Pharmacy Daily

Thu 20th Jan 2022

Today's issue of *PD*

Pharmacy Daily today features three pages of news plus the **MIMS January Update**.

Breaking point

GROWING demand for COVID-19 rapid antigen tests (RATs) is creating an unsustainable working environment for pharmacists, Pharmaceutical Society of Australia National President, Associate Professor Chris Freeman, warns.

Addressing the ongoing shortage of RATs, Freeman said PSA members have reported receiving an average of "four calls a minute in relation to RATs".

"This is simply not sustainable," he said.

"RATs are also available and being distributed through government testing clinics, free of charge – and I implore Australians to consider these services in order to alleviate pressure on our already-stretched pharmacist workforce."

Pharmacies claim $11m for COVAX

COMMUNITY pharmacies participating in the COVID-19 vaccination program claimed $11 million in Federal funding last week alone, making it the sector's single biggest professional service, Pharmacy Guild of Australia National President, Trent Twomey, has revealed.

Speaking during a Guild update webinar last night, Twomey told pharmacy owners that claims for the administration of COVAX program had become the sector's second biggest clinical function, after dispensing of medicines.

"In the week commencing 10 Jan, just a tick over 2,700 community pharmacies claimed for [more than] 430,000 vaccines in just one week," he said.

"That is over $11 million worth of professional service programs that went through the community pharmacy network.

"To get that into perspective, the $1.263 billion in the Seventh Community Pharmacy Agreement, through all of the different programs, excluding the Regional Pharmacy Maintenance Allowance, but for Dose Administration Aids, Staged Supply, Diabetes MedsChecks, MedsChecks, Home Medicines Reviews, Residential Medication Management Reviews, and Quality Use of Medicines, in their totality all of them together total about $3 million a year.

"So we're doing over three-and-a-half times that each and every week just in COVAX.

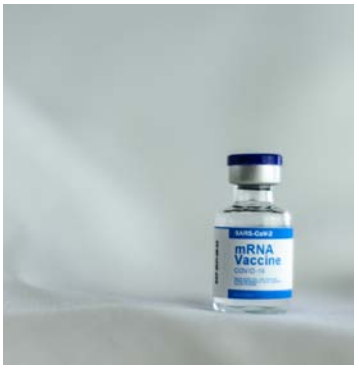
"Apart from the core clinical function of dispensing - which of course dispensing a prescription is the number one clinical occasion of service in community pharmacy - it is number two, bigger than any other professional service that we do."

Twomey noted that since the sector joined the rollout in Jun 2021, community pharmacies have administered more than 4.1 million doses of COVAX, including doses of the AstraZeneca, Pfizer-BioNTech and Moderna vaccines.

He urged the "3,000-odd pharmacies" that have not signed up to administer the vaccines to join the program.

"If you think you're a professional service pharmacy, you can't possibly be one unless you are participating in the vaccination program," he said.

MEANWHILE, Twomey confirmed that the COVAX Taskforce approved moves to increase site allocations of



the Moderna vaccine to pharmacies yesterday, however, existing limits on orders for the Pfizer-BioNTech will remain in place.

"If your site allocation was less than 600 [doses], you've been increased to 600," he said.

"If your site allocation was 600, that has been increased to 750, and if your site allocation was between 700 and 750, that's been increased to 900."

Twomey added that the Guild has continued to advocate for the vaccines to be distributed through the Community Service Obligation network, describing it as the "gold standard" and called on the Taskforce to wind back the "bespoke systems" currently being used to distribute the vaccines.

Candy author joins APP2022 line up

OSCAR nominated screenwriter and author, Luke Davies, will be speaking about harm minimisation at the Australian Pharmacy Professional Conference 2022 (APP2022).

Davies, whose book, *Candy*, was an autobiographical account of his experience of being addicted to heroin in his 20s, will give a first hand perspective of how pharmacists are helping patients in the opioid replacement therapy program.

Addictions Medicines Specialist, Dr David Jacka, will also discuss harm minimisation, as part of a stream during the conference exploring the use of licit and illicit drugs, and how pharmacists can help curb addictions to these substances.

CLICK HERE to register for APP2022.

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SHPA backs new workforce measures

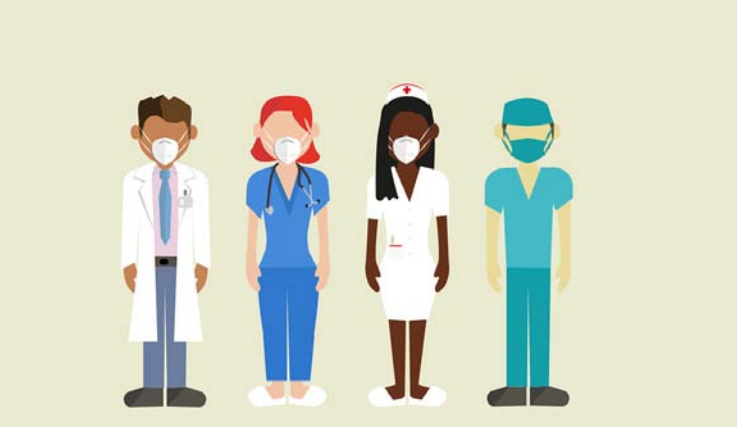
CHANGES to the definition of COVID-19 close contacts and the implementation of the Private Hospitals Agreement will help alleviate pressure on public hospital pharmacists, the Society of Hospital Pharmacists of Australia (SHPA) believes.

SHPA CEO, Kristin Michaels, told ***Pharmacy Daily*** that public hospital pharmacy teams have been stretched in recent weeks, with pharmacists having to isolate or take on additional roles in response to the increasing numbers of COVID-19 infections.

"Earlier this month, before the definition of close contacts was redefined, there were tens of thousands of hospital workers – including hospital pharmacists – who were unable to work due to infection with COVID-19 or isolation as a close contact," she said.

"This forced the redeployment of hospital pharmacists to cover critical clinical roles at very short notice – usually the same morning unplanned leave is advised – to ensure pharmacy services are maintained in designated COVID-19 wards, intensive care units, emergency departments and cancer wards.

"The redefinition of close contacts is a positive step but hospital pharmacy departments continue to operate with reduced staff



as hospitalisations continue to increase in many major centres.

"Most importantly, this period of intense pressure comes as hospital pharmacists, particularly in NSW and Victoria, are reporting unprecedented levels of burnout and stress as they do their best to maintain quality and safe medicines use and optimal pharmacy services for their patients, in a COVID-safe manner.

"Evidence of the severity is the Code Brown announced this week for Victorian hospitals, and protective barriers such as these must be put in place wherever needed to preserve and protect our hospital workforce."

Following the activation of the Private Hospitals Agreement by the Federal Government, State and Territory Governments will be able to access private hospital resources to alleviate workforce shortages.

Michaels noted that it was currently "unclear" how many hospital pharmacists would be included in the 100,000-plus health workers redeployed from private to public hospitals under the Agreement, but said the organisation would support members "helping out their public hospital colleagues where possible".

"Throughout the pandemic, public hospital pharmacy departments have welcomed relief staff from various pharmacy sectors, and our members will continue to welcome any additional staff to ensure the best possible care is provided during the current Omicron wave," she said.

Let students vax

PHARMACY students who have undergone appropriate immunisation training should be authorised to assist in the COVID-19 vaccination rollout, a Queensland-based academic believes.

James Cook University Academic Head of Pharmacy, Associate Professor John Smithson, said the institution had adapted its pharmacy program to introduce immunisation training earlier in the curriculum to allow students to administer shots under supervison.

Smithson said the change in the training program would ensure the university "will be ready to contribute a group of students trained to the same standard as qualified pharmacist immunisers", to support the vaccination push.

Pharmacy Guild of Australia National President, Trent Twomey, who was awarded the title of Professor in the Division of Tropical Health and Medicine at the University last year (***PD*** 09 Dec 2021) backed the move, noting that "bringing students on board the general vaccination program will benefit those wanting to get their vaccinations or booster shots".

Novavax earns long-awaited approval

MEDICINES regulators in Australia and the European Union have given the green-light for Novavax's protein subunit COVID-19 vaccine, Nuvaxoid.

The vaccine received provisional approval from the Therapeutic Goods Administration (TGA) this morning (***PD*** breaking news), while it has been given "conditional marketing authorisation" by the European Medicines Agency.

Under the TGA's approval patients aged 18 years and older will be able to receive the vaccine as part of a two-dose primary vaccination schedule, with the regulator recommending that the shots be administered three weeks apart.

However, the approval does not extend to the vaccine's use in children under the age of 18 years, or for its use as a booster.

Announcing its decision this morning, the TGA noted that the Federal Government has an advance purchase agreement for 51 million doses of the vaccine, with the first shipment due to arrive next month.

The Commonwealth Department of Health has yet to confirm how Novavax will be rolled out to the community.

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PBS listing planned for COVID drugs

FEDERAL Health Minister, Greg Hunt, is planning to distribute newly approved oral COVID-19 treatments, Lagevrio (molnupiravir) and Paxlovid (nirmatrelvir and ritonavir) through the National Medicines Stockpile (NMS) before transitioning to the Pharmaceutical Benefits Scheme (PBS).

In a statement issued in the wake of the Therapeutic Goods Administration's (TGA's) announcement that the medications had been granted provisional approval this morning (***PD*** breaking news), Hunt said the drugs would be used to treat patients with "mild to moderate COVID-19 who have a high risk of progressing to severe disease, reducing admissions to hospital and ICU and potential death".

Hunt noted that the Federal Government has ordered 300,000 treatment courses of Lagevrio from MSD, and 500,000 courses of Pfizer's Paxlovid.

"These oral antiviral treatments need a prescription and are taken every 12 hours for five days," he said.

"As with other TGA approved COVID-19 treatments not everyone who contracts COVID-19 will require access to Lagevrio and Paxlovid and these treatments will be of most benefit for people most at risk of severe disease and through the oversight from a healthcare professional.

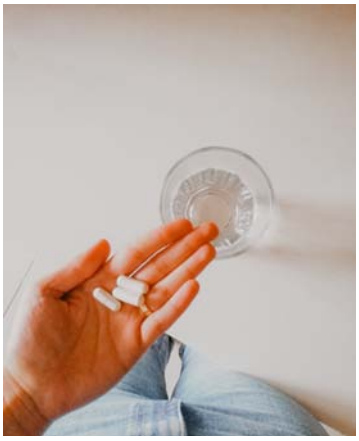
"We are working to target access to those most vulnerable including the elderly and those in aged care through the NMS with the view to transition to the PBS arrangements as supply continues to grow.

"By law medicines can only be listed on the PBS following a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC).

"Whilst vaccination remains the best protection against COVID-19 our Government continues work to ensure that Australians have early access to safe and effective treatments as they are approved for use by the medical experts.

"These agreements reinforce our strong response to managing COVID-19 outbreaks and ensures that Australia benefits from new pharmaceutical technologies.

"As with all COVID-19 treatments, both of these medications have been rigorously assessed by the TGA for safety, quality and effectiveness before being provisionally registered for use in Australia."



Welcoming the approval of the two medicines, Flinders University's College of Medicine and Public Health Microbiology and Infectious Diseases Laboratory Head, Associate Professor Jill Carr, said that while the take-home treatments were a "fantastic" development, they were "not a replacement for vaccination".

"The availability of these new drugs bodes well for offering clinicians treatment choices, for those most at risk," she said.

"Of note, these drugs work very well in the initial viral phase of illness... but will be of no benefit for patients already critically ill in hospital or on a ventilator."

Dispensary Corner

FRENCH authorities are investigating a Paris-based pharmacist who allegedly attempted to scam a State subsidised COVID-19 rapid antigen test (RAT) program.

The 46-year-old has been indicted and remanded in custody since late last year, after allegations that he issued fake invoices seeking reimbursement for more than 3.1 million RATs, worth more than $28 million, between 14 Sep and 09 Dec 2021.

Investigators reportedly found $1.25 million in cash at one of his pharmacies.

The investigation is ongoing with *The Connexion* reporting that police believe that other pharmacists may be implicated in the large-scale fraud.

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MIMS Monthly Update

January 2022

New Products

- **Eptinezumab (Vyepti)** is a humanised monoclonal immunoglobulin G1 (IgG1) antibody that binds to α- and β- forms of human calcitonin gene-related peptide (CGRP) ligand with low picomolar affinity preventing its activation of the CGRP receptors. Elevated blood concentrations of CGRP have been associated with migraine. Vyepti is indicated for the preventive treatment of migraine in adults. Vyepti concentrated injection contains eptinezumab 100 mg/mL and is available in a pack size of 1.

- **Fostemsavir (as trometamol) (Rukobia)** is a prodrug without significant biochemical or antiviral activity that is hydrolyzed to the active moiety, temsavir, upon cleavage of a phosphonooxymethyl group *in vivo*. Temsavir binds directly to the gp120 subunit within the HIV-1 envelope glycoprotein gp160 and selectively inhibits the interaction between the virus and cellular CD4 receptors, thereby preventing viral entry into, and infection of, host cells. Rukobia is indicated in combination with other antiretroviral agents for the treatment of heavily treatment-experienced adults with multidrug-resistant human immunodeficiency virus-1 (HIV-1) infection for whom it is otherwise not possible to construct a suppressive antiviral regimen due to resistance, intolerance or safety considerations. It is contraindicated in combination with strong CYP3A inducers including, but not limited to carbamazepine, phenytoin (anticonvulsants), mitotane (antineoplastic), enzalutamide (androgen receptor inhibitor), rifampicin (antimycobacterial) and St. John's wort (*Hypericum perforatum*, herbal supplement). Rukobia tablets contain fostemsavir 600 mg and are available in a pack size of 60.

- **Niraparib (as tosilate monohydrate) (Zejula)** is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, which play a role in DNA repair. Niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis and cell death. Zejula is indicated for the maintenance treatment of adult patients with advanced high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy; and as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. Zejula capsules contain 100 mg niraparib and are available in pack sizes of 56 or 84.

New Presentation

- **Tozinameran (Comirnaty (Tris/Sucrose Presentation))** contains nucleoside-modified messenger RNA formulated in lipid nanoparticles, which enable delivery of the non-replicating RNA into host cells to direct transient expression of the SARS-CoV-2 spike (S) antigen. Comirnaty elicits both neutralising antibody and cellular immune responses to the antigen, which may contribute to protection against COVID-19. Comirnaty (Tris/Sucrose Presentation) has provisional approval for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV2, in individuals 5 years to < 12 years of age (dilute-to-use) and in individuals 12 years of age and older (ready-to-use). Comirnaty (Tris/Sucrose Presentation) suspension for injection contains tozinameran 10 mcg/0.2 mL after dilution (dilute-to-use vial) or 30 mcg/0.3 mL (ready-to-use vial) and is available in pack sizes of 10 or 195 multidose vials (6 doses per ready-to-use vial; 10 doses per dilute-to-use vial).

New Indications

- **Nivolumab (Opdivo)** is now indicated, as monotherapy, for the adjuvant treatment of resected oesophageal or gastro-oesophageal junction cancer in patients who have received neoadjuvant chemoradiotherapy.

- **Romiplostim (Nplate)** is now indicated for treatment of thrombocytopenia in adult patients with primary immune thrombocytopenia (ITP) and paediatric patients aged 1 year and older with primary immune thrombocytopenia ITP for at least 6 months who are non-splenectomised and have had an inadequate response, or are intolerant, to corticosteroids and immunoglobulins; or are splenectomised and have had an inadequate response to splenectomy.

- **Sugammadex (as sodium salt) (Bridion)** is now indicated for reversal of neuromuscular blockade induced by rocuronium or vecuronium in patients 2 years of age and older.

- **Tipranavir (Aptivus)**, in combination with low dose ritonavir, is now indicated for combination treatment of HIV infection in antiretroviral treatment experienced adults and adolescents aged 12 years and older who have a BSA of ≥ 1.3 m^2 or weight ≥ 36 kg, with evidence of viral replication, who have HIV-1 strains resistant to more than one protease inhibitor.

- **Tocilizumab (Actemra)** now has provisional approval for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

New Contraindications

- **Voriconazole (Vfend)** is now contraindicated in combination with venetoclax (during the venetoclax initiation or dose titration phases), naloxegol, tolvaptan, and lurasidone.

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.