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## New RAPS reference

**THE** Regulatory Affairs Professionals Society has published the eighth edition of its essential reference book on US Food and Drug Administration requirements.

*Fundamentals of US Regulatory Affairs* has been updated with the latest information around pharmaceuticals, medical devices, biologics and other healthcare products intended for the US market, with new content including coverage of the 2012 Food and Drug Administration Safety and Innovation Act.

There are also new chapters on pharmacovigilance, health technology assessment and companion diagnostics.

The reference is available both in print and as an e-book for US\$249.95 for RAPS members, or \$309.95 plus shipping for non members - see [raps.org](http://raps.org).

## GMiA urges policy shift

**THE** Generic Medicines Industry Association, under its newly minted chairman Mark Crotty (**PD** Mon), has issued its election manifesto, urging the next government to promote and encourage the uptake of generic medicines as a way of delivering substantial savings to the national economy.

The document says the PBS is an investment in providing universal health care to all of Australia, adding that: "the Government must stop the practice of dismissing this important health subsidy scheme as a burden on taxpayers."

The GMiA points out that its members provided 35.4% of the volume of the PBS in 2011/12, for only 12.4% of the ex-manufacture sales figures, meaning generics gave "real value for money".

Key actions urged by the GMiA include providing patient incentives to increase the uptake of generics, with an estimate that if just 4% of branded products on the PBS were moved to generic medicines the savings would amount to over \$200 million every year.

The association is also urging an incoming government to redress the current imbalance in the intellectual property system, with generics currently being "inappropriately delayed" due to patent extensions.

And finally GMiA is urging support for the domestic generic medicines industry, which creates 2,400 skilled jobs, through "urgent taxation and industrial relations reform".

## Swisse CHC sponsor

**SWISS** Wellness has been announced as the major sponsor of the Complementary Healthcare Council of Australia annual conference, which will take place in Sydney 03-05 Sep.

Swisse ceo Radek Sali said the firm was a "passionate supporter of the complementary medicines industry...our approach to keeping customers happy is to follow our principles, deliver with passion and focus on people, all supported with science and research".

The conference theme is 'evolution or revolution: the future of complementary medicines'.

## Access ARTG via TGA

**THE** Department of Health and Ageing has announced an upgrade of the TGA website to include information from the Australian Register of Therapeutic Goods (ARTG) in search results.

Search results on the TGA website are now divided into 'ARTG results' and 'TGA website results'.

Pharmacists can now search for product names, active ingredients, AUST L numbers, AUST R numbers, sponsors and manufacturers to retrieve data from ARTG entries.

For all other information from the TGA website, you can continue to search using other keywords.

A search for ARTG results will display the three most recent ARTG entries relating to the product; from there you can go to more results from the ARTG, view an individual record, which also provides a direct link to the ARTG public summary, utilise the advanced search function or see what has been added to the ARTG in the past 2, 7, 14 or 31 days.

The search is updated nightly.

The ARTG results have not been modified, and people familiar with the eBusiness portal can still access and search the ARTG directly.

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## Antibiotic points

**NPS** MedicineWise has published new practice points for pharmacists to help people using antibiotics take them for the optimal duration, so that they treat their infection but help prevent antibiotic resistance.

NPS clinical adviser, Dr Philippa Binns, said the continued overuse and misuse of antibiotics means that one day the vital medicines may become ineffective.

"One way to stop the progress of antibiotic resistance is to minimise the duration of therapy where possible, and assist patients adhere to the intended duration," she said.

"To help patient adherence, we hope that pharmacists will reinforce the duration of antibiotic therapy according to the doctors' instructions," Binns added.

She said patients can also be advised to return unneeded antibiotics to the pharmacy.

The *NPS Direct* article 'Duration of antibiotic therapy and resistance' which deals with the issue is at [nps.org.au/antibiotics-how-long](http://nps.org.au/antibiotics-how-long).

## Win with Q.R Health this cold and flu season



Every day this week *Pharmacy Daily* is giving ten lucky readers the chance to win a Quick Response Health™ prize pack containing QR Defence and QR Immunity.

Suffering from a cold or flu? Need a boost this Winter? Try a great tasting EFFERVESCENT drink of:

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For more information go to [www.quickresponsehealth.com](http://www.quickresponsehealth.com).

To win, be one of the first 10 people to send in the correct answer to the question below to: [comp@pharmacydaily.com.au](mailto:comp@pharmacydaily.com.au).

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## Travel Specials

**WELCOME** to *Pharmacy Daily's* travel feature. Each week we highlight a couple of great travel deals for the pharmacy industry, brought to you by *Cruise Weekly*.

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**HELEN** Wong's Tours has reduced prices on a range of its trips to Asia, including a \$600 per couple saving on selected group tours to China and \$500 off for Vietnam holidays.

A 12-day China Discovery itinerary now costs \$3690 per person twin share including Cathay Pacific flights from Australia, while a 12 day Glimpse of Vietnam starts at \$3200.

Both bargains are available for bookings made and paid in full by 30 Aug, for travel from Feb 2014.

For details see your travel agent or call 1300 788 328.

**FANCY** heading off the beaten track?

MIAT Mongolian Airlines has released special fares from Australia to Ulan Baatar in Mongolia, starting from about \$1530 return in economy class.

Flights operate using partner airline Cathay Pacific, connecting through Hong Kong to MIAT's new 767-300ER services which fly twice a week to Mongolia.

Business class fares start at about \$5,350 on the same route - see your travel agent.

**MSC** Cruises is offering an 18-night *MSC Magnifica* transatlantic voyage from just \$1750 per person - that's only \$45 per day!

The itinerary takes in ports in Brazil, Spain, the UK and Germany and departs on 29 Mar 2014, with a second person in the same cabin paying just \$1 plus port charges - [msccruises.com.au](http://msccruises.com.au)

## TGA urged to revise KPIs

**THE** Therapeutic Goods Administration should expand the scope of its Key Performance Indicators, "in order to determine whether the business processes reforms are delivering outcomes for therapeutic product suppliers".

A submission to the TGA by the Australian Dental Industry Association (ADIA) welcomes the TGA's commitment to increased accountability and transparency.

However "greater emphasis needs to be on benchmarking outcomes of interest to industry," the ADIA said, adding that current KPIs identified by the TGA largely measure the agency's administrative performance.

"TGA needs to generate further measures that benchmark the knowledge of, and compliance with, the regulatory standards for therapeutic products among its stakeholders," the submission said.

"From ADIA's perspective, the TGA's objective in preparing quality

performance information is to inform stakeholders and decision makers of the extent to which TGA resources are being used efficiently and effectively, in order to competently administer the legislation for which the TGA is responsible," said ADIA ceo Troy Williams.

Williams said that data which provides guidance on familiarity of the regulatory standards for the approval of therapeutic products amongst those that must comply with them "would allow government to assess the reasons for the ever-increasing illegal imports" - see [adia.org.au](http://adia.org.au).

## Amgen a great place

**AMGEN** Australia featured last week in 16th place on the Business Review Weekly annual 50 Best Places to Work in Australia listing.

The company says it's the only pharmaceutical firm to be included.

## DDS pedal pushers support MS



**DISCOUNT** Drug Stores cofounder John Clark took his wife Sharyn, daughter Casey and 42 other riders along with him to compete in the annual MS Brissie to Bay Bike Ride (above).

It was DDS' third year of participation and its biggest team yet, with the group raising \$5,000 for research into multiple sclerosis during the 23 June event.

Four of the Discount Drug Stores

riders competed in the 25km course, 31 did 50km and ten braved the 100km journey.

"Being in the healthcare industry, we've seen how MS can take its toll and wanted to help in any way we could to give sufferers some form of relief," Clark said.

Other DDS charity efforts include year-round fundraising for Assistance Dogs Australia and Free to be Kids.

## DISPENSARY CORNER

**THE** latest move in the fight against tobacco addiction is new cigarette packets that play recorded messages urging smokers to quit, which have been created by researchers at Stirling University in the USA..

The packets play audio clips giving warning messages about the dangers of smoking when they are opened.

The recordings warn of the link between smoking and fertility as well as a helpline number to help smokers quit.

They are said to have worked well during tests carried out on a group of women aged 16 to 24.

Crawford Moodie, part of the team who invented the packs, said: "Tobacco companies may use talking packets in the future as part of marketing.

"This research shows how the idea can be used to promote 'positive health' to smokers."

**VIRTUAL** weight loss can help with the real thing, according to a study published in the Journal of Diabetes Science and Technology in which female "avatars" - online representations of women - were found to help them lose weight.

The researchers selected eight women, who each expressed an interest in using one of the electronic characters, to take part in the four-week avatar study.

The study was led by Melissa Napolitano of George Washington University.

Watching their avatar engage in positive activities apparently inspired the participants to lose weight in the real world.

During the study, participants lost an average of 3.5 pounds, according to the findings.

The hope is that by bonding with their avatar, people will be encouraged to make longer-term life changes.

Napolitano said that they were excited by the "potential of this technology as a scalable tool to help people learn the skills to be successful at weight loss".