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New IP legislation

MEDICINES Australia has hailed the passage in Parliament yesterday of the new *Raising the Bar* intellectual property bill which introduces a "research use exemption" which will allow scientists to conduct research on patented inventions.

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This week *Pharmacy Daily* is giving five lucky readers the chance to win a **Sukin Skincare pamper pack** valued at \$94.60 each.

Each pack includes: Cream Cleanser, Hydrating Mist Toner, Facial Moisturiser, Botanical Body Wash, Hydrating Body Lotion, Nourishing Lip Treatment, Certified Organic Rose Hip Oil and Purifying Facial Masque.

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

Sukin offers three shampoo varieties, what are they?

Hint! visit www.sukinorganics.com

Congratulations to yesterday's lucky winner **Joanna Campbell** from **Macquarie Hospital**.

Aussie pharma pain pact

ASX-LISTED pharmaceutical researcher QRxPharma has announced a new deal with generics giant Actavis, finalising the legal terms and conditions for the commercialisation of QRxPharma's MoxDuo IR in the USA.

MoxDuo IR is a combination of morphine and oxycodone, and the strategic partnership gives Actavis exclusive rights to commercialise and further develop MoxDuo IR for the US market, while assuming all costs for product launch as well as ongoing marketing and sales efforts in the USA.

Once the product launches Actavis will pay QRx Pharma royalties of up to 30% depending on net sales thresholds, after an initial 3-6 month period where QRxPharma will receive a hefty 50% royalty on US\$150m in cumulative sales of the product.

QRxPharma ceo John Holaday said that with the agreement in place "we are focusing our ongoing energies towards supporting Actavis" in the lead-up to the launch which is expected in the third quarter of 2012.

The Australian firm retains the rights to MoxDuo outside the US, and also owns the New Drug Application and is responsible for manufacturing the product at its outsourced contract producer, DSM Pharmaceuticals.

The letter of agreement gives Actavis an option to negotiate for US marketing and sales rights of another product, MoxDuo CR, a controlled release version of the

product, as well as MoxDuo IV for intravenous administration.

MoxDuo is a patented 3:2 ration fixed dose combination of morphine and oxycodone, and has undergone a successful Phase 3 clinical trial program in which more than 700 patients were treated, in head-to-head comparisons with morphine, oxycodone, Percocet and placebo.

The privately-owned Actavis is based in Europe with offices in a number of countries, and is the world's fourth largest generics maker.

Actavis US ceo Doug Boothe said "we are very optimistic about the opportunity for MoxDuo IR to successfully penetrate the \$2.5 billion acute pain market in the US."

Global device moves

THERAPEUTIC goods regulators from around the world are working towards standardised submission requirements for pre-market assessment of medical devices, with the issue discussed at the recent inaugural meeting of the International Medical Device Regulators Forum.

The conference took place in Singapore, wrapping up earlier this month and included regulators from Australia, Brazil, Canada, Europe, Japan, China, the Russian Federation and the USA.

The next meeting of the Forum will take place in Sydney during September this year, with an Open Stakeholder Session to be held on 26 September.

Guild supply assurance

THE Pharmacy Guild says the industry is working together to ensure ongoing PBS medicine availability, in response to several media reports about possible short supply as pharmacies prepare for the PBS price cuts on 01 April.

In a statement issued yesterday, the Guild said the largest set of reductions in the history of the PBS has created stock management challenges for all pharmacies, wholesalers and manufacturers.

However "many pharmaceutical companies - including some branded medicine manufacturers and virtually every generic medicine company - have risen to the challenge and reduced their prices in the supply chain well ahead of 1 April, to avoid any supply disruption," the Guild said.

"This will ensure that at least a generic version of the around 70 molecules affected by the price drops will have uninterrupted supply," the statement added.

Without this action community pharmacies would have been under more pressure to minimise stock of some products to avoid a major, overnight loss of stock value.

Notwithstanding the stock management issues, the Guild said that community pharmacies will always comply with the legislative requirement that "an approved pharmacist must, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called on to supply as pharmaceutical benefits" - see p2.

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Guild Update

This week's update from the Pharmacy Guild Supply continuity

Community pharmacies and the broader pharmaceutical industry are working together to ensure continuity of supply of important PBS medicines at the time of significant price changes on 1 April.

The Pharmacy Guild is pleased to report that many manufacturers and wholesalers have contributed to ensure uninterrupted supply.

The Guild and community pharmacies place the utmost priority on serving patients' medication needs.

They fully recognise and comply with their ethical, professional and legal responsibilities to maintain appropriate stocks.

The 1 April price reductions create stock management challenges for all pharmacies, wholesalers and manufacturers, but the industry is working together to ensure supply.

The PBS arrangements, across more than 5000 pharmacies around Australia, are part of what makes the PBS the best subsidised medicine scheme in the world.



The Pharmacy Guild of Australia

Advanced practice paper

THE Advanced Pharmacy Practice Framework Steering Committee (APFSC) is inviting comment from across the profession on a new Consultation Paper on Advanced Pharmacy Practice.

The paper outlines a generic advanced pharmacy practice framework in 'Patient Care' which has flexibility to be adapted to other areas of practice such as management and administration.

The generic framework is linked to the profession's competency standards and is intended to be a tool to support the professional development and growth of pharmacists in Australia, according to APFSC chair Dr Shane Jackson.

"We hope the paper will stimulate discussion and debate within the profession," he said.

FDA osteoporosis OK

THE US Food and Drug Administration has announced the approval of the first generic versions of Boniva (ibandronate) tablets, which are administered once a month to prevent osteoporosis in women after menopause.

FDA approval has been granted to Mylan and its subsidiary Apotex as well as Orchid Healthcare for the manufacture of generic 150mg ibandronate tablets.

When the items are dispensed the FDA mandates that a Medication Guide be given to patients and caregivers describing risks and adverse reactions.

"While recognition of advanced practice is likely to be sought by only a small number of pharmacists in the first instance, it is hoped that the framework will be used by those who aspire to achieve advanced performance levels, and for the future growth of the profession and professional roles".

Jackson said the committee is committed to pursuing formal recognition for pharmacists working at an advanced practice level, with the Paper hoped to underpin these efforts.

Submissions are invited by 15 May, with the Consultation Paper now available for download at www.psa.org.au/archives/8467.

Carer counselling

CARERS across Australia will have further access to emotional and psychological support, with Minister for Health and Ageing Mark Butler yesterday announcing that funding had been guaranteed for counselling services for carers for an extra year.

The National Carer Counselling Program (NCCP) and the Carer Information Support Service (CISS) are being funded to the tune of \$7 million, with the programs continuing to be delivered by Carers Australia and its national network of Carer Associations.

During 2010-11 the services provided support to nearly 20,000 carers across the country.

DISPENSARY CORNER



A US man is making his own bid for personal immortality, having created his very own Egyptian sarcophagus, with hopes that he can be mummified after he dies.

89-year-old Fred Guentert from Orlando, Florida has spent the last 25 years making the tomb out of cedar wood, using techniques gleaned from ancient Egyptian designs.

"This has been a great hobby and I am almost finished," he said.

"I do have one last wish before I am placed into the box: that everyone makes sure I am dead before they close it".

CLEARLY the anti-smoking message is taking a long time to filter through in some countries.

An eight year old boy from the western Javanese village of Sin Indonesia is attracting attention this week after he was found to have a pack-a-day cigarette habit.

Child welfare officials have stepped in to order a month of therapy, with the chairman of Indonesia's Child Protection Commission, Arist Merdeka Sirait, saying the boy needed emergency help because his addiction had reached "alert level".

"You can see a dramatic change of behaviour when he doesn't have a cigarette for a while...he acts like he's possessed by evil spirits," Sirait said.

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