

Friday 26 Apr 2013

Nutrition conference

THE third International Conference on the Science of Nutrition in Medicine and Healthcare will be held 03-05 May at Sydney's Sheraton on the Park. Topics will focus on "identifiable and modifiable factors in illness and disease" - CLICK HERE for details.



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Safety net sees PBS yo-yo

A SURGE in pharmaceutical prices seen in the ABS Mar guarter Consumer Price Index is being attributed to the "mechanics of the Pharmaceutical Benefits Scheme safety net".

Medicines Australia ceo Brendan Shaw said the most recent increase follows a 3.5% decline in the Dec 2012 CPI.

"The fall of the pharmaceutical price index throughout the year to December 2012 quarter was largely due to patients reaching the PBS safety net threshold and paying either a reduced co-

Novartis lawsuit

NOVARTIS is once again being sued by the US government, with a civil case filed earlier this week accusing the Swiss drugmaker of causing the US Medicare and Medicaid programs to pay tens of millions of dollars in reimbursements based on fraudulent claims.

The lawsuit alleges that Novartis induced at least 20 pharmacies to switch kidney transplant patients to its Myfortic immunosuppressant drug from competitor medications, in exchange for "kickbacks disguised as rebates and discounts".

"Novartis co-opted the independence of certain pharmacists and turned them into salespeople," said US Attorney Preet Bhahara in New York.

Last year Myfortic sales were worth \$579 million to Novartis, an increase of 12%.

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Statin compliance

payment in the case of general patients, or no co-payment at all in the case of concession card holders." Shaw said.

The first quarter always sees a strong rise in the pharmaceutical component of the index, and he said that in previous years this surge had been incorrectly interpreted by some observers as a result of undue price rises by pharmaceutical companies.

"What it shows is that the safety net is working," Shaw added.

He said the Mar quarter figures also don't include the consumer impact of the 01 Apr PBS price reductions resulting from the MoU betweeen MA and the government.

UK pharmacy move

HEALTH authorities in the UK have been recommended to expand a pilot program of so-called 'healthy living pharmacies,' in order to reduce GP workloads.

There are currently 478 of the special pharmacies across Britain, offering NHS funded services such as weight management, smoking cessation, emergency contraception and health checks, with 'health champions' available to give advice on a range of issues.

A survey by the Pharmaceutical Services Negotiating Committee found that 61% of patients surveyed about their experiences in one of the pharmacies would have gone to their GP instead for the treatment of minor ailments.

A NEW study backed by US health group Kaiser Permanente has examined the reasons why patients sometimes do not fill their initial prescriptions for statins.

Published in The American Journal of Managed Care, the study gives information about "qualitative evidence on primary nonadherence situations where patients do not pick up their initial prescription".

Researchers interviewed about 100 Kaiser Permanente Southern California members with a new but unfilled statin script.

The "semi-structured telephone interview" found that 63% of respondents did not fill the initial statin prescription because they had "general concerns about taking the medication".

63% also said they wanted to try lifestyle modifications rather than take a medication, while 53% reported a fear of side-effects.

The authors said doctors could improve adherence by better explaining their reasons for prescribing the medication.

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UK enforcement raid

THE British Medicines and Healthcare products Regulatory Agency has seized more than £500,000 worth of unlicensed erectile dysfunction, diet and hair loss drugs in a London raid.

Home Office Immigration Enforcement officers raided a flat in connection with a number of people who had overstayed their visas, and found about 150,000 tablets.

The majority were generic versions of Viagra, while there was also a stash of anabolic steroids.

"The quantity of illicit drugs seized in this raid was incredible," said MHRA Head of Operations, Danny Lee Frost.

He said the drugs were stored and packaged in filthy conditions, and it was believed they were being imported from India and then sold to British consumers online.



Find out what shape you're in as a result of the **April PBS changes** with our Health Check calculator.

For your free check and the chance to discover long term strategies that will protect the profitability of your pharmacy, call us now on 03 9860 3300 or email enquiries@pharmacyalliance.com.au



EMA medicine monitoring **THE** European Medicines Agency has outlined new procedures for additional post-market monitoring

of certain medications. An inverted black triangle will start appearing on the package leaflet of the affected drugs from later this year, to "actively encourage healthcare professionals and patients to report any suspected adverse reactions observed with the medicine".

Medicines subject to additional monitoring include those authorised after 01 Jan 2011 that contain a new active substance, biological medicines for which there is limited post-marketing experience, medicines with a conditional approval, and medicines requiring a post-authorisation safety study.

A medicine can be included on the list when it is approved for the first time or at any time during its lifecycle, and remains under additional monitoring for five years or until the EMA decides to remove it from the list, usually because

studies have further established the safety profile of the product.

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The organisation said the move was "an important deliverable of the new European pharmacovigilance legislation," with the holders of marketing authorisation of medicines on the list required to update the product information to include the new symbol and information by 31 Dec.

Actavis ADHD deal

ACTAVIS has announced a settlement agreement with Shire Pharmaceuticals, resolving patent litigation over Actavis' generic version of Intuniv (guanfacine hydrochloride) for the treatment of Attention Deficit Hyperactivity Disorder

The FDA approved Actavis' version last Oct, and under the terms of the deal Actavis can launch a generic version of Intuniv on 01 Dec 2014. Shire will receive a 25% royalty on Actavis' gross profits from the first six months of sales.

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Macquarie drops chiro

SYDNEY'S Macquarie University says the recent debut of its postgraduate medical school and private hospital has led to a decision to cease offering chiropractic degrees.

Macquarie is proposing talks with other higher education providers about transferring its chiropractic teaching elsewhere by 2015.

Executive Dean of Science, Professor Clive Baldock, said the move was based on a need for the Faculty of Science to build on the university's "recent major strategic investments in research-intensive disciplines such as biomedical science and engineering".

He said the chiropractic area does not meet Macquarie's requirements from a researchintensive perspective, with the uni to issue a Request for Tender relating to the course's transfer.



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New ACMS deadline

THE delegate of the Secretary of Health and Ageing has advised that "due to unforeseen circumstances," the scheduled notice inviting public submissions for the July Advisory Committee on Medicines Scheduling meeting will be published on 01 May, with the due date for comments 30 May.



FIRST aid should be at the ready for a group of British thrillseekers who have launched the UK's first "extreme unicycling" club.

They ride their one-wheeled contraptions down sheer rock faces, with the sport described as "a cross between mountain biking and rodeo riding".

A YouTube video features them in action - CLICK HERE to view.

US President Barack Obama has come up with a great way to dissuade his daughters from getting a tattoo.

Speaking on the NBC Today show yesterday, he revealed the ingenious strategy.

"What we've said to the girls is, 'If you guys ever decide you're going to get a tattoo, then mommy and me will get the exact same tatto, in the same place, and we'll go on YouTube and show it off as a family tattoo," he said.

"Our thinking is that might dissuade them from thinking that somehow that's a good way to rebel," Obama added.

FORGET rosemary as an aid to remembrance - a group of psychologists from Montclair State University in the US state of New Jersey say that memory can be improved simply by clenching the fists.

According to lead scientist Ruth Propper, clenching the right hand for 90 seconds helps in forming memories, while clenching the left improves recall.

The hypothesis is apparently that the fist clenching "activates" specific brain regions which are associated with memory.

Events Calendar

WELCOME to Pharmacy Daily's events calendar, opportunities to earn CPE and CPD points. If you have an upcoming event you'd like us to feature, email info@pharmacydaily.com.au.

30 Apr: Pain Management in Community Pharmacy seminar, ANU Canberra - PSA ACT.

o1 May: Cardiovascular Update and Adherence - full day workshop in Sydney hosted by Guild Clinical - 02 9567 7132.

02-09 May: PSA Offshore Refresher Conference, London more info 1300 139 293.

31 May-o2 Jun: PSA CPExpo, Hordern Pavilion Sydney - see www.psa.org.au/cpexpo.

7-9 June: AACP ConPharm'13, Hilton Hotel Adelaidewww.conpharm13.com.au/.

21-23 June: NSW Pharmacy-National Convention & Exhibition. For details see: www.nswpharmacy-nce.com.au.

5-8 July: Australian College of Pharmacy's Conference and Exhibition, Brisbane - see www.acp.edu.au.

10-14 Aug: Medici Capital Pharmacy Snow Business 2013, Mt Buller Vic - medici.com.au.

o4-o7 Sep: Navigating the Future - Pharmacy 2013: The Pharmacy Management Conference; Sheraton Mirage, Port Douglas; For more details see: pharmacyconference.com.au.

- 19-22 Sep: Medicines Management 2013, the 39th SHPA National Conference, Cairns Convention Centre www.mm2013shpa.com.
- 11-13 Oct: Pharmacy Australia Congress in Brisbane - details www.psa.org.au/pac.
- 14-16 Oct: Global Drug Safety Conference and Exposition, Brisbane - for more details email qldadmin@psa.org.au.

14 Nov: 2013 ASMI AGM, Conference & Awards - see www.asmi.com.au

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Bronchitol phase 3 failure

AUSTRALIAN pharmaceutical research firm Pharmaxis has been dealt a significant blow, with the failure of a phase 3 clinical trial assessing the effectiveness of its respiratory medicine Bronchitol in people with bronchiectasis.

According to an ASX release, top-line results of the double-blind, placebo controlled, randomised trial showed an 8% reduction in exacerbation rates among patients treated with Bronchitol compared with control, "which was not statistically significant".

The result saw Pharmaxis shares hammered, trading at just 15c each, down more than 50%.

The company said that although the study had failed its primary endpoint, "secondary endpoints on efficacy and safety" had been met.

And "the positive trend in the primary endpoint was supported by a number of statistically significant secondary endpoints," the Pharmaxis statement said.

"These included a delay in the time to a first exacerbation, reduced days on antibiotics and improved quality of life".

The 52-week study of 485 subjects was the largest ever undertaken in bronchiectasis, taking place across 84 hospitals in Australia, New Zealand, North and South America and Europe.

Bronchiectasis is an obstructive lung disease characterised by localised, irreversible dilation of part of the lung due to destruction of muscle and elastic tissue.

A polio-free world

THE Global Vaccine Summit held this week in Abu Dhabi has resolved to eradicate polio from the entire world by 2018.

The Global Polio Eradication Initiative has seen "global leaders and individual philanthropists" already pledge almost 75% of the \$5.5 billion cost of the project.

Polio is at its lowest level ever: just 223 cases in 2012 and only 19 so far this year, making a narrow window of opportunity to stop retransmission of the virus once and for all.

Pharmaxis ceo Gary Phillips said that due to the results of the trial the company would not be proceeding immediately with a regulatory submission for bronchiectasis.

However an analysis of the large amount of data collected in the trial suggests that Bronchitol performs better in some patients with high disease burden.

"It seems likely that a clinically meaningful subgroup of Bronchitol patients can be identified to form the basis for discussions with regulatory authorities on approvable clinical trial designs," Phillips said.

Bronchitol (mannitol) is an inhaled dry powder designed to hydrate the lung and restore normal lung clearance mechanisms, and is approved in Australia and Europe for the treatment of cystic fibrosis.

Bronchitol also has orphan drug designation for bronchiectasis in the USA - but does not have US approval for cystic fibrosis.

FDA releases new counterfeit tool

THE US FDA has announced a new public-private partnership to help identify counterfeit or substandard anti-malarial medicines.

It utilises an FDA-developed Counterfeit Detection Device. codenamed CD-3, with participants including the Skoll Global Threats Fund, the US Pharmacopeia, the National Institutes of Health, the Centers for Disease Control and Prevention, and the multi-agency President's Malaria Initiative.

The FDA has signed a letter of intent with Corning Incorporated to refine and improve the tool for eventual manufacture on a larger scale, and in the meantime the handheld CD-3 will be tested on the detection of substandard antimalarial medicines in Africa and parts of Southeast Asia.

The CD-3 illuminates a product with a variety of wavelengths of light to provide a visual comparison of an unverified product with an authentic sample.

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