

Today's issue of PD

Pharmacy Daily today features three pages of news, plus a full page from **Maxofen**, and the **November MIMS Monthly Update**.

Maximise your day

NEW Maxofen from Nova Pharmaceuticals combines paracetamol and ibuprofen for double-action relief from acute pain and fever.

Available in packs of 12 and 30 tablets - see **page four**.

Are your ads TGA compliant?

THE Therapeutic Goods Administration (TGA) has updated its 'Advertising therapeutic goods on social media' guidance to help advertisers to understand regulations around promoting therapeutic goods via these platforms.

The update is a response to an increase in unlawful advertising on social media, where businesses, health services and social media influencers are promoting prescription-only medicines, often using images, nicknames, hashtags and influencer-style endorsements.

Advertisers are encouraged to review both historical and newly posted social media content to ensure it meets the regulatory requirements under the *Therapeutic Goods Act 1989*.

Significant fines can be imposed for breaches of the Act - the updated guidance is available **HERE**.

Board accused of ignoring dissent

PEAK doctors groups have accused the Pharmacy Board of Australia of putting patients at risk of poorer health outcomes by suppressing debate about its proposed endorsement model for autonomous pharmacy prescribing.

In a joint letter to the board this week, the Australian Medical Association (AMA) and the Royal Australian College of General Practitioners (RACGP) expressed disappointment in the board's "uncollaborative pursuit of widespread pharmacy prescribing", with particular reference to a forum held on 30 Oct to discuss the proposal.

"We hoped the day would present an opportunity to have a meaningful discussion about how to safely incorporate pharmacist prescribing into a coordinated model of care where pharmacists and doctors work together for patients," the letter stated.

"The move to expand pharmacy prescribing comes with legitimate and real concerns about fragmentation of care, potential conflicts of interest and the removal of a key policy setting designed to maintain patient safety - namely the separation of prescribing and dispensing," the letter continued.

However, the doctors groups said the board "showed a complete disregard for meaningful debate", that the forum was set up in a way that ensured "any opposing views - even when grounded in rigorous evidence and supported by data - were discouraged" and key issues excluded from discussion.

"While there was some acknowledgement of the conflict-of-interest pharmacists face when both prescribing and selling medications, there was little



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substantive discussion on how to address this issue.

"This silence is troubling and will have serious consequences for patients."

The peak bodies also raised concerns about apparent variance between states around the preferred model.

"It was alarming that one jurisdiction threatened to ignore any endorsement issued by the board if it differed to the approach being taken in that state," they said.

"Queensland should not be allowed to hold the Board hostage to this demand."

The AMA and RACGP have urged the Pharmacy Board to reconsider its consultation process by enabling a more meaningful and substantive dialogue that addresses legitimate concerns about the

proposed model.

The Pharmacy Guild of Australia rejected the doctors bodies' letter today, saying it "fails to distinguish between allegations and opinions and contains no actual evidence".

"While the release claims the Pharmacy Board is pursuing a 'risky prescribing agenda', sadly these statements reflect the doctor lobby's fears not facts," a spokesperson for the Guild said.

"Why the doctor lobby groups would seek to undermine patient confidence and seek to divide the community instead of working together, only they can answer."

The Guild noted that pharmacists in Australia have a long history of prescribing schedule 2 and 3 medicines, including emergency supply, continued dispensing, and collaborative prescribing models.

"Every day, pharmacists identify and correct thousands of prescribing mistakes made by other prescribers," the Guild added.

"These same skills and knowledge form the basis for pharmacists to undertake additional training to qualify as an autonomous pharmacist prescriber."

Pharmacy Daily has approached the board for comment. **KB**



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Vax, immunisation resources updated

THE Department of Health, Disability and Ageing has released the fourth edition of the National Vaccine Storage Guidelines 'Strive for 5', featuring updates around cold chain management relating to community pharmacies.

For vaccines purchased in pharmacies, the Guidelines state: "All immunisation service providers who provide a prescription to their patient for the purchase of vaccine/s must advise the client that vaccine/s must be taken directly to their administering healthcare professional for administration or refrigerated storage."

In some cases the pharmacist may be able to administer the vaccine, but if not, it should remain in the pharmacy refrigerator until the patient can return to the administering health professional - patients should not store vaccines in their home.

It also clarifies that alfoil bags are not effective in maintaining cold chain.

See the updated guide [HERE](#).

MEANWHILE, an updated version of the Immunisation Handbook mobile app has been released, providing enhancements to search and browsing performance, bug fixes and improved analytics for ongoing optimisation.

It is available from the App Store or Google Play.

Act mandates better med use

AGED care advocates have welcomed the start of the new rights-based *Aged Care Act*, which came into effect on 01 Nov, providing older Australians with greater independence, autonomy, choice and control regarding their care.

With demand for aged care projected to grow dramatically due to Australia's ageing population, a new Act, framed in rights of the older person, was the number one recommendation of the Royal Commission into Quality and Safety in Aged Care's final report almost five years ago, with the Act passing into legislation late last year (**PD** 25 Nov 2024).

The Act reinforces that older people have the right to make their own decisions, with appropriate support if they need it.

It also provides strengthened quality standards and greater protections for those receiving aged care.

For Dr Isabelle Meyer, Executive Director of Dementia Training Australia, one of the key reforms was around medication prescribing, in particular the inappropriate use of medicines as "chemical restraints" in aged care facilities.

"It is now an offence to over-prescribe inappropriate medication for someone, particularly in residential aged care," Dr Meyer told **Pharmacy Daily**.

"The Act sets out what is regarded as appropriate in terms of prescribing medication in the first place, and then managing and monitoring the effect of that



medication," she explained.

"One of the things that the Royal Commission made very clear was that there is evidence of a very significant amount of overuse of antipsychotic medication for people living with dementia - that it was being used to sedate people to the point of non-responsiveness."

For nursing staff and GPs who are involved in prescribing medication inappropriately and not managing that, it is now an offence under the Act.

Dr Meyer explained that medication can be appropriately prescribed for the purposes of managing symptoms in relation to a specific episode, but it was often the case that people were prescribed the medication and were on it permanently, without review.

"It's still the case that if it is appropriate to prescribe medication, that absolutely should be part of how we improve the quality of life for these people," she clarified.

Within the context of the quality framework that applies to aged care, Dr Meyer said there are also far clearer directions on use of pharmacy as part of a palliative care or chronic care management plan, with a lot more emphasis on using lifestyle changes or changes to the living environment that can assist in improving someone's quality of life, rather than relying on pharmacy.

While there have been many positive signs, particularly around the uptake of training for dementia care, the next year will be critical for the Act, Dr Meyer said, particularly around costs and resourcing for its implementation.

"I think there will be some challenges around whether or not we can actually deliver the system that we want," she concluded. **KB**

PSA thanks outgoing WA CHO

THE Pharmaceutical Society of Australia (PSA) has congratulated Western Australia's Chief Health Officer (CHO), Dr Andrew Robertson, on the announcement of his retirement, marking the end of 22 years with WA Health.

The PSA's WA State Manager, Mayli Foong commended Dr Robertson for his contribution to public health and the wellbeing of the community.

"During his tenure, pharmacist practice in WA has grown in leaps and bounds, particularly in the areas of vaccination and a range of pharmacist prescribing initiatives," she said.

The WA Government has commenced recruitment for his successor.

Walter Mikac set to inspire APP2026

PHARMACIST Walter Mikac will present the Alan Russell Oration at the Australasian Pharmacy Professional Conference and Trade Exhibition (APP2026), where his speech, titled 'Resilience for life: turning tragedy into purpose', will offer a renewed perspective on life's challenges.

Mikac lost his wife and two daughters in the Port Arthur massacre, changing the direction of his life.

He has since become a speaker, author, advocate for positive change, and founder of The Alannah & Madeleine Foundation, a national charity dedicated to keeping children and young people safe from violence and trauma.

"We are delighted to welcome Walter Mikac to APP2026," said conference convenor Kos Sclavos.

"His ability to turn unimaginable personal tragedy into a message of hope and purpose will deeply resonate with our delegates."



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Dispensary Corner

IN the latest in TikTok trend news, Gen Z seems to be taking up a new activity called 'rawdoggging' (otherwise known as 'meditation', but let's not ruin it for them).

In an effort to cure them of their short attention spans, participants simply sit wherever they are for a period of time without any distractions - no music, TV, snacks or phone - but of course, they are often being filmed for social media.

Unsurprisingly, some have found it a challenge.

"[You] just overthink your whole life and every choice you ever made," said one TikTok user.

However, according to Dr Sandi Mann, the author of *The Science of Boredom*, there are real health benefits to the trend.

"When we give ourselves time away from our phones or other stimuli, we allow our minds to wander, and this can help to spark new ideas and creativity," Dr Mann told the *Daily Mail*.

"The firing of networks and connections, jumping from ideas to images to thoughts, becomes less conscious - we stop controlling where our brain is going," she added.

Meanwhile, psychologist Dr Daniel Glazer, even described rawdoggging as "a sort of impromptu meditation session".

"This forced introspection could provide an opportunity to grapple with thoughts, emotions and self-awareness that our minds typically avoid or suppress when flooded with distractions," he said.

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New Products

- Elafibranor (Iqirvo)** and its main active metabolite GFT1007 are peroxisome proliferator-activated receptor (PPAR) agonists, both of which activate PPAR- α , PPAR- γ , and PPAR- δ *in vitro*. *In vitro*, both elafibranor and GFT1007 demonstrated 3 to 8 fold higher activity for PPAR- α compared to PPAR- γ and PPAR- δ . Although the *in vitro* pharmacology studies detected PPAR- γ activation by elafibranor and its metabolite GFT1007, toxicology studies in rats and monkeys (species with plasma metabolite profiles comparable to human) showed none of the adverse effects that are associated with PPAR- γ activation. PPAR- α/δ are thought to be key regulators of bile acid (BA) homeostasis, inflammation and fibrosis. Activation of PPAR- α decreases BA synthesis, increases BA detoxification, and modulates BA output, resulting in decreased bile toxicity, and less injury to cholangiocytes and hepatocytes. Activation of PPAR- δ also regulates transporters that absorb and secrete bile components, contributing this way to decreased bile toxicity and improving cholestasis. Activation of PPAR- α and PPAR- δ also has anti-inflammatory effects by acting on different pathways of inflammation, nuclear factor kappa B and B-cell lymphoma 6 pathways, respectively. *Iqirvo is indicated for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.* Iqirvo tablets contain elafibranor 80 mg and are available in packs of 30.
- Elranatamab (cho) (Elrexio)** is a bispecific antibody that binds B-cell maturation antigen (BCMA) expressed on plasma cells, plasmablasts, and multiple myeloma cells and cluster of differentiation 3 (CD3) expressed on T-cells. Simultaneous binding of BCMA and CD3 by elranatamab leads to T-cell activation and proliferation and the release of pro-inflammatory cytokines, resulting in the lysis of BCMA-expressing tumour and normal cells. *Elrexio has provisional approval for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody and have demonstrated disease progression on the last therapy.* Elrexio solution for injection contains elranatamab 44 mg per 1.1 mL or 76 mg per 1.9 mL and is available in packs of 1 vial.
- Lumasiran (sodium) (Oxlumo)** is a double-stranded small interfering ribonucleic acid (siRNA) that reduces levels of glycolate oxidase (GO) enzyme by targeting the hydroxyacid oxidase 1 gene messenger ribonucleic acid (mRNA) in hepatocytes through RNA interference. Decreased GO enzyme levels reduce the amount of available glyoxylate, a substrate for oxalate production. This results in reduction of urinary and plasma oxalate levels, the underlying cause of disease manifestations in patients with primary hyperoxaluria type 1 (PH1). As the GO enzyme is upstream of the deficient alanine: glyoxylate aminotransferase (AGT) enzyme that causes PH1, the mechanism of action of lumasiran is independent of the underlying AGT gene mutation. *Oxlumo is indicated for the treatment of PH1 in all age groups.* Oxlumo solution for injection contains lumasiran 94.5 mg/0.5 mL and is available in packs of 1 vial.
- Tremelimumab (Imjudo)** is a selective, fully human immunoglobulin G2 antibody that blocks cytotoxic T-lymphocyte antigen 4 (CTLA-4) interaction with CD80 and CD86, thus enhancing T-cell activation and proliferation, resulting in increased T-cell diversity and enhanced antitumour immune activity. CTLA-4 is primarily expressed on the surface of T-lymphocytes. Interaction of CTLA-4 with its ligands, CD80 and CD86, limits effector T-cell activation, through a number of potential mechanisms, but primarily by limiting co-stimulatory signalling through CD28. In syngeneic mouse tumour models, blocking CTLA-4 activity resulted in decreased tumour growth and increased proliferation of T-cells in tumours. The combination of durvalumab, a programmed cell death ligand-1 (PD-L1) inhibitor, and tremelimumab functions to enhance anti-tumour T-cell activation and functions at multiple stages of the immune response, maximising anti-tumour immunity. *Imjudo in combination with durvalumab is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma who have not received prior treatment with a PD-1/PD-L1 inhibitor.* Imjudo concentrated injection contains tremelimumab 300 mg per 15 mL and is available in packs of 1 vial.
- Vorasidenib (Vorango)** is a small molecule dual inhibitor that targets the mutant isocitrate dehydrogenase (IDH) 1 and IDH2 enzymes. In patients with astrocytoma or oligodendroglioma, IDH1 and IDH2 mutations lead to overproduction of the oncogenic metabolite 2-hydroxyglutarate (2-HG), resulting in impaired cellular differentiation and increased cellular proliferation contributing to oncogenesis. Direct inhibition of the gain-of-function activity of the IDH1- and IDH2-mutated proteins by vorasidenib inhibits the abnormal production of 2-HG through the differentiation of the malignant cells and reduction of cellular proliferation. *Vorango is indicated for the treatment of Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 mutation or IDH2 mutation in adults and paediatric patients 12 years and older, who are not in need of immediate chemotherapy or radiotherapy following surgical intervention.* Vorango tablets contain vorasidenib 10 mg or 40 mg and are available in packs of 30.

New Presentations

- SARS-CoV-2 spike protein (mRNA) LP.8.1 vaccine (Comirnaty LP.8.1)** is now available. *Comirnaty LP.8.1 is indicated for active immunisation to prevent COVID-19 in individuals 6 months of age and older in accordance with official recommendations.* Comirnaty LP.8.1 suspension for injection contains SARS-CoV-2 spike protein (mRNA) LP.8.1 10 mcg per 0.3 mL (single dose vial with light blue cap or 6-dose vial with dark blue cap) or 30 mcg per 0.3 mL (single dose glass prefilled syringe or 6-dose vial with dark grey cap) and is available in packs of 10. Comirnaty LP.8.1 concentrate for suspension for injection contains SARS-CoV-2 spike protein (mRNA) LP.8.1 3 mcg per 0.3 mL (3-dose vial with yellow cap) and is available in packs of 10.

New Indications

- **Acalabrutinib (maleate monohydrate) (Calquence Tablets)** is now also indicated in combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma who are not eligible for autologous haematopoietic stem cell transplantation.
- **Inactivated quadrivalent influenza vaccine (surface antigen) (Fluad Quad)** is now also indicated for active immunisation against influenza in persons 50 years of age and older.

New Contraindications

- **Duloxetine (hydrochloride) (Duloxetine Sandoz)** is now contraindicated in severe renal impairment (creatinine clearance < 30 mL/min). The initiation of treatment with duloxetine is contraindicated in patients with uncontrolled hypertension that could expose patients to a potential risk of hypertensive crisis.
- **Methenamine hippurate (Hiprex)** is now contraindicated in hypersensitivity or allergy to formaldehyde; severe renal failure (eGFR < 10 mL/min/1.73m²), kidney infection, severe dehydration, or gout; severe hepatic impairment; and metabolic acidosis.

*This list is a summary of only some of the changes that have occurred over the last month.
Before prescribing, always refer to the full product information.*