

Mayne Pharma review

MAYNE Pharma this week confirmed that sales of its Doryx (delayed release Doxycycline) product have been impacted by the "unprecedented strength of the Australian dollar" as well as the repositioning of the product in the lead-up to the introduction of new dosage forms in the USA.

The company says it's confident that FDA approval for the new formulations will be received shortly, and possibly before 30 Jun.

In the meantime it's conducted a review of operations at its Salisbury production site, and identified a number of redundant roles and "other cost savings that will eliminate non-value added activity" with redundancy costs of \$1.1m and ongoing savings of \$2.9m a year.

Mayne also said the European approval process for its Subacap (itraconazole) is still "on track".

New chemo drug changes

THE Health Department has revealed details of new arrangements for the prescribing and dispensing of chemotherapy medicines, which will come into effect from 01 December this year.

The govt says the changes will "achieve greater efficiency" in the use of the medicines.

Under the new system, prescribers will write a dose-specific script for each individual chemotherapy infusion or injection, with the prescriptions taking the form of an order for an amount of a medicine, generally in milligrams.

Approved suppliers will only be paid for the "combination of vials that most cost-efficiently makes the prescribed patient dose".

Payments to approved suppliers will take the form of a series of new fees, including a preparation fee and a diluent fee.

Fees will be payable per infusion, including the distribution or wholesaler fee, which will replace the current wholesale mark-up.

Patients will pay no more than a

single co-payment for the entire duration of a cycle of treatment.

And same day prescribing rules will not apply to these medicines.

Previously proposed changes to the dispensing of chemotherapy medications were strongly opposed by the industry, and eventually deferred by the government until the finalisation last year of the Fifth Community Pharmacy Agreement.

One Touch Verio recall

A CONSUMER level recall has been announced for Life Scan One Touch Verio Blood Glucose Monitoring Systems, with the TGA warning that in some cases patients may not get a blood glucose result.

The TGA says that as of 20 May the manufacturer had received 186 complaints - almost all from Australia - about repeated 'error 2' warning messages when the self-testing systems are used in conditions of high temperature and/or humidity.

The products are supplied locally by Johnson and Johnson Medical, which has today advertised the recall in all States and Territories.

Apparently there's a problem caused by contamination occurring across the Strip Port Connector pins of the meter, due to the use of incorrect solder wire.

The recalled meters were made between Aug-Dec 2010, and patients using the Life Scan One Touch Verio meters are advised to call 1800 543 372 for more info.

Affected meters will be replaced with a working model at no cost.

Four pages today

TODAY'S issue of *Pharmacy Daily* is a special four page bumper edition which is being printed and distributed to attendees at the Pharmacy Expo in Sydney.

Please come and visit our stand at the show, which kicked off at 8.30am this morning and finishes on Sunday afternoon.

Pharmacy Daily is at stand 50, at the back of the hall near the cafe, so drop by and say hello!

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Infertility - the hidden causes is valued at \$24.95, and we have ten copies to give away today.

To win, be one of the first ten *Pharmacy Daily* readers to answer the following question:

Name another book written by Dr Sandra Cabot.

Email your answers as soon as possible to our competition address comp@pharmacydaily.com.au.

Hint: see cabothealth.com.au.



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CPD Calendar

WELCOME to Pharmacy Daily's Continuing Professional Development Calendar, featuring upcoming events and opportunities to earn CPE and CPD points.

If you have an upcoming event you'd like us to feature, email info@pharmacydaily.com.au.

This weekend!: Pharmacy Expo, Darling Harbour Sydney - details pharmacyexpo.com.au.

20 Jun: PPI Guild Roadshow, 6.30pm-8.30pm. The Sebel Cairns; details and registration admin.training@qldguild.org.au.

23 Jun: PPI Guild Roadshow, 6.30pm-8.30pm, Rockhampton Leagues Club; call 03 9389 3013.

23-24 Jun: Workshop - Medication Management Review Stage 1, Parkville VIC admin.training@qldguild.org.au

29 Jun-02 Jul: 9th International Conference on Life Long Learning in Pharmacy, Rotorua NZ - info at www.illpharm.com.

02 Jul: Sexual Health: What Every Pharmacist Needs to Know, NSW Central Coast - 02 9431 1125.

15-17 Jul: Pharmacy Women's Congress, Sebel Cairns - pharmacywomenscongress.com.au

24 Jul: Vitamin D Pharmacy Only Seminar, Sydney Hilton - 1300 650 455.

27 Jul: Vitamin D Pharmacy Only Seminar, Brisbane Hilton - 1300 650 455.

14-18 Aug: Medici Capital Pharmacy Snow Business Conference 2011, Mount Buller, Victoria - www.medici.com.au.

06-09 Oct: PAC11, Melbourne Convention Centre pac11.com.au

13-15 Oct: Pharmacy Assistant National Conference, Gold Coast - pharmacyassistants.com.au

Parliament slams PBS policy

THE pharmaceutical industry's push to reverse the Labor government's cabinet approval policy for new drugs received a boost yesterday with the passing of a motion against the move by Federal Parliament.

The motion said that the listing of new medicines on the Pharmaceutical Benefits Scheme should not be "subject to capricious political interference", and sends a strong signal to the government that voters want to return to a non-political process for new PBS listings, according to Medicines Australia.

The motion "deplores the Government's new policy that despite positive recommendations by the PBAC, all applications for listing will be further scrutinised by Cabinet" and that "listing of medicines can be deferred indefinitely".

Welcoming the stance, Medicines Australia acting chief executive Andrew Bruce said "The Cabinet's decision to block new listings on

NPSA Pfizer analysis

PEAK wholesaler body the National Pharmaceutical Services Association will next week release an Access Economics Report into the impacts of Pfizer's direct distribution model on the Australian pharmacy landscape.

According to a media alert, the report warns that other pharmaceutical companies may follow suit, "affecting patients who rely on their pharmacist for timely access to PBS medicines".

It's part of an NPSA campaign "in support of timely and reliable supply of medicines," with the report to be presented by Symbion ceo and NPSA president Patrick Davies.

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US ADR network

A NEW online system has launched in the US to make it simpler to track adverse drug reactions across the country.

Dubbed RxEvent, it's available to prescribers via integration with a range of online services including electronic health record platforms, as well as directly at RxEvent.org.

American Pharmacists Association ceo Thomas Menighan said APHA was working to ensure the system was available to all US pharmacists.

the PBS has caused a lot of angst among patients, doctors and the Australian medicines industry.

"The Government is bringing politics into clinical decisions where people's health, and indeed their lives, are at stake.

"They are pursuing the political imperative of a Budget surplus and they're using patients' medicines to do it," he added.

The new system puts medicines out of the reach of many Australians, leading to a two-tiered system where only the rich have access to the newest drugs, according to Bruce.

"Australia shouldn't be a country where we can't afford to provide medicines for sick people," he said, adding that it was time Australia reverted to the old system "that has served patients well.

"These are medicines that the expert Pharmaceutical Benefits Advisory Committee has found to be cost-effective and therefore a sound economic investment.

"Few, if any, other areas of government expenditure are subject to the same rigorous economic evaluation," he added.

Bioequivalence guide

THE Therapeutic Goods Administration has adopted a new European Guideline on the Investigation of Bioequivalence..

The TGA has added a note that the EU procedure for abridged applications claiming essential similarity to a reference product within the EU doesn't apply here.

"An application for registration of a generic product in Australia should generally include a bioequivalence study versus a leading brand obtained in Australia," the note states.



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FDA approvals

THE US Food and Drug Administration has approved an infant-specific dose of CREON (pancrelipase) Delayed-Release Capsules to treat exocrine pancreatic insufficiency due to cystic fibrosis.

The agency has also approved a new genetic test, Inform Dual ISH, that will help health care professionals determine if women with breast cancer are HER2-positive and, therefore candidates for the breast cancer treatment Herceptin (trastuzumab).

Also on the FDA's recent approval list is the first ceramic-on-metal total artificial hip system for patients with osteoarthritis, The Pinnacle Complete Acetabular Hip System.

Men need better self-care

AUSTRALIAN men need to start taking better care of themselves, according to the latest findings from the Australian Institute of Health and Welfare.

The *Health of Australia's Males* report looked at attitudes to health issues, rates of injury, illness and mortality and use of health services among Australian men.

Overall, Australian men were found to have good life expectancy rates by international standards, with the Aussie average being 79 years, compared to the OECD average of 76.3 years.

According to AIHW Director David Kalisch this can in part be attributed to the positive lifestyle choices including sport and physical activity, and a continued decline in rates of smoking.

Other good news highlighted by the report is an improvement in the survival rates for testicular and prostate cancer - attributed to better screening, early detection and improved treatments.

On the flip side, the report found Australian men still have a way to go to improve their health, with only 5% of males consuming the recommended daily intake of fruit and vegetables.

About two-thirds of all adult males were found to be obese, along with one quarter of all boys aged between five and 17.

Half of all adult males were also found to have a mental health condition, whilst one-third have a chronic health condition.

Worryingly only 40% of Australian men were found to discuss healthy lifestyle issues with health professionals, despite having higher rates of emergency department visits than women.

'Despite the gains that have been achieved, many Australian men are still at risk, with 4% rating their health as poor,' said Kalisch.

MEANWHILE responding to the report, the Department of Health has announced funding for DIY Male Health Toolboxes, to be sent to Men's Sheds around the country and which contain a combination of health promotion materials.

The Toolboxes will be available from Sep; see www.health.gov.au.

Mothballs mothballed?

AUSTRALIAN experts have renewed calls for a total ban on the sale of mothballs (naphthalene flakes), due to a link between naphthalene exposure and brain damage, disability and death in infants.

The calls come on the back of the Australian Pesticides and Veterinary Medicine Authority's decision to suspend sales of naphthalene flakes for domestic use last week.

One voice rising at the forefront of the naphthalene argument is that of Nick Evans, Associate Professor in Neonatal Medicine at the University of Sydney, who said that the adverse risk/benefit ratio for naphthalene in children, particularly babies, provides strong justification for its total withdrawal.

'In previously unpublished data in the *Medical Journal of Australia* in February we showed that NSW and Victorian poisons agencies each receive at least one call per week about a child exposed to naphthalene,' he said.

'That's probably an underestimate of the true rate of exposure'.

Naphthalene arguments are raging around the world, with the substance now having been totally banned for European domestic use.

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Food/skin connection

FOOD allergies and sensitivities may play a large role in gastrointestinal and skin disorders, according to researchers from the University Teaching Hospital in Pavia, Italy.

The study, *Evaluation of The ALCAT Test results in the non IgE-mediated pathology of the skin*, involved 35 patients and found that an elimination diet based on ALCAT Test results improved symptoms in 97% of patients, with 66% of those experiencing "significant" or "important" improvements.

Tomlinson at KJT

FORMER GlaxoSmithKline Executive Director, Jeff Tomlinson, has signed up with consulting and research company KJT Group as its new Senior Vice President of Research.

In his new role Tomlinson will be responsible for all of the organisation's custom research teams, and will also actively work with researchers in the "application of secondary data to research issues".

FDA sunscreen guidelines

SIGNIFICANT changes to sunscreen labelling are set to sweep across the USA next year, as part of new regulations put in place by the Food and Drug Administration.

The new rules are designed to help consumers decide on how to buy and use sunscreen by clarifying the effectiveness of individual products, and to ensure proper labelling and manufacture, and safety benchmarks are met.

Changes to the current sunscreen legislation will see the a shift from labelling standards which only focused on UVB radiation, to the establishment of a broad spectrum test procedure which measures both UVA and UVB rays.

As such, only sunscreens which pass the FDA's broad spectrum test will be able to carry 'Broad Spectrum' SPF labelling.

Broad spectrum sunscreens with an SPF value of 15 or higher will also be able to claim to reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures, whilst

non-Broad Spectrum sunscreens and Broad Spectrum sunscreens with an SPF value between 2 and 14 can only claim to help prevent sunburn.

In addition manufacturers will no longer be able to make "sweatproof" or "sunblock" claims on their product labelling, because, according to the FDA, these claims overstate their effectiveness.

Labelling must also not claim to offer over two hours worth of protection, or to provide immediate protection unless the FDA has approved these claims based on product data.

Products also cannot claim to be "waterproof", and any water resistance claims on the front of labels must indicate whether the sunscreen remains effective for 40 minutes or 80 minutes while swimming or sweating, based on standardised testing.

Sunscreens that are not water resistant must include a direction instructing consumers to use a water resistant sunscreen if swimming or sweating.

The new rules will take effect by May next year, however the FDA has said "consumers may begin to see changes to sunscreen labels before the effective date".

Australian incontinence

AT present around 4.8 million Australians are living with some form of incontinence, with that figure set to skyrocket to 6.5m by 2030, according to a new report entitled *The Economic Impact of Incontinence in Australia*.

Current incontinence costs to the health system of \$271m per annum are also set to jump to \$450m as the population ages, without clinical advances and new policies designed to combat the increase.

Set to launch during World Continence Week next Mon, the report's authors also found that over half of all current sufferers were aged above 50, with 80% of urinary incontinence sufferers found to be women.

See www.continence.org.au.

DISPENSARY CORNER

PERHAPS an eye check is in order?

Shoppers in China's Guangxi Province were left in a state of shock this week, after a woman, Ziang Zhen, drove down a shopping centre staircase in her bid to find a parking spot.

Ziang told media that she was following signs to the shopping centre carpark when the ground below her car "plummeted and became so bumpy".

Milling shoppers were instantly plunged into a state of panic, with many running for their lives down the stairs to avoid getting squished by the vehicle.

Realising her predicament, Ziang parked her car on the steps, calling a local tow truck company to winch it back to level ground.

The shopping centre has since apologised for its poor signage.

CELLS get carpenter put in a cell.

Trouble began for carpenter Jason Gaspard after he was called to repair a door smashed in during a robbery in East Sussex, UK.

During the course of the job Gaspard cut himself on the glass, leaving a bit of himself on the job after he had finished his work.

Police inspecting the crime scene then took a sample of the blood, and believing it to be that of the perpetrator promptly arrested Gaspard and threw him in prison.

After an hour cooling his heels in a cell police realised their mistake and released him without charge.

WISDOM comes with age.

A 99 year old US man, Leo Plass, has finally completed his teaching degree at the Eastern Oregon University in La Grande, having started it all of 81 years ago.

Plass told local media that he was just one semester short of achieving his qualification in 1932 when the Great Depression forced him to drop out of university and take up a job with a logging company.

He never gave up his teaching dream however, re-enrolling at university a few years ago, and finally graduating this week.

WIN AN INSTANT WRINKLE FILLER



Pharmacy Daily has teamed up with **Plunkett Pharmaceuticals** this week and is giving 4 lucky readers the chance to win an Instant Wrinkle Filler valued at \$39.95.

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Congratulations to yesterday's lucky winner, **Sarah Mross** from **Caringbah South Pharmacy**.