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Connecting health solutions

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Over the last 107 years, Sigma has evolved into Australia's largest retail pharmacy offering. We're a powerhouse of six standalone retail pharmacy brands with a solution for any pharmacy owner, including those who wish to remain independent. By joining the Sigma family you'll have immediate access to an integrated suite of proven tools and solutions to help you build a better business, as well as a world-class wholesale service from our upgraded national DC network. We've continued to reshape and invest in our business to support forward-looking pharmacists, who are ready to embrace a modern pharmacy retail landscape and run a better business. If you're a progressive pharmacist, who shares our excitement for the future, we'd love to hear from you today.

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Pharmacy Daily

Friday 03 May 2019

Today's issue of *PD*

Pharmacy Daily today has three pages of news, a front cover wrap from **Sigma Healthcare** plus the **MIMS Monthly Update**.

Winter Spotlight space limited

PHARMACY industry suppliers are now invited to take part in the second ***Pharmacy Daily*** *Winter Spotlight* feature, which will showcase products and services suitable for the cooler season.

The 14 May 2019 feature has now sold out, but limited spots are still available for the 21 May issue.

The spotlight features an image, description and call to action for each item, with the highly cost-effective promotion set to reach more than 12,000 ***Pharmacy Daily*** subscribers across the country.

For details email Mel or Hoda on advertising@pharmacydaily.com.au.

No unilateral CPA changes

A FEDERAL Government led by either of the two major parties will not impose unilateral changes on community pharmacists outside of the Community Pharmacy Agreement.

Speaking in a much-anticipated debate at the National Press Club yesterday, both Health Minister, Greg Hunt, and Shadow Health Minister, Catherine King, said no changes could be made without the support of the pharmacy profession.

Hunt said the Government would continue to "consider and consult" when provided recommendations by the Pharmaceutical Benefits Advisory Committee (PBAC), when asked "why did you side with 3,000 wealthy pharmacy owners at the expense of the hip pockets of Australian patients" on the recommendations to allow patients pick up two months' supply of certain medicines at once.

King was more explicit in her support for the CPA.

"The CPA is the process by which the Government negotiates with community pharmacies," she said.

"If you're going to do anything you've got to do it within this agreement."

The two parties were also on the same page with Labor supporting the Government's decision to cut the number of prescriptions required to access the Pharmaceutical Benefits Scheme (PBS) safety net for concession cardholders from 60 to 48 a year, effective from Jan 2020.

This change will save patients up to $80 per year "but more importantly it means over one million Australians will be able to access free medicine even quicker," said Prime Minister Scott Morrison.

Welcoming the backing from both parties for the changes, the Pharmacy Guild of Australia said, "this is a positive step, especially for chronically ill patients, many of whom struggle to fill prescriptions because of cost.

"We acknowledge the bi-partisan support for this measure, but note there is more that can be done to restore universality to the PBS through ensuring patients across Australia access subsidised medicines on the same terms.

"We also stress the importance of ensuring that the vital final component of the PBS supply chain – community pharmacies – are kept viable so that patients continue to have the world's best access to the medicines they need."

Chemistry checkup

SIGMA Healthcare is inviting pharmacy owners to "be part of something better" by joining one of its six standalone retail pharmacy brands with an integrated suite of tools plus "world-class wholesale service" - see the **cover page**.

Pharmacy Daily

Friday 03 May 2019

Queensland scripts slammed

QUEENSLAND'S trial of pharmacist prescribing is a "fundamental corruption of a safety check that has stood the test of time", according to the Australian Medical Association (AMA).

AMA President Dr Tony Bartone slammed the Qld Government's decision to approve a trial of pharmacist prescribing (***PD*** 18 Apr), warning it would create conflicts of interest in the health system.

"No other State or Territory in Australia allows these medicines to be prescribed by pharmacists," he said.

"The AMA supports non-medical health practitioners, including pharmacists, prescribing in a medically-led and delegated team environment.

"But pharmacists working within a retail pharmacy environment should never prescribe...pharmacists deriving an income from medicines they prescribe represents a fundamental conflict of interest.

"Doctors derive no income or any other benefit from prescribing medicines...the separation of prescribing and dispensing is critical for patient safety," Bartone fumed.

He said the Qld model was a fundamental corruption of a safety check that has stood the test of time, adding that "there must be a separation between prescribing by a doctor, who prescribes with no financial or other benefit, and the dispensing of that medication by a pharmacist, who is solely responsible for checking the dosage and frequency.

"The Queensland approach means that retail pharmacists, receiving a financial benefit from every prescription, will now have a licence to do both, which potentially puts patients at risk."

Bartone said it was extremely worrying that the Qld approach would see pharmacists prescribing with no consultation with doctors.

"Multiple prescribers caring for a patient, independent of each other, is just bad health care" he said.

Vaping call to cut cigs

ONE of the worlds' biggest manufacturers of tobacco cigarettes says it is changing its focus with the vision to "stop selling cigarettes".

Philip Morris is calling for Australian policy makers to urgently review the evidence supporting smoke-free products, following an historic decision in the United States yesterday, where the Food and Drug Administration (FDA) authorised the sale of the company's smoke-free product, IQOS, determining it is "appropriate for the protection of public health".

The company argues the IQOS device is a less harmful delivery of nicotine than the smoke product.

Gilenya for age 10-17

THE Therapeutic Goods Administration has approved Novartis' Gilenya (fingolimod) for the treatment of children and adolescents 10-17 years old with relapsing forms of multiple sclerosis.

The approval makes Gilenya the first and only licenced disease-modifying treatment for the condition for patients in this age bracket, with Novartis GM Australia/NZ, Richard Tew, saying it was a "significant milestone in our journey to change the course of MS".

Facebook fights antivax movement

SOCIAL media platform Facebook has announced it is taking several proactive steps to reduce the spread of misinformation about the value of vaccination through its social media channel, including reducing the ranking of groups and pages that spread misinformation in the website's News Feed and Search options.

Any advertisements that spread misinformation about vaccination will be rejected, Facebook Vice President of Global Policy Management, Monica Bickert, said in a company statement.

Bickert explained the online giant was exploring ways to share educational information about vaccines, when people come across misinformation on this topic.

Facebook also intends to remove access to fund-raising tools for pages that spread misinformation about vaccinations on its platform.

Leading global health organisations, such as the World Health Organization and the US Centers for Disease Control and Prevention have been identified as setting the standard for Facebook's quality of information - see the full statement at newsroom.fb.com.

Pharmacy Daily

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Dispensary Corner

A SNIFF test could become a standard medical procedure in the future, after researchers found people with a poor sense of smell were much more likely to die within the next ten years.

A study published in the *Annals of Internal Medicine* found that, compared with older adults with a good sense of smell, those with "poor nasal discernment" were at a 46% higher risk for death at 10 years, and 30% at 13 years.

The work by epidemiologist Honglei Chen reviewed figures from the US National Institute on Ageing in relation to about 2,300 patients aged between 71 and 82 who completed a smell test of 12 common odours.

He said a poor sense of smell was known as an early sign for some conditions, adding that it could be an "early and sensitive sign" for deteriorating health.

SOME shellfish really like to party.

That was the erroneous conclusion drawn by online commenters on a report about samples of prawns tested in a rural area of eastern England, which were all found to contain low levels of cocaine.

Scientists made the "surprise" discovery after sampling 15 locations across Suffolk and testing for levels of micro-pollutants in the creatures.

"Cocaine was found in all samples tested, and other illicit drugs such as ketamine, pesticides and pharmaceuticals were also widespread in the shrimp that were collected," they said.

While concentrations were low, the authors noted the compounds "might pose a risk to wildlife".

SHPA fears $44m PBS cuts

PROMISES of increased funding for new medicines will mean little if $44 million cuts to hospital pharmacy are implemented, the Society of Hospital Pharmacists of Australia (SHPA) warns.

SHPA CEO, Kristin Michaels, said the "Improving Access to Medicines - supporting community pharmacy" measure included in last month's Federal Budget, would severely impact jobs and funding for hospital-based medicines safety programs (***PD*** 24 Apr).

"Information provided by the Department of Health indicates the funding cut will remove $44 million from Australian hospitals annually, the majority from public hospitals," she said.

"The PBS is an invaluable mechanism improving equity of medicines access for all Australians, but it must be funded appropriately to ensure high-quality patient care, and that includes pharmacy review, counselling and medicines management.

"Rather than quietly cutting funds to the people who are experts in medicine management in acute settings, the government should be increasing support for hospital pharmacies to ensure that, as more and more complex medicines are added to the PBS, they can be used optimally and provided to more patients as effectively as possible.

"Hospital pharmacists are a key part of the multidisciplinary team and this budget cut will reduce their ability to provide patient services in the right place, at the right time – jobs will be lost and fewer patients will be able to be treated," Michaels said.

She said the SHPA had been speaking to all major parties about the changes "however we are yet to see evidence of any measures to reduce the negative impact of these cuts".

FIP partners with Pharmapod

THE International Pharmaceutical Federation (FIP) has announced a partnership with global medication error reporting platform Pharmapod to "offer an infrastructure for effective incident management and continuous quality improvement for pharmacists internationally".

Pharmapod offers a Global Learning Health System platform which helps drive quality and efficiency through machine learning along with response teams to analyse medication error data.

Amcal + ScriptWise

AMCAL Pharmacy has joined forces with non-profit organisation ScriptWise to raise awareness about opioid and benzodiazepine medication.

Launched this week, Medication Dependence Prevention Month (MDPM) aims to ensure Australians understand that long-term use of opioid and benzodiazepine medication might mean getting even worse pain or having more trouble sleeping.

Australians are more likely to die from a prescription medication related overdose than on Australian roads, Chairman of the Amcal & Guardian National Council, Marc Clavin, reports.

In addition, approximately 1.9 million Australian adults begin taking opioids each year.

"We want to encourage Australians to ask their Amcal pharmacist about a free personalised pain management plan and find the best solution for them," Clavin said.

See scriptwise.org.au for more.

Fentanyl patch recall

ALVOGEN has voluntarily issued a recall of two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level, in the USA.

A small number of cartons labelled as 12mcg/h actually contained 50mcg/h, a four-times stronger dose.

This level of dosing could result in serious, even fatal, respiratory depression.

No Australian supplies are known to be affected.

Events Calendar

WELCOME to ***Pharmacy Daily***'s events calendar, opportunities to earn CPE and CPD points.

If you have an upcoming event you'd like us to feature, email info@pharmacydaily.com.au.

04 - 05 May: Pharmeducation Clinical Update Seminar; Crowne Plaza Coogee Beach, Sydney; for details visit: www.pharmeducation.com.au

05 - 13 Jun: PSA Offshore Refresher Conference; Montreux, Switzerland and Lyon, France; registrations now open: www.psa.org.au

22 - 23 Jun: SHPA Electronic Medication Management Conference; Novotel Manly Pacific, Manly, NSW; register here: www.shpa.eventsair.com

28 - 30 Jun: ConPharm 2019; Pullman on the Park Melbourne; early bird offer here: www.aacp.com.au

26 - 28 Jul: PSA19; Hyatt Regency Sydney; early bird registrations now open: www.psa19.com

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MIMS Monthly Update

May 2019

New Products

- **Inotuzumab ozogamicin (rch)** **(Besponsa)** is a CD22-targeted antibody-drug conjugate (ADC). It is a humanised IgG4 antibody which specifically recognises human CD22. The small molecule, N-acetyl-gamma-calicheamicin, is a cytotoxic agent that is covalently attached to the antibody via an acid-cleavable linker. Nonclinical data suggest that the anticancer activity of inotuzumab ozogamicin is due to the binding of the ADC to CD22-expressing tumour cells, followed by internalisation of the ADC-CD22 complex, and the intracellular release of N-acetyl-gamma-calicheamicin dimethylhydrazide via hydrolytic cleavage of the linker. Activation of N-acetyl-gamma-calicheamicin dimethylhydrazide induces double-strand DNA breaks, subsequently inducing cell cycle arrest and apoptotic cell death. Besponsa is indicated for the treatment of adults with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukaemia (ALL). Use of Besponsa should be initiated and supervised by a physician experienced in the treatment of haematological malignancies. Besponsa is contraindicated in patients who have experienced prior confirmed severe or ongoing veno-occlusive liver disease/sinusoidal obstruction syndrome (VOD/SOS) and patients with serious ongoing hepatic disease (e.g. cirrhosis, nodular regenerative hyperplasia, active hepatitis). Besponsa powder for injection vial contains inotuzumab ozogamicin (rch) 1 mg in a pack size of 1.

- **Neratinib (maleate)** **(Nerlynx)** is an irreversible inhibitor of 3 epidermal growth factor receptors (EGFRs): EGFR (encoded by ERBB1), HER2 (encoded by ERBB2), and HER4 (encoded by ERBB4). Neratinib binds to the HER2 receptor, reduces EGFR and HER2 autophosphorylation, downstream MAPK and AKT signalling pathways, and inhibits tumour cell proliferation *in vitro. In vivo*, oral administration of neratinib inhibited tumour growth in mouse xenograft models with tumour cell lines expressing HER2 and EGFR. Nerlynx is indicated for the extended adjuvant treatment of adults with early-stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab based therapy. Nerlynx should be initiated and supervised by a physician experienced in the administration of anti-cancer medicinal products. Nerlynx is contraindicated in severe hepatic impairment and with concomitant strong CYP3A4/P-gp inducers (carbamazepine, phenobarbital, phenytoin, St John's wort, rifampicin) and moderate CYP3A4/P-gp inhibitors (fluconazole, diltiazem, verapamil, erythromycin). Nerlynx tablets contain neratinib (maleate) 40 mg and are available in a pack size of 180.

- **Rurioctocog alfa pegol (rch)** **(Adynovate)** is a full-length recombinant human coagulation factor VIII with an extended half-life. Its therapeutic activity is derived from its parent molecule, octocog alfa, covalently conjugated with the PEG reagent, which targets lysine residues. The PEG moiety is conjugated to the octocog alfa molecule to increase the plasma half-life through the reduction of the low density lipoprotein receptor-related protein-1 (LRP-1) receptor-mediated clearance of the factor VIII molecule. Adynovate is a long-acting antihaemophilic factor (recombinant) indicated in haemophilia A (congenital factor VIII deficiency) patients for: control and prevention of bleeding episodes, routine prophylaxis to prevent or reduce the frequency of bleeding episodes, perioperative management (surgical prophylaxis). Adynovate is not indicated for the treatment of von Willebrand disease. Treatment with Adynovate should be under the supervision of a physician experienced in the treatment of haemophilia. Adynovate is contraindicated in known life-threatening hypersensitivity reaction, including anaphylaxis, to octocog alfa, or mouse or hamster protein. Adynovate powder for injection vial contains rurioctocog alfa pegol (rch) 250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU or 3000 IU with 2 mL or 5 mL solvent (vial) in a pack of 1.

- **Tezacaftor/ivacaftor** **(Symdeko)** contains two components: tezacaftor, a broad-acting cystic fibrosis transmembrane conductance regulator (CFTR) corrector that facilitates the cellular processing and trafficking of normal or multiple mutant forms of CFTR (including F508del-CFTR), and ivacaftor, which potentiates the channel-open probability (or gating) of CFTR at the cell. The combined effect is increased quantity and function of CFTR at the cell surface, resulting in increases in chloride transport, airway surface liquid height, and ciliary beat frequency. Symdeko is indicated for the treatment of patients ≥ 12 years with cystic fibrosis who are homozygous for the *F508del* mutation or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence. Symdeko should only be prescribed by physicians with experience in the treatment of cystic fibrosis. Symdeko tablets are available in a composite pack of 56 (28 tablets of tezacaftor 100 mg/ivacaftor 150 mg and 28 tablets of ivacaftor 150 mg).

New Indications

- **Eltrombopag** **(Revolade)** in combination with standard immunosuppressive therapy is now indicated for the first-line treatment of adult and paediatric patients ≥ 2 years with severe aplastic anaemia.

- **Interferon beta-1a (rch)** **(Avonex)** is now indicated for the treatment of secondary progressive multiple sclerosis (MS) in patients in whom relapse is still a feature. Avonex should not be initiated in patients who have not experienced a relapse in the previous 12 months.

- **Pembrolizumab (rch)** **(Keytruda)** in combination with carboplatin and either paclitaxel or nab-paclitaxel is now indicated for the first-line treatment of patients with metastatic squamous non-small cell lung carcinoma.

- **Tocilizumab (rch)** **(Actemra)** is now indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients ≥ 2 years (IV formulation only).

New Contraindications

- **Abiraterone acetate (Zytiga)** plus prednisone/prednisolone is now contraindicated in combination with radium 223 dichloride.
- **Atorvastatin (calcium) (Lipitor)** is now contraindicated with concomitant glecaprevir/pibrentasvir.
- **Budesonide (Rhinocort)** is now contraindicated in patients with hypersensitivity to other corticosteroids.
- **Darunavir (Prezista)** is now contraindicated with concomitant dapoxetine, ivabradine, lomitapide or naloxegol.
- **Netupitant/palonosetron (HCl) (Akynzeo)** is now contraindicated during pregnancy.
- **Sodium valproate (Epilim/Epilim IV)** is now contraindicated in women of childbearing potential, unless the physician has provided information regarding the potential effects of valproate during pregnancy and recommendations on its use.

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.