



Tuesday 15 Nov 2016

TGA enforcement deficit

Pharmacy Daily today has two pages of news plus a full page from Lorella.

Today's issue of PD

NZ PHARMAC closed

WITH the impact of the earthquake in New Zealand, PHARMAC announced its offices in Wellington would be closed again today, but hope to be back Wed.

PHARMAC staff have been receiving regular text updates although some were taking a long while to get through and website service was interrupted briefly.

HIV steady, STIs rise

NEW HIV notifications in Australia have remained stable over the past four years, following a steady increase since 1999, according to the 2016 Australian Annual Surveillance Report into sexually transmissible infections and blood borne viruses, released by the Kirby Institute at the University of NSW.

Sexually transmitted infection (STI) reports, on the other hand, have increased in the same time period.

Chlamydia, gonorrhoea and infectious syphilis burden of disease has been disproportionately carried by Aboriginal and Torres Strait Islander people with up to six times the incidence of that recorded in the non-indigenous population in 2015, the report said.

The full report also contains data on viral hepatitis B and C, donovanosis and human papillomavirus infection. CLICK HERE to see the report.

Repairs

hands.

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damaged

THE Therapeutic Goods Administration (TGA) has KPI

marked itself down on its key performance indicator (KPI) scorecard for the period 2015-16 in relation to compliance and enforcement matters, but states that it performed to expectations on most other parameters.

The regulatory body said that in respect of the KPI requiring a streamlined and coordinated compliance and monitoring system, it does "not yet have a fully mature compliance and enforcement framework with graduated sanctions and penalties."

There is in place a "sound compliance structure" the report said, but "we do not yet have a range of regulatory tools which allow us to use the full range of compliance approaches."

The organisation has come under repeated fire from industry

Pharmacy Choice win

WITH over 400 pharmacies engaged in Symbion's Pharmacy **Choice Five Steps Incentive** Program, first prize was taken out by U Pharmacy South Yarra, sending owner Jane Nguy and her team on a luxury New Zealand trip.

The program took a structured scorecard approach and rewarded stores for their commitment to the Pharmacy Choice Five Steps Program: buy better, improve layout, ramp up marketing, train for better results and streamline operations.

DUIT

watchdog Ken Harvey for failure to sanction non-compliant complementary medicine advertisers in what is termed a "light touch" approach, given that that the TGA believed "low-risk" products required no pre-market

evaluation and trusted sponsors to obey the rules (PD 08 Nov 16). While Harvey had quoted

figures as high as 80% of products assessed had been found to be non-compliant, Complementary Medicines Australia ceo Carl Gibson said TGA Complaints Resolution Panel statistics quoted were "wildly out of date and do not reflect the current situation" (PD 09 Nov).

However, the TGA itself has highlighted the enforcement angle and has indicated an intention to correct the shortfall.

Most other KPIs were described by the Report as "met".

Visit www.tga.gov.au for details.

Celecoxib GI/ safety

CELECOXIB was found to be noninferior to ibuprofen or naproxen with regard to cardiovascular safety but proved superior to both with regard to gastro intestinal (GI) safety, according to a randomised, double blind, prospective clinical trial involving 24,081 patients.

Risk of renal events with celecoxib was also found to be lower than with ibuprofen but not compared with naproxen.

CLICK HERE to access the New England Journal of Medicine study.

Statins are lifesavers

ANTICHOLESTEROL statin medications are saving lives, with patients on higher doses gaining the most benefit, according to a recent "real-world practice" study

published in JAMA Cardiology More than half a million

patients



with atherosclerotic cardiovascular disease and an average age of 69 years being treated with varying doses of atorvastatin, rosuvastatin, simvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin or controls, were evaluated for longevity.

High-intensity statins, namely atorvastatin (originally Lipitor from Pfizer) 80 mg and rosuvastatin (originally Crestor from AstraZeneca) 40 mg, conferred the greatest survival advantage compared with submaximal doses of high-intensity statins.

CLICK HERE to access the study.

PBAC drug summaries

THE Pharmaceutical Benefits Scheme Advisory Committee (PBAC) has posted its Public Summary Documents relating to its Jul 2016 meeting.

Submissions for 45 medicines were addressed and the findings summarised, complete with background information, the clincial place for the drug, comparators, trials and comments from both consumers and sponsors. Visit www.pbs.gov.au for access.



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National antimicrobial plan



ONE Aussie biker must have found it a real pain in the butt trying hide his weapon, literally. Yes, the outlaw gang member had a loaded pistol "secreted

between his buttocks". The gun was uncovered during

a body search conducted by Queensland police after they discovered a handgun in the bikie's vehicle.

Given the location of the hidden revolver, it's a good thing it was wrapped in plastic.

You can see two guns (pictured below). Neither look like a they'd be a comfortable fit!



DIETARY requirements need to be catered for everywhere these days.

This includes the Catholic church where there is now a gluten free Holy Communion option.

Gluten free foods are no longer reserved for hipster cafes, with coeliac Catholics now taking advantage of the church's wheat free offerings.

While Canon Law states that the altar bread used for Holy Communion must be made from wheat and water, common sense is prevailing in many parishes around the word (including Australia) so parishioners with allergies can have their communion and eat it too.

HUMANS and animals will be better protected from the immediate global threat of antimicrobial resistance under the Australian Government's new National plan, developed in partnership with health professionals, research communities, veterinarians and agricultural industries, the Health Department announced.

Deputy Prime Minister and Minister for Agriculture and Water Resources, Barnaby Joyce and the Minister for Health and Aged Care, Sussan Ley, announced the implementation of the National Antimicrobial Resistance (AMR) Strategy 2015-2019 last week, developed with a commitment of \$9.4 million in funding from the 2016/17 Budget.

Ley said this funding will continue work already being done around AMR research and education.

"Antimicrobial resistance occurs when bacteria, viruses, parasites and other disease-causing organisms become resistant to the medicines used to treat the infections they cause," she said.

"A particular focus will be Australia's high use of antibiotics in general practice, which is 20% above the OECD average.

"Bringing prescribing rates down is critical, as high antibiotic use is the number one driver of the increasing resistance to antimicrobials."

The new plan is described as a "One Health" approach in recognition of the fact that human, animal and ecosystem health are inextricably linked, meaning the AMR battle demands attention to all impacting factors.

CLICK HERE to access the AMR Strategy plan document.

Probiotics for AD

ALZHEIMER'S disease (AD) has been extremely elusive to treat but a new randomised, doubleblind controlled trial published in Frontiers in Aging Neuroscience has described a 12 week 60-patient study where probiotics have supported cognitive function and metabolic statuses in these people. CLICK HERE to access the study.

Win with **Dermal** Therapy

This week Pharmacy Daily and Dermal Therapy are giving away each day a prize pack including Dermal Therapy Soap Free Wash, Anti-itch Soothing Cream, Hand Balm and Lip Balm.



Dermal Therapy Anti-itch Soothing Cream calms, relieves and soothers painful, itchy, red or swollen skin. Its unique 3 way action in an intense moisturising base with Colloidal Oatmeal, Canadian Willow Herb and Menthol.

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

Dermal Therapy Anti-itch Soothing Cream relieves itchy,

Congratulations to yesterday's winner, Rayan Nahas from Royal North Shore Hospital.

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Guild

NOMINATIONS are still open for the MIMS Pharmacy Guild of Australia Intern of the Year Award.

The competition aims to highlight the outstanding work and dedication of Guild interns completing the program. The winning intern will receive a \$4,000 travel and education scholarship awarded by MIMS Australia.

The 2014 Guild Intern of the Year Luke Vrankovich said the award inspired him to take his skills on the road as a locum.

"Being awarded the title of MIMS Pharmacy Guild of Australia Intern of the Year and receiving the scholarship, helped secure my attendance at the International Pharmaceutical Federation's (FIP) World Congress in Dusseldorf, Germany," he said.

"Attending the congress definitely opened my mind to the potential of pharmacy on an international scale; especially in regard to research and public and international relations.

The Pharmacy Guild of Australia is proud to support the future of our intern pharmacists through the Intern of the Year award. If you know a Guild Intern who deserves recognition, nominate them now at www. internpharmacist.org.au/mimspharmacy-guild-of-australiaintern-of-the-year-2016.html

You can follow the adventures of The Roaming Pharmacist on Facebook - www.facebook.com/ theroamingpharmacist

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