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Biosimilars suitable for substitution

THE Pharmaceutical Benefits Advisory Committee has advised that biosimilar products are “suitable for substitution at the pharmacy level”.

The ruling is an outcome of the April 2015 PBAC meeting, which decided that the “a” flagging of biosimilar products would be its default position.

Relevant considerations in establishing that a biosimilar product could be “a” flagged with the originator product include an absence of data to suggest significant differences in clinical effectiveness or safety; absence of identified population where the risks of using the biosimilar product are disproportionately high; availability of data to support switching between the products; availability of data for newly treated patients initiating on the biosimilar product; and whether the TGA has deemed a product to be biosimilar with the originator.

The PBAC also considers that where a biosimilar could not be “a” flagged at the time of PBS listing, data should be collected to support “a” flagging at a later point in time.

NICE early access

THE UK National Institute for Health and Care Excellence (NICE) is set to launch a new Office for Market Access, which aims to speed up the assessment process of innovative products through “early engagement with companies”.

The office will better link the UK science community with government, NICE said.

SHPA concern over 6CPA

THE Society of Hospital Pharmacists of Australia has expressed concern over the “lack of detail and patient focus” of the newly minted Sixth Community Pharmacy Agreement.

SHPA president Michael Dooley has raised particular misgivings about the strong focus of the agreement on “programs and services delivered through the four walls of a community pharmacy.”

“SHPA believes the Agreement should provide broader scope for pharmacists to practise and deliver professional services independently, such as the HMR and RMMR services provided by independent accredited pharmacists,” Dooley said.

He said that SHPA believes pharmacists should be able to deliver services in settings most appropriate and accessible for patients - including in general practices, as flagged by the proposed AMA non-dispensing pharmacist plan (see page two).

Dooley said it was unclear whether any of the \$600 million “contingency reserve” allocated for professional services in the 6CPA would be allocated to HMR and RMMR funding, with the Agreement not detailing indicative payments for years 2-5.

“This creates an uncertain environment for accredited pharmacists and for patients who require comprehensive medication reviews to avoid medication



misadventure and hospitalisation,” Dooley said.

“SHPA would also like more clarity on hospital-initiated home medication reviews, as well as whether the cap on the number of HMRs an accredited pharmacist can deliver will remain,” Dooley (pictured) said.

The “arbitrary caps” introduced in Mar 2014 are unacceptable, as they put vulnerable patients at risk by reducing their access to services that improve medication use, Dooley added.

Again, the \$50 million allocated in the 6CPA to trial new and expanded professional services via the Pharmacy Trial Program, is only available for community pharmacy program “and consequently innovative pharmacist programs within GP practices may not be considered”.

Dooley said that SHPA was “strongly encouraged” by the independent review process for professional services introduced with the 6CPA, which will ensure they are evidence-based, appropriately targeted and demonstrate cost-effectiveness.

He said the Society looked forward to more detail becoming available regarding the 6CPA.

MEANWHILE SHPA is also concerned about significant changes to chemotherapy funding which have been revealed in the Sixth Community Pharmacy Agreement - see separate story on page four.

Aspirin for leg ulcers

RESEARCHERS at Monash University are hoping to recruit more than 260 participants from wound clinics around Australia to take part in a study designed to determine whether aspirin can improve the healing rates of leg ulcers in older adults.

With an estimated 400,000 Australians suffering from venous leg ulceration (VLU) the cost to the country is around \$2-3 billion per annum, Monash claims.

Lead researcher Dr Carolina Weller from the Department of Epidemiology and Preventive Medicine said the study will involve 12 weeks of standard care in combination with 12 months of taking either aspirin or placebo.

“Current best practice involves compression bandaging therapy, however 30-50% of venous leg ulcers remain unhealed after two years and recurrence is common,” Weller said.

“Two small studies previously suggested that aspirin can improve healing rates and decreases recurrence and we plan to look at that further,” she added.

EU approves Synjardy

NEW combination pill Synjardy (empagliflozin/metformin hydrochloride) for lowering blood glucose in type 2 diabetes patients has been approved in the EU, with side effects identified as consistent with known safety profiles of the individual compounds.

Empagliflozin, the single compound, is available in Australia as Jardiance from Boehringer Ingelheim.



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AMA urges GP funds

BRIAN Owler, president of the Australian Medical Association, says the government should invest more in general practice, saying that if GPs were sufficiently funded "there would be no need for fragmented care in pharmacies".

Speaking at the AMA National Conference in Brisbane on Fri, Owler hailed the organisation's victory in resisting the Medicare co-payment, but said the current indexation freeze on the MBS is "harming general practice".

"With investment, GPs will continue their work in providing world class, patient-centred care," Owler said.

WA warns on premises

THE Pharmacy Registration Board of Western Australia says it has recently noticed that pharmacy relocations and alterations are not always in accord with original plans it had approved.

Where an application for new premises, a relocation or significant alteration is made, the Board approves the changes and once finished requires photographs of the completed project and a statutory declaration advising that the works are complete.

While in some cases the changes are minor, sometimes they have "impacted on areas such as areas

for private consultation, access to scheduled medicines and other significant matters," the Board said in a communiqué issued in May.

These matters have the potential for new plans, resulting in increased costs for the applicant and potential opening delays, the Board said.

The communiqué also reminded WA pharmacists that any changes in shareholdings of a pharmacist controlled company should be notified to the Board, even if it does not change the owners but rather just their percentage interest.

Under the WA Pharmacy Act 2010, premises can be owned by companies, partnerships or trusts, and a pharmacist must not hold a proprietary interest in over four pharmacy businesses at any time.

Actual changes which add or remove a pharmacist from an entity require an application to the Board.

GST changes for benzydamine

A SCHEDULING change for certain benzydamine products for the treatment of sore throats and other mouth conditions has resulted in an alteration to the GST treatment of these items.

The Australian Taxation Office has issued an alert about the changes, which will see some benzydamine preparations able to be supplied to end consumers by retailers other than pharmacies.

This means that they are subject to GST, with impacted products including Diffiam anti-inflammatory throat sprays and lozenges.

Up to and including 31 May all benzydamine preparations (except those for dermal use) were GST-free when supplied to consumers.

However effective immediately, benzydamine products in divided topical oral preparations containing 3mg or less of benzydamine; and in undivided topical oral preparations containing 0.3% or less of benzydamine in a primary pack containing not more than 50mg, are now exempt from scheduling.

Benzydamine preparations which continue to be scheduled under the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons are still GST-free.

AACP award winners



LAST weekend's ConPharm '15 held in Melbourne saw Joy Gailer and Dr Shane Jackson named as the joint winners of the 2015 AACP MIMS Consultant Pharmacist of the Year Award.

The award recognises an "outstanding contribution by an accredited pharmacist to the practice of consultant pharmacy" plus a travel grant to the value of \$5,000 to attend a pharmacy

conference, thanks to MIMS.

The award was presented (above) by AACP chair Grant Kardachi, AACP ceo Grant Martin and Dinah Graham from MIMS Australia.

AACP said both winners were experienced accredited pharmacists who had proven their dedication to advancing the profession of consultant pharmacy.

Erbitux extension

THE PBS listing for Erbitux (ceuximab) has been expanded, with the drug now reimbursed as a first-line therapy for patients with epidermal growth factor receptor (EGFR)-expressing RAS wild-type metastatic colorectal cancer.

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ASMI cuts fees for SMEs

THE Australian Self Medication Industry (ASMI) has restructured its fees for associate members, to make ASMI membership more affordable for small businesses and individual consultants.

Under the changes, ASMI associate membership subscription is now based on the number of employees in a company, and starts from \$1,500 annually.

ASMI marketing and business development director Filomena Maiese said the change would open doors for smaller businesses that supply goods and services to the consumer healthcare products industry.

"ASMI membership is a great way for small organisations to develop and grow their business by meeting potential clients, staying up-to-date with the latest developments in the sector and networking with other ASMI members and the ASMI Board," Maiese said.

She said associate members of ASMI are encouraged to participate

in subcommittees and working groups, providing opportunities to influence policy and practice within the sector and network with other members of the organisation.

"They are also able to access advice from ASMI's PR, regulatory, advertising and scientific experts," she said, with associates including suppliers to ASMI members.

\$122m for DAAs

UP to \$122 million of the Sixth Community Pharmacy Agreement funding for new and expanded community pharmacy programs has already been earmarked for Dose Administration Aids and Staged Supply, according to the Guild.

The funding is subject to cost-effectiveness outcomes and ministerial decisions, but the government "has acknowledged the likelihood of these programs being found cost-effective and recommended for further expansion is very high".

PBS 01 Jun update

THE Schedule of Pharmaceutical Benefits has been updated today, with the PBS website now detailing new formulary allocations, ex-manufacturer prices and drugs subject to price disclosure.

See pbs.gov.au.

NPS 'choosing wisely'

NPS MedicineWise ceo Lynn Weekes has detailed the organisation's "Choosing Wisely" initiative at the AMA conference in Brisbane, giving doctors a "top five list of tests, treatments and procedures to avoid".

These particular target reducing the use of proton pump inhibitors, opioid use and blood pressure medications, with the plans supported by recommendations from several medical colleges.

Weekes said that not all tests add value, with decisions needing to be based on the best evidence available and the program helping with the long term sustainability of the health care budget.

Fake drug sentence

BRITAIN'S Medicines and Healthcare Products Regulatory Agency (MHRA) has successfully prosecuted a man for the sale and supply of unlicensed medicines.

The long-running case saw 38-year-old Darrell Jacob sentenced to four years imprisonment, with charges also including one count of money laundering.

Jacob was part of a gang of 12 men and women, all of whom have now been sentenced to a total of more than 20 years in prison as a result of an MHRA investigation.

The group had been selling fake drugs on the internet since 2004 until its operation was closed down by the MHRA in 2011.

MHRA's head of enforcement, Alastair Jeffrey, said the case showed the sophistication and scale of "organised criminality" involved in the sale of unlicensed medicines in the UK.

"Those involved repeatedly tried to evade detection and made millions of pounds from their illegal activities," he said.

THANK YOU

To all the pharmacy owners, their staff, patients and stakeholders for supporting the Pharmacy Guild as we negotiated the Sixth Community Pharmacy Agreement (6CPA).

George Tambassis
National President
The Pharmacy Guild of Australia



Community Pharmacy Agreement

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Weekly Comment

Welcome to **PD's** weekly comment feature. This week's contributor is **Felicity Crimston, Manager at JR Pharmacy.**



Business health check

WITH the end of financial year looming, now is the perfect time to give your pharmacy a health-check. As well as understanding the impact of price reductions, this is an opportunity to refresh and enhance your business to improve everyday performance.

Consider the following:

- * Measure the impact that price cuts have on next year's profitability and consider cashflow requirements in a timely manner, for example, varying PAYG instalments for June 2015 in anticipation of reduced profitability so as to avoid unnecessary funds tied up with the ATO.

- * Redefine the roles of your employees by creating competitive points of difference without necessarily increasing wage costs. It is critical to communicate the business's response to the sector changes to staff and how this is important for the future of the pharmacy.

- * Consider broadening the use of online campaigns, promotions and social media marketing. While offering a website is important, websites generally only attract users who are familiar with your brand. By leveraging social media as part of your marketing plan, you can effectively increase the traffic flow to your website and ultimately, into your store.

While the industry challenges to profitability are significant our experience is that most pharmacies have the talent and opportunity to more than offset it.

6CPA chemotherapy alert

THE Sixth Community Pharmacy Agreement has indicated significant changes to the funding of chemotherapy medications.

Under "new arrangements yet to be determined," fees will be paid directly to compounders, with a \$40 fee for non-TGA-licensed providers such as hospital pharmacies, and \$60 for TGA-licensed providers.

The Society of Hospital Pharmacists of Australia says this has the potential to "substantially impact on the provision of these services in public and private hospitals.

"SHPA is also concerned that funding for the additional clinical pharmacy services required to ensure safe and effective delivery of chemotherapy treatments to patients has not been detailed," said SHPA president Professor Michael Dooley.

Current funding arrangements were amended on 01 Jan 2014, with the PBS Efficient Funding for Chemotherapy Schedule (EFC) allowing for reimbursement of up to \$152.66 per chemotherapy infusion to ensure the ongoing

viability of pharmacies delivering these services.

"This funding ends on 30 Jun 2014; it is not clear how the fees listed in the 6CPA for compounding chemotherapy relates to the EFC schedule, or if the EFC Schedule will be extended.

"If there is an overall reduction in the fees paid to those compounding chemotherapy, this could threaten the viability and sustainability of these providers, and many of the access issues that threatened the appropriate care for cancer patients in 2013 will be revisited," Dooley warned.

TGA ACE information

THE Therapeutic Goods Administration will host sponsor information sessions on the new Annual Charge Exemption (ACE) scheme, which will replace the existing low value turnover scheme.

Explanatory sessions will take place in Melbourne on Mon 15 Jun, Sydney on Tue 16 Jun and Brisbane on Fri 19 Jun.

RSVPs including full participant information can be directed to ace.scheme@tga.gov.au.

AHPRA Perth closure

THE Perth office of the Australian Health Practitioners Regulation Agency is closed today, due to a public holiday in Western Australia.

The office will reopen at 9am tomorrow morning.



DISPENSARY CORNER

A MAN from the US state of Missouri has caused an internet sensation by capturing the moment that a spider crawled out of his ear on his smartphone.

Bruce Branit said he had a lot of pain in his year, and was shocked to find that the irritation was actually caused by a spider which was crawling around inside his auditory canal.

"I got a super painful ear infection, tried to use my phone camera to see if I could see anything...Found this," he wrote in the caption of a YouTube video which has gone viral, having been viewed across the globe more than 185,000 times.

INFANT analgesia was definitely not needed in Tokyo over the weekend, where more than 100 babies faced off in a massive "crying sumo" event.

Taking place in the Japanese capital's Asakusa district, the annual event at the Sensoji Temple saw massive sumo wrestlers attempting to make their tiny charges bawl on command, in a tradition believed to bring good health to infants.

Pairs of toddlers were brought into the sumo ring where the wrestlers held them and shook them gently while a referee shouted "Cry! Cry!"

The winner was judged to be the baby who cried the fastest and loudest, with *AFP* reporting that some burst into screams with little prompting, while others didn't cry until one of the judges entered the ring wearing a devil mask.

Win a Dermal therapy pack

This week, **Pharmacy Daily** and **Nice Pak Products** are giving away a Dermal Therapy prize pack including Dermal Therapy Heel Balm Platinum, Dermal Therapy Hand Balm, Dermal Therapy Lip Balm and Dermal Therapy Very Dry Skin Cream.

Dermal Therapy is a clinically proven medicated skin and foot care range designed for people who are prone to very dry skin, Eczema, Psoriasis and Dermatitis. According to Nice Pak, all Dermal Therapy products have been clinically tested with proven visible results and are formulated with Urea. Dermal Therapy products are a combination of innovation and creative thinking that provides effective solutions to common skin and foot problems. Each product is of the highest quality and efficacy and has been developed with Advanced Active Technology with concentrated moisturising base to provide optimum hydration.

To win, be the first from **NSW** or **ACT** to send the correct answer to the following question to: comp@pharmacydaily.com.au

Fill in the blank: Dermal Therapy Heel Balm Platinum provides visible results in ___ days. How much Urea is in the Dermal Therapy Heel Balm Platinum formulation?

Check here tomorrow for today's winner.



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