

FDA social media guide

IN AN attempt to provide a consistent guide for drug and device marketers who wish to use or respond to social media in relation to their products, the US Food and Drug Administration (FDA) has released its first and second draft guidance documents.

The first guidance relates to the presentation of risk and benefit information where the technology restricts the amount of text available, such as Twitter, insisting that companies ensure there is included a means of accessing complete information.

The second guidance relates to companies wishing to correct third-party information about their product through social media channels.

CLICK HERE for full details.

FDA drug warnings

THE US Food and Drug Administration (FDA) is advising consumers not to purchase or use Sliming [sic] Diet, Sport Burner or Toxin Discharged Tea which contain either sibutramine or fluoxetine and can have serious side effects.

The FDA also warned against Miraculous Evil Root which has been shown to contain sildenafil but neither manufacturer nor the product have been approved.

TGA embraces EDQM

THE Therapeutic Goods Administration (TGA) is to strengthen its collaboration with the European Directorate for the Quality of Medicines and HealthCare (EDQM) by participating in and embracing EDQM's procedure for the Certification of Suitability to the monographs of the European Pharmacopoeia (CEPs).

More on methotrexate

THE Pharmacy Board of Australia said it was aware of four serious adverse events since 2011, including fatalities, related to errors in prescribing and dispensing methotrexate (*PD* 16 Jun).

It said this was "four too many" and it had raised the issue in its May communiqué as an important public safety message and to educate the profession.

A spokesperson for the Board said there had previously been cases involving errors in the administration and dispensation of methotrexate in the Victorian coroners' court, interstate and overseas.

The communiqué referred to this information and other investigations underway by other agencies that the Board was aware of, the spokesperson said.

This was unfortunately not a new concern for the Board, which had also raised the issue in its September communiqué and had issued guidance on dispensing medications.

The Board took its role in protecting the public and educating the profession about safety risks

seriously, it said.

The spokesperson said as regulators, Australian Health Practitioner Regulation Agency (AHPRA) and the Board were not able to release detail or make comment on individual matters.

"Any restrictions imposed by the Board on the registration of any pharmacist are published on the register of practitioners at www.ahpra.gov.au."

The AHPRA annual and National Boards 2012-13 report showed of the 429 notifications received about the pharmacy profession, 244 were about pharmacy/medication.

The Guild said in 2013 that community pharmacy dispensed about 200m prescriptions annually.

To read the May communiqué alerting the profession to the issue, **CLICK HERE**.

Acupuncture pain

NPS MedicineWise has posted a paper summarising the literature relating to the use of acupuncture for pain relief.

The article originally appeared in *Health News and Evidence* and was titled 'Is acupuncture effective for pain?'

As well as discussing the controversies surrounding the therapy, the article proposes that there is evidence of a modest effect on neck, back, osteoarthritic knee and head pains.

CLICK HERE to read the paper.

New AusPARS

THE Therapeutic Goods Administration has added new AusPARS for golimumab (rmc), olodaterol (as hydrochloride) and fentanyl (as citrate).

CLICK HERE for more.

Pharmacy Daily app

NEEDING to keep up with the latest pharmacy news on the go?

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The app will work on iPhones and iPads with an Android version in the works.

Check out **page four** for more information.

AMA position update

DOCTORS are to maintain an arm's length relationship with product and service suppliers and retain a focus on the patient, the Australian Medical Association (AMA) has said in its 2014 updated Position Statement relating to Advertising and Public Endorsement.

The Position Statement had been reworked to include ethical principles for advertising and endorsement by doctors, the AMA said.

The use of gifts, discounts, or prizes in advertising by doctors was not appropriate and the nature of the doctor's relationship with the relevant organisation (or individual) should be open, accountable, and transparent, the statement said.

AMA President associate professor Brian Owler said the overarching principle in regard to advertising or endorsements is that a doctor's primary duty is to act in the best interests of patients.

CLICK HERE to access the updated Position Statement.

Soliris UK recall

ALEXION Pharma UK is recalling certain batches of Soliris (eculizumab) 300mg Concentrate for Solution for Infusion because they were manufactured using the same process as a batch of Soliris (which was not distributed to the UK market) where a small number of vials were found to contain visible particles (*PD* 04 Jun).

The company said it believed there was little affected stock remaining in the UK and there had been no safety signals around this issue.



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\$80,000 immunisation

GLAXOSMITHKLINE (GSK) has launched its 2014 Immunisation Grants for local communities that aim to improve access and timely delivery of vaccination services.

Four grants of \$20,000 each have been made available with a closing date of 15 Aug; GSK said in 2013, Tasmania Medicare Local used the grant to provide free flu vaccination clinics for people accessing crisis support services.

The grants were offered for specific child or adult programs on alternate years but had been merged to help health professionals apply for the grants closer to the start of their project - [CLICK HERE](#) for more.

Labour, occupancy costs

THE Productivity Commission's interim report found for most retailers, labour and occupancy costs comprised a major share of the costs of doing business.

The report, the final form of which is expected in October, found that labour expenses were the single largest expense for retail businesses, while occupancy costs were often major expenses for many retailers and changes in these costs were more significant for smaller retailers.

It said larger stores did not consider rent and occupancy costs as major issues; when looking at rent as a percentage of costs of

doing business, it found pharmacies came in at under 15% compared with furniture stores at about 40% and just above supermarkets and grocery stores at about 7.5%.

As a percentage of the cost of doing business for pharmacies, wages were the highest expense at about 60% and other expenses at about 20%, the report found.

Pharmacy Guild of Australia executive director David Quilty said in *forefront* that the Guild intended to provide further input to the report.

"In particular, we need to clarify some of the data in the interim report which appears to overstate the level of labour costs in pharmacy and understate the increases in occupancy (or tenancy) costs."

The report's key points included that costs of doing business in the retail sector were inflated by unnecessary regulations and governments' progress to address "costly anti-competitive provisions" had been "slow and patchy".

To read the report, [CLICK HERE](#).

Bexsero app to FDA

NOVARTIS has submitted a biologic license application to the FDA for marketing approval for the use of Bexsero, its meningitis B vaccine candidate, in children and young adults from age 10 to 25 years old.

This follows FDA approval for a breakthrough therapy designation (*PD 09 Apr*).

Stay in Bed Day - AMDF

NEEDING to stay in bed to rest is a common outward symptom of the debilitating and potentially fatal genetic disorder mitochondrial disease ("mito"), so Stay in Bed Day is an apt way for pharmacy teams to support sufferers in the lead up to the event and on the official day.

The Australian Mitochondrial Disease Foundation (AMDF) is asking pharmacists on 29 Jun to support its awareness and fundraising event, National Stay in Bed Day - for more, [CLICK HERE](#).

Obesity a 'disability'

DENMARK has asked the European Court of Justice to rule on a case of a 160kg childminder who says he was sacked for being too fat, *BBC News* reported.

The court's ruling will be binding across the EU and if obesity is determined to be a disability due to a medical condition, this may involve new employer requirements such as non-discriminatory recruitment, office redesign and parking provision.

The Billund authority has argued the number of children enrolled in the service had declined and that it paid for him to go to the gym for three months.

Fast orals post dental

FASTER acting analgesic formulations provide earlier onset of pain relief, better overall pain relief and a less frequent need for additional analgesia, according to a recent study.

Published in the *European Journal of Pain*, the research looked at individual patient data analysis of 322 participants in a trial of placebo, paracetamol, ibuprofen sodium and ibuprofen-poloxamer following third molar extraction.

Visual analogue scale pain intensity (VASPI) scores were found to fall rapidly following both ibuprofen formulations and rapid reduction in the first hour correlated with good overall pain relief with lesser need for additional analgesia within six hours, the research said.

To read the study, [CLICK HERE](#).

Phaxan patent

AUSTRALIAN company Drawbridge Pharmaceuticals has been granted a new anaesthesia patent for its water-based anaesthetic formulation of the neuroactive steroid alphaxalone, Phaxan.

Ceo Dr Anthony Filippis said patents had been granted in the United States, UK, Hong Kong, Singapore, Australia and New Zealand, and that the patent in China would provide coverage to 2031.

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HSV-infected newborn

HSV-INFECTED newborns are four times more likely to be born to under 20 year old mothers according to new research.

"Neonatal HSV infection is usually acquired during delivery following maternal genital HSV infection, but can also be acquired post-natally from an infected contact," says the study's lead author, University of Sydney Professor of Paediatric Infectious Diseases, Dr Cheryl Jones.

The study, published in *Clinical Infectious Diseases*, confirmed international research showing that HSV-1 has replaced HSV-2 as the leading cause of neonatal HSV disease - **CLICK HERE** to read more.

Travel Specials

WELCOME to Pharmacy Daily's travel feature. Each week we highlight a couple of great travel deals for the pharmacy industry.

Spurn the winter chills and save up to 30% at three Outrigger resorts with these special offers.

Stay at Outrigger Laguna Phuket Beach Resort from THB3,495 (about A\$115) (plus taxes and charges) in a deluxe room, at Outrigger Phi Phi Island Resort and Spa from THB4,479 or about A\$147) (plus taxes and charges) in a deluxe garden villa and at Outrigger Laguna Phuket Resort and Villas from THB3,299 or about A\$109 (plus taxes and charges).

The offers for two include buffet breakfasts and must be booked before 30 Jun and are valid for stays up to 30 Sep.

To book, contact the hotels.

MEANWHILE Emirates Wolgan Valley Resort & Spa is offering a two night Winter Warmer package, available from 01 Jul until 15 Sep, which includes two nights in a luxury Heritage suite with private swimming pool and verandah, gourmet breakfast, lunch and dinner daily, all non-alcoholic beverages, a select range of local wines and beer with meals, and two on-site nature based activities per day.

All this is on offer for \$740 per person per night for a twin share, a saving of \$570 per couple.

Visit www.wolganvalley.com for more information or to book.

Oz health #4 in world

THE Commonwealth Fund's report on 11 nations' health care systems has found Australia ranks number four overall.

The report uses patients' and physicians' survey results on care experiences as well as information from the World Health Organisation and the Organisation for Economic Cooperation and Development.

It found Australia was number two when it came to quality care, following the UK and ahead of Switzerland and New Zealand at four, while the UK came top in overall ranking, with Switzerland second and the US last.

For cost related access problems, where Australia came ninth overall, the report found 16% of people did not fill a prescription, skipped a recommended medical test, treatment or follow-up, or had a medical problem but did not visit a doctor or clinic in the past year due to cost.

For adults of below average income, 14% reported they did not fill a prescription or skipped doses because of cost in the past year, compared with 8% of those with above average income.

For the former, Australia had a

lower percentage only than the Netherlands (20%), New Zealand (18%) and the US (30%).

AMA president associate professor Brian Owler said the report showed Australia had a sustainable health system with the lowest level of expenditure on health as a percentage of GDP across all the countries.

However, he said it showed that the cost of accessing health care was a significant issue.

To read the report, **CLICK HERE**.

Heart health check

To support healthcare professionals, the Heart Foundation has developed two short videos with cardiologist Cathie Coleman from St Vincent's Hospital to explain what a heart health check is and why it's important to reduce risk for women in Australia, with heart disease the single biggest killer for this group.

The Foundation urges you to encourage your patients to get a heart health check and learn their risk of heart disease.

To view the two or four minute video, visit www.goredforwomen.org.au.



DISPENSARY CORNER

BEST survey so far.

If you stock hair dye in your pharmacy or if you just enjoy a good pun, you might want to take a look at the latest results from Roy Morgan's annual survey of about 10,745 women aged 14 and over.

Entitled 'A good (hair) day to dye hard: for more affluent women, at least', the research looks at the fall in sales of home hair-colouring products, but the rise in the percentage of affluent women buying home hair dye.

The research found in the year to March 2014, 32% of Australian women purchased home hair-colouring products in an average six months, down from 36% in the year to March 2010.

However, 27% of women who earned \$100,000 or more purchased home hair colour in the same period, up from 25% in 2010.

This equated to 70,000 women, Roy Morgan said.

TAKE that, Phil Neville!

World cup fever is upon us - whether sales of Panadol for said fever have increased remains to be seen (badum tschhh), but a radiator salesman from Suffolk may be ruing the tournament's inception, given he became the victim of a torrent of Twitter abuse aimed at World Cup commentator, Phil Neville.

The fairly unremarkably named Neville from Suffolk began receiving abuse after his commentator doppelganger was criticised for his lack of emotion and monotone style during the England versus Italy match in the weekend, the *Telegraph* reported.

The BBC told the publication it received 445 complaints after the game.

Meanwhile, the radiator salesman has joked that he is also available for commentary work, the *Telegraph* reported, which, judging from the number of complaints, might not be such a far off possibility.

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Every day this week **Pharmacy Daily** is giving one lucky reader the chance to win a set of **Sukin's** top four best sellers.

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From what kind of pressing and extraction process is the Sukin Rose Hip Oil obtained?

Congratulations to yesterday's winner; **Suen Yee Chew** from **Miranda Day and Night Pharmacy**.

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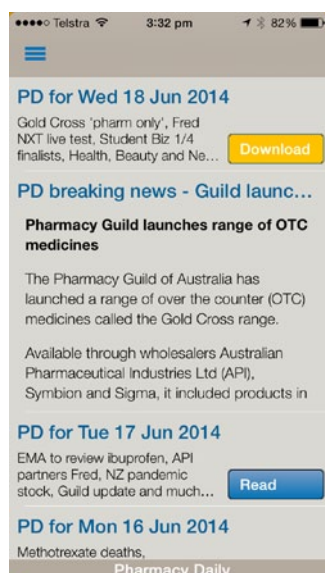
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