

Tuesday 22 Apr 2014

False Herceptin alert

THE European Medicines Agency (EMA) is warning healthcare professionals across the EU to be aware that vials of the cancer medicine Herceptin (trastuzumab) have been tampered with and re-introduced into supply chains in some countries.

The vials were thought to have been stolen from Italy and reintroduced under false credentials, with warning signs including batch numbers and expiry dates that do not match, and liquid in some of the vials when Herceptin is a powder.

None of the falsified product had been identified at hospital level and no harm had come to patients, the EMA reported.

Authorities were investigating, the EMA said.

TGA Cilantro alert

THE Therapeutic Goods Administration (TGA) said investigations had shown people in Australia may have bought Swanson Full Spectrum Cilantro, item SW1112, which has been voluntarily recalled in the US due to potential salmonella contamination.

To read more, CLICK HERE.

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API's \$131m impairment

AUSTRALIAN Pharmaceutical Industries Ltd (API) announced it would incur an asset impairment charge of \$131m (PD breaking news 17 Apr).

Following an extended trading halt on shares, the company said the non-cash charge was comprised of, in part, \$15m for New Zealand manufacturing, due to the strong Kiwi dollar.

The unit would make a first half loss of about \$750,000, compounded by declines in contract volumes due to a large amount of stock carried over by the industry as a result of the relatively mild cold and flu season last year, API said.

The company told **PD** it would continue to review the role of the unit, given that it had "real potential" to manufacture private label products for the Australian business.

Other factors contributing to the overall charge included pharmacy customers with long term debts.

The company said as a matter of policy it never commented on the number or ownership of pharmacies involved.

"Finalisation of documentation will occur when these customers

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"We expect this to be concluded in the second half of the year, which then provides API with flexibility to review the assets again at the full year, which may result in a write back."

Another contributing factor was \$20m for Clifford Hallam Healthcare (CH2), due to "continued underperformance."

API said CH2 was an investment and not core to its strategy.

"We will continue to work with management and the other major shareholders to maximise performance with a view to a sale at an appropriate time."

A charge of \$44m for retail was a result of impairment modelling on store network growth rates, driven by the Board's decision to take a more conservative approach to the size of the network over the five year horizon, API said.

"In combination with the relatively high discount rate of 17.5% the regrettable outcome is formulaic and reflects the appropriate accounting standards.

"As indicated in our announcement, the trading performance for Priceline and Priceline Pharmacy has been very strong in the first six months with market leading like for like growth of 5.3% and a further growth of 10 stores since the full year."

API said its Sister Club had a database of 4.6m registered members who had joined either in-store or online.

FDA nods Ragwitek

THE US Food and Drug Administration (FDA) has approved Ragwitek to treat ragweed pollen induced allergic rhinitis (hay fever).

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SHPA forum and chat

THE Society of Hospital Pharmacists of Australia (SHPA) is inviting members to sign up for its Accredited Pharmacists' forum and online chat service.

The organisation said the service was for pharmacists interested in medication review services and to share information and ask questions.

Members can sign up by sending an email to cpd@shpa.org.au with a request to join.



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Electronic drug track

THE US Food and Drug Administration (FDA) is working with The Drug Supply Chain Security Act, signed into law last November, to create a system that will help identify and trace certain prescription drugs as they are distributed within the US.

The system will provide a history of the transactions involving each product, the ultimate goal being to identify each individual prescription drug package to enable rapid verification of the legitimacy of the product.

If a counterfeit or other harmful drug is discovered, the FDA can readily notify patients, health care professionals, hospitals and others about the public health risk.

August price reduction

THE 01 Aug price reductions for the 2014 supplementary cycle A have been released, with only one drug, Riluzole, announced.

Used to treat amyotrophic lateral sclerosis, the drug will see a 19.41% reduction.

FDA approves Cyramza

THE US Food and Drug Administration (FDA) has approved Cyramza (ramucirumab) for use in patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma.

The treatment was an angiogenesis inhibitor which blocked blood supply to tumours, the FDA said, and was intended for patients whose cancer could not be surgically removed or had spread.

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Pharmacists in Focus

subgroups in society.

In addition, a future supply

expanded scopes of practice,

issue cited was the potential for

such as those raised in the recent

Grattan Institute report, including

pharmacists as immunisers and

pharmacist repeat prescribing.

MEANWHILE following the

Pharmacy Guild of Australia's

survey of pharmacy services,

day per week.

diabetes support.

editorial in full.

executive director David Quilty said

that one in 10 pharmacies will be

forced to drop at least one trading

Quilty was writing in his editorial

for forefront and summarised

some of the results including a

list of pharmacy services such as

dose administration aids, home

deliveries, after hours care and

"The last thing a pharmacy wants

to do is reduce the services to its

patients, or charge more for such

crucial basic services, but they are

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Century Epidemics', at the Sofitel

Sydney Wentworth Hotel heard

about mounting evidence to link

insulin resistance and cancer; how

off and even assist chronic kidney

disease, with a major Australian

clinical trial currently underway;

US Integrative & Preventative

survivor, Dr Lise Alschuler told

a link between higher insulin

Medicine practitioner, and cancer

delegates that studies had found

levels and many cancers including

colorectal, breast and endometrial

"Insulin resistance is one of the

most critical risk factors for cancer

For a summary of highlights from

development and progression."

the symposium, CLICK HERE.

chronic inflammation.

cancers

and the role of curcumin in treating

healthy gut flora could help to ward

with the theme of 'Unravelling 21st

being left with no choice."

report by CLICKING HERE.

CLICK HERE to read Quilty's

DELEGATES at the second

HEALTH Workforce Australia (HWA) has released a report which examines pharmacist training, their various roles, issues, projects and workforce viability in Australia and New Zealand.

The report, titled 'Pharmacists in Focus', compares the pharmacist role to that of other registered health care professionals.

In 2012, there were 27,025 pharmacy registrations, 22,676 (83.9%) of whom were in the workforce and 21,331 (94.1%) of whom were employed.

There were 2.3% more males in pharmacy roles in 2012 than in 2011, and 4.6% more females who comprised 58% of the total work force.

Average age was approximately 40 years with females having a much younger profile, implying their future dominance of the pharmacy role.

Average working hours were similar for 2012 and 2011 at 38.8 hours for males and 33.7 hours for females, the majority working 35-39 hours per week.

Issues raised by the various peak bodies representing pharmacies and pharmacists highlighted government funding policies around medication reviews and hospitals supplying PBS drugs.

They also emphasised the changing role of the hospital pharmacists from mainly a 'supply service' to a consultative member of a healthcare team, as well as the increasing numbers of non-community pharmacists into specialised roles with specific

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Generics save billions

GENERIC medicines have played a "critical role" in saving billions of dollars for the US health system and the economy according to president and ceo of the Generic Pharmaceutical Association (GPhA) Ralph G. Neas.

Neas was quoted in a report titled 'Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013', which pointed out that even though medical services increased, the cost of medicine went up by 3.2%, an historically low rate.

In addition, the savings were being passed on to retail customers he said, with 57% of medications available for five dollars or less.

The report is quoted on IMS' website - to read it, CLICK HERE.

Anxiety nasal spray

FROM a study out of US and Mexican university psychiatric departments comes a novel treatment for social anxiety in the form of a nasal spray.

The authors conducted a phase II, multicenter, randomized, doubleblind, placebo-controlled study using a single-dose of PH94B.

Ninety-one women aged from 19 to 60 years of age with generalised social anxiety disorder were involved, with the study recording a significantly greater decrease in mean Subjective Units of Distress scores.

The authors concluded that PH94B may be an effective, and well-tolerated acute treatment for performance and social anxiety in women with social anxiety disorder. CLICK HERE to access the study.

No Heartbleed for eRx

ERX Script Exchange has said it is not affected by the Heartbleed vulnerability.

The software security bug has been making the news rounds, with affected websites including Amazon and Tumblr and reports that account information could have been exposed.

eRx said it did not use the technology that was targeted by the bug and therefore was not affected by the vulnerability.

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MHRA Business Plan

THE Medicines and Healthcare Products Regulatory Agency (MHRA) published its business plan.

The MHRA said that this is an important document that sets out key work over the next year to progress their 2013-18 Corporate Plan - CLICK HERE to read.



Upholding the law on unapproved pharmacies

The Guild has recently provided detailed evidence to the Government in relation to eight unapproved pharmacies in Queensland and New South Wales from which pharmaceutical benefits are being supplied, despite the pharmacies' lack of approval to do so. This is on top of 11 other batches of evidence that have previously been provided.

Last month the Guild was represented at a meeting involving the office of the Minister for Health, representatives of the **Commonwealth Departments** of Health and Human Services, a Queensland pharmacy owner and that owner's local Member of Parliament. This was an important and productive step in finding and implementing solutions to this problem and was followed two weeks ago by a meeting in Canberra that also involved the Pharmacy Board of Australia.

Let's be clear - there are no grey areas in the law in this area. There are no loopholes. Supplying a pharmaceutical benefit at or from an unapproved premises is a contravention of the National Health Act 1953. The practices that are used to facilitate this activity may also breach state law, professional standards and codes of conduct and ethics.

The relevant Commonwealth Departments and the Pharmacy Board of Australia are now working collaboratively and proactively on this issue and the Guild will pursue it alongside the Government.



The Pharmacy **Guild of Australia**

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ABS report on medicines

THE 17th Edition of the

'Australian Statistics on Medicines' has been released by the Australian Bureau of Statistics (ABS).

Subsidised prescriptions were dominated by cardiovascular therapies at \$71m for 2011, followed by nervous system therapies at \$43m and alimentary tract products at \$29m, all slightly variant from the prior two years. Anti-infectives were the largest category in non-subsidised prescriptions.

Adverse event reporting had more than doubled since 2008 due mainly to increased reports being passed through sponsor companies who had heightened pharmacovigilence, with 52% of reports coming through that route, the edition said.

Drug Utilisation sub-committee chair Geoff McColl said ABS data contributed to monitoring and quality assurance of the PBS.

"Knowledge about the usage, cost and trends over time in prescription medications is clearly relevant for all four aspects of the National Medicines Policy: access

to medicines; guality, safety and efficacy of medicines, quality use of medicines; and a responsible and viable medicines industry."

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To read the report, CLICK HERE.

Corruption enquiry

UK drug company GlaxoSmithKline (GSK) is under investigation for alleged bribery of doctors to encourage prescription of its asthma therapy Seretide (fluticasone with salmeterol).

According to BBC Panorama, a former sales representative has blown the whistle implicating at least one GSK employee and drawing a confession from one doctor who in accepting a £100 payment for a lecture that he didn't have to give, told BBC Panorama, "They kept tempting, and I am just a man."

GSK UK said on its website that it was starting a two year process to end the practice of paying doctors to speak on the company's behalf.

It said it had been disclosing aggregate sums paid to healthcare professionals annually since 2013.



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BEST pizza in the world in Oz.

The country of origin of the pizza, Italia, has awarded the Pizza World Championship, officially The Campionato Mondiale Della Pizza, to an Australian chef, Di Francesco, owner of the 400 Gradi restaurant in Melbourne.

According to Yahoo News, he had to beat some 600 contestants with his version of the margherita pizza, which is only allowed to include basil leaves, garlic, olive oil, mozzarella, salt and tomatoes.

"A lot of people think it is easy to produce a margherita but it is one of the hardest [pizzas] to produce," he told the Australian website Good Food.

"With a margherita there is no hiding anything that isn't right."

HOW to dodge \$28K in tolls. A thrifty New York taxi driver has been charged with stealing more than \$28k from the Metropolitan Transit Authority (MTA) by "crossing the Robert F. Kennedy (RFK) Bridge and entering the Midtown Tunnel without making a toll payment on more than four thousand separate occasions by 'piggybacking' on cars directly in front of his cab between 2012 and 2014," reported Yahoo News.

His technique to avoid road tolls was to tailgate other cars so closely that the boom gate would not come down until both vehicles had passed through, apparently not an uncommon trick but rarely taken to this extreme.

\$1M Poker or passover? Eric Afriat of Montreal, Quebec, who was expected to join his family for the Jewish holiday of Passover, skipped the social event to pursue his passion at the final night of a poker tournament being held at the Seminole Hard Rock Hotel & Casino.

While perhaps not the most pious of actions, according to the Sun Sentinel he made the right choice, as he left the tournament with a cool \$1 million in hand.