Pharmacy Daily

Tuesday 04 Sep 2018

Today's issue of *PD*

Pharmacy Daily today has two pages of news plus the latest **MIMS Monthly Update**.

FIP female empowerment

PHARMACISTS across the globe are being urged to explore services that empower women, with a new International Pharmaceutical Federation (FIP) report highlighting the potential to "support women in their often overlooked role as informal caregivers".

The paper, released in Glasgow at this year's FIP World Congress, says the accessibility of pharmacists means they are in an ideal position to communicate to women the need to be well informed about health and medicines and to support health literacy.

The report includes examples of how pharmacists in different countries are supporting women caregivers, who are often the ones assuming health responsibilities for their households and families, and who visit pharmacies.

"And as the world's population ages, the number of women performing this role looks set to increase," said chair of the working group and FIP Professional Secretary, Ema Paulino.

She said the report could be used as a basis for developing targeted interventions, with the full paper now online at fip.org.

AMH launches new App for Desktop

THE Australian Medicines Handbook has today formally released its new AMH App for Desktop, which can now be downloaded at no charge.

The AMH App for Desktop includes the AMH prescribing guides, with advice on prescribing and use of medications in special populations.

A subscription purchase is required in order to access the full content of the Handbook.

The new AMH App for Desktop replaces the current AMH Download, and once loaded with product content allows full access offline, without the restrictions of slow internet speeds and dropouts.

It is available for download onto PCs with Windows 10 (64 bit) and Apple Macs with macOS Sierra 10.12 or later.

More info at amh.net.au.

Paramedic AHPRA

THE Australian Health Practitioner Regulation Agency has opened applications for paramedic registration, in the lead-up to the start of regulation of paramedics under the National Registration and Accreditation scheme later this year.

The term "paramedic" will become a protected title only able to be used by those registered under the new scheme.

Nabiximols S4 comments sought

THE Therapeutic Goods Administration is inviting comments on a proposal to reschedule Sativex (nabiximols) from its current S8 classification to Schedule 4.

The product is a botanical extract of *cannabis sativa* in a buccal spray, with the application noting that it is currently available on prescription in 26 countries with scheduling that is similar to S4 in Australia.

The Advisory Committee for Medicines Scheduling is also considering a proposal to create a new Schedule 4 group entry for racetams, with input on the consultation sought by 28 Sep - for details see tga.gov.au.

PSA consultation

THE Pharmaceutical Society of Australia is extending the consultation period on its *Pharmacists in 2023 Discussion Paper* (***PD*** 30 Jul 2018), with submissions now due by Fri 14 Sep.

PSA gm Policy & Advocacy, Belinda Wood, said a number of incredibly detailed submissions had already been lodged, and "we want to ensure all stakeholders have enough time to address the important issues of embedding, equipping and enabling pharmacists" - see psa.org.au.

Asthma blindness

A NEW national poll shows that asthma impacts the lives of 63% of Australians, yet 31% are unaware that the disease is life-threatening and long term, Asthma Australia said at the launch of National Asthma Week last Sun.

Asthma Australia ceo Michele Goldman said more needs to be done to educate Australians around the risks of asthma - **CLICK HERE**.

Corum in the black

LISTED pharmacy software specialist Corum Group Limited has recorded a $251,000 net profit after tax for the year to 30 Jun, a significant turnaround on last year's $5.9 million full year loss which included a significant non-cash goodwill impairment.

Total revenue for the year was down $2.2 million (14.8%) to a total of $12.6 million, with sales particularly impacted by "several pharmacy groups implementing prior decisions to change software platforms".

The company's chairman, Bill Paterson, said in FY19 the company would focus on the marketing of Corum Clear Dispense and other upgraded software products.

He said ongoing automation and productivity programs continued to positively impact the operating cost base of the business, while enhancements to the Corum product had also raised customer satisfaction.

Cross-selling of peripheral products to existing customers rose strongly in the second half of the financial year, he added.

Paterson also noted that Corum was "very active in evaluating merger, acquisition and partnering opportunities during the year".

S19A amiloride tick

HL PHARMA has been awarded Section 19A(1) approval by the Therapeutic Goods Administration to supply amiloride 5mg tablets.

The approval aims to help address short supply/unavailability of Kaluril (amiloride) 5mg tablets.

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Dispensary Corner

AUTHORITIES in Kuwait have reportedly ordered the closure of a fish shop after it was found to be sticking fake eyes on its produce to make it look fresher.

The creative retail merchandising technique was discovered after a video recorded by a local female customer, showing her washing the fish only to find the plastic googly eyes fell off, went viral on social media.

Kuwaiti news service *Al-Bayan* confirmed the story, with the country's ministry of commerce moving the scales of justice quickly after identifying the location of the fishy fabrication.

MILLENNIALS rejoice!

A new study in the USA is seeking 1,000 volunteers to eat avocados for six months.

The "Habitual Diet and Avocado Trial" research project, conducted by the University of California Los Angeles, Loma Linda University, Penn State and Tufts University, aims to discover whether the popular fatty fruit can help with weight loss.

Participants will be required to either eat one avocado daily during the trial period, or eat only two avocados per month.

The study is being funded by the Hass Avocado Board, and subjects who complete the trial will receive $300 along with a special gift of 24 avocados after the six month period.

instigo launches Bose sleepbuds

INSTIGO has announced the upcoming debut of a new category for the pharmacy channel, after being engaged by upmarket consumer electronics maker Bose to build a strategy for its first health and wellness device.

The new Bose noise-masking sleepbuds (**pictured**) use preloaded, soothing masking sounds to cover unwanted night-time noise to make it easier to get to sleep and stay asleep.

The sleepbuds have rechargeable batteries which provide up to 16 hours of use, and come with the Bose Sleep app to allow users to customise their experience.

A pilot program will run from 11 Sep in selected strategic launch locations and partner pharmacies, including some with existing sleep service business, high performing professional services pharmacies and some in high socioeconomic areas and with larger premises.

Instigo gm Andrew Pattinson said the partnership between Bose and instigo was about providing "a genuine opportunity for innovation and differentiation within community pharmacy".

Participating premises will be provided with display units, a POS pack, eDMs and social assets.

Instigo has also identified a range of molecules across general retail, S2, 3 and 4 medicines which would indicate a potential customer in one of the three target groups: the traveller, the environmental noise sufferer, and the partner of snorers.

The RRP of the devices is $379.95 in Australia and $439.95 in NZ.

Pattinson said it was crucial for health providers to add more value to their traditional service offering.

"We want pharmacies to not just stay relevant but push the boundaries of innovation and take hold of opportunities within communities to really change lives," he said.

Guild Update

Influenza statistics reflect well on community pharmacy

THE latest national influenza data reflects very well on the amazing effort community pharmacy has put into raising vaccination rates across Australia.

Comparing 2017 to 2018, the national figures to this point last year showed 143,000 people had reportable cases of flu. As of 28 August this year, it was 25,000.

At this point last year, 610 people were reported as having lost their lives to flu. The comparable figure this year was 38.

As Minister Hunt said in a speech last week, that's an extraordinary achievement which is in part due to the nature of this year's virus, in part due to the strength and the targeted nature of the vaccines that are available, but also due to the higher level of vaccination across the community.

So, all the hard yards we have covered to get pharmacist vaccination up and running across all States and Territories – the lobbying, the training, and the day-to-day work - have made a significant and measurable contribution to a big improvement in public health and a significant downturn in the impact of influenza this year.

To view the data: www.health.gov.au/flureport.

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MIMS Monthly Update

September 2018

New Products

- **Apalutamide (Erlyand)** is an androgen receptor (AR) inhibitor that binds directly to the ligand binding domain of the AR. Apalutamide prevents AR nuclear translocation, inhibits DNA binding, impedes AR mediated transcription, and lacks androgen receptor agonist activity in preclinical studies. Erlyand is indicated for the treatment of non-metastatic, castration resistant prostate cancer. Patients should concurrently receive a gonadotropin-releasing hormone (GnRH) analogue, unless they have had a bilateral orchiectomy. Erlyand is contraindicated in women who are or may become pregnant. Erlyand tablets contain apalutamide 60 mg and are available in packs of 120.

- **Rufinamide (Inovelon)** is a carboxamide derivative antiepileptic that modulates the activity of sodium channels, prolonging their inactive state. Inovelon is indicated as adjunctive therapy in the treatment of seizures associated with Lennox Gastaut syndrome in patients 4 years of age and older. Treatment with Inovelon should be initiated by a physician specialised in paediatrics or neurology with experience in the treatment of epilepsy. Inovelon is contraindicated with hypersensitivity to triazole derivatives. Inovelon tablets contain rufinamide 200 mg or 400 mg and are available in packs of 60.

New Indications

- **Dabrafenib (Tafinlar)** in combination with trametinib is now indicated for the adjuvant treatment of melanoma with a BRAF V600 mutation and involvement of the lymph node(s), following complete resection.

- **Denosumab (rch) (Xgeva)** is now indicated for prevention of skeletal related events associated with multiple myeloma.

- **Nivolumab (Opdivo)** in combination with ipilimumab is now indicated for the treatment of: unresectable melanoma; intermediate/poor risk, previously untreated advanced renal cell carcinoma.

- **Osimertinib (mesilate) (Tagrisso)** is now indicated for first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) tumours with activating epidermal growth factor receptor (EGFR) mutations.

- **Terlipressin (Lucassin)** is now indicated for treatment of bleeding oesophageal varices.

New Contraindications

- **Enoxaparin sodium (Clexane and Clexane Forte)** is now contraindicated with immune mediated heparin induced thrombocytopenia (HIT) within the past 100 days or in the presence of circulating antibodies.

- **Erythromycin (Eryc Capsules, Mayne Pharma Erythromycin)** is now contraindicated with terfenadine or astemizole. Do not use erythromycin concomitantly with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.

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.

Black triangle scheme

Black triangle medicinal products are subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at http://www.tga.gov.au/reporting-problems.

Black triangle medicinal products currently in MIMS include **apalutamide (Erlyand)**, **avelumab (Bavencio)**, **baricitinib (Olumiant)**, **cabozantinib (Cabometyx)**, **dupilumab (Dupixent)**, **everolimus (Afinitor)**, **glecaprevir/pibrentasvir (Maviret)**, **ixekizumab (Taltz)**, **lurasidone hydrochloride (Latuda)**, **rufinamide (Inovelon)** and **sofosbuvir/velpatasvir/voxilaprevir (Vosevi)**.

Black triangle scheme to promote adverse event reporting

The Therapeutic Goods Administration (TGA) is implementing a black triangle scheme.

Commencing January 2018, the scheme is designed to help health professionals and patients to identify certain types of new prescription medicines, and to encourage the reporting of adverse events associated with their use. A similar scheme currently operates throughout the member states of the European Union, including the United Kingdom.

When a medicine or vaccine is first registered and made available in Australia, information about its safety and efficacy is usually available only from clinical trials. Clinical trials generally have strict inclusion criteria and relatively limited numbers of participants. This means it is common for new adverse events to be identified after new medicines are used more broadly in the population.

Accompanying text for PI: 'This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information in Australia. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.'

The black triangle symbol, and accompanying text, will appear on Product Information (PI) and Consumer Medicines Information (CMI) documents of newly registered prescription medicines (with the exception of biosimilar medicines, generic versions of already approved prescription medicines and seasonal influenza vaccines).

It will also be used for all provisionally registered medicines, including those with a provisionally approved indication.

Additionally, other medicines may be included following approval of an extension of indication that is for:

- a significantly different condition; and/or
- use in a significantly different patient population.

The black triangle will also appear in TGA related material, such as Australian Public Assessment Reports for prescription medicines (AusPARs). Future work will be conducted to include the black triangle in other sources of medicine information.

For medicines included in the scheme, the black triangle will appear on the PI and CMI for five years, starting from the date of first supply.

For provisionally registered medicines, the black triangle symbol will appear for a period of not less than five years. This will include the entire period of provisional registration, and may include a period of time following full registration. The duration following full registration will be determined during the evaluation of data to support full registration.

The black triangle does not denote that there are known safety problems, just that the TGA is encouraging adverse event reporting to help us build up the full picture of a medicine's safety profile more quickly. Adverse event reporting remains important for all products, including those without a black triangle.

For further information about the TGA's Black Triangle Scheme visit www.tga.gov.au/black-triangle-scheme.