

Apotex recall

THE Therapeutic Goods Administration has advised that Apotex is recalling one batch of APO-Cabergoline 500mcg tablets "due to a packaging issue which could potentially lead to the product degrading over time in moist conditions".

The affected batch is MK0903 with an expiry date of Feb 2017, with the batch number displayed on the bottom flap of the carton as well as on the side of the bottle.

Apotex has written to pharmacists asking them to alert any patients using the product about the issue.

Consumers are being urged to return any tablets from the affected batch to the dispensing pharmacy for a refund or a replacement.

APO-Cabergoline is a medicine used to prevent the production of breast milk in women after giving birth, or to treat abnormally high levels of prolactin - tga.gov.au.

Oct reforms impact 2000

OVER 2,000 brands of medicines will have their prices cut from 01 Oct, in what health minister Sussan Ley is describing as a "win-win for consumers and taxpayers".

Ley confirmed yesterday that one in three medicine brands on the PBS would become cheaper and about 1,600 of the reductions would see a direct saving to consumers because they're priced below the \$38.20 general PBS co-payment.

The rest of the repriced medicines under the PBS Access and Sustainability Package will benefit taxpayers to the tune of almost \$900 million over the next 4 years.

Ley also reiterated a Coalition commitment in Government "that we will list medicines on the PBS without fear or favour if recommended by the independent expert Pharmaceutical Benefits Advisory Committee".



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MEANWHILE Fairfax Media yesterday reported Ley would this week finally release the government's response to the Sansom review of the regulation of medicines and medical devices.

The report said a recommendation that would give earlier access to new drugs before they gain final TGA approval will be adopted.

The independent review report was handed down in Jul last year and it has taken the government over a year to give its response.

Further submissions on parenteral meds

THE Pharmacy Board of Australia has confirmed ongoing discussions with the TGA about draft revisions to the long-delayed *Expiry of compounded parenteral medicines* section of the Board's compounding guidelines.

In a communiqué issued following the most recent Board meeting, feedback received in the Feb-Mar public consultation period has led the Board to identify a range of outstanding issues, and once the TGA discussions are finalised the submissions will be published.



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Always read the label. Use only as directed. If symptoms persist consult your healthcare professional.

ETHB421 - 09/16

The team at Willach wishes to congratulate the PSA Health Destination Pharmacy program on its internationally recognised award



Willach Pharmacy Solutions

Another PATY winner

ESPERANCE pharmacy assistant Bryan Hann from Castletown Chemist will represent Western Australia at the upcoming national finals of the 2016 Pharmacy Assistant of the Year Award.

Hann (pictured) was selected from 15 other state finalists at a workshop last week after demonstrating his pharmacy knowledge and customer service skills.

The finals will take place during the Pharmacy Assistant National Conference on 28 Oct on the Gold Coast.

The PATY awards are sponsored by GuildSuper.



Vale Graeme Douglas

THE New Zealand pharmacy sector is mourning the death late last week of Auckland pharmacist Sir Graeme Douglas, the founder of Douglas Pharmaceuticals which now has more than 450 staff and manufactures a range of products sold in 35 countries.

Raxone orphan

THE Therapeutic Goods Administration has added Raxone (idebenone) film coated tablets as a designated orphan drug.

Raxone is sponsored by TudorRose Consulting, and is indicated for the treatment of Duchenne muscular dystrophy.

CHF urges prevention

THE Consumers Health Forum says it's time for Australia to restore an "effective national preventive health program," saying in contrast to the burgeoning costs of healthcare it would be relatively inexpensive to improve population-wide awareness and action on healthy lifestyle.

CHF ceo Leanne Wells said the low level of health literacy among Australians is often overlooked, leading to "a failure to understand the ill effects of poor diet, failure to comprehend the necessity of taking the right medication, failure to seek counselling at times of mental strain, or worse, failure to seek any form of healthcare at all".

She said improving preventive health programs should be accompanied by strong primary healthcare arrangements, with GPs working with a team of healthcare providers to provide "wrap around" services, particularly for those with complex conditions.

"Better informed consumers will result in better health services," the CHF ceo said.

PPA's review briefing

PROFESSIONAL Pharmacists Australia has met with Stephen King, chair of the government's review into Pharmacy Remuneration and Regulation, to discuss the "important role that employee pharmacists will play in the future direction of the profession," according to PPA president Geoff March.

March said topics on the table included the challenges facing many employee pharmacists such as workload pressures, the tension between retail and healthcare, pharmacy automation, the need for robust accountability measures and the under-utilisation of pharmacists' skills.

He said Professor King urged employee pharmacists to contribute to the review, with the union group collating submissions - redacting any identifiable information - and attaching them to the Professional Pharmacists Australia submission to the review.

Pharmacists wishing to take part via PPA can do so online at professionalpharmacists.com.au.

MIMS

Monthly Update

New Products

Descovy (emtricitabine (FTC) and tenofovir alafenamide (TAF) fumarate) contains emtricitabine (FTC) a nucleoside analogue that inhibits HIV replication through incorporation into viral DNA by the HIV reverse transcriptase, which results in DNA chain-termination. FTC has activity that is specific to human immunodeficiency virus (HIV-1 and HIV-2) and hepatitis B virus. Descovy also contains tenofovir alafenamide (TAF) fumarate, a phosphonamidate prodrug of tenofovir, it is permeable into cells and due to increased plasma stability and intracellular activation through hydrolysis by cathepsin A, TAF is more efficient than tenofovir disoproxil fumarate (TDF) in loading tenofovir into peripheral blood mononuclear cells (PBMCs), including lymphocytes and macrophages. Intracellular tenofovir is subsequently phosphorylated to the pharmacologically active metabolite tenofovir diphosphate. Tenofovir diphosphate inhibits HIV replication through incorporation into viral DNA by the HIV reverse transcriptase, which results in DNA chain-termination. Descovy is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and adolescents aged 12 years

and older with a body weight of at least 35 kg. The patients must not have a history of treatment failure or known mutations associated with resistance to the individual components of Descovy. Descovy is not for use in pre-exposure prophylaxis (PrEP). Descovy is available as Descovy 200/10 mg tablets containing 200 mg of FTC and 10 mg of TAF respectively and Descovy 200/25 mg tablets containing 200 mg of FTC and 25 mg of TAF respectively in bottles of 30's.

MS-2 Step (mifepristone, misoprostol (GyMiso)) contains mifepristone, a synthetic steroid with an antiprogesterone action as a result of competition with progesterone at the progesterone receptors and misoprostol, a synthetic analogue of prostaglandin E1. MS-2 Step is indicated in females of childbearing age for the medical termination of a developing intrauterine pregnancy, up to 63 days of gestation (confirmed by ultrasound). MS-2 Step is contraindicated in the following situations: lack of access to emergency medical care in the 14 days following the start of treatment (i.e. administration of mifepristone); suspected or confirmed ectopic pregnancy;

IUD in place; uncertainty about gestational age; chronic adrenal failure; concurrent long term corticosteroid therapy; suspected or known haemorrhagic disorders or treatment with anti-coagulants.

MS-2 Step is available as a composite pack containing a green carton with one Mifepristone Linepharma 200 mg tablet and a purple carton with 4 GyMiso misoprostol 200 micrograms tablets (two blisters of two tablets each).

New Contraindications

Cordilox SR (verapamil hydrochloride) is now contraindicated in the following situations. Patients concomitantly administered ivabradine; simultaneous initiation of treatment with dabigatran etexilate and oral verapamil; and in treatment initiation with oral verapamil in patients following major orthopaedic surgery who are already treated with dabigatran etexilate.

Ikorel (nicorandil) is now also contraindicated in patients with severe hypotension or with a risk of developing severe hypotension including acute myocardial

infarction with acute left ventricular failure and low filling pressures and hypovolaemia. It is also now contraindicated in patients receiving any soluble guanylate cyclase stimulators.

Solu-medrol (methylprednisolone sodium succinate) is now also contraindicated in the following. The 40 mg Act-O-Vial presentation includes lactose produced from cow's milk. This presentation may contain trace amounts of milk ingredients and is therefore contraindicated in patients with a known hypersensitivity to cow's milk or its components, or to other dairy products.

Truvada (tenofovir disoproxil fumarate; emtricitabine) is now also contraindicated for pre-exposure prophylaxis in individuals with unknown or positive HIV-1 status.

New Indications

Cosentyx (ecinumab rch) is now also indicated for the treatment of adult patients with active psoriatic arthritis when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Cosentyx is now also indicated in the treatment of adult patients with active ankylosing spondylitis.

Truvada (tenofovir disoproxil fumarate; emtricitabine) is now also indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples.

New Presentation

Dysport (botulinum toxin type a) is now available as 125 Ipsen units in vials of 1's. This list is a summary of only some of the changes that have occurred over the last month. Before prescribing, always refer to the full product information.

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Weekly Comment

Welcome to PD's weekly comment feature. This week's contributor is **Catherine Cervasio**, Founder -

Aromababy Natural Skincare.

Choosing a baby massage oil

RESEARCH suggests unscented product in general is best for new babies or those with a family history of allergies. Following the first several months, if parents then wish to use baby massage oil with added aromatherapy benefits, this oil should be a simple formulation, free from additives and artificial fragrance.

There are numerous baby massage oils to choose from, which can become confusing for new parents. A natural product which has a short list of ingredients is best and can help minimise the likelihood of allergic reaction.

The more ingredients present, the higher the risk of an infant being allergic to an ingredient. The oil which makes up the majority of the product will be listed first; jojoba, actually a liquid wax (and of all the natural oils, the one which most closely resembles our skin's sebum) is an ideal primary ingredient in a first massage oil.

A pre-blended product that is unscented (no essential oils or added fragrance) with a simple mix of cold pressed, natural oils such as natural vitamin E or evening primrose oils, may further benefit dry and sensitive skin types. These oils are rich in natural fatty acids & vitamins and can help to moisturise whilst providing a medium for gentle, fluid movement.

The natural vitamin E also helps to prolong a product's shelf life. Store organic oils in the fridge to keep fresh and suggest parents warm a little oil in their hands prior to applying to the skin.



FDA tightens opioid labels

FOLLOWING a review of the evidence, the US Food and Drug Administration (FDA) has announced that it is requiring class-wide changes to drug labelling, including patient information, to help inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines.

Among the changes, the FDA is requiring boxed warnings, (the FDA's strongest warning) and new patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines.

Nearly 400 products are affected and must include information about the serious risks associated with using these medications.

Risks identified by the FDA include extreme sleepiness, respiratory depression, coma and death.

The labelling changes are part of the agency's Opioids Action Plan, which "focuses on policies aimed at reversing the prescription opioid abuse epidemic, while still providing patients in pain access to effective and appropriate pain management".

"It is nothing short of a public

health crisis when you see a substantial increase of avoidable overdose and death related to two widely used drug classes being taken together," said FDA commissioner Robert Califf.

"We implore health professionals to heed these new warnings and more carefully and thoroughly evaluate, on a patient-by-patient basis, whether the benefits of using opioids and benzodiazepines - or CNS depressants more generally - together outweigh these serious risks," Califf added.

The FDA has conducted a data review which showed doctors have increasingly been prescribing these types of medications together, which has been associated with adverse outcomes.

Novo Nordisk ceo

NOVO Nordisk has announced a number of executive changes including the appointment of current head of region China, Pacific & Marketing as executive vp and head of North America.

The company's ceo Lars Rebien Sorensen will also step down from 01 Jan 2017, to be succeeded by Lars Fruergaard Jorgensen.



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Dispensary Corner

BEWARE of English seagulls off their beaks, tripping on acid.

According to media reports out of the UK the scavenging birds have been ingesting formic acid while eating swarms of fire ants.

The acid is said to lower their inhibitions and impact their cognitive abilities.

A gull expert told the *Plymouth Herald* the ants leave the gulls "distracted and excitable" and they forget to look where they are flying.

Odd activities recorded include the gulls stealing food from people's hands, raiding bins and flying into the path of buildings or vehicles.



CONDOMS filled with chilli powder and firecrackers are being used as a slightly unorthodox way of keeping wild elephants away from farmland and villages.

The solution was discovered after conservationists found locals in northern Tanzania were either planting chillies or letting off fire crackers in a bid to deter the animals from their land - as an alternative to spearing the beasts.

Therein came the idea to combine the two solutions in one.

Condoms are being used as casing of choice because they're readily available at the local markets and work well.

The loud bang and powder of chilli smoke is said to frighten the elephant without harming them - whatever works!

WIN WITH SOS SKIN RESCUE

This week Pharmacy Daily and SOS Skin Rescue are giving readers each day the chance to win a family pack including four SOS Skin Rescue Creams and four SOS Lip Balms.

Introducing your family's new must haves: SOS Skin Rescue Cream and SOS Lip Balm. Made in Italy by Farmaceutici Dottor Ciccarelli, since 1821, these protective, healing and soothing products are now in Australia. SOS Skin Rescue has the power to soothe skin irritation and rashes, burns, bites, dry skin and more. SOS Lip Balm provides powerful soothing to dry and chapped lips.

To win, be the first person from NSW or ACT to send the correct answer to comp@pharmacydaily.com.au

In what country are the SOS Skin Rescue and Lip Balm made?

Check here tomorrow for today's winner.



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Postal address: PO Box 1010, Epping, NSW 1710 Australia

Street address: Suite 1, Level 2, 64 Talavera Rd, Macquarie Park NSW 2113 Australia

P: 1300 799 220 (+61 2 8007 6760) F: 1300 799 221 (+61 2 8007 6769)

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Publisher: Bruce Piper info@pharmacydaily.com.au

Reporter: Mal Smith

Contributors: Nathalie Craig, Jasmine O'Donoghue, Bonnie Tai

Advertising and Marketing: Magda Herdzik, Sean Harrigan, Melanie Tchakmadjian

advertising@pharmacydaily.com.au

Business Manager: Jenny Piper accounts@pharmacydaily.com.au

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