Pharmacy DAILY
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Fluarix approved for US

GLAXOSMITHKLINE'S four-strain seasonal influenza vaccine, Fluarix Quadrivalent has received US FDA approval for the immunisation of children (three years and older) and adults to help prevent disease caused by seasonal influenza (flu) virus subtypes A and type B contained in the vaccine.

Fluarix Quadrivalent is the first intramuscular vaccine to cover against four influenza strains.

EMA committs for 2013

THE European Medicines Agency has outlined its 2013 priority as ensuring that assessment activities are conducted to the highest standards of quality, regulatory and scientific consistency.

To this end the EMA has said that a "number of initiatives are taking place to increase the support to the scientific committees and to further assure the quality and consistency of the Agency's scientific outputs".

"These include a review and optimisation of the scientific processes, including the coordination among the committees, and the continuing implementation of the conflicts of interest policies and their monitoring," the EMA added.

AF review sparks new delays

A FIFTEEN month review of *Anticoagulation Therapies in Atrial Fibrillation* has set a stumbling block on the road to PBS listing for new anticoagulant therapies such as Boehringer Ingelheim's Pradaxa, with its recommendation that the PBAC review its previous recommendations of new (or novel) oral anticoagulants (NOACs).

Penned by Emeritus Professor Lloyd Sansom, the review stated that "while warfarin will retain a place in the management of stroke risk in patients with atrial fibrillation (AF), NOACs offer an important clinical benefit in reducing the incidence of intracranial haemorrhages in AF patients who receive anticoagulants and offer patients who are unable to take warfarin an effective alternative".

"However, the net overall benefit of NOACs in clinical practice and the subsequent impact on cost-effectiveness is uncertain at this stage, given the further information about dabigatran use that has become available since the PBAC decision regarding this NOAC in 2011," the review added.

As such, the review recommended that the PBAC consider the establishment of a managed entry scheme for the PBS availability of NOACs which would take into account the identified uncertainties while acknowledging the need for effective alternatives to warfarin.

"In considering a managed entry scheme, PBAC should evaluate the entry price that addresses the uncertainties and what 'fit for purpose' evidence would be required to address these to ensure that acceptable," the review said.

In addition, the review advised the PBAC to consider the PBS listing of NOACs as a restricted benefit for patients unable to tolerate warfarin therapy and/or who are unable to obtain satisfactory INR control despite specific measures.

"There would need to be a definition of 'satisfactory INR control' together with a price–volume arrangement which addresses the risk to the Government of use beyond any restriction," the review said.

The review has unsurprisingly drawn the ire of Boehringer Ingelheim, which responded to the report by saying it "is extremely concerned that a new delay in the form of yet another PBAC review will further postpone patients' access to new treatment options".

"Today is a sad day for many atrial fibrillation patients and their families," the company added.

MEANWHILE the PSA has welcomed the review, in particular its recommendations for shared care and collaboration between health professionals in the management of anticoagulation therapy in patients with AF.

One such recommendation was the use of point-of-care testing for the measurement of INR values, which determine appropriate dosing, as an option for warfarin management, particularly in the community setting.

The report also pointed to the need for the development of resources to improve the health outcomes of patients with AF.

"Pharmacists could potentially become more involved in the identification of people with AF, helping to implement guidelines, educate patients, improve the use of anticoagulant medications and monitor patients," the PSA said in a statement.

Morphine shortage

THE Therapeutic Goods Administration is quelling fears over shortages of morphine, issuing a statement that it has secured an alternative to Hospira's 10mg/1mL injections.

The furor started when the company advised the TGA that an upgrade problem at it's European manufacturing plant was set to cause shortages of the it's morphine 10mg/1mL injections.

The company also told the TGA that it expects the shortages would last up to the first half of 2013.

To offset this issue the TGA worked Hospira, and has now confirmed that it has secured an alternative supply of the injectable morphine from another source.

"We are confident that there will be no shortage of morphine 10mg/1ml injections in Australia," the TGA said in a statement.

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FOBruary campaign

LET'S Beat Bowel Cancer and Bowel Cancer Australia are getting behind Australian pharmacists in a bid to raise awareness about FOBruary 2013.

The initiative urges Australians aged 50 and over to take a FOB (Faecal Occult Blood) Test during the month of February to screen for bowel cancer.

From January 2013, the National Bowel Cancer Screening Program will send an iFOB Test to Aussies turning 50, 55, 60 and 65 only, excluding millions of people.

As such, the duo are urging pharmacists to encourage relevant patients aged 50 and over to purchase a FOB Test.

"Pharmacists will be supported by a national advertising campaign, highlighting the need to do a FOB Test and the options for purchasing a BowelScreen Australia test kit," said Julien Wiggins, Chief Executive, Bowel Cancer Australia.

Pharmacies interested in providing the BowelScreen Australia Program should call 1800 55 65 75 (option 3).

Sigma settlement approved

THE Federal Court has today approved the proposed settlement of the long-running class action brought against Sigma Pharmaceuticals (***PD*** 24 Oct), which will see the company make a $57.5 million payout without admission of any liability.

The case related to claims that the company did not disclose material information to the stock market when it was raising capital, prior to a shock downgrade in the value of its generics business.

According to an update issued this morning, settlement of the action was conditional upon approval by the Federal Court of Australia, and now that this has gone through payment is expected to be made within a week.

"As a result of the Federal Court approval, the settlement payment will now be distributed to class members by Slater & Gordon," Sigma said, with the matter then to come back before the court for Final Orders, including that the class action be dismissed.

Sigma said the settlement payment will be reported as a "material non-recurring item" in its 2012/13 full year results.

MEANWHILE Sigma has also issued a trading update, saying that business in the second half of the year has "continued to be in line with expectations".

Sales have been slightly stronger, which is expected to flow through to gross profit, however consistent with the first half result "logistic costs have been higher than expected".

Sigma also disclosed a recent refrigeration failure at its Newcastle Distribution Centre, which will result in an unbudgeted expense of around $3 million.

The company said that cash at the end of the financial year will be lower, reflecting the payment of the $57.5 million class action settlement as well as its ongoing share buyback program, dividend payments "and some incremental investment in inventory levels to improve customer service levels".

New medical grants

$127.9 MILLION has been announced by the Department of Health, to fund 151 grants for "ground-breaking health and medical research" across Australia.

Grants are being directed to a range of key areas including chronic diseases (cardiovascular, cancer, diabetes, arthritis, asthma and obesity); ageing; mental health; child health and HIV.

See www.health.gov.au.

Poison amendments

THE Poisons Standard Amendment No. 5 of 2012 has been registered on the Federal Register of Legislative Instruments this week.

Changes in the Standard include an amendment to ibuprofen, placing it in Schedule 2 when in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen: in liquid preparations when sold in the manufacturer's original pack containing 8 grams or less of ibuprofen; or in divided preparations, each containing 200mg or less of ibuprofen, in packs of not more than 100 dosage units except when: as the only therapeutically active constituent (other than phenylephrine or when combined with an effervescent agent); packed in blister or strip packaging or in a container with a child-resistant closure; in a primary pack containing not more than 25 dosage units; compliant with the requirements of the Required Advisory Statements for Medicine Labels; not labelled for the treatment of children 6 years of age or less; and not labelled for the treatment of children under 12 years of age when combined with phenylephrine.

Moreover the amended schedule also sees five new entries to Schedule 4: abiraterone acetate, boceprevir, fidaxomicin, ridaforolimus, and telaprevir.

Penflufen and aminocyclopyrachlor have also been added to Schedule 5, with the amendments effective from 01 Jan.

To view the amendments **CLICK HERE**.

WIN A HYDRALYTE PRIZE PACK

Every day this week *Pharmacy Daily* is giving four lucky readers the chance to win a Hydralyte prize pack, valued at $60.

Each prize pack includes 2 Orange Effervescent Tubes and 2 Apple Blackcurrant Effervescent Tubes.

Hydralyte is an oral rehydration solution which is scientifically formulated. It contains the correct balance of electrolytes and glucose required for rapid rehydration.

Hydralyte helps replace water and electrolytes lost due to vomiting, diarrhoea, heavy sweating, vigorous exercise and other dehydrating conditions such as excessive consumption of alcohol or due to a hot and dry environment.

For your chance to win this great prize pack, be one of the first four readers to send the correct answer to the question below.

What formats does Hydralyte come in?

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

Congratulations to yesterday's lucky winners, Lynda Carter from Flinders Medical Centre, April Pearce of Ayr District Hospital, Barbara Wager from The Pharmacy Guild of Australia and Anna Develin from The Pharmacy Guild of Australia.

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Health, Beauty and New Products

Welcome to our weekly feature with all the latest health, beauty and new products for pharmacy!

Suppliers wanting to promote products in this feature should email advertising@pharmacydaily.com.au.

The lashes you always wished you had

Designer Brands pre-glued, self-adhesive, reusable **Lashes** are designed to provide fast, easy, and affordable glam. The handmade lashes are light weight, so they don't sit heavily on your lids, and unlike most adhesive lashes on the market, they do not require glue. They come with an adhesive strip already attached, so that it is simple to remove them from the pack, cut to size and then press on. As an added bonus the lashes come with additional adhesive strips. The Lashes come in several styles ranging in levels of dramatic effect, from Adorable, Tempt, Glamorous, Delicate, Tender, Lofty, Whispering, Charming, to Sunburst and Lovely.

RRP: $8.99
Stockist: 02 9817 8731
Website: www.dbcosmetics.com.au

Purify the party out of your skin

Palmer's Cocoa Butter Purifying Mask is formulated with kaolin clay and sweet almond oil as its base. Kaolin clay is a natural Chinese clay that gently absorbs oil on the surface of skin and helps clear breakouts, whilst sweet almond oil is a non-greasy, super moisturizing, emollient which is rich in Vitamins B1, B6, B2 and E, as well as Omega-9 and Omega-6 fatty acids. With these key ingredients, the mask works to dry and draw out impurities, whilst other ingredients, including shea butter (naturally high in Vitamins A, E and F), and Vitamin E work to nourish the skin.

RRP: $9.99
Stockist: 1300 191 918
Website: www.palmersaustralia.com.au

Lean and mean in 2013

Aminoplex Lean is crafted using high quality protein from wholegrain brown rice with green coffee, green tea, chia fibre, probiotics, digestive enzymes, medium chain triglycerides, l-carnitine, l-glutamine, vitamins and minerals. It is formulated to nourish the body during a weight loss program and is intended to be used in conjunction with a balanced diet and appropriate exercise. Key features of the product include 23g protein per serve, and probiotic strains lactobacillus acidophilus and bifidobacterium lactis to support healthy digestive bacteria balance. The product is vanilla flavoured and is suitable for both vegetarians and vegans.

RRP: $39.95
Stockist: 1300 650 455
Website: www.bioceuticals.com.au

Go underground this Christmas

Estee Lauder's new **Pure Color Violet Underground** is glam rock at its best, offering a line-up of deep, vibrant violet and fuchsia tones. Featured in the collection is a **Pure Color Five Color EyeShadow Palette** which includes a mix of deep violet, crimson and fuchsia powders with pale pink and matte black shade at the center. The powders are formulated using 'tribrid' technology that allows for two finish options: apply wet for a vibrant-chrome charged flash of colour or dry for a subtle shine finish. This is then combined with a cyber-metallic finish that can create a range of daring looks.

RRP: $90.00
Stockist: 1800 061 326
Website: www.esteelauder.com.au

DISPENSARY CORNER

LIVING dangerously.

Russia's Plosky Tolbachik volcano is drawing thousands of thrill seeking tourists, after it erupted.

The volcano which has been dormant for four decades, began to spew forth hot magma, volcanic ash and gases from its underground magma chamber recently, which instead of causing widespread panic across the country, caused a tourism boom.

So fierce was Plosky's wrath that it destroyed a nearby recreational base and set the surrounding forest on fire.

But this was not enough to keep the thrill seeking tourists away, with some vying for the 2012 Darwin Awards by posing for pictures close to lava flows and burning trees.

"It was worth doing it, it's marvelous, incredibly beautiful, you can't express it with words, you should just see it, feel it, touch it with your own hands, it's just great," said one tourist to media after paying to take a trip to the smoking volcano.

DO not rest in peace.

A Swedish inventor, Fredrik Hjelmquist, has debuted an unusual new invention tailored for those that love their music, a coffin with an in-built stereo system.

The CataCombo Sound System is being dubbed as the "perfect gift for music lovers who do not want to rest in peace".

Purchasers of the coffin are able to create their own afterlife play list, which will be streamed into their coffin after they are interred under six feet of earth.

The system includes two-way front speakers, four-inch midbass drivers, tweeters and an-eight-inch subwoofer, and has a 2.1 amp power supply with a cooling system to prevent overheating.

For those that are concerned about disturbing the peace of their resting neighbours, Hjelmquist said that the system is completely soundproof.