



Monday 11 Oct 2010

Weekly Comment

PHARMACYDAILY.COM.AU

Abbott withdraws sibutramine

Welcome to Pharmacy Daily's weekly comment feature. This week's contributor is Vanessa Law. General Manager at healthlinks.net.

The evolution of the CMI

IN June 1995, the first electronic CMIs were distributed to pharmacies on floppy disk, and the pharmacist was required to load the disk and perform a CMI Update, which, depending on your computer at the time, might have taken a couple of hours.

Nowadays, most software vendors distribute CMIs electronically, usually with monthly drug updates, and you don't even realise the CMIs are updated each month.

Shortly, CMIs will be available to pharmacies in real time, ensuring the CMI printed is always the most current version.

CMI Evolution is not limited to distribution.

Accessibility to CMIs has been significantly improved, and CMIs are now available in multiple outputs, including standard and large print PDF; html; audio; and the provision for Braille.

The same utility that enables CMIs in real time at the point of dispense will also enable pharmacists to select the CMI output that best suits the needs of the individual, be it a print document, an email link to the audio, or an electronic request to Vision Australia to print the CMI in Braille.

In the current age of technology, you might ask what's next for CMIs.

A mobile friendly version of www.medicines.org.au that allows an individual to view the CMI or listen to the audio on their mobile phone?

Well, that's only a couple of weeks away..



AUSTRALIAN pharmacists will cease to receive any more supplies of Abbott's weight loss drug Reductil (sibutramine) after the manufacturer voluntarily withdrew the therapy from the market.

The withdrawal follows close consultation with the Therapeutic Goods Administration, over the final results of a major study titled the Sibutramine Cardiovascular OUTcomes (SCOUT) study.

The study, six years in the making, involved 10,000 participants and was requested by European regulatory authorities as a post-marketing committment to evaluate cardiovascular safety in high-risk patients.

According to the study's final results, overweight and obese patients taking sibutramine had a higher rate of cardiovascular events than patients who managed their weight through diet and exercise alone.

The study's preliminary results, released in November last year, indicated a higher risk of cardiovascular events in patients taking sibutramine, and prompted the TGA "reinforce its existing [PI] advice" to shorten the maximum duration of therapy and strengthen the criteria for ceasing treatment, pending the study's final results.

Today, Abbott released a statement contending that under the current labelling and prescription regulations, most of the study's participants would, in Australia, have been ineligible to receive Reductil.

"Sibutramine was approved in Australia for weight loss in patients who are either obese or overweight, have no previous history of cardiovascular disease and have been unable to lose weight through diet and exercise," the statement

Merck scores top marks **GERMAN** pharmaceutical

company, Merck Serono, has scored a top ten position in the best biotechnology industry employer category, by the peer-reviewed publication Science.

2,444 individuals participated in the "top ten" survey, ranking companies on 23 characteristics incl. leadership and direction, work culture/environment, intellectual challenge and corporate image.

continued.

"Abbott's evaluation of the SCOUT study does not change its assessment that sibutramine has a positive benefit/risk profile when used appropriately in the approved patient population," the statement added

The TGA has however posted comment on its website saying that "the increased risk [of cardiovascular events in patients taking the drug] is not significantly different across various patient subgroups in the study, including the subgroup that most closely approximates the approved use of sibutramine in Australia.

"Although it has to some extent been possible to address emergent safety signals through modifications to the PI, it remains unclear whether the safety of sibutramine is acceptable even in those who respond to the medicine," the TGA added.

Patients in Australia currently taking Reductil are now advised to cease their usage and consult with their GP over other weight-loss avenues, and in turn GPs are also being advised to stop issuing prescriptions for the drug.

Abbott has also set up a toll free number where patients and healthcare professionals can seek advice on 1800 225 311 - or by visiting www.sibutramine.com/ Australia.

MEANWHILE following the study's final conclusions, the European Medicines Agency has also suspended its sibutramine approval, and in the USA Abbott has also agreed to voluntarily withdraw its Meridia sibutramine product.

"Meridia's continued availability is not justified when you compare the very modest weight loss that people achieve on this drug to their risk of heart attack or stroke," said John Jenkins, director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research. "Physicians are advised to stop

prescribing Meridia to their patients and patients should stop taking this medication.

"Patients should talk to their health care provider about alternative weight loss and weight loss maintenance programs," he added

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Slimming secrets

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THE US Food and Drug Administration has issued a warning over Slimming Beauty Bitter Orange Slimming Capsules, which contain sibutramine.

According to the FDA the product's use of sibutramine is not included in its labelling, and could cause harm to consumers, particularly those with cardiovascular conditions.

"FDA lab tests reveal that the product contains excessive amounts of sibutramine that may be dangerous to people who have a history of cardiovascular disease, because it can lead to elevated blood pressure, stroke, and heart attack," the Agency said.

Currently a popular internet weight-loss drug, sold by Beautiful Health Inc (formerly LL Health and Beauty) the product contains false labelling which claims it to be "100% herbal".

According to the FDA the company has also been known to distribute sample packets of the drug which indicates that it is a "vitamin and calcium capsule" suitable for use in people aged two years and up.

Anti-ageing cordyceps

RECENT research released by LifeGen Technologies and Nu Skin Enterprises have linked anti-ageing effects with a property (Cs-4) found in a Chinese mushroom Cordyceps sinensis.

According to researchers Cs-4 was found to help reset youth gene clusters in mice that affected cellular mitochondria (the energy factories of the cells) to behave in "more youthful expression patterns" in skeletal muscle and brain tissue.

Pharmacy Daily **Pharmacy Job** of the Day!

Jobs4Careers is Australia's leading source for pharmacy jobs ... click here to find out more and see the Pharmacy Daily Job of the Day ...





How many products are in the Pamper Kit?

Email your answer to: comp@pharmacydaily.com.au

The first correct entry received will win!

Hint: Visit www.dbcosmetics.com.au

THE Generics Medicines Industry additional data table to back up its statement that the current level of non-price benefits as a proportion of total benefits provided to pharmacy by its members is less than 1% (PD Fri).

Having drawn industry heat over its lack of supporting evidence for the 1% figure, a table in a GMiA submission to the ACCC last week shows that in 2009 its members Alphapharm, Sigma (generics only), Apotex, Hospira and Ascent provided non-price benefits as a proportion of total benefits to pharmacy of less than 1%.

However it's likely that the controversy will continue, with no breakdown of the the 1% figures provided except to say that they are from "member declarations"

GMiA said the figures, cited from the Pharmaceutical Benefits Pricing Authority's Annual Report for the year ended 30 June 2009, prove unequivocally that "non-price

WIN AN ORGANICS PAMPER KIT

Certified Organics are great and even better when buying them in a gift set, the perfect Christmas present for all ages.

This week **Pharmacy Daily** is giving readers the chance to win an Organics Pamper kit one of the great gift bags from the NEW Organic Collection.

Designer Brands Organics provides intense moisturising protection for hair and skin, leaving it soft and supple for complete head to

toe hydration. With the launch of Designer Brands Organics, certified organic skin care no longer means having to pay the price for purity. This paraben-free, urea-free, SLS-free, artificial colour-free range is certified organic, dermatologist tested and is biodegradable. Good for you and the planet!

Based on the healing and nurturing power of organic Aloe Leaf Juice, this is beauty without boundaries when it comes to skin and hair loving benefits and affordability.

For your chance to win, simply send through the correct answer to the daily question below:

GMiA backs up its own 1% Pharmacists has announced one of its five themes headlining its 36th Association has provided an

benefits provided by members of GMiA are of immaterial financial value and directed at the enhancement of pharmacy services and / or building a business relationship between the supplier and the pharmacist.

Just one click away from keeping up to date v the breaking news as it comes to har

"As such this is not a major factor in a pharmacy's decision to use a particular brand of product.

"Just as importantly, the relationship between the supplier and the pharmacy does not influence or change the type of generic medicine dispensed and therefore there is little or no impact on the patient," the Association added.

Non-price benefits figuring in the 1% calculation, according to GMiA's members included stock replacements for expired items, QUM programs, access to tools designed to increase generic substitution, training and educational events for pharmacists/ pharmacy assistants, pharmacy aids e.g. prescription holders and patient information sheets, cooperative merchandising, T-shirts, conference sponsorship, dinner/ lunch/breakfast meetings and small value items such as coupons, vouchers and movie tickets.

The Association said the ACCC has as yet failed to identify any detriment which would possibly arise from its membership making "educational events" available to pharmacists.

"It is unacceptable for the ACCC in exercising its statutory duty under the TPA, to ignore the valid and highly relevant arguments which GMiA have made to the ACCC about this issue [of public detriment through the provision of non-price benefits]," the Association said.

"In GMiA's view the ACCC must specifically and directly address GMiA's arguments in relation to the lack of any public detriment arising from educational events... rather than falling back on the tired refrain of "transparency" as the sole justification for an unnecessary and onerous condition," the Association added.

Medicines Australia has also made a further submission saying it remains of the view that reporting benefits to pharmacists is appropriate, regardless of the amount.

CORNER

50 CENT may halt traditional drugs. eBlockwatch, a South African community policing group has approached controversial rap artist '50 Cent' to become the following two horrific poaching

According to reports the rhino was shot a total of nine times by poachers in two attacks this year, mirroring nine bullets taken by 50 Cent from rival gang members prior to his rise to fame.

"We want to ask him if he wants to become the godfather of our rhino so that he can create awareness worldwide about rhino poaching," said Andre Snyman of eBlockwatch.

Snuman told reporters that to protect the rhino after the first attack, her owner removed her horn, however poachers returned soon after to shoot her and dig out the stub from her skull.

Despite its current highly endangered listing, poaching of black rhinos in South Africa has doubled this year from 122 to 227, a trend which experts are blaming on the rise of the use of its horn in traditional medicines in China and Vietnam.

If 50 Cent agrees to be her champion, the black rhino will be named One Pound, due to her having a much fuller figure than the rapper.

SCIENTISTS to solve bigfoot mystery. A group of Chinese scientists are currently seeking financial aid in order to investigate 400 sightings of a bigfoot-style creature roaming the mountains of Hubei.

Although no conclusive proof has ever been found of the existence of the two-metre tall hairy beast, the scientists are drawing on a collection of hair and excrement as well as a footprint collected by explorers in the region in the 1970s and 80s to support their bid. Currently the team are seeking

around \$1.5 in funds, as well as

volunteers from across the world

to join in the hunt.

Godfather of a black rhino, attacks on its life.





MLife goes on: MM

National Conference in November

THE Society of Hospital

Held between 12 and 13

November the conference will

including: expanding roles, the

future of hospital in the home;

pharmacogenomics demystified;

medication management during

residential care; homelessness and

See www.mm2010shpa.com.

Blackmores on Autism

BLACKMORES is hosting a 'Whole

Body Approach to Autism & Related

seminar, featuring Martha Herbert

between 9am-5pm on 17 October

2010 at the University of NSW; call

Neuro-Development Disorders

The seminar will take place

02 9337 3600 for details or to

register visit www.mindd.org.

of Harvard Medical School.

transition from hospital to

its burden of disease; and

"a difficult pill to swallow" -

understanding dysphagia.

feature a series of expert sessions

will be 'Life Goes On'.