

Today's issue of PD

Pharmacy Daily today has three pages of news plus a full page from MIMS.

FDA ticks Imbruvica

THE US Food and Drug Administration (FDA) has expanded the approval of Imbruvica (ibrutinib) to include the treatment of adult patients with chronic graft versus host disease (cGVHD) under specific conditions, the first FDA-approved therapy for cGVHD.

Visit fda.gov for details.

Victorian guideline revision

THE Victorian Pharmacy Authority is inviting feedback on new draft guidelines, which specify that where dispensing stations are designed for forward dispensing "there should be at least one additional non-forward dispensing station which is not accessible to the public".

Other proposed changes specify further details of first aid aid couches, and mandate that where a pharmacy undertakes complex compounding, all surfaces such

as walls, benchtops and shelves in the laboratory area must be washable, with the floor to have an impervious cover.

Comments on the revised guidelines are sought by 31 Aug 2017, with the Authority saying it will consider input to the consultation before finalising the new Guidelines for publishing effective from about 01 Oct.

NZ group strong

NEW Zealand listed pharmacy group Green Cross Health says it's not concerned about plans by Chemist Warehouse to launch across the Tasman (PD 18 Jul).

Speaking at the company's agm yesterday, ceo Grant Bai said he believed a discount model would be harder to operate in NZ due to "logistical challenges and already tight margins" but added that "a changing competitor set is a beauty of the retail sector".

The company won't change its model to compete, but is shoring up its proposition by boosting equity stakes in medical centres.

Green Cross operates a total of 354 pharmacies in NZ under the Unichem and Life Pharmacy brands.

Gorilla missed TGA

THE TGA has warned that 'Germany Black Gorilla' tablets pose a serious risk to health and should not be taken, containing the undeclared prescription-only substance sildenafil.

TGA investigations show that a number of people in Australia may have bought the product online.

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RB settles for \$3.5m

NUROFEN manufacturer Reckitt Benckiser (RB) will pay \$3.5m compensation to consumers who, according to their class action, claim to have been misled by the company's Specific Pain range packaging.

The arrangement, managed by Bannister Law, is yet to be confirmed by the Federal Government Court.

A third party will distribute the funds to eligible consumers who purchased the products between 2011 and 2015 in the belief they were buying different products to relieve specific separate pain.

The original fine proposed for RB by the Federal Court was \$1.7m (PD 29 Apr 16) in spite of ACCC and others such as Choice calling for a \$6m fine (PD 13 Apr 16, 21 Dec 16).

RB New Zealand was fined \$1m for its marketing of the Nurofen Specific Pain range (PD 07 Feb 17).

New vision for Early Career Pharmacists



THE Pharmaceutical Society of Australia launched a landmark Early Career Pharmacist White Paper at last weekend's PSA17 conference in Sydney, with the document the result of widespread consultation.

The White Paper (which can be viewed at psa.org.au) makes recommendations to ensure a practical and sustainable long-term plan for Early Career Pharmacists (ECPs) to have "satisfying and rewarding careers while contributing to Australia's healthcare system".

The paper sets out 10 key recommendations, including negotiating to raise the Pharmacy Industry Awards, pursuing alternative remuneration models for pharmacy services, identifying new roles and models of practice for pharmacists, and taking "decisive action to ensure a robust and sustainable community pharmacy sector".

PSA national president Shane Jackson said the ECP White Paper would provide an "exciting, member-driven pathway forward".

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API warns of soft demand

AUSTRALIAN Pharmaceutical Industries yesterday halved its profit growth expectations, saying it now expects its results for the 12 months to 31 Aug to be up 5% on the previous financial year (*PD* breaking news yesterday).

Previously the company had flagged a 10% uplift, but now cites a “further decline in consumer sentiment” in recent months.

“While we continue to see good market share results, solid growth in transactions across our network at 4% up on FY16 and the roll-out of new stores has remained on track, overall like-for-like sales has weakened due to consumers spending less per basket and on lower value items,” said ceo

Richard Vincent, adding: “we are experiencing similar consumer sentiment as reported by other retailers over recent weeks”.

However despite the challenging conditions Vincent said API was holding market share, with several significant new product launches set to stimulate demand across the coming months.

The API ceo also said the company would build on the “newly enhanced Sister Club loyalty program to further personalise the shopping experience”.

“We are in a strong market position, our balance sheet remains healthy, and we are confident that we are well positioned to take advantage of any upswing in consumer sentiment,” he added.

PBS website update

THE latest update to the Pharmaceutical Benefits Scheme (PBS) website includes advance notice for Sep changes to the prescriber bag, the usual additions, deletions and alterations pages, as well as highly specialised drugs program adjustments, IVF program updates, chemotherapy funding and more.

For all changes, visit pbs.gov.au.

Guild supports carers

THE Pharmacy Guild has announced its sponsorship for the upcoming 7th International Carers Conference which will take place at the Adelaide Convention Centre from 04-06 Oct this year.

The Guild will sponsor the gala dinner at the event which is hosted by Carers Australia - registrations open at carersaustralia.com.au.



PSA staffer takes off

NEWLY formed aviation lobby group Airlines for Australia and New Zealand (A4ANZ) has today announced the appointment of the Pharmaceutical Society of Australia's (PSA's) Dr Alison Roberts (*pictured*) as its inaugural ceo.

Roberts has been executive director of policy, advocacy and innovation at the PSA and her eminent career includes her 2016 Innovative Pharmacist of the Year award presented at a UTS Sydney Graduate School of Health gala event (*PD* 29 Sep 16).

A4ANZ chair Professor Graeme Samuel welcomed Roberts, saying “Alison has a strong track record of championing the interests of her stakeholders in a complex, highly regulated industry, for an important sector of the economy”.

“A PhD in change management and current role leading a national policy and advocacy team for a peak body, provide a solid foundation in analytical thinking, the identification of trends, challenges and opportunities at a systemic level and effective implementation,” Samuel said.

Roberts commenced her new role with A4ANZ earlier this week.



Pregnancy vaccines

HEALTHCARE providers need to discuss the benefits and the safety of vaccination during pregnancy, especially highlighting the benefits for the unborn baby are important in helping women decide, according to a newly published *Australian Prescriber* article.

‘Immunisation and pregnancy – who, what, when and why?’ gives a ‘five-minute read’ of the issues involved.

“Only two vaccines are routinely recommended during pregnancy – influenza vaccine is recommended throughout, and pertussis vaccine is recommended at 28–32 weeks but can be given later,” authors wrote.

“Some other vaccines can be administered in special circumstances but are not routinely recommended.”

In particular all live attenuated vaccines are contraindicated in pregnancy, “although there has been no evidence of adverse effects from inadvertent administration”.

“Recommending vaccination to pregnant women is important as evidence shows they are more likely to get vaccinated if their healthcare provider advises it.”

Go to nps.org.au for the article.

MEANWHILE, a CPD for pharmacists article in the same edition focuses on the safety of over-the-counter pharmacy dispensing of naloxone.

“After brief training, numerous evaluation studies have confirmed naloxone can be safely administered by laypeople, and is effective in reversing opioid overdose with no abuse potential,” authors explain.

Health professionals are “uniquely placed to identify those at risk” of overdose, provide “a life-saving drug” and also train family and friends of the person at risk of overdose - **CLICK HERE**.

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Gonadotrophin a-flag

THE Pharmaceutical Benefits Scheme (PBS) advises pharmacists that an a-flag should have been applied to the following items in the Aug data, the item codes for these human chorionic gonadotrophin products considered equivalent for the purposes of substitution: 11148R and 1581F; 11154C and 6178E; 11156E and 6181H.

These will be rectified in Sep.



MAGIC HAPPENS WHEN MANUKA BLOSSOMS

For more details please click on BLOSSOMS

Dispensary Corner

DOCTORS in India have discovered that a newborn baby boy was found to be "pregnant" with his parasitic twin brother shortly after he was born.

The medical team discovered the half-formed baby after conducting a routine scan of the newborn nine-days after his birth.

Medics said the half-formed baby was complete with a brain, arm and legs - behind the otherwise-healthy newborn baby's stomach.

They successfully operated to remove the 7cm mass which they now suspect was a rare 'fetus in fetu' twin pregnancy - one of less than 200 ever recorded.

The 19-year-old mother and her son from Mumbai, in Thane city near Mumbai in India, are now both healthy and doing well.

EVER wanted a pet, but couldn't for whatever reason?

A team of researchers at Queensland's Griffith University have reported that there can be "significant" benefit in having a robot pet in your life - especially for dementia patients and those with anxiety.

The study follows on previous research by the team, which shows the introduction of a robotic seal called "Paro" could bring positive benefits for people with dementia, including reduced anxiety and a decreased tendency to wander.

"Paro" is invented by Japanese engineers, sells for \$8,500, responds to touch, temperature, voice and can learn names.

The robot has been used for robotic pet therapy in situations where live animals can't be used.

NPSA joins anti-Review chorus

THE National Pharmaceutical Services Association (NPSA) has called for a more robust assessment of the role Australia's full-line wholesalers play in the delivery of the National Medicines Policy (NMP) in its response to the Review of Pharmacy Regulation and Remuneration's Interim Report.

The NPSA expressed both general and specific issues it has with the Interim Report's findings, "which fail overall to sufficiently recognise the complex, interdependent relationships that exist across the pharmaceutical supply chain and for the wholesaling industry in particular".

NPSA chairman Mark Hooper said "There is a lack of rigour in assessing the practical implementation and the subsequent implications, intended or otherwise, of its alternatives".

The Review recommended a



distribution model which places the obligation of medicine delivery directly on manufacturers through a panel of distributors, a model which "offers no obvious benefit and has significant drawbacks, including greater regulatory burden for government; greater administrative burden for pharmacy;

increased risks to medicines availability due to diminished system redundancy; greater complexity across the supply chain and the potential for market power imbalance," Hooper said.

"In the interests of Australian consumers and our community pharmacy customers who are dependent on it, CSO wholesalers remain committed to finding a workable outcome for Government and sustainable remuneration for the sector," Hooper added.

See NPSA's formal submission to the interim report from the King Review at npsa.org.au.

WIN WITH GAIA

This week Pharmacy Daily and GAIA are giving away each day a "nappy suite" prize pack including Soothing Cream, 100g Powder, 80 pack of wipes and two 20 packs of wipes.

GAIA's Natural Baby Soothing Cream slips easily into your bag, making it your nappy change essential from the leading Australian brand of natural baby skincare. Containing beeswax, zinc, castor oil and marshmallow along with all the usual GAIA goodies, this Soothing Cream is the perfect companion to soothe and protect skin. **CLICK HERE** to find out more.



To win, be the first from SA or NT to send the correct answer to the question to comp@pharmacydaily.com.au

What is the RRP for 100mls of Soothing Cream?

Congratulations to yesterday's winner, Antonella Panajia from Main Street Pharmacy.



Travel Specials

WELCOME to *Pharmacy Daily's* travel feature. Each week we highlight a couple of great travel deals for the pharmacy industry, brought to you by *Cruise Weekly*.

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CLICK HERE for the brochure.

Crystal 2017 Getaways

CRYSTAL Cruises has released a total of 17 Crystal Getaways from four to 13 days in length from Aug through to Dec.

Crystal Symphony and *Crystal Serenity* sailings include up to eight elegant dining venues, unlimited fine wines and many more inclusions, from \$940 per person - crystalcruises.com.



New Products

- **Alecensa (alectinib)** is a tyrosine kinase inhibitor that targets anaplastic lymphoma kinase (ALK) and rearranged during transfection (RET) tyrosine kinase. Alecensa is indicated for the treatment of ALK positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) in patients who have progressed on or are intolerant to crizotinib. Alecensa 150 mg capsules are available in a multipack of 224 (4 packs of 56).
- **Obizur (susoctocog alfa (bhk))** is a recombinant analogue of porcine coagulation factor VIII, with the B domain deleted. Patients with acquired haemophilia A have normal factor VIII genes but develop autoantibodies against their own factor VIII (i.e. inhibitors), creating a functional deficiency of this procoagulant protein. Obizur is indicated for the treatment of bleeding episodes in adults with acquired haemophilia A. Safety and efficacy of Obizur have not been established in patients with baseline antiporcine factor VIII inhibitor titre greater than 20 BU. Obizur is not indicated for the treatment of congenital haemophilia A or von Willebrand disease. Obizur 500 unit single use vials are available in packs of 1, 5 and 10.
- **Pedea (ibuprofen)** is indicated for the treatment of haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 34 weeks of gestational age. Pedea should not be administered in life threatening infection; active bleeding, especially intracranial or gastrointestinal haemorrhage; thrombocytopenia or coagulation defects; significant impairment of renal function; congenital heart disease in which patency of the ductus arteriosus is necessary for satisfactory pulmonary or systemic blood flow (e.g. pulmonary atresia, severe tetralogy of Fallot, severe coarctation of the aorta); known or suspected necrotising enterocolitis. Pedea 5 mg/mL solution for intravenous infusion is available in 2 mL ampoules in packs of 4.

New Indications

- **Atozet (ezetimibe/atorvastatin (as calcium trihydrate))** is now also indicated in patients with coronary heart disease and a history of acute coronary syndrome taking their maximum tolerated dose of atorvastatin and in need of additional lowering of low density lipoprotein cholesterol in the expectation of a modest further reduction in the risk of cardiovascular events following at least one year of therapy.
- **Opdivo (nivolumab (rch))** as monotherapy is now also indicated for the treatment of adults with relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant and treatment with brentuximab vedotin. The approval of this indication is based on objective response rate.

New Contraindications

- **DBL Dexamethasone Sodium Phosphate Injection (dexamethasone phosphate (as sodium))** is now also contraindicated in nonfungal systemic infections unless specific anti-infective therapy is given.
- **Kaletra (lopinavir/ritonavir)** should not be coadministered with elbasvir/grazoprevir.
- Coadministration of **Videx (didanosine)** with stavudine is now contraindicated due to the potential for serious and/or life threatening events notably lactic acidosis, liver function abnormalities, pancreatitis and peripheral neuropathy.

*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.*