

Today's issue of PD

Pharmacy Daily today has two pages of news plus a full page from Wizard Pharmacy.

FDA pings Delta Labs

THE US Food and Drug Administration (FDA) has sent a warning letter about manufacturing practices at NSW-based Delta Laboratories, in relation to its facility in Somersby, near Gosford.

Following a five-day inspection last Mar, the FDA found a number of defects including a failure by Delta to thoroughly investigate release and stability testing failures in two batches of a drug product.

"For example, you found tubes swelling at the 3-month stability time point. You did not investigate this significant defect, which can be indicative of microbial growth and spoilage," the letter said.

In addition, the FDA said Delta "lacked adequate process validation studies, did not have adequate stability data and failed to provide an adequate response to the agency on taking corrective actions to bring operations into full compliance".

Despite admitting struggling with manufacture of the product, items continued to be commercially distributed to consumers, with the FDA saying the findings indicated Delta's quality unit was "not fully exercising its authority".

The FDA recommended that Delta employ a qualified Current Good Manufacturing Practice (CGMP) consultant to address the violations and until they are corrected it may withhold approval of any new applications or supplements listing Delta as the manufacturer.

API warns of slow sales

AUSTRALIAN Pharmaceutical Industries this morning alerted investors that its half year result would be down about 9% on the previous corresponding period, with "suppressed retail conditions" persisting until late in the key Christmas trading period.

Overall sales across the Priceline Pharmacy network, including dispensary, for the financial year to date are up 2%, while like-for-like front of store sales had dipped 2.4% over the same period.

"In contrast to the strong sales we experienced during 2016, consumer spending remained subdued throughout the 2017 calendar year and we did not see that change during the Christmas period," said ceo Richard Vincent.

He said API was reacting to the tougher retail environment, with a range of measures including "investments to enhance our total customer experience".

That includes in-store changes and the company's digital transformation program which is designed to enhance Priceline's Sister Club loyalty program.

S3 ad clarification

THE Therapeutic Goods Administration has stressed that the proposed changes to advertising of Schedule 3 medications (**PD** Fri) are part of a draft new Scheduling Policy Framework which is still subject to public consultation.

In the meantime, advertising of S3 products not contained in Appendix H is not permitted, the TGA said.

"We have adjusted the business cost base while we've strengthened and streamlined our retail leadership team to drive a more responsive business in the changing consumer environment, particularly in the important beauty segment," Vincent said.

He said API's expectations for growth in store numbers for the Priceline and Priceline Pharmacy network remained unchanged, while API's pharmacy distribution business continued to perform to expectations.

Vincent said API now expected its half year net profit after tax (NPAT) for the six months to 28 Feb to be about \$26.5 million, while full year NPAT would likely be marginally above that of FY2017.

Opioid consultation

OPTIONS for a regulatory response to opioid use and misuse in Australia are being canvassed in a new discussion paper released by the Therapeutic Goods Administration on Fri.

The TGA noted that several overseas jurisdictions were already facing 'crises' in the widespread misuse of prescribed opioids, "and evidence shows Australia trending down a similar path".

The paper proposes a range of responses including smaller pack sizes for S8 opioids, a review of indications, restriction of high dose products to authority prescribing, strengthening risk management plans, label information reviews, raising awareness of alternatives and more - see tga.gov.au.

Metformin recall

APOTEX is recalling one batch of APO-Metformin XR 1000 mg tablets (batch number E16539) after a report of a small piece of white plastic - most likely from a cable tie - being embedded in a tablet.

Pharmacists are being asked to inspect stock and quarantine any products from the affected batch.

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Dispensary Corner

MEDICINAL marijuana is the subject of several clinical trials, however, administering the substance en masse to a bunch of fifth-graders is, let's face it, far more ethically questionable.

That's what happened at a primary school in Albuquerque recently when a student began handing out medical marijuana lollies she thought were just regular candy.

Most students only ate one of the gummies and felt dizzy as a result, however the one student who gobbled down four pieces soon found herself unconscious.

Thankfully all of the students recovered from the incident without injury and the school's tuck shop also reported a huge spike in sales at recess.



MEN of the cloth have often claimed throughout history to be able to perform medical miracles, and while it may have been far from a miracle on this occasion, Pope Francis at the very least proved himself to be a good bloke on his visit to Chile recently.

When a policewoman was thrown from her horse as the pontiff passed by in his pope-mobile, he reportedly stopped the procession and waited with her until medical help arrived. Amen brother!

Concern over CM ad changes

THE Federal government has been accused of attempting to bypass a Senate Committee review of proposed changes to advertising of complementary medicines, on the basis that the *Therapeutic Goods Amendment Bill* is "non-controversial".

Friends of Science in Medicine spokesman John Dwyer highlighted the issue in a statement on Fri, saying requests for a public hearing about concerns relating to the legislation over the Christmas-New Year period were rejected because Senators were on holiday.

"This bill is anything but non-controversial...that is particularly true for changes suggested for the regulation of the advertising of complementary medicines," he said.

Dwyer said concern was so great among a number of "civil society organisations" that they had combined to hold a public hearing to debate contentions provisions of the proposed legislation.

Participants backing the event include Monash University, The Foundation for Effective Markets

and Governance, The School of Regulation and Global Governance at the Australian National University (ANU), consumer group *CHOICE* and Friends of Science in Medicine.

The public hearing will be held at ANU on 24 Jan 2018, from 2-5 pm.

Contentious aspects cited include:

1. the removal of pre-approval of advertisements for therapeutic goods in favour of self-regulation;
2. the TGA's plans to take over the advertising complaint system without ensuring ongoing stakeholder input and transparency of complaint outcomes, and
3. the Bill indicates it will endorse an industry-submitted list of 'permissible indications' for complementary medicines.

Monash University's Professor Ken Harvey said vetting of advertisements prior to publication is "economically efficient because fraudulent therapeutic claims create unnecessary health expenditure and divert scarce health resources from remedies that work, to ones that don't".



Weekly Comment

Welcome to **PD's** weekly comment feature.

This week's contributor is **Eleni Yiasemides**,



Consultant dermatologist specialist and Mohs micrographic surgeon.

Treatments

FOR teens suffering from oily or acne prone skin, it's important that they take the necessary steps towards managing and treating their skin to keep future breakouts at bay.

Some steps that teens can take is actively engaging in the 3-step process- cleansing, treating and moisturising each day.

Cleansing, treating and moisturising is a simple regime to help teenagers manage oily or acne prone skin.

The second step, treating, targets acne-causing bacteria and unblocks pores. This can be very important for teens suffering from multiple breakouts who want to take control of their skin.

Treatments can improve the appearance of the skin, and lead to a better quality of life for teenagers living with acne. In terms of active ingredients in treatments, treatments containing Acrylates Copolymer and Benzoyl Peroxide can help to treat acne.

Treating is an important step in the process and if done correctly with cleansing and moisturizing can give teens the potential to help achieve a clear, radiant complexion.

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