

Today's issue of PD

Pharmacy Daily today has two pages of news plus two full pages from Promisia supporting Arthrem.

Arthrem safe

FOLLOWING the NZ Medsafe "potential risk" alert around joint-support product Arthrem, from Promisia and marketed by Pharmabroker, Promisia explains it is safe when taken "strictly as directed" - see the full story on **two pages** after the news.

Metformin XR recall

APOTEX, in consultation with the TGA, is recalling one batch of APO-Metformin XR 1000 mg tablets (batch number E16539) due to potential contamination. Go to tga.gov.au for details.



Dermal Therapy

Replenish dry & chapped lips with Dermal Therapy.



Find out more: www.dermaltherapy.com.au

Always read the label. Use only as directed. If symptoms persist, consult your healthcare practitioner.

TGA CM advertising debate

BOTH science and civil society organisations have continued to raise a storm over the passage through parliament the 2017 Measures No.1 Bill, according to an *MJA Insight* article.

The TGA had persuaded major parties that the bill with its creative 'permitted indications' inclusions such as "disinhibit water", "stimulate stagnant Qi", and "subdue yang", was "non-controversial", wrote public health advocates Monash's Ken Harvey, independent chair of the Therapeutic Goods Advertising Complaint Resolution Panel Allan Asher and the Australian National University's (ANU's) John Braithwaite.

The bill has been widely lampooned in the broader media and blasted as "bizarre" and "not supported by scientific evidence" (*PD* 09 Feb 18).

Authors expressed the core concerns arising from the public forum on the matter conducted at ANU on 24 Jan, namely the abolition of pre-approval of advertisements for therapeutic products, the aforementioned permitted indications list and the lack of effective compliance and complaints systems.

While the forum had said, "some aspects of the Bill were commendable," others "posed a public health risk".

As has been widely reported, Greens leader Senator Richard Di Natale sought an amendment which would have mandated an advisory statement on traditional

evidence indications: "This traditional indication is not in accordance with modern medical knowledge and there is no scientific evidence that this product is effective."

Major parties rejected the amendment, noting "that complementary medicines are a \$4 billion export industry," *Insight* authors highlighted.

Go to doctorportal.com.au to access the full article.

The Australian Self Medication Industry (ASMI) has commended the passage of the Bill saying it enables "a package of several important reforms that will strengthen protection for consumers".

"This system will continue to protect consumers from exposure to potentially false and misleading advertisements," an ASMI spokesperson said.

"It will also help medicines advertisers, publishers and broadcasters to ensure that advertisements comply with the Therapeutic Goods legislation.

"The Bill will also provide the TGA with stronger compliance and enforcement powers, including graduated penalties for non-compliant behavior."

ASMI said it also supports the expansion of the permitted indications list.

"This will clean up the free text mechanism, which is where medicine sponsors make up their own indications," says ASMI ceo Deon Schoombie.

See asmi.com.au for more.



By the end of 2018, all Australians will have a My Health Record, unless they decide not to have one.

The Pharmaceutical Society of Australia (PSA) is supporting pharmacists to integrate use of the My Health Record system into patient care. Find out more at www.psa.org.au/digitalhealthhub

Pharmaceutical Society of Australia

Australian Government Australian Digital Health Agency

My Health Record

Meds reconciliation

HIGHER accuracy of complex medication reconciliation can be achieved through improved design of electronic tools according to new work out of the USA published in the *Journal of the American Medical Informatics Association*.

The paper reports on a direct comparison of two different medication reconciliation tools integrated into electronic health record systems that are aimed at determining the accuracy of the two different tools.

The authors found that clinicians using one platform made significantly fewer errors with the better performing tool presenting lists in a side-by-side view, automatically grouping medications by therapeutic class and more effectively identifying duplicates.

CLICK HERE for the research.

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Dispensary Corner

SUFFERERS of conditions like irritable bowel syndrome beware - it might get you involved in a brouhaha at 40,000 feet.

A man suffering from "uncontrollable" flatulence found himself used by two angry Dutchmen as a giant whoopee cushion after they became irate at his perpetually foul odour.

The Transavia Airlines flight was on route to the Dutch capital of Amsterdam from Dubai when it was forced to make an emergency landing after a brawl broke out over the issue of passing wind.

One witness said the obese man accused of constantly breaking wind became quite angry when confronted, claiming he retorted by really letting one rip.



NUTRITIONISTS are always telling us to lay off the sugar, well it makes it much harder when a city opens an entire Museum dedicated to the infamous carb.

New York is gearing up to introduce the Museum of Candy to its citizens, a temple of sweetness that contains the world's largest gummy bear.

The museum follows the opening of the Museum of Ice Cream, famed for its swimmable sprinkle pool.

Anybody caught with a concealed vegetable on the tour of the museum is promptly beaten up with toffee apples before being asked to leave.

Pharmacy training offers

THE Pharmaceutical Society of Australia (PSA) has announced it has resumed training for community pharmacy qualifications across Australia for pharmacy staff, including dispensary and pharmacy assistants.

Enrolments are now open for the Cert III in Community Pharmacy, Cert IV in Community Pharmacy and Cert IV in Community Pharmacy (Dispensary).

PSA said it would also be adding the popular Dispensing short course to the suite of training opportunities.

Mundipharma buys Tolmar for Eligard(R)

FOLLOWING several months of comprehensive due diligence and negotiation, Mundipharma has announced the acquisition of specialist pharmaceutical company, Tolmar Australia, supplementing its own oncology portfolio by including exclusive distribution rights for the oncology medication Eligard and Bi-Eligard (leuprorelin acetate) in Australia and New Zealand.

As the peak national body for all pharmacists, PSA has Government contracts for subsidised places and traineeships in most states for eligible pharmacy staff for Cert III and IV in Community Pharmacy.

Funded places are also available in some states for the Diploma of Leadership and Management. Visit psa.org.au for details.

Precision medicine

THE future of precision medicine in Australia is developed in a report by that name from the Australian Council of Learned Academies (ACOLA), supported by the Department of Health and launched at the end of Jan.

The full report is now available online drawing on an expert working group's exploration of the issues.

Precision medicine combines knowledge of a person's unique genetic makeup along with a range of other information, including the patient's environment, so as tailor care for specific individual needs. Visit acola.org.au for the report.

Win with Dreambaby®

Each day this week Pharmacy Daily and Dreambaby® are giving readers the chance to win the latest from Dreambaby® valued at \$44.90.

Prize includes 'Herbert' the Turtle Room & Bath Thermometer - RRP: \$19.95. Made from BPA Free and Phthalate Safe durable waterproof material, Herbert gives fast and accurate temperature readings. You can also win Dreambaby®'s new non-slip super light-weight and simple-to-clean EZY-Potty - RRP\$24.95. www.dreambaby.com.au or call 02 9386 4000.

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



What is Dreambaby®'s Herbert the Turtle made from?

Congratulations to yesterday's winner, Laura Little from Jetty Village Pharmacy Coffs Harbour.

Dispensing error decriminalisation

NEW legislation to protect community pharmacists in the UK from prosecution over dispensing errors has been signed into law by the Privy Council, and could come into force as soon as Apr this year, reports the *Pharmaceutical Journal*.

The Pharmacy (Preparation and Dispensing Errors - Registered Pharmacies) Order 2018 will introduce new defences for inadvertent dispensing errors by registered pharmacy professionals working in registered pharmacies.

It is intended to encourage a more transparent culture of error reporting by reducing the fear of criminal prosecution, thereby allowing pharmacy teams to learn from mistakes.



Guild Update

Workplace resources

GUILD Members may be interested to know that the Guild website now offers a useful set of revamped workplace relations resources.

There are more than 80 resources (documents and information) which can assist Guild members in managing staff and complying with their employer obligations. The resources also provide guidance with issues such as performance management or workforce planning.

The expanded set of resources can be viewed here (Member log in required): www.guild.org.au/resources/workplace-relations/member-resources.

Advisory re: Medsafe alert "Arthrem – potential risk of harm to the liver"



www.medsafe.govt.nz/safety/EWS/2018/Arthrem.asp

19 February 2018

THE ISSUE

Late last week Medsafe issued an advisory relating to 14 reports of liver toxicity associated with the use of Arthrem, from February 2016 up until 31 December 2017.

Many of the reports included jaundice as a reaction. Where information was provided (liver function tests and biopsy results), the pattern of liver toxicity was either hepatocellular or mixed (hepatocellular and cholestatic). All the patients stopped taking Arthrem and at the time of reporting most had already recovered or were improving.

Arthrem is a dietary supplement for maintenance and support of healthy joints. It is sold as soft gel capsules that each contain 150 mg extract of *Artemisia annua*, grape-seed oil, glycerine and gelatine.

IS ARTHREM SAFE?

When taken as directed, Arthrem is safe and effective.

Safety is – and has always been - our top priority. That is why Arthrem is the world's only clinically trialled and safety trialled *artemisia annua* joint support product. Both trials were conducted by Otago University, and published in peer-reviewed journals (*Clinical Rheumatology* and *New Zealand Medical Journal*). The clinical trial informed the product formulation and dosage advice. Unlike other *artemisia annua*-based joint support products on the market, Arthrem is formulated deliberately in twice-daily dosages (rather than a larger dose once daily) in order to reduce the risk of toxicity.

There have been an extremely small number of reported cases of adverse reaction. This level of adverse reaction is considered to be very rare by the World Health Organization's adverse reactions guidelines – less than 0.007% of all bottles sold (i.e. under 1 in 14,000).

WHAT WE ARE DOING

Promisia takes this Medsafe Alert very seriously. In addition to communication with pharmacies, retailers and health professionals, we are also taking the following steps:

- Update bottle labelling to note that 'in rare circumstances *artemisia annua* may be associated with liver harm'. Until new labels are available a sticker will be produced and sent to all pharmacies with the above caution.
- Amending the advice provided on our website to note the potential but rare risk of liver harm, identifying potential symptoms including: nausea (feeling sick), stomach pain, pale stools, dark urine, itching all over, the whites of the eyes turning yellow or the skin is yellow (jaundice). In the event of these symptoms being observed the person is advised to stop taking Arthrem and consult their doctor.
- Amending messaging on labels, point-of-sale material, etc., to stress that the product must be taken strictly as directed.
- The amended point of sale material will be included with all product sold via our website

WHAT TO ADVISE CUSTOMERS WHO ARE BUYING OR INQUIRING ABOUT ARTHREM

At the point of sale, please stress the importance of taking Arthrem strictly as directed and to stop taking it immediately if they experience any adverse reactions. Adverse reactions may include (but are not limited to):

- nausea (feeling sick)
- stomach pain
- pale stools
- dark urine
- itching all-over
- the whites of the eyes have turned yellow or the skin is yellow (jaundice)

Remind the customer that this is the case when taking any kind of pharmaceutical medication or natural health remedy.

Please note that it is perfectly safe to keep taking Arthrem provided the person is not suffering adverse effects or has any contraindicated condition/s. Arthrem is not suitable for:

- People who have elevated liver enzymes, liver disease or liver cancer
- Anyone who is pregnant, planning to become pregnant or breastfeeding
- People who are taking antiretroviral drugs for HIV
- Anyone who is taking drugs that are known to prolong QT interval
- Children

FOR FURTHER INFORMATION

Please don't hesitate to contact us on our 24 x 7 toll-free helpline (1 800 256 966) if you have any questions or concerns.