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Owner guilty of breach of obligations

PHARMACY owners in NSW are being reminded of the importance of complying with their obligations after one owner landed an \$8,500 fine for operating a pharmacy in an unapproved premises.

In a statement the Pharmacy Council of NSW reported it had prosecuted the owner of two pharmacies in the state after discovering the individual had been using a premises that had not been approved by the Council and "operating a pharmacy business in the absence of a pharmacist".

The owner pled guilty to both counts and was sentenced at the Downing Centre Local Court.

During the sentencing hearing, Magistrate Carolyn Huntsman, noted pharmacists are in positions of trust and provide services to vulnerable people, adding that financial interest holders should be aware of their obligations under the *Health Practitioner Regulation National Law (NSW)*.

Huntsman said that each time an offence of this nature occurs, patients' health and safety is put at risk, and made orders for convictions to be recorded on the owner's criminal record for both charges and issued a \$8,500 fine.

"Pharmacists are the gatekeepers of pharmacy services and play a very specific and important role in the proper and appropriate supply of restricted substances from pharmacies," the Council's statement said.

"Pharmacists should be aware



that under the *National Law*, unsatisfactory professional conduct includes failures to observe obligations relating to the operation of pharmacy businesses."

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Today's issue of PD

Pharmacy Daily today features three pages of news, plus a full page from Seipel Group.

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New therapeutic iron supplements for the prevention and treatment of medically diagnosed iron deficiency, iron deficiency anaemia and folic acid deficiency anaemia

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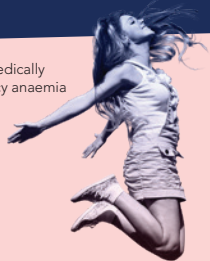
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Review full PI before recommending or supplying Resolve Plus 1.0. PI available on request from Ego Pharmaceuticals.

References: 1. Resolve Plus Product Information. Date of Most Recent Amendment 26 October 2018. 2. Van Cutsem JM, Thienpont D. Miconazole, a broad-spectrum antimycotic agent with antibacterial activity. *Chemotherapy* 1972;17:392-404.

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AZ to seek TGA evaluation for COVAX

ASTRAZENECA (AZ) is set to submit data from two phase II/III clinical trials of its COVID-19 candidate vaccine (COVAX) to the Therapeutic Goods Administration (TGA) for review and evaluation.

The vaccine developed by AZ and Oxford University was the first of three COVAX candidates to be granted a provisional determination by the TGA last month (PD 12 Oct), paving the way for it to be registered on the Australian Register of Therapeutic Goods (ARTG).

The data from the trials found the vaccine efficacy was 90% for patients who received an initial half-dose followed by a full dose of the a month later, while the efficacy for those who received two full doses was 62%.

AZ Australia and New Zealand Country President, Liz Chatwin, said the vaccine would need to pass the TGA's rigorous assessment and approval process before being made available in Australia.

"Through our global partnership with Oxford University, AstraZeneca has committed to providing broad and equitable access to the vaccine, at no profit during the pandemic, to address an urgent global public



health need and support economic recovery," she said.

"We have committed to supplying 33.8 million doses for the Australian Government; 30 million doses will be produced onshore by CSL and manufacturing is already underway here in Australia."

The company added that while the development program was "faster than typical, patient safety is of paramount importance".

"Timelines have been accelerated by investing in building manufacturing capacity of the vaccine in advance," AZ said.

"AstraZeneca has the largest manufacturing network around the

world, and with its manufacturing partners, has capacity for more than three billion doses of the vaccine for broad and equitable global distribution."

Under the Federal Government's Australian COVID-19 Vaccination Policy, the vaccines are likely to be administered only by doctors for an initial period of three to six months in case of adverse events, before pharmacists and other qualified immunisers are authorised to vaccinate patients (PD 23 Nov).

MIMS/Guild Intern of the Year

NOMINATIONS are now open for the 2020 MIMS/Pharmacy Guild of Australia Intern of the Year.

Nominees must be enrolled in and have successfully completed the Guild Intern Training Program during the calendar year.

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Dispensary Corner

PHARMACISTS have faced numerous challenges throughout 2020, but few if any have been as offensive and stomach churning as being bombarded with photos of scruffy-looking journalists sporting the facial hair of crime suspects of bygone days.

Thankfully, *Pharmacy Daily* can report that Editor, Nick O'Donoghue, and his *Australian Journal of Pharmacy* counterpart, Chris Brooker, are set to foam-up and shave-off their mo-growing efforts next week, as their month-long #MoFoe fundraising campaign for the Pharmacists' Support Service (PSS) comes to an end.

Throughout Nov O'Donoghue has been cultivating what has been described as an "a la Souvarov" moustache, a style that has been out of fashion for some decades - if not centuries at this stage.

The cycling enthusiast has described himself as looking like "a poor man's Hulk Hogan impersonator who forgot to take his vitamins, with the skin tone of a hot dog" (comparison picture below).

You can support the PSS by making a donation [HERE](#) and adding #MoFoePD or #MoFoeAJP in the message box.



Scheduling decisions confirmed

DECISIONS to down-schedule certain preparations of migraine treatment, eletriptan, and anti-inflammatory, ibuprofen, from 01 Feb 2021 have been confirmed by the Therapeutic Goods Administration (TGA) (PD 10 Sep).

However, a third bid to make erectile dysfunction treatment, sildenafil, Pharmacist-Only, has again come up short.

In the TGA's Notice of final decisions to amend (or not amend) the current Poisons Standard, released this morning, the Delegate of the Secretary of the Department of Health announced a new Schedule 3 Appendix H entry for eletriptan tablets containing 40mg or less per tablet, when in a pack containing not more than two dosage units.

"[Eletriptan] satisfies the Schedule 3 scheduling factors on the basis that the risk profile of eletriptan is well defined and the risk factors for adverse effects, interactions

and contraindications are known, identifiable and manageable by a pharmacist," the Delegate said in its interim decision.

"I have decided to include a pack size limit in the new S3 entry to mitigate the risks of medication overuse headache, unintentional and intentional overdose."

The Delegate also confirmed the decision to amend the S2 entry for ibuprofen in divided immediate release preparations containing 400mg or less of ibuprofen in a primary pack with a maximum of 12 dosage units, when labelled "not for the treatment of children under 12 years of age".

Announcing its decision not to amend the current Poisons Standard for sildenafil to S3, the Delegate noted the Pharmaceutical Society of Australia (PSA) had issued a submission supporting calls to down-schedule the medication.

However, the Delegate said, "no



new information has been provided to mitigate my concerns that the down-scheduling of sildenafil may lead to risk for consumers accessing sildenafil without medical intervention and lack of follow-up".

The delegate also decided against amending the scheduling of oxymetazoline and clotrimazole.

It also confirmed that decisions relating to amendments to the current Poisons Standard for nicotine and cannabidiol will be made in mid and late Dec respectively.

Di Natale joins MCIA Advisory Council

FORMER Australian Greens Leader, Dr Richard Di Natale, has been named as the inaugural Chair of the Medicinal Cannabis Industry Australia's (MCIA) new Healthcare Practitioner/Patient Advisory Council.

MCIA Chair, Peter Crock, said the group led by Di Natale would play a key role in providing independent advice to and engaging with the Australian medicinal cannabis industry, medical experts and patient advocates to raise awareness of the applications of the drug.

"This Group will be an important forum to ensure that patient access and the

healthcare sector remain at the forefront of the medicinal cannabis industry and to facilitate access to this important new medicine that has potential to positively contribute to health outcomes for the community," Crock said.

Di Natale will be joined on the Advisory Council by, Olivia Newton-John Cancer Wellness and Research Centre, Cancer Immunobiology Program Group Head, Professor Jonathan Cebon, Australian College of Nursing CEO, Adjunct Professor Kylie Ward, Epilepsy Action Australia CEO, Carol Ireland, and other leading experts.

Hygiene Labs gets TGA tick

SYDNEY-BASED biotechnology company, Hygiene Labs, has secured verification from the Therapeutic Goods Administration (TGA) that its new disinfectant treatment can inactivate the COVID-19 virus on surfaces for up to 28 days per application.

The TGA has reviewed Hygiene Labs' claim under the Hospital Grade and Commercial Grade categories, and listed the product on the Australian Register of Therapeutic Goods.

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*Schoendorfer et al, BMC-CAM, January, 2018. Research funded by the Australian Federal government and Seipel Group. For relief of urinary incontinence and urgency associated with medically diagnosed overactive bladder.



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