

GBMA hails biosimilar tick

HOSPIRA has announced that **Inflectra** (infliximab), biosimilar to Janssen-Cilag's **Remicade**, has been registered in Australia.

As the first monoclonal antibody to be approved, the registration potentially paves the way for the government to reduce the cost of some of the most costly drugs on the PBS, with **Remicade** alone coming in at around \$100m a year.

Inflectra has been registered in Australia for the treatment of eight inflammatory conditions: rheumatoid arthritis (RA); psoriatic arthritis; ankylosing spondylitis (AS); adult and paediatric Crohn's disease; refractory fistulising Crohn's disease; adult and paediatric ulcerative colitis; and plaque psoriasis.

The PBAC is also considering a PBS listing for **Inflectra**, with a

recommendation expected today.

The Generic and Biosimilar Medicines Association (GBMA) has welcomed the approval as a landmark event for the biologicals market presently worth \$2.3b in Australia equivalent to 25% of annual PBS expenditure.

"The approval of biosimilar infliximab is great news for patients as it provides an additional treatment option for those living with some of the most debilitating autoimmune diseases and will create savings allowing greater access to newer, more expensive medicines," said GBMA ceo Belinda Wood.

"Importantly, the approval of biosimilar infliximab increases the TGA's experience in appropriately evaluating biosimilars, including extrapolating indications from the reference biological medicine.

"This is essential if Australia is to unlock the full value offered by biosimilars," she added.

Clinical trial FAQs

THE Therapeutic Goods Administration (TGA) has posted an update of its frequently asked questions (FAQs) relating to clinical trials which need to access unapproved therapeutic goods.

See www.tga.gov.au.

NZ OTC NSAID labels

THE New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) has decided to align with the Australian Therapeutic Goods Administration oral diclofenac labelling requirements due to implemented by 01 July 2016 (PD 12 Jun) following extensive public consultation (PD 11 May).

The new labelling will reflect, but not necessarily be identical to, the Australian requirements that refer to allergic reactions to non-steroidal anti-inflammatory drugs, pregnancy warnings, length of treatment, dosing maximum, kidney and heart warnings.

See www.medsafe.govt.nz for more information on the outcome of the diclofenac consultation.

WIN A HARLEY OR A HOLIDAY



Novo Nordisk pharmacy focus



DIABETES specialist Novo Nordisk has set its sights firmly on the Australian pharmacy market, with an update yesterday confirming the company has ambitions to partner more effectively with pharmacies.

As well as working to optimise activity under existing professional programs such as MedsCheck, the NDSS and medication reviews, Novo Nordisk believes there's potential for new areas of collaboration, as pharmacy evolves its role in primary care and with the strong focus on professional services in the Sixth Community Pharmacy Agreement.

The diabetes pandemic means that there are many Australians on the cusp of developing the condition, and if pharmacies can get involved in managing these patients and encouraging diet and exercise it could push them away

from type 2 diabetes.

"Pharmacy is so well placed to do this screening," according to a presentation from Novo Nordisk in Sydney yesterday.

The company is also actively seeking new partnership opportunities with pharmacies, and is inviting pharmacists with ideas to make contact to explore possibilities.

Novo Nordisk is one of the largest suppliers of insulin for the world market, with other areas of focus including obesity, haemophilia and growth disorders.

Pictured above at yesterday's event are, from left: Andrew Rolls, Novo Nordisk (NN) senior product manager, Endocrine; Maxine Hogan, NN national key account development manager; and former Guild President Kos Sclavos, Sinapse senior health strategist.

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- **Clinical Pharmacist** - Darwin, NT (Job# 2011593)
Clinical Pharmacist - 6 month contract - subsidised accommodation.

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Events Calendar

WELCOME to *Pharmacy Daily's* events calendar, opportunities to earn CPE and CPD points.

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

24 Aug: Pharmacists in General Practice Forum; Sofitel Sydney Wentworth; details at: www.psa.org.au

25 Aug: Australian Pharmacy Council 2015 Colloquium; Canberra; further details at: www.pharmacycouncil.org.au

26 Aug: Cardiovascular Update: Atrial Fibrillation and Anticoagulants; St Leonards; visit: www.guild.org.au

29 Aug: CPD Day; Travelodge Newcastle; more info at: www.psa.org.au

1 Sep: Work Priorities workshop; Melbourne; more info at: www.cpd.shpa.org.au

4-5 Sep: The Friendlies' Conference - 2015; Stamford Grand, Glenelg; more info at: pharmacyconference.com.au

8 Sep: QCPP Refresher Training; Cairns; info and registration: www.guild.org.au/qldcpd

9 Sep: CPD Accredited First Aid; Brisbane; info and registration: www.guild.org.au/qldcpd

10-11 Sep: Australasian Disease Management Association 11th Annual Conference; Brisbane Convention Centre; visit: www.adma.org.au

12 Sep: CPD Accredited First Aid; Gold Coast; info and registration: www.guild.org.au/qldcpd

16 Sep: Cardiovascular Update: The Role of Pharmacy; St Leonards; more info at: www.guild.org.au

DDS spotlight on breasts

DISCOUNT Drug Stores has this month launched a major initiative aiming to highlight breast health, with all of its 115 stores across the country offering clinics where women will be taught how to check their own breasts.

With the number of Australians with breast cancer set to rise to over 17,000 per year in five years, the project is aiming to encourage regular self-examination at home.

Customers will be taught by a registered nurse using a silicone breast model, with the clinics designed to be "quick and easy to fit into a busy day" with appointments as short as 15 minutes, according to DDS Professional Services Manager, Casey Clark.

The cost of running the breast health clinics will be funded entirely by Discount Drug Stores, but consumers will be asked to make a donation to the McGrath

Foundation, once booked into the clinics, supporting the provision of McGrath Breast Care Nurses in the community.

Clark said the initiative will teach Australian women how to check their own breasts for changes and explain to them the different signs and risk factors to look out for, without a physical examination being conducted in store.

"Breast cancer affects people of all ages and in most cases, lumps or changes are discovered by the patient themselves or their own doctor, which is why self examinations are so important," she said.

The clinics will run until October and bookings are essential - www.discountdrugstores.com.au.

Wireless TENS device

EVOMED'S new Painmate (PD Wed) is being offered via the pharmacy channel for \$49.95, as a Transcutaneous Electrical Nerve Stimulation (TENS) device which fits in the palm of a patient's hand.

Suitable for people aged over 18 the device is completely wireless, and offers 50 treatments before the batteries and gel pads need to be replaced - for more information see www.painmate.com.au.

ASMI ad seminar

THE Australian Self-Medication Industry is inviting registrations for its next Therapeutic Goods Advertising Code Seminar, which will be held in Sydney on 23 Sep.

Attendance costs \$595 for ASMI members and \$795 for non-members - to register **CLICK HERE**.

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According to the HOYTS Corporate Solutions website, what are Private Screenings perfect for?

Congratulations to yesterday's winner, Michelle McPherson from Sanofi.



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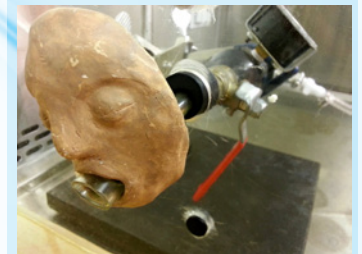
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DISPENSARY CORNER

PROVING there is truly no limit to what scientists can do when they set their minds to it, researchers in the USA have created a "vomit machine" to test how a common virus is spread.

The pretty much totally gross device (below) aims to answer the question of what happens to norovirus when a sufferer with the gastric disorder blows chunks.



Norovirus is notorious for spreading like wildfire, particularly in closed environments such as cruise ships or catering halls - but it's not clear whether it is aerosolised when it is vomited.

The virus vomit evaluator was created using a range of known "vomit metrics" such as pressure and volume (and perhaps the fact that it ALWAYS contains carrots).

The scientists from North Carolina State University and Wake Forest University then conducted a series of tests, with the device allowing them to control the "volume, viscosity and pressure of the simulated vomiting incidents".

They used jelly to make the laboratory vomit have a good consistency, with the results published in the *PLOS ONE* journal.

Yes, the virus has the potential to aerosolise and yes, it can travel a long way, the researchers said.

Being suspended in the air and subject to air movements, the virus has the potential to travel many metres and land on many surfaces at infectious levels.