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Monday 05 Feb 2018

Senate probe ticks TGA bill

Today's issue o<u>f PD</u>

Pharmacy Daily today has two pages of news plus a full page from **PARA'KITO**.

Quad meningitis vax

THE Federal Health Department has announced the addition of Nimenrix, a new quadrivalent meningococcal vaccine, to the National Immunisation Program (NIP) ahead of the next peak meningococcal season which is expected to take place in the second half of the year.

The new vaccine protects against the A, C, W and Y strains of the disease (MenACWY), Minister for Health Greg Hunt said.

"In recent years we have seen a rise in the number of invasive meningococcal cases in Australia," Hunt explained.

"In 2017, there were 382 cases reported nationally, compared with 252 cases in 2016 and 182 cases in 2015...deaths associated with meningococcal have also risen, with 28 deaths in 2017, compared with 11 deaths in 2016 and 12 deaths in 2015," he added.

Currently, infants aged 12 months are given a single-strain Meningococcal C vaccine.

The announcement today follows the decision earlier last week by PBAC to recommend the listing of Nimenrix for infants aged 12 months of age.

In Mar the Pharmaceutical Benefits Advisory Committee will also consider the listing of a MenACWY vaccine for adolescents.

The Department of Health has created a public awareness posting at campaigns.health.gov.au. THE Senate Community Affairs Legislation Committee has completed its review of two key Bills relating to the Therapeutic Goods Administration, and urged that they be passed into legislation.

The Senate referred the Therapeutic Goods Amendment (2017 Measures no. 1) Bill 2017 and the Therapeutic Goods (Charges) Amendment Bill 2017 to the committee in late Nov, with the final report delivered on Fri.

Key provision of the bills support the implementation of recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation (the MMDR Review) - including significant changes to the advertising regulation of therapeutic goods.

There's also a new assessment pathway, allowing sponsors to provide self-assessment and certification of the safety and quality of products.

As well as recommending that the bills be passed, the committee suggested that the government ensure the TGA continues to carry out "comprehensive, appropriate and timely consultations with industry and key stakeholders". The TGA was also urged to

investigate ways to better support

Biosimilar awareness

THE TGA has posted a report around the evidence related to the Biosimilar Awareness Initiative, based on a University of South Australia comprehensive literature search and review on the subject. See the report at health.gov.au. the functioning of self-regulatory models by industry, "including the potential for further strengthening of the penalties regime if needed".

Adequate resources for the TGA were also recommended by the committee, so the organisation "is able to carry out its surveillance and monitoring functions in relation to advertising compliance".

The outcome of the inquiry was welcomed by Complementary Medicines Australia, with ceo Carl Gibson saying he hopes all stakeholders will respect the recommendations and support the legislation's passage.

"There is much good in the bill. "If you really support increased research in complementary medicines then you should get behind the bill and support it, because the new Registration Pathway will drive the evidence base for our sector," he said.

GSK, RB bid for Pfizer

PFIZER has confirmed there are only two bidders remaining for its consumer products division, with GlaxoSmithKline and Reckitt Benckiser still having their hats in the ring, according to a *Bloomberg* report in the US on the weekend.

Brands up for grabs include Advil, ChapStick, Centrum and more, with GSK and RB set to gain access to Pfizer's data room to begin due diligence before submitting final offers in the next few weeks.

The deadline for non-binding offers for the business was 01 Feb, with the deal estimated to be worth US\$15-\$20 billion.

PARA'KITO promo

PARA'KITO is offering a 10% discount on a range of popular insect repellent products, with the deal valid for purchases to 28 Feb.

The environmentally sensitive items include wrist-bands, clips, kids bands and refills - for details see **page three**.

New registrations, generics & biosimilars

THE Therapeutic Goods Administration (TGA) has posted details around eight new or extended uses of registered medicines as well as new generics.

The products listed with broader listings are Roche's Alecensa (alectinib hydrochloride), Shire's Vyvanse (lisdexamfetamine dimesilate), Revlimid (lenalidomide) from Celgene, BMS' Orencia (abatacept), MSD's Keytruda (pembrolizumab), Saxenda and Victoza (liraglutide) from Novo Nordisk and Novartis' Afinitor (everolimus).

The TGA also listed one new biosimilar (Hadlima from Samsung Bioepis AU - an adalimumab biosimilar) and nine new generics including many forms of tadafil for erectile dysfunction, lower urinary tract symptoms and benign prostatic hyperplasia - tga.gov.au.

Prenatal microbiomes

MOTHERS taking antibiotics during pregnancy may increase by up to 20% the risk of infants being hospitalised through the impact on microbiomes, according to research by the Murdoch Childrens Research Institute and Denmark University.







THE health and safety of American football fans has been assured, with the help of several thousand litres of oil.

Today sees the annual season culminate in the Superbowl spectacular, with the New England Patriots taking on the Philadelphia Eagles.

In Philadelphia apparently they celebrate in a somewhat dangerous fashion, by climbing up telegraph poles to shout their delight to the world.

Police have stepped in to protect the citizenry in case the Eagles win, with the *Philadelphia Inquirer* reporting that officers were out yesterday slathering hydraulic fluid onto light poles to make them too slippery to climb.

The move follows a promise from the city's police commissioner who vowed to ensure the safety of fans, "as well as the people they could fall down on".

TIMING really wasn't on the side of a recent New York lottery winner, who used some of his winnings to pay for a long-delayed visit to the doctor only to be told he had terminal cancer.

Newsweek reports on the sad tale of Donald Savastano, who won US\$1m in the "Merry Millionaire" game and at the time told reporters he planned to buy a new truck, pay off some debt and invest for the future.

"Being a self-employed carpenter I didn't really have a plan for retirement," he said.

However during the doctor's appointment he was told he had stage four cancer in his lung and brain, with the 51-year-old dying just three weeks later.

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Drug prices Trumped?

US PRESIDENT Donald Trump has singled out drug pricing as one of his greatest priorities followed hotly by the opioid crisis in his State of the Union address.

"Prices will come down," Trump stated unequivocally, striking fear into the hearts of big pharma companies around the world, fully aware of the knock-on effects that such a move could have on global pricing.

Without being too specific, Trump indicated he would target a stronger switch to generics as part of the measure, echoing preelection promises.

Ibuprofen pregnancy

IBUPROFEN taken in the first trimester of pregnancy may harm the future fertility of baby girls according to an *ex vivo* study published in *Human Reproduction*.

The study found taking ibuprofen for 2-7 days during the first three months may impact the store of eggs in the ovaries of baby girls.

The researchers said there was a need for further investigations on "the cellular and molecular mechanisms that underlie the effect of ibuprofen on fetal ovary development" - **CLICK HERE**.

Australian Self Medication Industry (ASMI) Regulatory and Legal director, Steve Scarff, said in response, "OTC ibuprofen has a well-established safety profile and a long history of safe use in Australia and around the world for acute pain and fever."

Moreover, ibuprofen, "like all other medicines, should only be used during pregnancy under the advice of a healthcare professional," Scarff said.

Wizard Pharmacy win



A WOMAN from Hervey Bay in Queensland now has 11,000 more reasons to love her local pharmacist after winning Wizard Pharmacy's major membership prize.

Jessica Burton, 19, signed up for a loyalty card after popping into a Wizard Pharmacy in Pialba before forgetting all about it.

That was until she recently received a call to say she had won \$11,000 as part of the pharmacy's Christmas Cash Giveaway. "I just thought it can't be right,"

Burnett said.

"I've told friends and family; they don't believe it's true".

She was officially handed her winning cheque by pharmacy staff at the Stockland Hervey Bay store this week, joined by her elated partner Tom O'Neill and sevenyear-old sister Olivia.

When asked how she would spend the cash prize, Burnett said she would not fritter it away on the typical avenues like shopping and holidays, instead she is wisely opting to put the money away for a house deposit.



Welcome to PD's weekly comment feature. This week's contributor is Debbie Capuano,



Recruitment Consultant at Raven's Recruitment.

What is the heart and soul of pharmacy?

I BELIEVE the heart and soul of every successful pharmacy - community or hospital - is undoubtedly its people.

Unfortunately, it's a stark truth that we speak with pharmacy staff every day who feel undervalued by their employers and are looking to leave for this reason.

There are pharmacy owners who have appealing values, positive work culture and a willingness to invest in their staff. These are all aspects of a business which are real drawcards to attract the best talent.

If you want people with passion, drive and a shared sense of purpose to join your team and help build your business, can I suggest that you evaluate your business values and culture for starters?

If you're not sure how you're going, perhaps do a survey of your current people letting them know you will value their feedback and won't hold it against them in any way. That would certainly be a daring and bold move, but one for which I believe you would be respected for.

It's a tough market with not enough well-skilled, motivated people, so this could be the most valuable thing you could do today for your business. Not only to attract good people, but also to keep those you already have on board.

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