

Reason codes

SERVICES Australia is seeking pharmacists' feedback as part of a review of the effectiveness of the Pharmaceutical Benefits Scheme reason codes.

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Education is key to boosting wages

RAISING education standards across the pharmacy sector will be crucial to increasing wages, Pharmacy Guild of Australia National President, Trent Twomey, believes.

Speaking at the Guild's inaugural Pharmacy Industry Roadshow event in Sydney last night, Twomey said efforts to increase pay across the sector would require pharmacy workers to boost their training qualifications in line with the Australian Qualification Framework (AQF).

"It's not just as simple as the Guild sitting down with PPA (Professional Pharmacists Australia) and saying, 'let's do a deal and put everyone up a few bucks an hour, or a couple of tens of thousands of dollars a year,'" he said.

"The Fair Work Commission (FWC) makes us benchmark to other graduates and para-professionals with a similar qualification.

"To raise wages we first have to raise education."

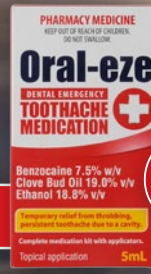
Twomey's comments came days after he urged pharmacy owners to invest in training pharmacy assistants beyond "the mandatory minimum requirement to be QCPP (Quality Care Pharmacy Program) accredited", to Certificate 2, 3 or 4 on the AQF, at Pharmacy Connect (PD 05 Sep).

Twomey told delegates at the roadshow that moves to boost

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pharmacists' training to a Master of Pharmacy Extended - allowing graduates to use the title Doctor of Pharmacy - were on track, with Education Ministers set to vote on the proposed qualification upgrade "exceptionally soon".

The proposed creation of Doctor of Pharmacy was included under clause 12.4 of the Seventh

Community Pharmacy Agreement (PD 23 Jun 2020).

Twomey reassured pharmacists that there will be pathways for them to update their current qualifications to the Doctor of Pharmacy level through pharmacy schools and the Australasian College of Pharmacy, but noted there will be an additional training requirement.

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Reference: 1. Grieve KA, Barnes TM. Increased bioavailability of hydrocortisone dissolved in a cream base. *Australas J Dermatol.* 2015; 56(2):30–4. 2. Spada F et al. *Dermatol Ther.* 2021;34(4):e14970. (n=100) Study sponsored by Ego Pharmaceuticals Pty Ltd.

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Prepared July 2022



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Today's issue of PD

Pharmacy Daily today features three pages of news, plus the September MIMS Update.



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*#1 selling non-prescription menopause relief product in Switzerland. References: 1. Lopatka L et al, *Journal of Menopause* 2007; 2:16-21. 2. IQVIA, national sales data Switzerland, sell-in (Pharmacy, Drugstore, Self-dispensing Doctors), turnover (ex-factory) in CHF, MAT June 2021.

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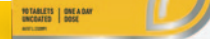
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Seek the support you need: McBride

PHARMACISTS are being urged to be proactive in seeking support for their mental health.

Speaking at Pharmacy Connect on Sat, pharmacist and Assistant Minister for Mental Health and Suicide Prevention, Emma McBride, stressed the need for pharmacists to overcome “self-stigma” to ensure they look after themselves.

McBride encouraged pharmacists to access services provided by indemnity insurer, Pharmaceutical Defence Limited (PDL) and the Pharmacists’ Support Service (PSS).

“As people who want to help other people we often do that at the expense of our own mental health and wellbeing,” she said.

“As healthcare workers it’s something that there is still a lot of stigma and self-stigma.

“We’re people who are trained to help other people and so we can feel quite overwhelmed when we need to seek that help ourselves, but I would encourage you to seek that help that is available

to you, and to make sure your mental health and wellbeing is well supported.

“It’s something that we as healthcare workers do overlook while we’re caring for others.”

Pharmacists were also advised to reach out for support at last night’s Pharmacy Guild of Australia Pharmacy Industry Roadshow in Sydney last night.

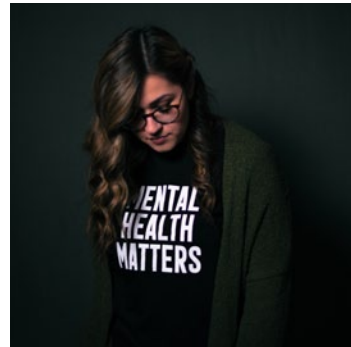
Responding to a question about what support is available to pharmacists who are burnt-out by the stresses and strains of the COVID-19 pandemic, PDL Chair, Paul Naismith, encouraged pharmacists to seek support.

“You are not alone in the pressure you feel,” he said.

“That’s why we have services like PSS, if you feel you can’t cope... we all have challenging times.

“All I can do is encourage you to ring that number and you’ll speak to someone just like you.

“You’ll speak to another pharmacist who has also had times



where they’ve worried about their role, how they’re going to cope.

“If you can’t do that, I encourage you to speak to your colleagues, your friends.”

PSS Board member, Curtis Ruhnau, told attendees that the services can be contacted every day of the year between 8am and 11pm AEST/AEDT on 1300 244 910.

“The only person you’ll talk to is a volunteer pharmacist who has given up two days of their time to learn how to be there as a crisis councillor for us,” he said.

Grant for Aussie COVID treatment

THE Medical Research Future Fund has issued a \$1 million grant to Melbourne biotech firm, Esfam, to support research into its COVID-19 treatment, delcetravir.

Esfam CEO, Professor Albert Frauman, said the medication had the potential to treat active infections, as well as preventing infection in people exposed to COVID-19, based on the results of an initial animal model.

Frauman added that the company was developing a dry powder inhalation formulation, similar to an asthma inhaler.

“There are obvious advantages in using a hand-held puffer for acute and preventative treatment, in particular delivering the drug directly into the main target of COVID infection - the lungs,” he said.

TGA flags Trikafta packaging error

PHARMACISTS should inspect all packs of cystic fibrosis treatment, Trikafta (elexacaftor/tezacaftor/ivacaftor) with the batch number #1846070, prior to supplying them to confirm the correct orientation of all tablets.

The Therapeutic Goods Administration (TGA) has issued a warning that morning and evening doses of the medication

may have been incorrectly packed.

Pharmacists have been told to open the carton via the instructions on the front panel and open each medicine wallet to inspect the orientation.

“Any product affected by this problem should be quarantined until returned,” the TGA said.

CLICK HERE for more.

Wegovy gets green light from TGA

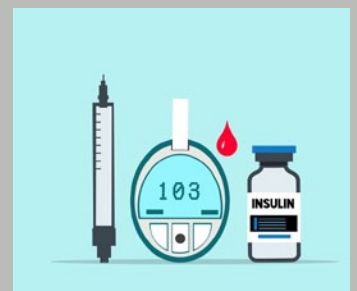
NOVO Nordisk’s Wegovy (semaglutide) solution of injection has been approved for inclusion on the Australian Register of Therapeutic Goods (ARTG) for chronic weight management, by the Therapeutic Goods Administration (TGA).

The medication contains the same active ingredient as type 2 diabetes treatment, Ozempic (semaglutide), which is currently in short supply, but had different approved indications.

“Ozempic and Wegovy are not interchangeable,” the TGA said.

“Due to the ongoing limited availability of Ozempic, prescribers should consider alternatives before initiating Ozempic as achieving the desired health outcomes may be tied to patients’ ability to secure supply in a timely manner.

“[And] health professionals should continue to prioritise supply of Ozempic for people with type 2 diabetes, where



other diabetes medications are not suitable, to enable continuity of care.”

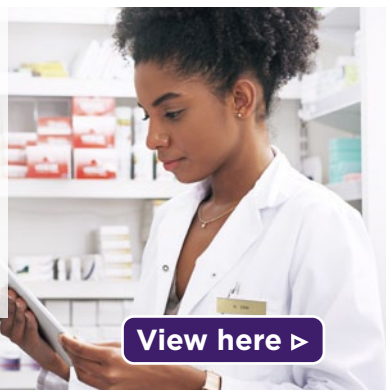
Despite the approval decision, the TGA noted that Novo Nordisk is not currently supplying Wegovy in Australia.

Current shortages of Ozempic are expected to continue until the end of Dec, as a result of extensive off-label prescribing for obesity management.

To alleviate shortages, the TGA has approved a number of overseas registered products under Section 19A of the *Therapeutic Goods Act 1989*.

bDMARDs quick reference guide PBS listed information:

Rheumatology
dermatology
gastroenterology



[View here >](#)



Dispensary Corner

THOSE early toilet paper-hoarding days of the COVID-19 pandemic led to a massive boom in sales of high-tech Japanese toilets in the US.

The unexpected side-effect sees many more American backsides treated to heated seats and artfully directed jets of warm water, with manufacturer Toto Limited confirming that sales of its Washlet more than doubled, and continue to grow despite the toilet paper panic subsiding.

The electronic toilets were initially created for hospital patients suffering severe haemorrhoids, but now feature in more than 80% of Japanese households.

Toto has long been cultivating the US market, with spokesperson Nariko Yamashita saying explosive sales growth over the last two years was "a situation where the seeds sown for decades are finally flowering," according to *Fortune*.

THE US Drug Enforcement Administration has highlighted a worrying trend which has seen the creation of brightly coloured fentanyl pills in an attempt to target young Americans with the synthetic opioid.

The organisation said it was increasingly seizing "highly addictive and potentially deadly fentanyl made to look like candy", in forms including pills, powder and chalk-like blocks.

"Every colour, shape and size of fentanyl should be considered extremely dangerous," the agency warned.

PPA seeks full scope say

EMPLOYEE pharmacists' union, Professional Pharmacists Australia (PPA), wants authorities to engage with it before giving the green light for the expansion of the profession's scope of practice.

Responding to reports that the Pharmacy Guild of Australia has consulted with State and Territory governments across the country to introduce programs similar to the Urinary Tract Infection Pharmacy Pilot - Queensland (UTIPP-Q) (*PD* 05 Sep) PPA CEO, Jill McCabe flagged concerns.

"While we are broadly supportive of programs that increase pharmacists' scope of practice and ability, any proposed expansion of services must involve consultation with PPA, take account of the views of working pharmacists and importantly provide increased remuneration for the additional work that pharmacists will be expected to undertake," she said.

"PPA is concerned that it has not been consulted about what this will actually entail for working pharmacists.



"We have not been engaged in any discussions about the North Queensland expanded scope of practice trial, nationwide UTI treatment programs, or the Pharmacists in Aged Care Homes program design, which means the voices of working pharmacists are not being heard in the design of new initiatives.

"For too long, employee pharmacists have had their workloads increased and work practices have changed without adequate consultation or compensation."

Cyclotek Queensland cops \$93k fine

THE Therapeutic Goods Administration (TGA) has issued multiple infringement notices totalling \$93,240 to Cyclotek Queensland, for alleged breaches of its manufacturing licence.

Unacceptable manufacturing practices that presented a risk of unsafe products were identified by a recent Good Manufacturing Practice (GMP) inspection.

"The infringement notices were issued due to the seriousness of the breaches and for not taking appropriate steps to investigate and address manufacturing

failures," the TGA said.

"These infringement notices are in response to past breaches, and it can continue manufacturing.

"The affected batches [of radiopharmaceuticals used in Positron Emission Tomography scans] are no longer in supply and there have been no reports of adverse events associated with their use.

"The TGA is working with Cyclotek Queensland to develop and implement effective preventative measures to address the GMP failures."

Guild Update

Women's Health Week

SEPTEMBER is an important month for the healthcare sector during which we celebrate Women's Health Week, a nationwide campaign of events and online activities aimed at improving women's health and helping women to make healthier choices.

This year Women's Health Week is being held from 05-11 September 2022 and is a reminder for women to set aside time for their health and wellbeing.

An area that many women may be unaware of is the provision of women's health services through community pharmacies which are increasing in importance, as more and more women turn to their pharmacists and pharmacy staff for help and advice.

Being able to walk into a pharmacy, many of which are open after normal hours and at weekends, can make the world of difference for a woman seeking to meet her health needs.

The help is there where she needs it, and when she needs it. For more details visit the [website](#).



New Products

- **Asciminib (hydrochloride) (Scemblix)** is an oral and potent inhibitor of ABL/BCR::ABL1 tyrosine kinases. Asciminib inhibits the ABL1 kinase activity of the BCR::ABL1 fusion protein, by specifically targeting the ABL myristoyl pocket. *Scemblix is indicated for the treatment of patients 18 years of age and above with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase (CP) previously treated with two or more tyrosine kinase inhibitors; and in Ph+ CML in CP with the T315I mutation.* Scemblix tablets contain asciminib 20 mg or 40 mg and are available in packs of 20 or 60.
- **Estradiol (hemihydrate) and progesterone (Bijuva 1/100)** is a combined hormone replacement therapy (HRT). *Bijuva 1/100 is indicated for use during continuous combined HRT for estrogen deficiency symptoms in postmenopausal women with an intact uterus and with at least 12 months since last menses.* Bijuva 1/100 is contraindicated in patients with known, past or suspected breast cancer; known or suspected estrogen-dependent malignant tumours (e.g. endometrial cancer); undiagnosed genital bleeding; untreated endometrial hyperplasia; previous or current venous thromboembolism (deep vein thrombosis, pulmonary embolism); known thrombophilic disorders (e.g. protein C, protein S, or antithrombin deficiency); active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction); acute liver disease or a history of liver disease as long as liver function tests have failed to return to normal; and porphyria. Bijuva 1/100 capsules contain estradiol 1 mg and progesterone 100 mg and are available in a pack size of 28.
- **Selinexor (Xpovio)** is a reversible covalent selective inhibitor of nuclear export (SINE) compound that specifically blocks exportin 1 (XPO1). XPO1 is a major nuclear export protein that transports cargo proteins and several classes of mRNA from the nucleus to the cytoplasm. XPO1 cargoes include many tumour suppressor proteins (TSPs), growth regulator proteins (GRPs) and mRNAs of growth promoting (oncogenic) proteins. XPO1 inhibition by selinexor leads to marked accumulation of TSPs and GRPs (such as p53, p21, FOXO and IκB) in the nucleus (their site of action), and reduced expression of several oncoproteins (such as c-Myc, Bcl2 and cyclin D1) and translation/chaperon proteins (Hsp70), resulting in cell cycle arrest and apoptosis of cancer cells. *Xpovio is indicated, in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy; and, in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies and whose disease is refractory to at least one proteasome inhibitor, at least one immunomodulatory medicinal product, and an anti-CD38 monoclonal antibody.* Xpovio tablets contain selinexor 20 mg and are available in packs of 16, 20 or 32.
- **Somapacitan (Sogroya)** is a long-acting recombinant human growth hormone (GH) derivative. The mechanism of action of somapacitan is either directly via the GH-receptor and/or indirectly via insulin-like growth factor-1 (IGF-1) produced in tissues throughout the body, but predominantly by the liver. When GH deficiency is treated with somapacitan, a normalisation of body composition (i.e. decreased body fat mass, increased lean body mass) and of metabolic action is achieved. *Sogroya is indicated for the replacement of endogenous GH in adults with GH deficiency.* Sogroya is contraindicated in patients with any evidence of activity of a tumour and anti-tumour therapy must be completed prior to starting Sogroya therapy; and in patients with acute critical illness suffering from complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions. Sogroya solution for injection contains somapacitan 10 mg/1.5 mL and is available in a pack of 1 pre-filled pen.

New Presentation

- **Elasomeran (Spikevax)** is now also available as a suspension for injection containing elasomeran 100 mcg/mL in packs containing ten 2.5 mL multidose vials or ten 0.5 mL pre-filled syringes.

New Indications

- **Atezolizumab (Tecentriq)**, as monotherapy, is now indicated as adjuvant treatment following complete resection and no progression after platinum-based adjuvant chemotherapy for adult patients with stage II to IIIA (as per 7th edition of the UICC/AJCC staging system) NSCLC whose tumours have PD-L1 expression on ≥ 50% of tumour cells.
- **Dupilumab (rch) (Dupixent)** is now indicated as add on maintenance treatment in patients aged 6 years and older with moderate to severe asthma with type 2 inflammation (elevated eosinophils or elevated fractional exhaled nitric oxide) that is inadequately controlled despite therapy with other medicinal products for maintenance treatment.
- **Elasomeran (Spikevax)** now has provisional approval for the active immunization of individuals 6 months of age and older to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.
- **Leuprorelin acetate (Eligard)** is now indicated for the treatment of children 2 years of age and older with central precocious puberty. This indication is for the 45 mg 6-month presentation only.
- **Nivolumab (Opdivo)**, as monotherapy, is now indicated for the adjuvant treatment of patients with muscle invasive urothelial carcinoma (MIUC) who are at high risk of recurrence after undergoing radical resection of MIUC.
- **SARS-CoV-2 rS (NVX-CoV2373) (Nuvaxovid)** now has provisional approval for the active immunization of individuals 12 years of age and older to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

- **Trastuzumab deruxtecan (Enhertu)** is now indicated, as monotherapy, for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who previously received trastuzumab and a taxane for metastatic disease, or one prior anti-HER2-based regimen and developed disease recurrence during or within six months of completing neo-adjuvant or adjuvant therapy.

New Contraindications

- **Dobutamine hydrochloride (DBL Dobutamine Hydrochloride Injection)** is now contraindicated in patients with mechanical obstruction affecting left ventricular filling or outflow, especially in the case of obstructive cardiomyopathy or constrictive pericarditis.
- **Gemeprost (Cervagem)** is now contraindicated in patients at risk of hemorrhage due to procedures for placenta previa, ectopic pregnancy, etc; and in patients with fever due to pelvic infection.
- **Midostaurin (Rydapt)** is now contraindicated with concomitant administration of potent CYP3A4 inducers (e.g. rifampicin, St. John's Wort (*Hypericum perforatum*), carbamazepine, enzalutamide, phenytoin).

Safety Related Changes

- **Neratinib (Nerlynx)** is no longer contraindicated with concomitant moderate CYP3A4/P-gp inhibitors (e.g. fluconazole, diltiazem, verapamil, erythromycin).

*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.*