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Flu recommendations

THE Australian Influenza Vaccine Committee has agreed to adopt World Health Organisation recommendations for next year's influenza vaccine in Australia.

The components for 2011 have been agreed as A(H1N1)-like strain, 15uG HA per dose; A (H3N2)-like strain, 15uG HA per dose; and B-like strain, 15uG HA per dose.

Cyanokit expanded

THE European Commission has approved a new presentation of Merck Serono's Cyanokit(R).

The new presentation contains the starting dose of 5g hydroxocobalamin in a single vial, for the treatment of known or suspected cyanide poisoning.

"Immediate administration of an emergency treatment on the scene of a fire within the first minutes after rescue is critical for the survival of a smoke inhalation victim," said Merck Serono's Executive Vice President Research and Development, Dr. Bernhard Kirschbaum.

"By simplifying the reconstitution and administration processes, we believe that the new Cyanokit 5 g presentation represents a major improvement, allowing for rapid management of cyanide poisoning, a vital asset particularly when treating more than one victim," he added.

Shire acquires Movetis

BIOPHARMACEUTICAL

company shire has acquired 99.21% of the shares of Movetis NV, a drug developer specialising in treatments for gastrointestinal diseases.

The remaining shares will, according to reports, be "squeezed-out" in an additional tender offer.

FDA biphosphonate alert

THE US Food and Drug Administration has overnight issued a warning about possible increased risks of thigh bone fractures in patients taking biphosphonates.

The FDA has mandated new labelling changes warning about the possible risks of long term use of the osteoporosis drugs.

Medications covered by the warning include oral biphosphonates indicated for osteoporosis including Fosamax, Fosamax Plus D, Actonel, Actonel with Calcium, Boniva, Atelvia and their generic equivalents.

The FDA is also warning about injectable biphosphonates such as Reclast and Boniva, but labelling changes won't apply to biphosphonates used for Paget's disease such as Didronel, Zometa and Skelid.

The warning follows a Drug Safety Communication issued by the FDA in March which announced an ongoing safety review of biphosphonate use and the

occurrence of atypical femur fractures.

The FDA says it's since reviewed all available data including a key report from a task force at the American Society for Bone Mineral Research which recommended "additional labelling, better identification and tracking of patients experiencing these breaks, and more research to determine whether and how these drugs cause the serious but uncommon fractures".

Based on the FDA review the Warnings and Precautions section of all biphosphonate products for osteoporosis will be revised, and the agency has also ordered the inclusion of a Medication Guide "to better inform patients of the possible increased fracture risk".

However the FDA added that patients taking biphosphonates for osteoporosis should not stop using their medication unless advised to by their health professional.

"Those taking biphosphonates should also report any new thigh or groin pain to their health care provider and be evaluated for a possible femur fracture," the FDA alert added.

Natural tinnitus relief

A NEW study published in the *Panminerva Medica* has found a connection between Pycnogenol, an antioxidant plant extract derived from the bark of the French maritime pine tree, and the relief of tinnitus symptoms.

The study involved 85 patients with mild-to-moderate tinnitus in one ear (caused by restricted blood flow in the inner ear).

After four weeks of treatment, researchers found that patients' inner ear systolic and diastolic blood flow velocities had risen significantly, causing a reduction in tinnitus symptoms.

"Publish all trials"

PHARMACEUTICAL

manufacturers should be forced to publish all data from clinical trials rather than just positive findings, according to an article in this month's *British Medical Journal*.

The paper has been written by a team of researchers at the German Institute for Quality and Efficiency in Health Care, who cited a number of examples including Pfizer's Edronax (reboxetine) which has been rejected by the US FDA despite being marketed in Europe.

They say there is unpublished data for the medication, including eight Pfizer trials which the German scientists say show that the reboxetine is no better than placebo in terms of remission and response, and also had higher side effects.

"Our findings underline the urgent need for mandatory publication of trial data," they wrote, with the lack of information meaning regulators are unable to make well-informed decisions.

In the US it is already a requirement that all trial data be published, with the UK MHRA planning to implement this in the coming years.

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

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Congratulations to yesterday's winner, Cathy Campbell, from Hunter New England Area Health Service.

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Wholesaling principles

THE National Coordinating Committee on Therapeutic Goods yesterday released a range of amendments to the draft "Code of Good Wholesaling Practice" taking into account feedback received from the industry during a consultation period last year.

Major amendments include changes to sections 4 (Stock Handling and Stock Control) and section 6 (Management of Complaints, Return of Unused and/or Damaged Goods, and Product Recalls) so that handling of damaged, returned and recalled medicines is included in Section 6.

Section 7 (Management of Records, Documentation and Standard Operating Procedures) now includes a provision that documentation should be adequate to achieve the required standard of recording and control for quarantined stock.

And Section 8 (Cold Chain Medicines) now includes a principle that the cold-chain should be maintained according to the sponsor's recommended conditions in regard to product integrity, as set out on the TGA approved product packaging.

The tga.gov.au update also includes feedback on some submissions relating to such areas as batch tracking, education programs, performance monitoring, and "impact on small businesses/pharmacies".

Submissions made during the consultation period are now available on the TGA website, and the final Code incorporating the changes is set to become effective on 01 April 2011.

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AMA generic disclosure push

THE Australian Medical Association has added its voice to the chorus calling for the Generic Medicines Industry Association Code of Conduct to include mandatory reporting of non-price benefits for pharmacists.

In a submission to the ongoing ACCC enquiry into the draft Code, AMA Therapeutics Committee chair Associate Professor John Gullotta points out that the administrative burden of such reporting should not be onerous, given that "it is already a requirement to report non-price benefits, together with commercial trading terms data, to the Department of Health and Ageing" as part of the price disclosure requirements of the PBS reforms implemented in recent years.

"Given this, there should be minimal additional work involved for GMiA members to report on this as proposed by the ACCC," Gullotta continued.

The AMA said it supports the inclusion of the condition requiring price disclosure on the basis that it

means the public can be "confident the medicine dispensed is in their best interests and has not been unduly influenced, irrespective of the monetary value of the non-price benefits".

Disclosure also "makes transparent the pecuniary interest community has in dispensing medicines," the submission added, pointing out that this applies to S2, S3 and S4 medicines, all of which are supplied by generics makers.

"In the future there should be a move to work towards parity between the GMiA and Medicines Australia Code, including conditions around the supply of gifts, benefits and loyalty rewards, which are prohibited in the Medicines Australia Code," the AMA submission concluded.

Under the terms of an extension requested by the GMiA, the ACCC has extended consideration of the application until 11 Nov, and is expected to deliver its final determination sometime before the end of the year.

Travel Specials

WELCOME to *Pharmacy Daily's* travel feature.

Each week we highlight a couple of great travel deals which we're sure will be of interest to everyone in the pharmacy industry.

VALUE TOURS is offering ski packages on its Big White and Silver Star USA product.

Prices start from \$475ppts for seven nights accom at The Whitefoot Lodge & Condominiums and a four day lift pass.

Silverstar has a Luxury Ski break package priced from \$954ppts inc seven nights accom at the Snowbird Lodge in a Studio Condominium and a six day lift pass - for more details see your travel agent or valuetours.com.au.

BENTOURS is giving its clients savings of 10-20% on its 2011 Hurtigruten cruises to Spitsbergen.

The full discount is being offered on the Svalbard Explorer with the special price of \$5151pp on Aug

departures and the Climate Voyage leaving in Jul starting at \$3087pp.

A discount of 10% is being applied to Kingdom of the Polar Bear; Bears, Islands and Fjords and Polar Encounters tours, when booked by 31 Dec 2010 - more details at bentours.om.au.

AIRASIA has launched a massive seat sale offering one way economy fares on flights from Perth to Kuala Lumpur priced from \$99, or departing from Melbourne and the Gold Coast from \$149 - and other destinations include Bali, China and London.

Fares from Kuala Lumpur to Penang, Langkawi, Kota Bahru, Alor Setar and Johor Bahru start from \$3 - see www.airasia.com.

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DISPENSARY CORNER

THIS won't help stop the spread of the obesity crisis into Asia.

Fast food chain McDonald's has announced that three of its outlets in Hong Kong are now offering special wedding packages.

Burger-crazy couples can now book to host up to 100 of their friends at the eateries, with the reservations effective 01 January.

The deal doesn't include a celebrant who must be supplied by the bride and groom, and attendees will have to make do with Sprite, Coke or Fanta for the toasts because none of the restaurants are licensed.

Special features will include a McDonald's Apple Pie wedding cake for dessert.

A spokesperson for the fast food chain said the move will be extended to more eateries if it's a success.

"Many couples meet or have their first dates at McDonalds.

"That makes it meaningful and memorable to hold a wedding party there," the company said.

IT has probably been difficult to get volunteers to sign up to take part in this clinical trial.

An eastern European research project is using a robot to attack subjects in order to explore robotic understanding of human pain thresholds.

According to the *New Scientist* publication, the research involves a "powerful robot" which has been programmed to "hit people over and over again in a bid to induce anything from mild to unbearable pain".

It's the brainchild of Professor Borut Povse, who said the increasing prevalence of robots means it is important for the cyber-creatures to be taught about human pain.

"Future robots will not work behind safety guards with locked doors or light barriers.

"Instead they will be working in close cooperation with humans which leads to fundamental concern of how to ensure safe physical human robot interaction," Prof Povse wrote.