

Today's issue of PD

Pharmacy Daily today has two pages of news, plus a full page from **Corum Group**.

New year TGA fees

THE Therapeutic Goods Administration (TGA) has greeted the pharmaceutical industry with its planned changes to fees and charges effective 01 Jan 2016.

Go to www.tga.gov.au for details.

In addition, the TGA is introducing pilot changes to the pre-submission phase of the prescription medicines registration process.

The pilot commences 01 Feb 2016, is not compulsory and is suited to all Type A (New Chemical and New Biological Entities and Biosimilars) and Type D (New Generic Medicine) applications.

The pre-submission pilot will evaluate the effectiveness of removing the need to provide a 'Module 2 or equivalent' with Pre-submission Planning forms (PPFs) and should reduce the workload for applicants and the overall registration timeline by at least a month, the TGA said.

Applicants are reminded that the current registration pathway will still be available.

Got to www.tga.gov.au for more.

RB 'did not set out to mislead'

RECKITT-BENCKISER (RB) says its "specific-pain" range had been launched with the aim of helping consumers navigate their pain relief options, "particularly within the grocery environment where there is no healthcare professional to assist decision making".

In a statement following the ACCC's confirmation that the products will be removed from retail shelves within three months (*PD* yesterday), RB spokesperson Montse Pena said the company did not set out to mislead consumers.

"Nurofen has co-operated with the ACCC in relation to these proceedings and will fully comply with the court order made today.

"Nurofen is committed to the quality use of medicines and promoting and protecting the health of Australians," Pena said.

A further hearing will determine



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a probiotic such as Inner Health Plus may assist in maintaining the balance of good bacteria.

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Devil in reform detail

AUSTRALIAN Self Medication Industry (ASMI) representatives Annaliese Scholz and Steve Scarff participated in a Department of Health stakeholder forum examining the complementary medicines (CM) section of the recently published recommendations from the Review of Medicines and Medical Devices Regulation.

Three members of the Expert Review Panel, representatives from industry, members of academia, professional groups, consumer groups and the Therapeutic Goods Administration also participated.

Emeritus Professor Lloyd Sansom AO lead the discussion and ASMI said there was "open, frank and robust discussion" but all agreed "the devil would be in the detail" such as efficacy monographs, revised listing pathways and other regulatory frameworks' roles.

Of particular interest to ASMI are the Panel's recommendations on complaints around advertising.

Corum LOTS one

CORUM Health is today promoting its Corum LOTS ONE upgrade, which offers significantly improved performance and faster response times with a MS SQL back end database.

For details see **page three**.

penalties in relation to the case, with Reckitt Benckiser potentially facing millions of dollars in fines.

The company will be permitted to use the same packaging and product names for nine months after the withdrawal as long as a label is attached confirming that the products are equally effective for other types of pain, while new packaging is developed.

ACCC chairman Rod Sims said the court decision was a win for consumers, who could potentially overdose by taking several products from the range without realising they are in fact identical.

MEANWHILE the issue has gone global, with the UK Medicines and Healthcare products Regulatory Agency also commenting on the ruling which does not affect products in Britain.

RB sells pain-specific products in the UK, including Nurofen Migraine Pain, Nurofen Tension Headache and Nurofen Express Period Pain.

A spokesperson told the *BBC* that all Nurofen products remain available in the UK "and there will be no changes to packaging".

The MHRA said that for OTC medicines "informative names are permitted to help patients select an appropriate product without input from a health professional".

RGH E-Bulletin

THE Repatriation General Hospital Pharmacy E-Bulletin this week examines a new antipsychotic, Latuda (lurasidone).

The mechanism of the drug is not fully understood, said the Bulletin, but it is indicated for schizophrenia and is available in Australia as 40mg and 80mg tablets, which can be subsidised under the PBS with a streamlined authority.

CLICK HERE to access the Bulletin.

New PHA ceo signed

PRIVATE Healthcare Australia (PHA) has announced the appointment of former medical practitioner and director of government affairs and policy for the Johnson & Johnson Family of Companies in Australia and New Zealand, Dr Rachel David, to the ceo role for the organisation.

PHA president Rob Bransby in making the announcement added, "This [is] an important period for the PHI Industry and Dr David's extensive career in healthcare policy, in both Government and the private sector ensures she is vastly qualified for this challenging and rewarding role."

David is expected to commence in the role late January 2016.

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* Brod M et. al. Patient Intelligence Survey
Nov 2014, pp 43 – 60.



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Screening saves lives

A **NEW** study confirms that New Zealand's organised breast screening programme, BreastScreen Aotearoa (BSA) has reduced deaths from breast cancer by a third in women aged 45 to 69 years, says BSA clinical leader Dr Marli Gregory.

Guild Update

Revamped Members Only Emergency Management Resources

The Guild has updated its Emergency Management Resources toolkit to help members manage their businesses during natural disasters such as bushfires, storms and floods.

Recent bushfires in Western Australia and South Australia and the prospect of a hot dry summer have reinforced the need for pharmacists to prepare an emergency management plan.

The plan should cover issues such as staffing, insurance, financial, regulatory arrangements for medicines supply and business recovery during an emergency and also includes advice on business continuity and recovery planning.

Pharmacists play a critical role in ensuring continuity of medicine supply to consumers in emergencies where patients may have lost or do not have access to their medicines and/or prescriptions.

Guild Members can access the resources by logging into myGuild and visiting the Emergency Management page.

Guild responds on discount

A **WAR** of words has erupted over the \$1 PBS co-payment discount, with the Pharmacy Guild yesterday warning of the flow-on effects that will impact concessional patients who choose to receive the full reduction on their prescriptions.

"All Australians need to be aware of the impact that Federal Government changes to the PBS will have on the number of prescriptions they will need to fill in order to reach their Safety Net entitlement," commented the Pharmacy Guild in a statement.

"This means that concessional patients who choose to receive a full one dollar discount will need to fill an additional 11 prescriptions during the year to reach their Safety Net and access free medicines."

NICE new standards

THE UK's National Institute for Health and Care Excellence (NICE) has published new guidelines and quality standards, with the latest updates being *QS103 Acute heart failure: diagnosis and management in adults* and *QS104 Gallstone disease*.

Go to www.nice.org.uk/guidance.

The Guild's rebuttal comes in light of last Fri's announcement by Chemist Warehouse, which intends to pass on the full dollar markdown to their customers; with its commercial group manager stating there will be "absolutely no effect on the Safety Net - discounting or not you need to spend the exact same amount of money in a year to qualify" (*PD* yesterday).

Changes to the PBS co-payment will go into full effect from 01 Jan.

Thalidomide dialogue

NO FEWER than thirteen articles have been devoted to a section of The Conversation website titled *Thalidomide Series*.

For those who don't recall the details, the site contains a useful history of the saga in which thalidomide was prescribed as a sedative for morning sickness in the 1950s and 1960s resulting in significant birth defects in over 10,000 infants.

There's an infographic along with information on the fate of victims, lessons learned and the future of the product which has applications in cancer treatment.

See theconversation.com/au.

DISPENSARY CORNER



HOW not to escape the police.

One 22-year-old man suspected of burglarising homes in the US state of Florida was attempting to flee police in hot pursuit with tracker dogs and found a unique, but terminal, means of 'escape'.

To foil the sniffer dogs and avoid police detection he wandered into a lake to hide but met a fate somewhat worse than the law had in mind for him.

A 3.4 metre alligator considered the man a gift of food and summarily dealt with him.

The man drowned and was partially eaten before his body could be retrieved, the autopsy confirming the cause of the result.

Unfortunately for the alligator, it also met an untimely end to enable a necropsy to reveal parts of the man's body in its stomach.

US MARRIED men gunshot risk.

Married men in the US are at the highest risk of suffering a self-inflicted gunshot wound with more than one third of all firearms housed in the country, according to a study in the *Medical Journal of Australia*.

The study titled "Americans shooting themselves in the foot: the epidemiology of podiatric self-inflicted gunshot wounds in the United States" showed almost 90% of victims were male, with young married men under 34 years of age most at risk of injuring themselves in this way - by looking at data from the Firearm Injury Surveillance Study which recorded non-fatal gun-related injuries during patients' initial emergency department visits.

The researchers creatively warned that men should take care during the festive season "to avoid being caught under the missing toe" - **CLICK HERE**.

WIN WITH KEY SUN

This week Pharmacy Daily and Key Sun are giving away every day a prize pack of 2 x Key Sun Sunmilk.

Key Sun Sunmilk Coconut SPF50+ Spray is a high protection sunscreen offering broad spectrum protection from UVA and UVB in an easy to use spray bottle. Thereby protecting against premature skin-ageing, skin reddening and sunburn. Key Sun Sunmilk Coconut SPF50+ is 4 hours water resistant. Visit www.keysun.com.au

To win, be the first from **QLD** to send the correct answer to the following question to comp@pharmacydaily.com.au

Fill in the blank: Key Sun Sunmilk provides _____ long water resistance.

Congratulations to yesterday's winner, Toni Soffer from Woolloomooloo Pharmacy.



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Part of the Travel Daily group of publications.

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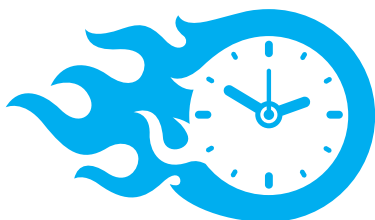
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