

Today's issue of PD

Pharmacy Daily today has three pages of news including our weekly **Health & Beauty** feature and the latest **MIMS Monthly Update**.

Special Access Scheme online system

THE Therapeutic Goods Administration has released details of its new online system to enable the electronic submission of Special Access Scheme (SAS) applications and notifications to the TGA.

This month the system was updated to allow the submission of Authorised Prescriber applications, with the system aiming to reduce the administrative burden on health practitioners.

While lodgement of SAS and AP applications and notifications via the online system is not mandatory, it is the preferred method of submission, with the TGA aiming to move the submission of all SAS and AP requests online by 01 Jul 2019.

The TGA noted that in certain circumstances the SAS online system should not be used for medicinal cannabis submissions.

Such situations include where the prescriber of the unapproved therapeutic good is not a medical practitioner, or where the prescriber is in possession of a current TGA approval and the notification/application only relates to a particular state or territory.

Medical practitioners actually prescribing the medicinal cannabis product must make the submission via the system - tga.gov.au.

AZ direct supply backdown

ASTRAZENECA (AZ) has announced a transition away from its current exclusive direct supply arrangements for 14 high-cost medicines (**PD** 31 Oct 2017), with the full range of products to become available both through current provider DHL and the key pharmaceutical wholesalers from 01 Feb 2019 (**PD** breaking news yesterday).

The change means AstraZeneca's controversial direct supply model will have only lasted for just over twelve months, and during a transition period which started yesterday the full range of AZ medications will be available from DHL, while transitional arrangements with the other wholesalers are finalised.

AZ Country President, Liz Chatwin, said the move follows feedback received following last year's decision to make particular items available directly, and exclusively, to pharmacy via DHL.

"Community pharmacy and wholesalers asked us for choice and access to all of our medicines.

"We are confident that our new model will provide this, it will be competitive, and deliver for patients," Chatwin said.

"It won't cherry-pick and there will be no exclusive distribution," she added.

The announcement came just

days after the Health Department released its Invitation to Apply for the Community Service Obligation funding pool (**PD** Mon), which has put the squeeze on direct supply by not allowing any CSO payments in relation to items which are subject to exclusive arrangements.

AstraZeneca will partner with Arrow Pharmaceuticals during the transition to support pharmacists, and

also confirmed that the 14 exclusive supply medications would return to wholesalers, meaning the full range of 77 items is available through the normal distribution chain.

Chatwin said the company was committed to rolling out the new model as fast as possible, bearing in mind the busy Christmas and New Year period coming up.

"Our transition to our new distribution model is a process that we want to get right by working with all relevant stakeholders," she said, with the 01 Feb deadline set to give wholesalers the access they have asked for "in a timeframe we can deliver on".

Pharmacy Guild National President George Tambassis thanked AstraZeneca for addressing concerns about direct supply.

"Our members will now have choice, which we welcome, to ensure patients have access to these important medicines from multiple sources," Tambassis said.



PBS forms online

THE Department of Human Services has made new forms available online for pharmacists and customers to download.

The range includes "PBS/RPBS Safety Net prescription record form and application for a Safety Net Card" (PB240) which is used to help customers keep a record of how much they have spent on PBS medicines; "PBS Safety Net claim for payment" (PB241) used to make a claim for issuing customers with a PBS Safety Net Card; and "Approved supplier manual payment reconciliation" (PB242) for approved suppliers to use when manually claiming or reconciling a payment for supplying PBS items or highly specialised drugs.

Old paper forms in stock can be used until they run out.

ASMI AGM last week

THE Australian Self Medication Industry (ASMI) has elected Theresa Agnew, GSK Consumer Healthcare Area General Manager Australia and NZ to its Board of Directors.

Last week's ASMI annual general meeting in Canberra also saw the re-election of Doug Cunningham, MD Johnson & Johnson Pacific and Mark Sargent, GM ANZ Consumer Health Care for Bayer Australia to the organisation's board.

Elected directors hold office for two years and join the rest of the board including Robert Barnes of Aspen, Glen Cochran from Reckitt Benckiser, Andrew Jenkin of Pfizer, Alan Oppenheim of Ego, Seona Wallace from HealthOne, and Chairperson Lindsay Forrester.



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Chisholm Chemist is Capital Champ



CANBERRA'S Capital Chemist Chisholm has been named the top Pharmacy of the Year for the Capital Chemist group.

The accolade was awarded last weekend at the Museum of Australian Democracy in Old Parliament House, Canberra, with about 350 guests in attendance.

The Pharmacy of the Year competition focuses on a total of 39 parameters which are judged as representative of success, such as growth, services development and implementation, demonstration of core values, customer service and pharmacist access.

The award was presented by Geoff Weir, Senior Relationship Manager at Westpac which is a long-term trading partner of the group and the award's major sponsor.

Capital Chemist Chisholm Managing Partner Rebecca Young said the award was the culmination of years of hard work and dedication, acknowledging the efforts of her staff and the support given by the group's head office.

"We don't operate in isolation - we work as part of the Capital Chemist group and this award shows exactly what is possible."

Runner up for the Pharmacy of the Year award was Capital Chemist Garran, while the Team Member of the Year award went to Kim O'Dea, retail manager of Capital Chemist Southlands.

As well as her day job, O'Dea was hailed for her tireless behind

the scenes work at many Capital Chemist Community Program events - and her son is the "body" of the Capital Chemist mascot, Billie Bilby.

Rebecca Porter from Capital Chemist Calwell was the runner up for Team Member of the Year.

Capital Chemist also has an extensive charity and community support program in the ACT, with Capital Chemist Southlands taking out the 2018 Community Engagement Award.

Capital Chemist Group Business Manager, Andrew Topp, paid tribute to all the winners, saying they had shown a dedication to the organisation's model of community engagement, service and advice, & excellence in professional services.

Pictured from left are Jeff Weir, Westpac with Rebecca Young from Capital Chemist Chisholm.

Maxigesic study

A NEW large randomised trial just published in Clinical Therapeutics comparing a US formulation of Maxigesic to equivalent doses of paracetamol and ibuprofen shows that combined product provides significantly superior pain relief than either paracetamol or ibuprofen on their own.

The work, published in Clinical Therapeutics, showed Maxigesic also "reduced opioid rescue medication use and shortened time to meaningful pain relief".

Fasenra onto PBS

ASTRAZENECA has announced the Pharmaceutical Benefits Scheme listing of its Fasenra (benralizumab) for patients with severe eosinophilic asthma who meet specific criteria.

Fasenra is a monoclonal antibody that works with the body's immune system to specifically target eosinophils, a particular type of white blood cell which are present in half of Australians with uncontrolled severe asthma.

It is administered by a healthcare professional as a subcutaneous injection every eight weeks, following initiation with three four-weekly doses.

Medlab to Europe

LISTED medical life sciences company Medlab Clinical Limited has launched a wholly owned subsidiary in the EU, with the aim of managing current and future dealings with its NanaBis and proposed drug registration models with the European Medicines Agency (EMA).

The newly incorporated MDC Europe will further the agenda advised during the company's recent annual general meeting, which detailed discussions with the EMA on the pathway for registration of NanaBis.

Conditional approval is likely, but registration with a significant fee reduction requires the company to be domiciled in Europe.

A rose by any other...

"**A ROSE** by any other name would smell as sweet", said William Shakespeare's Juliet, but a drug name pronounced differently may not, according to an editorial in this month's edition of *Australian Prescriber*, the official organ of NPS MedicineWise.

Former editor of *NPS RADAR* Craig Patterson highlights the challenges facing dispensers and clinicians trying to pronounce some new drugs such as xekizumab, rovalpituzumab, tofacitinib and idelalisib.

"The problem of lookalike and soundalike drug and brand names is well recognised, but there is an evidence gap regarding any impact that mispronunciation may have on patient safety," Patterson wrote.

Telephone orders between prescribers, clinical handovers, voice-recognition software and text-to-speech systems are all part of the problem - see the three-minute read at nps.org.au.

Omega-3 health

THE secret to healthy ageing may, in part, be linked to consuming an extra serving of fish each week, new research published in the *British Medical Journal* has reported this week.

Higher levels of long chain omega-3 fatty acids were associated with 18% lower risk of unhealthy ageing among older adults - visit bmj.com.

Win with Nutri-Synergy

Everyday this week Pharmacy Daily and Plunkett's are giving away NS Protective Hand Cream 80g, NS Hands and Nail Cream 80g and NS Cuticle & Nail Repair Treatment 15g valued at \$30.

Plunkett's have just released a new hand care product - NS Hand and Nail Cream which is a light yet intensive cream delicately scented with natural essential rose oil. It is non-greasy and absorbs quickly leaving your hands soft and silky and your nails strong and supple. Visit: www.NutriSynergy.com.au.

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

What does NS stand for?

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Pharmacy Daily

Dispensary Corner

CAN changing language help reduce our reliance on fatty meat products? Well, animal rights charity PETA certainly believes it can, in fact the organisation has been pushing for “harm-free” alternatives to specific animal-related phrases for some time.

The rationale is to move away from normalising phrases that infer harm to animals and therefore reduce animal abuse and meat consumption.

Suggested substitutes for common phrases include: “Bring home the bagels” instead of “Bring home the bacon”, “Feeding two birds with one scone” in lieu of “Killing two birds with one stone”, and “Taking the flower by the thorns” as opposed to “Taking the bull by the horns”.

Only time will tell if this is an effective method for curbing our carnivorous desires or whether changing language to alter an outcome is simply flogging a dead horse, errgh sorry, we mean stroking a fed horse, right?



WHEN somebody tells you that an experience was a real kick in the pants, they generally weren't too thrilled about it.

But for jockey Ryan O'Connor, being thumped in the groin by an angry horse literally saved his life.

Upon tending his injury in hospital, doctors discovered he had a cancerous tumour that if untreated would have spread.

Thanks to the kick, O'Connor was given the all-clear in Jan.

Health, Beauty and New Products

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

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

Flo Travel Nasal Spray

One of the impressive Flo range of nasal sprays, Flo Travel is a gentle, moisturising nasal spray containing Carrageenan (1.6mg/mL of red seaweed extract) in an isotonic and preservative-free saline solution. It helps relieve nasal dryness and wash away germs. It has also been shown to temporarily relieve and reduce the duration of cold symptoms. Maintaining well hydrated nasal tissues whilst travelling and on-the-go may help support your immunity against common cold viruses and bacteria and prevent your nose from becoming dry or crusty as a result of air conditioning.



Stockist: 1300 857 912
RRP: \$13.95
Website: www.enttech.com.au

Neutral with Neptune 9 Shade Palette

Designer Brands (DB) brings you its **Neutral with Neptune 9 Shade Palette** - it has nine cool, earthy-toned shades inspired by this mysterious, outer planet. The palette is comprised of six matte shades and three shimmer shades with a lightweight palette and integrated mirror. Ready to use anywhere, on-the-go, in the salon or in the air, this compact set of eyeshadows can give any woman the sultry, sexy or surprising look she desires. As with all DB products, these shades have not been tested on animals and are certified Vegan.



Stockist: 03 8544 8000
RRP: \$14.99
Website: www.dbcosmetics.com.au

Kids Manuka Honey & Vitamin C



All Natural Kids Manuka Honey & Vitamin C are throat lozenges enriched with manuka honey from New Zealand and vitamin C. Manuka honey offers bacteria fighting properties which may help to soothe coughs and sore throats while vitamin C contributes to iron absorption and may help the normal functioning of

the immune system. Flavoured for wide acceptance, All Natural Kids Manuka Honey & Vitamin C may help children have a more pleasant Christmas break as well as taking some pressure off the parents.

Stockist: 1800 791 381
RRP: \$14.95 for a pack of 12 lozenges
Website: www.allnaturalkids.com.au

Gel Activ Insoles for Extreme Heels



Christmas is right upon us bringing us party after party and more than we sometimes want - but it's the time when women will want to, or be expected to, stand around eating, drinking and socialising for hours at a time in their best looking high heels, especially those channelling Julie Bishop. Trusted footcare company Scholl brings the perfect answer: **Gel Activ Insoles for Women: Extreme Heels**. This

insightful product design offers extreme comfort for the longest stints being in the Christmas moment.

Stockist: 1800 226 766
RRP: \$19.99
Website: www.scholl.com.au

CRITICAL UPDATE

Panadol (Children) Liquid Formulations - Please be informed of a critical correction in the Dosage section of Panadol (Children) Liquid Formulations...

New Products

- **Benralizumab (rch) (Fasenra)** is a humanised monoclonal antibody selective for the alpha subunit of the human interleukin-5 receptor (IL-5R α). The IL-5 receptor is specifically expressed on the surface of eosinophils and basophils. Benralizumab reduces eosinophilic inflammation through immune effector cell mediated apoptosis of eosinophils and basophils. Fasenra is indicated as add-on therapy in patients aged ≥ 12 years with severe eosinophilic asthma (blood eosinophil count ≥ 300 cells/microlitre or ≥ 150 cells/microlitre if on oral corticosteroid treatment). Fasenra should be prescribed by a healthcare professional in consultation with a specialist physician experienced in the diagnosis and treatment of severe asthma. Treatment with high dose inhaled corticosteroids and long-acting β -agonists should be optimised prior to commencement of treatment with Fasenra. Fasenra solution for subcutaneous injection pre-filled syringe contains benralizumab 30 mg/1 mL and is available in a pack of 1.
- **Ertugliflozin (pyroglutamic acid) (Steglatro)** is a sodium-glucose co-transporter 2 (SGLT2) inhibitor. Steglatro is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus: as monotherapy when metformin is considered inappropriate due to intolerance; in combination with other antihyperglycaemic agents. Steglatro is contraindicated in patients with chronic kidney disease (CKD) receiving dialysis; eGFR < 30 mL/min/1.73 m² or eGFR persistently < 45 mL/min/1.73 m² (CKD stage 3B, 4 and 5). The efficacy of Steglatro is dependent on renal function. Steglatro tablets contain ertugliflozin 5 mg or 15 mg in a pack size of 28.
- **Ertugliflozin (pyroglutamic acid)/sitagliptin (phosphate monohydrate) (Steglujan)** combines two antihyperglycaemic agents with complementary mechanisms of action to improve glycaemic control in patients with type 2 diabetes: ertugliflozin (a SGLT2 inhibitor) and sitagliptin (a dipeptidyl peptidase-4 [DPP-4] inhibitor). Steglujan is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Steglujan is contraindicated in patients with CKD receiving dialysis; eGFR < 30 mL/min/1.73 m² or eGFR persistently < 45 mL/min/1.73 m² (CKD stage 3B, 4 and 5). The efficacy of Steglujan is dependent on renal function. Steglujan tablets contain ertugliflozin 5 mg/sitagliptin 100 mg (Steglujan 5/100) or ertugliflozin 15 mg/sitagliptin 100 mg (Steglujan 15/100) in a pack size of 28.
- **Migalastat (Galafold)** is a pharmacological chaperone that selectively and reversibly binds with high affinity to the active sites of certain mutant (abnormally folded and unstable) forms of lysosomal enzyme α -galactosidase A (α -Gal A), stabilising the mutant enzymes. Mutations in the GLA gene result in a deficiency of α -Gal A in the lysosomal storage disorder Fabry disease. Galafold is indicated for long-term treatment of adults and adolescents ≥ 16 years with a confirmed diagnosis of Fabry disease (α -Gal A deficiency) and who have an amenable mutation. Galafold capsules contain migalastat 123 mg and are available in a pack size of 14.
- **Tenofovir alafenamide (fumarate) (Vemlidy)** is a phosphonamidate prodrug of tenofovir. Intracellular tenofovir is phosphorylated to the pharmacologically active metabolite tenofovir diphosphate. Tenofovir diphosphate inhibits hepatitis B virus (HBV) replication through incorporation into viral DNA by the HBV reverse transcriptase, which results in DNA chain termination. Tenofovir has antiviral activity specific to HBV and human immunodeficiency virus (HIV-1 and HIV-2). Vemlidy is indicated for the treatment of chronic hepatitis B in adults. Vemlidy tablets contain tenofovir alafenamide 25 mg and are available in a pack size of 30.

New Indications

- **Cabozantinib ((S)-malate) (Cabometyx)** is now indicated for the treatment of advanced renal cell carcinoma in treatment naïve adults with intermediate or poor risk.
- **Lenvatinib (mesylate) (Lenvima)** is now indicated for the first-line treatment of unresectable hepatocellular carcinoma.
- **Pembrolizumab (Keytruda)** is now indicated for the treatment of adult and paediatric patients with refractory primary mediastinal B-cell lymphoma, or who have relapsed after 2 or more prior lines of therapy. The approval of this indication is on the basis of objective response rate and duration of response from non-randomised studies.
- **Quadrivalent influenza vaccine (split virion, inactivated) (Fluarix Tetra)** is now indicated for active immunisation of children from 6 months of age for the prevention of influenza disease caused by the influenza virus types A and B contained in the vaccine.
- **Venetoclax (Venclexta)** in combination with rituximab is now indicated for the treatment of adults with chronic lymphocytic leukaemia who have received at least one prior therapy.

New Contraindications

- **Pralatrexate (Folotyn)** is now contraindicated in pregnancy.
- **Protamine sulfate (Fisons Protamine Sulfate Injection BP)** is now contraindicated with hypersensitivity to protamine (including protamine contained in insulin NPH [Neutral Protamine Hagedorn]).
- **Tretinoin (ReTrieve Cream, Stieva-A)** is now contraindicated in pregnancy and women planning a pregnancy.

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.