

## Indications under fire

A PROPOSED new TGA list of permitted indications for complementary medicines has been blasted as “bizarre” and “not supported by scientific evidence” in a major *Fairfax* report today.

The indications are part of the Therapeutic Goods Amendment bill, with the front page *Sydney Morning Herald* story today accompanied by an opinion piece from health activist Ken Harvey.

Health claims highlighted include “tonifies kidney essence” and “opens body orifices,” with almost all of the particularly offending claims related to Chinese traditional medicine usages.

Critics say the extensive list, with more than 1,000 indications, is “misleading, potentially harmful and based on pseudoscience,” the report states, citing TGA Advertising Complaints Resolution Panel chair Allan Asher as saying “The TGA held industry consultations and lost the plot; it gave them a licence to deceive”.

If the legislation is passed complementary medicine sponsors will only be able to draw from the list of permitted indications when registering and labelling products.

The report also quotes RACGP president Dr Bastian Seidel saying the TGA “should not endorse wannabe indications that are not based on science, logic or common sense...its role is to protect the public from made-up claims”.

Consumer group CHOICE is calling for mandatory disclaimers saying the claims are “not accepted by most modern medical experts”.

## New Vic pharmacy rules

THE Victorian Pharmacy Authority (VPA) has warned of significant changes to approval processes for new pharmacy premises, including consideration of cases where there may be “undisclosed proprietary interests or undue influence”.

The measures are seen as likely to impact on pharmacies launching under a range of strongly-branded franchise groups such as Chemist Warehouse, Ramsay Pharmacy and others, involving “increased scrutiny of pharmacy business commercial arrangements”.

Applications will be assessed on a case-by-case basis, and those initially assessed as high risk - involving complex and technical commercial arrangements or having apparent gaps in supplied documentation - to be referred to

a monthly meeting of the Authority for further consideration.

The committee then may refer these applications to external lawyers, accountants or auditors.

The VPA has warned the new processes may result in increased costs to licensees as well as extended processing times.

Guidelines on pharmacy business commercial arrangements are currently being developed, with further details available this month.

“The Authority will continue to assess franchise agreements for compliance with the ownership and undue influence provisions of the Act progressively on a risk basis,” a VPA communiqué said yesterday.

## SafeScript regulations

THE Victorian Government has released the details of proposed new legislation governing the operation of the state’s SafeScript real-time prescription monitoring system (PD 20 Oct 2017), with input from stakeholders sought.

SafeScript is being developed by Guild offshoot Fred IT, with funding of \$29.5 million and expectations it will roll out from later this year.

All 58 medicines will be covered by the system as well as other high-risk medicines, with a planned 18 month phase-in period before SafeScript becomes compulsory.

For more information on the system see [health.vic.gov.au](http://health.vic.gov.au).

## Malaria drug review

THE US Food and Drug Administration has granted Priority Review Designation for a new drug to help prevent malaria.

Tafenoquine from 60 Degrees Pharmaceuticals was developed under a cooperative agreement with the US Army, and offers a weekly dosing regimen for malaria prophylaxis.

## New data breach laws

MOST community pharmacies in Australia will be subject to new legislation on “data breaches” when the laws come into effect on 22 Feb 2018, after being passed by Federal Parliament this week.

The *Privacy Amendment (Notifiable Data Breaches) Bill 2016* means the Australian Information Commissioner and people compromised by any ‘eligible data breach’ must be notified.

Businesses that fail to report a breach face fines of up to \$360,000 for individuals and \$1.8 million for organisations.

The law applies to data breaches where there is unauthorised access to or disclosure of personal information, or a loss of personal information held by an entity; that is likely to result in serious harm to one or more individuals; and that the entity has not been able to prevent the risk of serious harm with remedial action.

The Pharmacy Guild says it will be providing further information to support members with their obligations under the new laws in the coming weeks.

More details at [oaic.gov.au](http://oaic.gov.au).

## Pain alternative?

THE compounding pharmacy sector may have a “gentler, non-addictive answer” for sufferers of chronic pain, according to National Custom Compounding (NCC), which is highlighting the benefits of palmitoyletanolamide (PEA).

Described as a “curious old compound,” the endogenous fatty acid amide is the subject of a paper published in the *Journal of Pain Research* which outlines several case studies where PEA significantly reduced the level of pain experienced by long-term chronic pain sufferers, NCC said.

The company said PEA is currently classified as a food product and an “unscheduled supplement” by the Therapeutic Goods Administration - [customcompounding.com.au](http://customcompounding.com.au).

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## Dispensary Corner

**TYPICALLY**, providing medical advice to pregnant women doesn't extend to the colour of the snacks they are eating, however one mum from England thinks maybe it should.

Emelia Jackson, 23, is obsessed with gorging on spicy Cheetos, a habit she is convinced delivered her newborn son's fiery red hair. "Throughout my pregnancy, flaming hot Cheetos were all I ever wanted...I'd even wake my boyfriend up in the middle of the night to go get me some because the cravings were so intense," an orange-faced Jackson said.

The chip addict even went so far as to pose in a bath full of Cheetos instead of milk to celebrate the final weeks of her pregnancy.

Medical experts are sceptical about the woman's hair colour claim, however, they remain open to the prospect that the 320 family-sized bags of Cheetos she consumed during the pregnancy made the baby pretty darn thirsty.



**RESEARCHERS** at the University of Queensland recently conducted an online survey of more than 5,000 adults and found that "anti-vaxxers" are more likely to believe in kooky conspiracy theories.

The connection between respondent's vaccine wariness and conspiracy belief was also found to be at its highest in western countries.

## MedAdvisor flu facilitation

**LISTED** medicines adherence specialist MedAdvisor has flagged an enhancement to its PlusOne pharmacy platform which aim to streamline management of flu jabs for the upcoming season.

The new features are also claimed to increase demand for flu vaccinations from customers, helping pharmacists leverage data and automation through PlusOne to both promote consumer awareness and simplify the management and recording of immunisations.

The Flu Vaccination Program will be part of the new PlusOne Health Services Hub, described as a "virtual marketplace for health services in pharmacy".

The software is said to allow pharmacies to send health-related messages to targeted customers via the MedAdvisor app, SMS or email, and then use the integrated

booking system to manage appointments.

Consumers will be able to book an appointment for a flu vaccination with a single click, with MedAdvisor saying the new feature will be available from next month.

"MedAdvisor has a successful track record of providing technology through PlusOne that enables pharmacy to connect with their customers in a simple and convenient way," said MedAdvisor ceo Robert Read.

Pharmacies that are already part of the MedAdvisor network can register their interest by **CLICKING HERE** - for more information see [www.medadvisor.com.au](http://www.medadvisor.com.au).

## Cost consultation

**THE** Therapeutic Goods Administration has opened a public consultation on its current good manufacturing practice (GMP) fees and charges.

Proposed new arrangements aim to improve the accuracy and transparency of cost recovery arrangements, and "address a significant under-recovery over the past four financial years".

The consultation closes on 05 Mar 2018 - see [www.tga.gov.au](http://www.tga.gov.au)

## Bipolar 1 approval

**LUNDBECK** and Otsuka have welcomed the approval of Abilify Maintena (aripiprazole once-monthly long-acting injectable) for the treatment of bipolar 1 disorder.

The new indication is in addition to Abilify Maintena's previous approval for schizophrenia.

## Guild Training New Year • New Units • New Training Package



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\*Eligibility criteria apply. RTO (0452). All information correct at time of publication (FEB 2018)

## Tax win for CVS

**US PHARMACY** giant CVS has confirmed a US\$1.2b profit windfall from the tax reforms introduced by President Donald Trump.

The company said it would use some of the proceeds to boost its minimum wage for staff and also offer a paid parental leave program.



## Events Calendar

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If you have an upcoming event you'd like us to feature, email [info@pharmacydaily.com.au](mailto:info@pharmacydaily.com.au).

**16-18 Mar:** Annual Therapeutic Update 2018; Fairmont Resort, Blue Mountains; for details and registrations visit: [www.psa.org.au](http://www.psa.org.au)

**16-18 Mar:** Foundation Seminar in Clinical Medication Management; Rydges Sydney; register here: [www.shpa.org.au](http://www.shpa.org.au)

**21-22 Mar:** eMedication Management Conference; Raddison Blu Plaza Sydney; book your spot at: [www.informa.com.au](http://www.informa.com.au)

**3-6 May:** APP 2018; Gold Coast Convention and Exhibition Centre; find out more and register at: [www.appconference.com](http://www.appconference.com)

**27 May-8 Jun:** 43rd PSA Offshore Refresher Conference; San Francisco; travel information and registrations at: [www.psa.org.au](http://www.psa.org.au)

**30 May - 1 Jun:** National Medicines Symposium (NMS) 2018; National Convention Centre, Canberra; registrations now open: [www.nps.org.au](http://www.nps.org.au)