

Risk consultation

THE TGA has opened consultation for its Risk Management plan Guideline - see www.tga.gov.au.

Rosuvastatin claims

ASTRAZENECA has made patent infringement claims against Apotex in relation to its rosuvastatin molecule, following Federal Court action by the latter aimed at having AstraZeneca's 5 mg and 10 mg rosuvastatin dosing patent revoked. "It is important to note that AstraZeneca has no patent protection over the rosuvastatin molecule in Australia," a statement from Apotex said.

"Instead, AstraZeneca is seeking to rely on some secondary patents. "Apotex is confident that it does not infringe any of those patents and that it will prevail in this litigation," the statement added.

In its claim, AstraZeneca is seeking to obtain an injunction to prevent Apotex offering for sale or selling its rosuvastatin product.

The Federal Court hearing over the issue is now set for 31 January 2012, however in the meantime AstraZeneca is also seeking a short term injunction to be heard by the Federal Court next week.

"Challenging bad patents is an investment Apotex is prepared to make so that it can bring important products to the market, with long term benefits to its customers and their clients," Apotex said.

"Apotex is continuing with its launch plans for rosuvastatin and anticipates PBS listing on 1 April 2012," Apotex added.

What's in store for the TGA

A COMPREHENSIVE package of reforms is set to sweep across the Therapeutic Goods Administration in stages, to enhance the TGA's current processes and ensure that its regulatory framework remains able to adapt to new scientific developments and community expectations.

The reforms are the result of major reviews across various regulatory areas including: communications and stakeholder engagement; advertising of therapeutic products; complementary medicines; medical devices; and promotion of therapeutic goods.

Under the Blueprint, reforms to the TGA's communications and stakeholder engagement will see the TGA give priority to actively engaging with the community and providing improved information and education materials over the next 12 to 18 months, as well as establishing an Australian Therapeutic Goods Advisory Council.

Improvements to the advertising of therapeutic goods will include the creation of a central point for all complaints about advertising, as well as the development of options for broadening the current arrangements for pre-approval of ads to include medical devices and therapeutic goods on TV; and developing a more effective approach to sanctions and penalties for advertising breaches.

To reduce the level of non-compliance by complementary medicines sponsors, the Blueprint has said the TGA will (in consultation with stakeholders)

update, and include in the regulations, the *Guidelines for the levels and kinds of evidence to support indications and claims*.

Other complementary medicines regulatory changes include the amendment of the Electronic Listing Facility to provide increased guidance and cautionary notes for sponsors about the potential consequences of providing misleading or unsubstantiated claims, and eliminate sponsors' access to free text.

In terms of medical devices the TGA has said it will increase the rigor of pre-market regulatory assessment of higher risk medical devices, and ensure an appropriate level of evidential review is undertaken to assure safety, quality and efficacy of these devices.

Changes will also see amendments to the way in which a kind of medical device is included in the ARTG with the requirement for sponsors to nominate product names under each ARTG entry for each kind of medical device, improving the ability of the TGA to facilitate medical device recalls.

Lastly in terms of advertising, the Blueprint said that Government's preference is to maintain an emphasis on self-regulation and that the TGA strongly supports industry's initiative to harmonise codes of conduct to incorporate the industry-led working group's new framework of high level principles.

For more details see www.tga.gov.au.

MA funds dialysis truck

A MOBILE renal dialysis unit funded by Medicines Australia is set to be launched tonight in Alice Springs.

The state of the art \$400,000 truck will be presented to the Western Desert Nganampa Walytja Palyantjaku Tjutaku Aboriginal Corporation and will mean patients from remote communities in the Western Desert who are receiving dialysis treatment at hospitals in major centres can return home from time to time to visit family.

Pharmacy Cricket

PHARMACY Cricket has announced that former test cricket umpire Peter 'Porky' Parker will be the guest speaker at the National Pharmacy Cricket Carnival Trophy Presentation Dinner to be held in January in Mooloolaba.

Parker will also umpire with Associate Professor Margaret Robinson at the National Pharmacy Cricket Carnival final in Queensland on Saturday 28 January.

For more details email hodgsong@bigpond.com.

PD comp winners

CONGRATULATIONS to Kelly Forrester, Symbion; April Pearce, Ayr District Hospital Pharmacy and Debra Prout, AFT Pharmaceuticals, who were the lucky winners of last Friday's Protec competition.

For more chances to win, see page two of today's issue.

Catch the early wave in 2012



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Weekly Comment

Welcome to *Pharmacy Daily's* weekly comment feature.

This week's contributor is **Richard Moore** on behalf of **Nurofen**.



Dosing Accuracy

Current research has found that parents using dosing cups to administer medication to their children are more likely to make large dosing errors than those using droppers, spoons or oral syringes¹.

In infants and small children, even an extra millilitre can represent a significant increase in the recommended dose, making accuracy in measuring medicine a subject of utmost importance.

Reckitt Benckiser is committed to working closely with pharmacists and pharmacy assistants to ensure strategies that reduce errors are available.

For example, Nurofen for Children's easy-dose syringe helps parents measure out the dose accurately and easily from the medicine bottle, and is a practical solution for ensuring young children get the right amount of analgesic.

Training is also available on Reckitt Benckiser's popular online training program, PainPod.

The new PainPod Module 5, called Kids Pain and Fever, focuses exclusively on training pharmacy assistants to recommend the appropriate product for a child's pain and provides guidance on the types of questions pharmacy assistants can ask to help make the best recommendation.

The training is in line with the Quality Use of Medicines principles and on completion of the module, pharmacy assistants earn half an hour of QCPP Approved Refresher Training.

1. Yin HS et al. Arch Pediatr Adolesc Med 2010; 164(2): 181-6.

NPS' new dispensing advice

PHARMACISTS want improvements to both the information and presentation of drug interaction alerts in prescribing and dispensing software, according to an NPS survey.

The survey was designed to gauge Australian doctors' and pharmacists' preferences in relation to content, format and usability of drug interaction alerts in prescribing and dispensing software, and as such looked at survey responses from 219 Australian GPs and 170 pharmacists.

Published in the *Medical Journal of Australia* the results of the survey found that the three most important things GPs and pharmacists would like addressed in drug interaction alerts are: increasing the relevance of drug interaction alerts to practice; improving the format and presentation of drug interaction alerts; and differentiation of drug interaction alerts by severity.

"Health professionals want clearer guidance on the severity and clinical effects of drug

interactions, as well as how to manage drug interactions," an NPS statement said.

"This research has enabled NPS to develop a number of recommendations to improve drug interaction decision support in prescribing and dispensing software," said NPS CEO Dr Lynn Weekes.

"By better meeting the information needs of GPs and pharmacists, software vendors and providers of knowledge bases can help support patient safety and quality use of medicines in practice," Weekes added.

Other findings in the survey revealed that, the vast majority of GPs and pharmacists considered severity, clinical effects and management advice to be mostly or sometimes useful in drug interaction alerts; whilst the most popular drug interaction alert format, favoured by 69% of GPs and 83% of pharmacists, was one with headings and one or two succinct bullet points under each.

ESSENTIALLY INNOXA GIFT GIVING

This week *Pharmacy Daily* is giving five lucky readers the chance to win 2 body packs, valued at \$44.80, courtesy of **Innox**.

Essentially Innox provides 3 mini collections of essential home pamper products for every occasion. Enrich is a luxurious range with scents of Cocoa & Shea Butter. Restore is a calm soothing range with scents of Bora Bora & Sweet Almond Oil. Exhilarate is a

revitalising range with scents of Moroccan tangerine, melon & bamboo.

The prize Includes:

- **Nourish pack:** including Exhilarate mini hand cream 50ml, Restore mini hand cream 50ml, Enrich hand mini hand cream 50ml & Wooden nail brush. All packaged in a complimentary cylinder.
- **Enrich & Nourish pack:** including Enrich Shower Crème 350ml, Enrich Hand Cream 150ml & Shower Cap. All packaged in a reusable mesh bag.



To win, simply be the first person to send the correct answer to the daily question below to: comp@pharmacydaily.com.au.

How many collections are in the Essentially Innox range?

Hint! Visit www.innox.com.au.

DISPENSARY CORNER



IT'S a bird! No, it's a plane! No, it's Espen Fadnes.

A Norwegian man, Espen Fadnes, is claiming to be the fastest man in the world after he jumped from a mountain-top in Stryn wearing a 'wingsuit', and 'flying' at speeds of up to 240kms.

The 1,240 metre drop was captured on a headcam worn by Fadnes as he rocketed towards Stryn fjord, and has so far clocked up 300,000 hits on YouTube, with one user saying "That's not flying - that's falling with style".

EXTRA speedy mobility.

Officials in the UK town of Doncaster have confiscated a mobility scooter which had been converted to travel at speeds of up to 96kms.

Utilising a supercharged 140cc petrol engine go-kart wheels and a large exhaust, the scooter had been reported after it was spotted scaring local wildlife.

"We don't want to stop people having fun and this is obviously quite a feat of engineering, but when they build machines like this they should be used at licensed tracks and not in areas where they annoy others," said local councilor, Cynthia Ransome.

Pharmacy translation

THE Pharmacy Guild of New Zealand has published an updated Pharmacy Translation Kit for pharmacists, designed to help them assist non-English speaking patients more effectively.

The kit features pharmacy related phrases and over 80 words in 11 languages including Māori, Chinese, Hindi, Japanese, Korean, Samoan, Tongan, Arabic, French, Spanish and Thai.

Phrases detailed in the kit include basic greetings, questions about medical history, information about prescriptions, instructions for using medicines and explanations about what medicines are for.

For more info, or to obtain a kit visit www.pgnz.org.nz.