



## Dengue vax trial

**JAPANESE** pharmaceutical giant Takeda has announced the enrolment of over 20,000 children and adolescents in a global Phase 3 trial of the company's new vaccine candidate for dengue fever.

The Tetravalent Immunisation Against Dengue Efficacy Study (TIDES) will evaluate the efficacy of two doses of candidate vaccine TAK-003 administered three months apart, to protect against all four strains of dengue virus regardless of previous exposure.

## NZ reconsiders codeine

**AUTHORITIES** in New Zealand have confirmed that the country's Medicines Classification Committee will consider whether codeine based medicines should become prescription only.

The item is set for discussion at the next committee meeting on 16 May, with the move following the controversial TGA decision in Australia which will see medicines with codeine move to S4 from 01 Feb next year (**PD** 20 Dec 16).

NZ's Medsafe regulator has prepared a range of options for the committee to consider, including moving codeine to prescription only or maintaining the status quo.

The discussion paper includes the rationale of the Australian decision, with the agenda item suggesting investigation of the possibility trans-Tasman harmonisation of codeine regulation.

The organisation also cited NZ addiction specialists who had indicated there were persistent

problems with the abuse of OTC codeine products.

The previous committee meeting recommended a review of the relationships between the Australian and NZ markets, the role of codeine in cough and cold products and whether the benefit of its use outweighs the risk of harm - [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

## Eccentric exercise

**CONTRARY** to intuitive understandings, walking downstairs appears to have more beneficial effects on the health of obese people than walking upstairs, according to researchers from Edith Cowan University's School of Medical and Health Sciences.

Called "eccentric" exercise, walking downstairs places load on the muscle as it is lengthening as opposed to shortening, said lead researcher Professor Ken Nosaka.

This approach actually helps protect against metabolic syndrome and diabetes, also improving balance, bone mineral density, resting heart rate & blood pressure.

**CLICK HERE** for the study as published in *Medicine & Science in Sports & Exercise*.

## Shortages update

**THE** Therapeutic Goods Administration has advised of extensions to three current and ongoing medicine shortages.

The current medicine shortage for Bactroban (mupirocin) 20mg/g ointment tubes has been extended until 03 May 2017.

To address the shortage another supplier has been granted approval to import an alternative product under section 19A of the Therapeutic Goods Act 1989.

Arrow Pharmaceuticals has also advised the TGA that shortages of anginine and lycinate tablets are expected to continue through until 16 Oct 2017.

Consequently the TGA has again granted approval for the importation and supply of alternative products.

And finally Vepesid etoposide 50mg capsule blister shortages are also now expected to continue until 05 Jun 2017.

Alternative product Etoposide 100mg/5mL is now available.

Advertising regulations around therapeutic goods prohibit **Pharmacy Daily** from publishing details of alternative suppliers of the various products but full details can be freely accessed on the TGA website at [tga.gov.au](http://tga.gov.au).

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## Avoid the Qld water

**THE** Queensland Government is warning South-East Queenslanders to avoid any water activities after tropical cyclone Debbie caused sewerage systems to overflow and become contaminated.

The lower reaches of the Brisbane River and Logan River as well as waters around Moreton Bay and the Sunshine Coast have been said to be effected.

Gastroenteritis, lung, eye, nose, and skin and wound infections and dermatitis have been listed as side effects, according to Dr Heidi Carroll, acting executive director of communicable diseases at Queensland Health.

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## FDA biosimilar guidance

**WHILE** Australia has taken on the relatively simplistic a-flagging policy for biosimilars using the in-situ pharmacy substitution approach used for small molecule generics (PD 04 Apr), the US Food and Drug Administration (FDA) is adopting a more complex approach, releasing its draft guidance on biosimilar interchangeability for consultation, noting that there is "no single data package that will work for all proposed interchangeable products."

The draft calls on companies to use so-called "switching studies" to determine whether alternating between a biosimilar and its reference product two or more times impacts the safety or efficacy of the treatment.

There appears to be some resistance in some of the feedback the FDA has received so far, according to the Regulatory Affairs Professionals Society.

For example the Ohio Public Employees Retirement System (OPERS) described the study requirements as "burdensome"

in terms of the length of time required for review and substantial patient study size", potentially delaying access and increasing costs which will ultimately be passed on to the consumer.

Non-US comparator products are also inappropriate according to the guidelines and there is strong support from the Coalition of State Rheumatology Organizations for using "actual patients" in switching studies as opposed to healthy volunteers.

**CLICK HERE** to access the FDA guidance and the RAPS summary.

### Hepatitis C potential

**AUSTRALIA** has the potential to eradicate hepatitis C in the next 10–15 years, according to Associate Professor Simone Strasser, gastroenterologist at Royal Prince Alfred Hospital in Sydney.

Writing in the latest edition of *Australian Prescriber*, Strasser says that the new oral antiviral treatments for hepatitis C are so effective and well tolerated that 95% of patients will be cured with a short course of treatment.

With the PBS availability and a wide prescriber base that includes GPs, new cases will become rare - in turn reducing the incidence of liver disease, liver cancer and the need for liver transplantation.

It is estimated that 82% of the 227,000 people living with hepatitis C in Australia have been diagnosed - but many still are not aware of the implications, Strasser warns - see [nps.org.au/australian-prescriber](http://nps.org.au/australian-prescriber).

### Nucala AusPAR

**GLAXOSMITHKLINE'S** Nucala (mepolizumab) is the subject of a new Australian Public Assessment Report (AusPAR) by the Therapeutic Goods Administration as a new biological entity.

Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in patients aged 12 years and over.

Access the AusPAR at [tga.gov.au](http://tga.gov.au).

### Staff accused of fraud

**TWO** workers at a pharmacy in Hong Kong are facing a fraud conviction after allegedly charging a tourist from the Chinese mainland HK\$50,000 for two bottles of menthol drops.

The items were normally priced at HK\$30 each, with the pair making various claims about how the error occurred, including accidentally entering additional zeros into a credit card machine.

A lawyer for one of the defendants told the court his client had committed the 2015 crime to please his employer.

The pharmacy, located in Mong Kok, has since been closed.

### Protecting vax turf

**ONE** day after the Department of Human Services announced it was formally inviting pharmacies to apply to become vaccination providers under the new Australian Immunisation Register (AIR) (PD yesterday), the Immunisation Coalition has launched its #HitMeWithYourBestShot campaign in what could be interpreted as an effort to protect the GP immunisation business.

Campaign spokespeople include Dr Robert Booy of the Influenza Specialists Group who last month erroneously claimed pharmacies were offering 2016 vaccines.

More altruistic rationale supports the campaign at [flusmart.org.au](http://flusmart.org.au).

### Donor rego grants

**THE** Federal Government has opened applications for \$473,000 in Community Awareness Grants, in order to support initiatives to boost the number of registered organ donors in Australia.

Minister for Aged Care, Ken Wyatt, said the funding was available to support community-based activities that promote awareness of the Australian Organ Donor Register and encourage Australians to register online.

"Only a third of Australians aged 16 and over have joined the national Register, despite 81% believing that registration is important," he said.

Applications are open for registration drives and supporting activities to be held during DonateLife Week 2017 (Sun 30 Jul-Sun 06 Aug) or for other targeted community awareness and education activities to promote organ and tissue donation.

Applications close at 10am on Thu 27 Apr - [www.donatelife.gov.au](http://www.donatelife.gov.au).

### Superstar wanted

**NOMINATIONS** are now open for the Pharmacy Guild of Australia/Maxigesic Pharmacy Assistant of the Year Award (PATY), which recognises and celebrates the 'best of the best' in community pharmacy.

Nominations close 26 May - see [pharmacyassistants.com](http://pharmacyassistants.com) for info.

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#### Jobs of the Week

- Retail Manager** - Inner Sydney Suburb, QLD (Job# 200013951)  
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- Pharmacist** - Murray Region, VIC (Job# 200013838)  
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## Dispensary Corner

### INTO fizzy drinks and into coffee?

A company based in Nelson, New Zealand, may have created your favourite new drink- RAD Cold Brew Coffee - which is a combination of coffee brewed from African beans and lightly carbonated sparkling water

The coffee is left to soak for 10 hours cold so it doesn't get a bitter taste, the creators said, with the beverage then reduced to a concentrate before being watered down with the fizz.

The first 4,000 bottles were produced last week, with each pop said to contain just over a double-shot of coffee, "perfect for a hot day when someone wants more than a milky beverage to quench their thirst".



**SKINCARE** maker Nivea has been forced to withdraw an online advertisement because it was interpreted as being racist.

The ad (pictured) was for a deodorant and showed a woman with the tag line "white is purity".



After being posted on Nivea's Middle East Facebook page the ad quickly garnered accusations of racism - but was also shared by accounts which had previously posted content promoting white supremacist views, with the company quickly taking it offline.

## iNova bids below expectations

**VALEANT** Pharmaceuticals is reportedly "weighing its options" for iNova, its Australian subsidiary, after final bids in a sale process for the business (**PD** 23 Sep 2016) have come in much lower than the \$1 billion expected.

The *Australian* is reporting the offers came in around \$900 million, with bidders including private equity firms as well as trade buyers including Mundipharma and Stada.

Valeant is currently in the process of trying to divest itself of more than US\$8 billion in assets.

iNova markets a range of OTC and prescription medicines in Australia and New Zealand, with brands including Diffiam and Nyal as well

as Bausch & Lomb and Duromine.

The company also acts as the sales, marketing and distribution agent of the Pharmacy Guild of Australia's Gold Cross brand.

Valeant paid about \$700 million when it acquired the business (**PD** 22 Nov 2011) from private equity firms Archer Capital and Ironbridge.

## Poor web prescribing

**BRITAIN'S** Care Quality Commission (CQC) has issued formal reprimands to several online health sites, highlighting several cases compromising patient safety.

The CQC cited one example in which a doctor associated with one service took as little as 17 seconds to review patient questionnaires, while in another case a site called Frosts Pharmacy Ltd was found to be dispensing large quantities of asthma inhalers without checking if a patient's diagnosis was confirmed, the *BBC* reports.

In a further example, White Pharmacy Ltd was prescribing high volumes of opioid-based painkillers without a system to confirm patients' medical histories.

## NZ bulk paracetamol

**NEW** Zealand's Pharmaceutical Management Agency PHARMAC has announced the funding of bulk dispensing packs of the country's most prescribed medicine, paracetamol, from 01 Jul 2017.

The new bulk packaging enables pharmacists to take advantage of new robotic technology efficiencies, PHARMAC said - **CLICK HERE**.

## WIN WITH DESIGNER BRANDS

This week Pharmacy Daily and Designer Brands are giving away their NEW Escape Collection Cosmetic Bag Trios.



Stay organised, and accessories in style with Designer Brands 3 Piece Cosmetic Bag Trio. Perfect for storing all your beauty needs, these 3 compact beauty purses are the ideal size to pop in your handbag for on the go necessities. Available in 2 great



shades, Onyx and Crimson, these bags are also perfect for gifting! TIP: Use the handy clear purse to grab what you need quickly. **CLICK HERE** to see more.

To win, be the first from VIC or TAS to send the answer to the question to [comp@pharmacydaily.com.au](mailto:comp@pharmacydaily.com.au)

Which purse in the cosmetic bag trio is great for grabbing what you need quickly?

Congratulations to yesterday's winner, Melanie Sykes-Bridge from the Pharmacy Guild of Australia.



## 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](mailto:info@pharmacydaily.com.au).

**29-30 Apr:** Victorian Pharmacy Conference 2017; Monash University, Parkville; register here: [www.psa.org.au](http://www.psa.org.au)

**21 May:** 2017 PSA WA Annual Seminar; Pan Pacific Perth; register here: [www.psa.org.au](http://www.psa.org.au)

**4-5 Jun:** Naturally Good Expo; ICC Sydney; pre-register for free or \$30 at the door - details here: [naturallygood.com.au](http://naturallygood.com.au)

**16-18 Jun:** ConPharm 2017; Hotel Grand Chancellor, Hobart; find out more: [www.aacp.com.au](http://www.aacp.com.au)

**28-30 Jul:** PSA17; Hyatt Regency, Darling Harbour, Sydney; for details see: [www.psa17.com](http://www.psa17.com)

**5-9 Aug:** Medici Capital Pharmacy Snow Business Conference 2017; Mt. Buller, Victoria; register your interest here: [www.medici.com.au](http://www.medici.com.au)

**1-3 Sep:** Pharmacy Connect; Hilton Hotel Sydney; register here: [www.pharmacy-connect.com.au](http://www.pharmacy-connect.com.au)

**26-28 Oct:** Pharmacy Assistant National Conference; QT Gold Coast; for details see: [www.pharmacyassistants.com](http://www.pharmacyassistants.com)

**16-19 Nov:** Medicines Management Conference 2017; ICC Sydney; details tbc: [www.shpa.org.au](http://www.shpa.org.au)

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