Oncology**

- Atezolizumab combined with bevacizumab and platinum-based therapy for platinum-sensitive ovarian cancer: placebo-controlled randomized Phase III ATALANTE/ENGOT-ov29 trial - [link](#)
- Survival of patients with cancer with DPYD variant alleles and dose-individualized fluoropyrimidine therapy—a matched-pair analysis - [link](#)
- Randomized Phase III Study Comparing Neoadjuvant Chemotherapy Followed by Surgery Versus Chemoradiation in Stage IB2-IIB Cervical Cancer: EORTC-55994 - [link](#)
- Oral Selinexor as Maintenance Therapy After First-Line Chemotherapy for Advanced or Recurrent Endometrial Cancer – [link](#) – [SPS commentary](#)
- Effect of metformin versus placebo on new primary cancers in Canadian Cancer Trials Group MA.32: a secondary analysis of a Phase III randomized double-blind trial in early breast cancer - [link](#)

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

- Selecting performance indicators for hospital pharmacy practice: A Canadian initiative - [link](#)
- A retrospective study investigating the management, risk factors, and outcomes of patients diagnosed with Clostridioides difficile infection - [link](#)

### **Lancet**

- Childhood nephrotic syndrome - [link](#)
- series on cystic fibrosis – [link](#) – [SPS commentary](#)

### **Lancet Diabetes & Endocrinology**

- The optimal healthy ranges of thyroid function defined by the risk of cardiovascular disease and mortality: systematic review and individual participant data meta-analysis - [link](#)
- Current insights and emerging trends in early-onset type 2 diabetes - [link](#)

### **Lancet Gastroenterology and Hepatology**

- Efficacy and safety of dupilumab up to 52 weeks in adults and adolescents with eosinophilic oesophagitis (LIBERTY EoE TREET study): a multicentre, double-blind, randomised, placebo-controlled, phase 3 trial - [link](#)
- NASH (nonalcoholic steatohepatitis), drug treatment development: challenges and lessons - [link](#)

### **Lancet Haematology**

- Second primary malignancies in patients with lymphoma in Denmark after high-dose chemotherapy and autologous haematopoietic stem-cell transplantation: a population-based, retrospective cohort study - [link](#)

### **Lancet HIV**

- Emergent HIV drug resistance in non-inferiority trials - [link](#)

### **Lancet Oncology**

- Olaparib plus abiraterone versus placebo plus abiraterone in metastatic castration-resistant prostate cancer (PROpel): final prespecified overall survival results of a randomised, double-blind, phase 3 trial – [link](#) – [SPS commentary](#)

### **Lancet Respiratory Medicine**

- Completion, safety, and efficacy of tuberculosis preventive treatment regimens containing rifampicin or rifapentine: an individual patient data network meta-analysis – [link](#) – [SPS commentary](#)
- Effect of once-per-day tacrolimus versus twice-per-day ciclosporin on 3-year incidence of chronic lung allograft dysfunction after lung transplantation in Scandinavia (ScanCLAD): a multicentre randomised controlled trial – [link](#) – [SPS commentary](#)

### **Medical Journal of Australia**

- Activating pharmacists to reduce the frequency of medication-related problems (ACTMed): a stepped wedge cluster randomised trial - [link](#)
- Management of opiate dependence related to dihydrocodeine–sorbitol misuse - [link](#)

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

- Phase 3 Trial of Concizumab in Hemophilia with Inhibitors – [link](#) – [SPS commentary](#)
- Current and Emerging Issues in Wilson’s Disease - [link](#)
- Antibiotic Prophylaxis in Infants with Grade III, IV, or V Vesicoureteral Reflux – [link](#) – [SPS commentary](#)

### **Organic Process Research & Development**

- Formation of N-Nitrosamine Drug Substance Related Impurities in Medicines: A Regulatory Perspective on Risk Factors and Mitigation Strategies - [link](#)

### **Pharmacotherapy**

- CYP2D6-guided opioid therapy for adults with cancer pain: a randomized implementation clinical trial - [link](#)
- Fluoroquinolone-Associated Adverse Events of Interest among Hospitalized Veterans Affairs Patients with Community-Acquired Pneumonia Who Were Treated with a Fluoroquinolone: A Focus on Tendonitis, Clostridioides difficile Infection, and Aortic Aneurysm - [link](#)
- Transitioning Disopyramide to Mavacamten in Obstructive Hypertrophic Cardiomyopathy: A Case Series and Clinical Guide - [link](#)
- Switching from intravenous vancomycin to oral antibiotics reduces adverse events in a retrospective cohort of outpatients with orthopedic infections - [link](#)

### **Prescrire – French Medical Journal**

- Nivolumab (Opdivo®) in advanced gastric or oesophageal cancer - [link](#)
- Dulaglutide, exenatide, liraglutide and other GLP-1 receptor agonists: thyroid cancer - [link](#)
- Glucarpidase (Voraxaze®) for high-dose methotrexate toxicity - [link](#)
- Conditional marketing authorisation: easier to grant than to revoke - [link](#)
- Drugs to avoid in the name of better patient care - 2023 update - [link](#)

### **Thorax**

- COVID-19-associated pulmonary aspergillosis in mechanically ventilated patients: a prospective, multicentre UK study - [link](#)
- Super-responders to anti-IL-5/anti-IL-5R are characterised by high sputum eosinophil counts at baseline - [link](#)
- Atopic and non-atopic effects of fish oil supplementation during pregnancy - [link](#)

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

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### **TGA**

- Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, November 2023, closes 29 September 2023 - [link](#)

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## WEBINARS & PODCASTS

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### Australian Prescriber Podcasts

- [Episode 146](#): Medicines and children

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

- FDA Drug Topics: Naltrexone Injection for Opioid Use Disorder - FDA's Efforts to Reduce Medication Errors - October 24, 2023 - [link](#)

### MJA Podcasts

- [Episode 23](#): Lower urgency care in the emergency department

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## UPCOMING EVENTS

(New additions listed in TAGMail)

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### AHHA

- Value-Based Health Care (VBHC) Congress 2023, 26-27 October 2023, Brisbane - register [here](#)  
- 15th Hospital in the Home Society Annual Scientific Meeting, 15-17 November 2023, Adelaide – register [here](#)

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

- National Medicines Symposium 2023, 8 November 2023 10:00-16:30 (AEDT), virtual – register [here](#)

### FIP

- 81<sup>st</sup> FIP World Congress of Pharmacy and Pharmaceutical Sciences, 24-28 September 2023, Brisbane – still time to register [here](#)

### NHMRC Medicines Intelligence Centre of Research Excellence

- 2023 Annual Research Symposium, 1-2 November 2023, Surry Hills Sydney – free registration [here](#)

### Institute for Safe Medication Practices (ISMP)

- Improving Medication Safety, Costs, and Patient Outcomes Symposia, Saturday 14 October 2023 12:00pm to 1:00pm, San Francisco - register [here](#)

### Society of Hospital Pharmacists (SHPA)

- Medicines Management 2023, 47<sup>th</sup> SHPA National Conference, 2-4 November 2023, Cairns – register [here](#) by 2 October for early bird

### Sydney Children's Hospital Network SCHN & Children's Medical Research Institute

- Westmead Research and Innovation Conference, 21-22 September 2023, Westmead, Sydney – [program](#) - [registration](#) – [abstract submission](#)  
- Advanced therapeutics joint symposia, 29-30 November 2023, Westmead, Sydney – save the date and [get on the mailing list](#)

### UNSW

- Cardiac, Vascular, and Metabolic Medicine Symposium, 13 October 2023 12:00-18:00, Garvan Institute, Darlinghurst - free registration [here](#)

### World Pharmacists Day

- 25<sup>th</sup> September 2023

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## TAG Mail

**31<sup>st</sup> August 2023**

A fortnightly newsletter for quality use of medicine healthcare practitioners

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## NSW TAG ACTIVITIES

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### **New [open](#) email discussions**

Review of medicines labelling rules and request for feedback by 7th September 2023. Further information sent in email to NSW TAG members 25<sup>th</sup> August 2023.

### **Recently completed email discussions**

Re-purposing of medicines enquiry. See email sent to NSW TAG members 15/8/2023.

### **Upcoming TAG meeting [dates](#)**

NSW TAG General Meeting 19<sup>th</sup> October 3-4.30pm

NSW Annual General Meeting 19<sup>th</sup> October 4.30pm

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## **OTHER NEWS**

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### **NSW Health**

- Bring back memories not measles - [link](#)
- Occupational Assessment, Screening and Vaccination Against Specified Infectious Diseases ([PD2023\\_022](#))
- Preparation of pharmaceutical and advanced therapeutic products ([PD2023\\_021](#))

### **TGA**

- New reporting requirements for medicine shortages - [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](#)

- Trauma-informed mental health care organisational self-assessment tool - [link](#)
- Delivering palliative care virtually - [link](#)

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

- Improving health outcomes for people with diabetes and cardiovascular disease - [link](#)
- Supporting all Australians to be healthy through affordable, person-centred primary healthcare - [link](#)

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

- Cancer data in Australia- [link](#)
- Aged Care data- [link](#)

### **MIMS monthly updates**

- New Products
- [Avatrombopag](#) (as maleate) (Doptelet): an orally bioavailable, small molecule thrombopoietin receptor (TPO-R) agonist for thrombocytopenia in adults with chronic liver disease scheduled to undergo a procedure, or with chronic immune thrombocytopenia (who have had an insufficient response to a previous treatment).
- [Carboprost](#) (as trometamol) (Carboprost-Reach): a synthetic 15-methyl analogue of dinoprost (prostaglandin F2alpha), a uterine stimulant with a more prolonged action than dinoprost. When used in postpartum haemorrhage, it stimulates the uterus to contract in a manner similar to that normally observed in the uterus following delivery
- [Lenacapavir](#) (as sodium) (Sunlenca): a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (CA) subunits and inhibits HIV-1
- [Durvalumab](#) (Imfinzi): now indicated in combination with tremelimumab for unresectable hepatocellular carcinoma in adults who have not received prior treatment with a PD-1/PD-L1 inhibitor
- [Vedolizumab](#) (Entyvio): now indicated for moderate to severe chronic pouchitis in adults, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy

### **PBS**

- Efficient Funding of Chemotherapy (EFC) Review – Final Report - [link](#)
- Recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) – [July 2023](#)
- Estimating overall survival in people receiving Pharmaceutical Benefits Scheme (PBS)-listed cancer medicines in Australian clinical practice - [link](#)

## TGA

- [Database](#) of section 19A approvals to import and supply medicines to address medicine shortages
- Australian prescription medicine decision summaries:
  - [Columvi](#) (glofitamab) is provisionally approved to treat adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

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## REPORTS AND PUBLICATIONS – INTERNATIONAL

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### Canadian Agency for Drugs and Technologies in Health

- Utilization of Opioid Agonist Therapies in Canada - [link](#)

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

- New products
  - Skyrizi ([risankizumab](#)) 360 mg solution for injection in cartridge and 600 mg concentrate for infusion solution

### Food and Drug Administration (FDA) USA

- New Drug approvals
  - First Vaccine [Abrysvo](#) (Respiratory Syncytial Virus Vaccine) for Pregnant Individuals to Prevent RSV in Infants
  - [Tyruko](#) (natalizumab), the first biosimilar to treat multiple sclerosis
  - [Sohonos](#) (palovarotene) first treatment for Fibrodysplasia Ossificans Progressiva - [link](#)
  - [pozelimab](#) (Veopoz) for treatment of CD55-deficient protein-losing enteropathy (CHAPLE disease)
- New drug updates
  - [canakinumab](#) (Ilaris) new indication for gout flares
  - [luspatercept](#) (Reblozyl) first-line treatment of anemia associated with MDS
  - [valbenazine](#) (Ingrezza) selective VMAT2 inhibitor for chorea associated with Huntington disease
  - [aflibercept](#) intravitreal (Eylea HD) Nnw high-dose regimen approved for wAMD, DME, and DR
- Applications
  - Priority Review for enzalutamide for earlier treatment in prostate cancer - [link](#)

### Institute for Healthcare Improvement

- IHI Framework for Improving Joy in Work - [link](#) – [with health system examples](#)

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

- MHRA reinforces anaphylaxis emergency guidance as hospital admissions rise - [link](#)

### NHS England

- Community pharmacy independent prescribing - [link](#)
- NHS to rollout subcutaneous atezolizumab - [link](#)
- Supporting clinical decisions with health information technology - [link](#)

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

- Ectopic pregnancy and miscarriage: diagnosis and initial management, updated ([NG126](#))
- Otitis media with effusion in under 12s ([NG233](#))
- NICE draft guidance recommends [novel](#) treatment for debilitating inherited skin condition EB

### Nuffield Trust

- Healthcare-associated infections - [link](#)
- Are patients told about medication side effects? - [link](#)

### Royal Pharmaceutical Society

- RPS says codeine linctus should be made a prescription-only medicine, in response to MHRA consultation - [link](#)

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

- Pharmacological management of migraine - [link](#)
- National clinical guideline for stroke for the UK and Ireland - [link](#)
- Cutaneous melanoma - [link](#)
- Care of deteriorating patients - [link](#)

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

- New product evaluations August 2023 - [link](#)
- Giving intermittent intravenous infusions by gravity in adults - [link](#)

### **The Royal Society**

- COVID-19: examining the effectiveness of non-pharmaceutical interventions - [link](#)

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

- Global partners commit to advance evidence-based traditional, complementary and integrative medicine - [link](#)

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## **MEDICATION SAFETY**

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

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

- Lemtrada (alemtuzumab) - Alopecia areata added as an uncommon potential ADR
- Zithromycin (azithromycin) - use with caution in patients taking medicines such as hydroxychloroquine that are known to prolong the QT interval
- Bimzelx (bimekizumab) - updated with detail needed to support its use for adult axial spondyloarthritis (a newly licensed indication)
- Calcipotriol/Betamethasone ointment - additional data on use in children, but still only licensed for use in adults
- Co-amoxiclav Injection - drug-induced enterocolitis syndrome (DIES) - an allergic reaction with the leading symptom of protracted vomiting reported with treatment, mainly in children
- Lonquex (lipegfilgrastim)- Class effect warning for acute myeloid leukaemia & myelodysplastic syndrome to advise GCSF can promote growth of myeloid cells and some non-myeloid cells in vitro. As safety & efficacy of Lonquex not been investigated in these patients, it should not be used in them
- Ofev (nintedanib)- Although not licensed in children, SPC updated to include information about possible ADRs in children, but highlights that long term safety data are not available. Information about administration of Ofev capsules with soft foods (apple puree & chocolate pudding) also included
- Targinact (oxycodone)- updated to include warnings that oxycodone can increase intrabiliary pressure and spasm because of its effects on the sphincter of Oddi. Clinicians are advised to monitor patients using it who have biliary tract disease for worsening symptoms
- Losec (omeprazole) - Acute tubulointerstitial nephritis added as a rare ADR
- Ultomiris (ravulizumab) - updated to support its use in treatment of adult neuromyelitis optica spectrum disorder and anti-aquaporin 4 (AQP4) antibody-positive (newly licensed indication)
- Noxafil (posaconazole) - now contraindicated in patients with chronic lymphocytic leukaemia receiving venetoclax during the initiation or dose-titration phases due to an increased risk of tumour lysis syndrome and neutropenia
- Zelboraf (vemurafenib) - Thrombocytopenia added as a common ADR
- Vera-Til SR (verapamil) - updated to warn metabolism is delayed to a greater or lesser extent depending on severity of hepatic dysfunction, thus potentiating and prolonging effects of verapamil. Also efficacy of metformin may be reduced with concomitant administration of verapamil
- Risk minimisation materials
- Tibsovo ([ivosidenib](#)) – patient alert card
- Vaxchora ([cholera vaccine](#)) – reconstitution and administration information
- Olumiant ([baracitinib](#)) - A patient held card and separate guidance for healthcare professionals involved in prescribing this product for atopic dermatitis or alopecia areata or for rheumatoid arthritis

### **EMA**

- EMA review of data on paternal exposure to valproate - [link](#)

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

- Gadolinium-based contrast agents for MRI: safety in pregnancy - [link](#)
- FDA alerts patients and health care professionals about clinical trial results showing an increased risk of death associated with Pepaxto (melphalan flufenamide) - [link](#)

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

- Medication Safety Alert! [August 24, 2023](#)
- Obstetrical Patient Receives Ampule of Digoxin Instead of BUPivacaine for Spinal Anesthesia - [link](#)
- Drug Name Confusion: More than 80 New Drug Pairs Added to List - [link](#)

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

- Drug Safety Update [August 2023](#)
- Fluoroquinolone antibiotics: risk of disabling and potentially long-lasting or irreversible side effects - [link](#)
- Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions - [link](#)
- Drug Safety Update [July 2023](#)
- Hyoscine hydrobromide patches (Scopoderm 1.5mg Patch or Scopoderm TTS Patch): risk of anticholinergic side effects, including hyperthermia - [link](#)
- Codeine linctus: public consultation on the proposal to reclassify to a prescription-only medicine - [link](#)

### **MIMS monthly updates**

- New Contraindications
- Naproxen ([Naprosyn](#), Naprosyn SR and Anaprox 550) is now contraindicated in the 3rd trimester of pregnancy

### **Pharma**

- [belantamab mafototin](#) (BLENREP) - series of materials aimed at patients, physicians and eye care professionals to help reduce the risk of this medicine causing corneal adverse reactions when it is used to treat multiple myeloma
- [isatuximab](#) (Sarclisa) - patient alert card and healthcare professional brochure with information about this medicine's potential to interfere with blood compatibility tests by giving false positive reactions in the indirect antiglobulin test when used to treat multiple myeloma

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

- Medication Safety Update [August 2023](#)

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## **PAPERS OF INTEREST**

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

- Pharmacotherapy considerations with finerenone in the treatment of chronic kidney disease associated with type 2 diabetes - [link](#)
- Evaluation of inpatient medication guidance from an artificial intelligence chatbot - [link](#)
- Provision of ambrisentan from a health-system specialty pharmacy affiliated with a pulmonary hypertension Center of Comprehensive Care - [link](#)
- Implementation of a multidisciplinary inpatient drug desensitization program - [link](#)

### **Arthritis & Rheumatology**

- Risk–Benefit Analysis of Primary Prophylaxis Against Pneumocystis Jirovecii Pneumonia in Patients With Rheumatic Diseases Receiving Rituximab - [link](#) – [SPS commentary](#)

### **Australian Prescriber**

- Medicines stewardship - [link](#)
- Chimeric antigen receptor T-cell therapy - [link](#)
- An update on wound management - [link](#)
- Editorial: Limitations of randomised controlled trials as evidence of drug safety – [link](#)
- New Drugs: [Brexucabtagene autoleucl](#) for mantle cell lymphoma, B-cell precursor acute lymphoblastic leukaemia; [Opicapone](#) for Parkinson's disease

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

- Therapeutic drug monitoring and virological response at week 48 in a cohort of HIV-1 infected-patients switching to dolutegravir/rilpivirine dual maintenance therapy (ANRS-MIE-BIRIDER Study) - [link](#)

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

- How do we best use Paxlovid and other covid antivirals? - [link](#)
- How the FDA approved an antipsychotic that failed to show a meaningful benefit but raised the risk of death - [link](#)
- Pathophysiology, diagnosis, and management of neuroinflammation in covid-19 - [link](#)
- Turning down the spice: tackling the problems of synthetic cannabinoids - [link](#)
- Venous eczema and chronic venous disease - [link](#)
- New treatments for Alzheimer's disease - [link](#)

### **BMJ Open**

- Effect of monitoring adherence to regular inhaled corticosteroid (ICS) alone or in combination with a long-acting  $\beta$  2-agonist (LABA) using electronic methods on asthma outcomes: a narrative systematic review - [link](#)
- Pain related to intravitreal injections for age-related macular degeneration: a qualitative study of the perspectives of patients and practitioners - [link](#)
- Long-term efficacy and safety of erenumab in Japanese patients with episodic and chronic migraine: results from a 28-week open-label treatment period of a randomised trial - [link](#)
- Screening over 100 000 patients in 39 general practices in the Netherlands for anticoagulation underprescription in atrial fibrillation: a descriptive, cross-sectional study - [link](#)
- Prophylactic antibiotic use for infective endocarditis: a systematic review and meta-analysis - [link](#)

### **Circulation**

- Blinded Withdrawal of Long-Term Randomized Treatment with Empagliflozin or Placebo in Patients With Heart Failure - [link](#)
- Development and Validation of the DOAC Score: A Novel Bleeding Risk Prediction Tool for Patients With Atrial Fibrillation on Direct-Acting Oral Anticoagulants - [link](#)
- Edoxaban for 12 Months Versus 3 Months in Cancer Patients With Isolated Distal Deep Vein Thrombosis (ONCO DVT study): An Open-label, Multicenter, Randomized Clinical Trial - [link](#)
- Outpatient Worsening Among Patients with Mildly Reduced and Preserved Ejection Fraction Heart Failure in the DELIVER Trial - [link](#)
- Safety of Switching from a Vitamin K Antagonist to a Non-Vitamin K Antagonist Oral Anticoagulant in Frail Older Patients with Atrial Fibrillation: Results of the FRAIL-AF Randomized Controlled Trial - [link](#)

### **Cochrane**

- Monotherapy treatment of epilepsy in pregnancy: congenital malformation outcomes in the child - [link](#)
- Psychological therapies delivered remotely for the management of chronic pain (excluding headache) in adults - [link](#)
- Hormone therapy for sexual function in perimenopausal and postmenopausal women - [link](#)
- Mental Health First Aid as a tool for improving mental health and well-being - [link](#)
- Pharmacological treatment of gastro-oesophageal reflux in children - [link](#)
- Addition of long-acting beta2 agonists or long-acting muscarinic antagonists versus doubling the dose of inhaled corticosteroids (ICS) in adolescents and adults with uncontrolled asthma with medium dose ICS: a systematic review and network meta-analysis - [link](#)
- Paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs, alone or combined, for pain relief in acute otitis media in children - [link](#)

### **Diabetes Care**

- Glucose Monitoring Metrics in Individuals With Type 1 Diabetes Using Different Treatment Modalities: A Real-World Observational Study - [link](#) – [SPS commentary](#)
- Diabetic Nephropathy: Update on Pillars of Therapy Slowing Progression - [link](#) – [SPS commentary](#)

### **Drug and Therapeutics Bulletin**

- FDA-approved drugs not meeting primary endpoints - [link](#)

- No benefit of vitamin D on cognition in older adults - [link](#)
- Intravenous vitamin injections: where is the evidence? - [link](#)

### **European Heart Journal**

- Carat, clarity, colour, and cut: grading the DIAMOND trial - [link](#)
- Detailed safety analysis of DIAMOND trial: 'primum non nocere'? - [link](#)
- Epilepsy and long-term risk of arrhythmias - [link](#)
- Mineralocorticoid receptor antagonists with sodium–glucose co-transporter-2 inhibitors in heart failure: a meta-analysis - [link](#)
- 2023 ESC Guidelines for the management of acute coronary syndromes: Developed by the task force on the management of acute coronary syndromes of the European Society of Cardiology (ESC) - [link](#)
- 2023 ESC Guidelines for the management of cardiomyopathies- [link](#)
- 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure - [link](#)
- Sodium-based paracetamol: impact on blood pressure, cardiovascular events, and all-cause mortality - [link](#)
- Long-term efficacy and safety of lerodalcibep in heterozygous familial hypercholesterolaemia: the LIBerate-HeFH trial - [link](#)
- Recommendations for statin management in primary prevention: disparities among international risk scores - [link](#) – [SPS commentary](#)
- Renal Function and Decongestion With Acetazolamide in Acute Decompensated Heart Failure: The ADVOR Trial - [link](#)

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

- Physicochemical stability of high-concentration cefuroxime aqueous injection reconstituted by a centralised intravenous additive service - [link](#)
- Spice-drug interactions: a case report on the use of turmeric, curry and ginger in a renal transplant patient on tacrolimus - [link](#)

### **Heart**

- Management of secondary mitral regurgitation: from drugs to devices - [link](#)
- Alcohol Intake and Blood Pressure Levels: A Dose-Response Meta-Analysis of Nonexperimental Cohort Studies - [link](#)

### **Internal Medicine Journal**

- Weight loss with subcutaneous semaglutide versus other glucagon-like peptide 1 receptor agonists in type 2 diabetes: a systematic review - [link](#)

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

- Pharmaceutical Care Network Europe definition of quality indicators for pharmaceutical care: a systematic literature review and international consensus development - [link](#)
- Analysis of the association between Janus kinase inhibitors and malignant skin tumors using the Food and Drug Administration Adverse Event Reporting System - [link](#)

### **Journal of Allergy and Clinical Immunology**

- Oral difelikefalin reduces moderate to severe pruritus and expression of pruritic and inflammatory biomarkers in subjects with atopic dermatitis - [link](#)

### **JAMA**

- Aspirin for Secondary Prevention of Cardiovascular Disease in 51 Low-, Middle-, and High-Income Countries - [link](#)
- Preexposure Prophylaxis to Prevent Acquisition of HIV: US Preventive Services Task Force Recommendation Statement - [link](#)

### **JAMA Cardiology**

- Health Claims and Doses of Fish Oil Supplements in the US - [link](#)
- Association Between Fluoroquinolone Use and Hospitalization With Aortic Aneurysm or Aortic Dissection - [link](#)



### **JAMA Dermatology**

- Safety and Efficacy of Tralokinumab in Older Adults with Moderate-to-Severe Atopic Dermatitis. A Secondary Analysis - [link](#)

### **JAMA Internal Medicine**

- Changes in the Use of Long-Term Medications Following Incident Dementia Diagnosis - [link](#)

### **JAMA Network Open**

- A Fast-Acting Pill Received Approval for Postpartum Depression—Is It a Game Changer? - [link](#)

### **JAMA Neurology**

- Teriflunomide and Time to Clinical Multiple Sclerosis in Patients with Radiologically Isolated Syndrome. The TERIS Randomized Clinical Trial - [link](#)

### **JAMA Oncology**

- Immune Checkpoint Inhibitors for Child-Pugh Class B Advanced Hepatocellular Carcinoma: A Systematic Review and Meta-Analysis - [link](#)

### **The Joint Commission Journal on Quality and Patient Safety**

- Anesthesia Risk Alert Program: A Proactive Safety Initiative - [link](#)

### **Journal of Clinical Oncology**

- Adding Ovarian Suppression to Tamoxifen for Premenopausal Women with Hormone Receptor–Positive Breast Cancer After Chemotherapy: An 8-Year Follow-Up of the ASTRRA Trial - [link](#)

- Integrative Oncology Care of Symptoms of Anxiety and Depression in Adults With Cancer: Society for Integrative Oncology–ASCO Guideline - [link](#)

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

- Testing a medicine information needs identification tool (MINI-Q) with hospital inpatients in New Zealand - [link](#)

### **Lancet**

- The emerging fentanyl–xylazine syndemic in the USA: challenges and future directions - [link](#)

- Value of intravenous thrombolysis in endovascular treatment for large-vessel anterior circulation stroke: individual participant data meta-analysis of six randomised trials - [link](#)

### **Lancet Diabetes & Endocrinology**

- Adjuvant mitotane versus surveillance in low-grade, localised adrenocortical carcinoma (ADIUVO): an international, multicentre, open-label, randomised, phase 3 trial and observational study - [link](#)

### **Lancet Psychiatry**

- Comparative efficacy and tolerability of pharmacological interventions for acute bipolar depression in adults: a systematic review and network meta-analysis – [link](#) – [SPS commentary](#)

- Non-pharmacological and pharmacological interventions for the reduction or prevention of topographies of behaviours that challenge in people with intellectual disabilities: a systematic review and meta-analysis of randomised controlled trials – [link](#) – [SPS commentary](#)

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

- The Impact of an Antimicrobial Stewardship Clinical Pharmacy Specialist on Antimicrobial Days of Therapy through Education Driven Policies, Procedures, and Interventions - [link](#)

- Antibiotics and Lipid-Modifying Agents: Potential Drug–Drug Interactions and Their Clinical Implications - [link](#)

### **Medical Journal of Australia**

- Current debates and research in cardiovascular medicine - [link](#)

- Letters: Current and emerging medications for the management of obesity in adults – [link](#) -

### **National Institute for Health Research (NIHR) Signals**

- Epilepsy: what are the chances of having a second seizure? - [link](#)

### **Pharmacotherapy**

- International consensus recommendations for the use of prolonged-infusion beta-lactam antibiotics: Endorsed by the American College of Clinical Pharmacy, British Society for Antimicrobial Chemotherapy, Cystic Fibrosis Foundation, European Society of Clinical Microbiology and Infectious Diseases, Infectious Diseases Society of America, Society of Critical Care Medicine, and Society of Infectious Diseases Pharmacists - [link](#) – [Executive Summary](#)
- Approaches to Precision-Based Anticoagulation Management in the Critically Ill - [link](#)
- Antimicrobial pharmacokinetics and dosing in critically ill adults receiving prolonged intermittent renal replacement therapy: A systematic review - [link](#)
- Baricitinib versus tocilizumab in critically ill COVID-19 patients: A retrospective cohort study - [link](#)

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

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

- Model of Care for the Management of Low Back Pain –closes 6 September 2023 5pm - [link](#)

### **TGA**

- Guidelines for the Quality of Listed Probiotic Medicines, closes 10 September 2023 - [link](#)
- 2023-2024 Proposed changes to the Permissible Ingredients Determination – Low-negligible risk - [link](#)

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## **WEBINARS & PODCASTS**

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

- Regulatory Framework for Human Drug Compounding – 26 September 2023 - [link](#)

### **MJA Podcasts**

- [Episode 21](#): Improving Aboriginal and Torres Strait Islander health outcomes
- [Episode 20](#): Organ donation after voluntary assisted dying

### **NEJM**

- Prescribing Large Language Models for Medicine: What's the Right Dose? – 18 October 2023 12:00-2:00 PM ET – register [here](#)

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## **UPCOMING EVENTS**

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

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### **AHHA**

- Value-Based Health Care (VBHC) Congress 2023, 26-27 October 2023, Brisbane - register [here](#)
- 15th Hospital in the Home Society Annual Scientific Meeting, 15-17 November 2023, Adelaide – register [here](#)

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

- National Medicines Symposium 2023, 8 November 2023 10:00-16:30 (AEDT), virtual – register [here](#)

### **NHMRC Medicines Intelligence Centre of Research Excellence**

- 2023 Annual Research Symposium, 1-2 November 2023, Surry Hills Sydney – free registration [here](#)

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

- Improving Medication Safety, Costs, and Patient Outcomes Symposia, Saturday 14 October 2023 12:00pm to 1:00pm, San Francisco - register [here](#)