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PD comp winners

CONGRATULATIONS to Danielle Bugeja of Blooms the Chemist Kingaroy and Sharon Miller of Mc Crae Pharmacy, VIC, who were the lucky winners of last Friday's U Little Beauty comp.

WIN an [A'kin] Day & Night Duo



Pharmacy Daily has teamed up with [A'kin] this week and is giving five lucky readers the chance to win the [A'kin] Day & Night duo valued at \$79.90.

Experience skin radiance with the [A'kin] Day & Night duo which includes the [A'kin] Rose De Mai, Anti-Oxidant Day Creme and [A'kin] Lavender & Rose, Repairing Anti-Oxidant Night Creme.

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

Name 2 benefits of the [A'kin] Lavender & Rose, Repairing Anti-Oxidant Night Creme

Hint! Visit www.purist.com
Congratulations to yesterday's lucky winner, **Katrina Heck** of **Lowood Guardian Pharmacy**.

Investigation under fire

AUSTRALIAN manufacturer CSL has been hit with a warning letter from the US Food and Drug Administration, over lapses in current good manufacturing practice requirements (CGMP).

The letter stemmed from an FDA site inspection of CSL Biotherapies' facility in Parkville, Victoria, in March this year.

During the inspection FDA representatives noted "deviations from current good manufacturing practice requirements in the manufacture of licensed biological vaccine Afluria and monovalent influenza bulks".

These deviations included CSL's "unsatisfactory" investigation processes of post-manufacturing deviations and adverse events, regarding the adverse febrile reactions that occurred in children in April 2010.

According to the inspectors, CSL had "no documentation of the Adverse Event investigation," contrary to requirements.

The FDA also found there "was a limited analysis of the manufacturing process to determine why there was a substantial increase in Adverse Event reports of fever and convulsions in the 2010 Southern Hemisphere influenza season in comparison to previous seasons".

Other examples of breaks in CGMP noted by inspectors further illustrated issues with the methodology used by CSL to manage its processes and investigations, in particular the fact

that it does not thoroughly investigate problems that are detected.

The letter advised CSL that it needed to address its deficiencies, and that failure to respond within 15 days "may result in regulatory action without further notice" and that "...such actions may include license suspension and/or revocation".

CSL has since responded to the FDA addressing the observations, including details of corrective steps that had already been undertaken as well as further actions underway.

"We will work diligently with the FDA to resolve these GMP issues as quickly as possible while continuing to fulfill our commitments to public health programs in Australia and internationally," said Dr Jeff Davies, Executive Vice-President CSL Biotherapies.

Mutating gonorrhoea

RESEARCH from the Swedish Research Laboratory has found a new strain of gonorrhoea, H041, which is resistant to antibiotics.

"While it is still too early to assess if this new strain has become widespread, the history of newly emergent resistance in the bacterium suggests that it may spread rapidly unless new drugs and effective treatment programs are developed," said Dr Magnus Unemo, from the Swedish Research Laboratory.

SensaSlim delayed

THE controversial court case lodged by SensaSlim against Dr Ken Harvey has been postponed until 15 August, at the request of the plaintiff.

Boostrix approval

THE US FDA has approved Boostrix vaccine to prevent tetanus, diphtheria, and whooping cough in people ages 65 and older.

EMA reviews Multaq

THE European Medicines Agency is reviewing the cardiovascular drug profile of the anti-arrhythmic drug Multaq (dronedarone) approved for use in non-permanent atrial fibrillation patients, following the cessation of the PALLAS study (PD yesterday).

Manufactured by Sanofi-Aventis, the drug was being trialled in patients with permanent atrial fibrillation, however the trial was stopped after the occurrence of severe cardiovascular events in some patients.

The EMA's Committee for Medicinal Products for Human Use (CHMP) started a review in January 2011 of the overall benefit-risk of Multaq following reports of severe liver injury, and as a result of the PALLAS research the review will now be expanded to assess the information contained in the study.

The EMA has said that the CHMP will determine the need for any further action at its next meeting taking place between 18-21 July.

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www.psa.org.au

Guild Update

This week's update from the Pharmacy Guild

The New Pharma program will be officially launched at the Guild's Pharmacy Women's Congress in Cairns, which begins this Friday and continues through the weekend.

New Pharma is a truly unique and innovative online program to assist pharmacists with purchasing a pharmacy.

The program has been designed by industry experts and successful proprietors exclusively for potential pharmacy owners.

The online diagnostic program will help prospective pharmacy owners to avoid the many pitfalls that exist in purchasing a pharmacy and set them on the right track to operating a successful pharmacy business.

Developed by the Guild with the support of Guild Accountants and Meridan Lawyers, New Pharma is an indispensable resource for anyone wanting to buy a pharmacy.

The Guild hopes that the development of New Pharma will see many more pharmacists become owners and prevent situations where young pharmacists are attracted into partnerships where they have little equity or influence in the business.

Sign up now by going to www.newpharma.org.au.



The Pharmacy Guild of Australia

Aussies to be MedicineWise

AUSTRALIANS are set to get an educational boost from their local pharmacy, with the launch of a new NPS MedicinesWise resource kit.

In keeping with the NPS' directive to educate consumers about medicine brand choices, the in-pharmacy resource kits contain point-of-sale materials, counter mats and repeat prescription folders featuring key messages designed to give consumers confidence when making choices between medicine brands.

In addition, the kits contain a detailed brochure created for consumers which provides them with extra information, including how to find and identify an active

ingredient, as well as an NPS Medicines List, to help them keep track of all the drugs they are taking.

The kits will be distributed to pharmacies throughout July and August.

Waterproof hearing aid

AUSTRALIA'S first waterproof hearing aid has been launched this month, titled the Siemens Aquaris.

A break-through for many hearing-impaired Australians, the waterproof hearing aid allows users to wear it whilst showering and swimming.

"With hearing loss affecting one in six Australians and 60 per cent of the population aged over 60, the Aquaris has the potential to be a life-changing hearing aid for many people," said Gina Mavrias, Executive Manager of the Australian Hearing Retail Network.

For more details on the Siemens Aquaris visit www.hearing.com.au.

Pfizer sues Apotex

PFIZER has initiated legal action against Apotex over the latter's plans to market a generic version of the nerve-pain therapy Lyrica.

Pfizer's Lyrica patent is due to expire in 2018, and in its lawsuit the drug giant claims that a generic version would infringe on this patent and that the company would "be substantially and irreparably harmed" by an Apotex generic.

OxyELITE Pro warning

THE Therapeutic Goods Administration is warning Australians of the presence of the prescription-only Yohimbine in OxyELITE Pro capsules.

Sold over the internet and marketed as having super thermogenic (weightloss) properties, OxyELITE Pro is not approved by the TGA, and supply of the tablets is illegal.

Yohimbine is not approved for supply in any registered medicine within Australia, and can pose serious health risks for people with underlying risk factors.

As such, the TGA is advising Aussies who have purchased OxyELITE to cease use and discard any remaining product.

DISPENSARY CORNER



SIZE was no obstacle.

A tiny two-year old dachshund named Cherry has beaten the odds and managed to find her way home after being dog-napped.

Cherry was on a trip to Warsaw from Sochaczew in Poland with her owner, Edyta Kowalska, when a car pulled up and forcibly took Cherry away.

Fearing the worst Kowalska reported the theft to police but was given little hope of ever seeing Cherry again.

Five days later Cherry trotted, bedraggled and skinny, back down Kowalska's backyard path, 56kms from where she was dog-napped.

EXERCISE for love.

A Chinese man, Liu Peiwen, has walked 1,000 miles hoping to win the hand of his girlfriend, Ling Hsueh, who loves the band The Proclaimers.

According to reports, Liu was prompted into action after Hsueh jokingly told him that she would only accept his proposal if he walked 1,000 miles (as in the Proclaimer's famous chorus).

"The distance from here to her hometown in the Guangdong province, in southeastern China, is 1,600 kilometers - which is exactly 1,000 miles," he said.

"When I get there I hope she is waiting for me and I will ask her again - and I hope she says yes".

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