



TGA takes action on **Peptide Clinics**

THE Therapeutic Goods Administration has kicked off legal action against Peptide Clinics Australia, claiming the company advertised compounded prescription-only therapeutic goods to the general public.

The TGA investigated the company's advertising of 'peptides' on its website and other social media platforms, saying it included references to serious forms of diseases and to conditions such as anxiety and depression.

"These references require approvals or permissions, for which it is alleged there are none," the TGA advised.

The advertising is also alleged to be in breach of the Therapeutic Goods Advertising Code 2015 because it contained statements, claims and implications that the advertised peptides were safe or alternatively could not cause harm, and encouraged inappropriate use of the medicines.

"The promotion of these peptides to consumers is also alleged to have contained scientific information that was inaccurate, imbalanced and misleading," the TGA said.

Peptide Clinics has undertaken to remove the relevant advertisements from its website pending final hearing of the matter, while the Department of Health said the Court will be asked to impose financial penalties when the matter is heard next year.

API plots Sigma takeover

SIGMA Healthcare Limited has advised its shareholders that there is "no certainty" that the indicative merger proposal received from Australian Pharmaceutical Industries on Fri (PD breaking news) will result in a transaction.

The company responded to API's announcement by confirming that it had received the proposal in Oct 2018, with the rival firm offering to acquire all the shares in Sigma via a scheme of arrangement.

Under the Indicative Proposal Sigma shareholders would receive 0.31 API shares plus 23c in cash for each Sigma share held.

"The Indicative Proposal was subject to a number of conditions including due diligence, a unanimous Board recommendation and receipt of all regulatory approvals including any required competition approvals," Sigma said.

The Sigma board said it had commissioned consulting firm Accenture to undertake an assessment of the future expectations of the company on a standalone basis, with initial conclusions suggesting a "material value opportunity for all Sigma shareholders post a restructure of the business following the company's decision not to renew its contract with Chemist Warehouse".

API has taken a 12.95% stake in Sigma Healthcare, saying the rationale for a merger is "more compelling than ever" due to

ongoing Community Service Obligation funding being flat while costs are increasing, PBS reforms continuing to drive price deflation, and the industry landscape remaining highly competitive "with new entrants and further disruption likely".

"The merged business would provide scale and volume, which will give greater scope for the ongoing investment in technology that is essential to ensure a competitive, sustainable and efficient wholesale model in the future," said API Chair, Mark Smith.

API is estimating \$60 million in gross financial benefits through merging the companies, and is urging the Sigma Board to engage in order to allow the full merger benefits to be reviewed.

The company hopes to deliver a binding proposal early in 2019.

Fri's announcement saw Sigma shares surge over 43% to 58c.

2019 Choosing Wisely

NPS MedicineWise has opened registration and abstract submissions for its 2019 Choosing Wisely National Meeting.

Set to take place on Thu 30 May 2019 at the Melbourne Cricket Ground, the annual event will bring together Choosing Wisely members and supporters, policymakers, consumer advocates and other healthcare influencers for a day of discussion on highlights, challenges and opportunities for the initiative.

Trish Greenhalgh, Professor of Primary Care Health Sciences at the University of Oxford has been announced as keynote speaker.

Abstract submissions that highlight advances and learnings in supporting the Choosing Wisely Australia initiative will be accepted as abstracts for posters or "lightning talks" while a prize will also be awarded for the best abstract submitted by a student studying in a health profession.

CLICK HERE to register.



Topical corticosteroid options for eczema, dermatitis and other steroid responsive skin conditions.34,5

DermAid: Use for the temporary relief of minor skin irritations, itching and rashes due to eczema, dermatitis, cosmetics, jewellery, itching genital and anal areas and sunburn. DermAid 1% cream: Apply a thin layer to affected skin 1–2 times daily as required. Klowema: Short term (up to 7 days) treatment of milder forms of eczenne, dermatitis and other steroid responsive skin conditions.

Dosage: For 12 years and over. Apply a thin film and gently rub in, using only enough to cover the affected area twice daily for up to 7 days.

Contraindations: Klowema cream should not be used in patients with a history of hypersensitivity to clobetasone butyrate or to any of the excipients in the product. Rosacea, acne, pruritis without rash, perioral dermatitis; Untreated bacterial infections such as those associated with tineal (eg athlete's foot, jock lidh); Viral infections including cold sores (herpes simplex), chicken pox or shingles (Varicella zoster) or vaccinia; Parasitic infestations such as cableits. Fon to use on broken or infected skin or or inflamed skin near chronic ulcers. Topical corticosteroids inhibit wound healing processes and are contraindicated in skin ulcers, cuts and abrasions.

Before prescribing/recommending please refer to the full Product Information. Full Product Information is available on request from Ego Pharmaceuticals Pty Ltd. Click here for Zatamil Approved Product Information.

PBS Information: Zatamil Lotion and Zatamil Ointment 15g: Restricted benefits Treatment of corticosteroid-responsive dermatoses. Zatamil Lotion and Zatamil Ontment Authority Required (Streamlined) for increased quantities. Refer to PBS Schedule for full authority in Zatamil Hydrogel and Zatamil Ointment 45g: These products are not listed on the PBS.

Prepared October 2018

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Monday 17 Dec 2018



Dispensary Corner

AT LEAST it won't clog your arteries.

American fast food giant KFC is getting into the festive spirit with the launch of a new fire log designed to smell exactly like its signature fried chicken.

The KFC 11 Herbs & Spices Firelog has been created in partnership with a firm called Enviro-Log and is being hailed as a major breakthrough.

"For more than a million years, mankind has been attempting to improve upon the simple fire," the promotional blurb states.

"We've tried burning different things like sticks or leaves or various incriminating documents.

"We've tried making fires last longer. We've even figured out how to turn them into different colours," it continues.

"All of that experimentation, all of that innovation, has culminated in this event, the KFC 11 Herbs & Spices Firelog," KFC concluded.

The limited edition log is only available in the USA and costs US\$18.99 while supplies last - so people had better get in quick if they want to have a Kentucky Fried Christmas.

Fortunately for potential customers it also comes with a handy safety tip, with formal instructions advising "Please don't put face directly into fire in attempt to smell fried chicken".



New Vic guidance

THE Victorian Pharmacy Authority has released further guidance on pharmacy business commercial arrangements, with the aim of assisting pharmacists and stakeholders to check that their business arrangements comply with the legislation.

Published guidance documents now include items on pharmacy franchising, leasing, intellectual property licence agreements, loan agreements & security agreements, partnerships, sale of business agreements and service agreements.

The new documents supplement existing guidance on pharmacy trusts, and highlight "important provisions of the Pharmacy Regulation Act 2010" to be aware of when negotiating or entering into such agreements.

The Authority has also issued a reminder to proprietors about their responsibilities, confirming expectations that all owners of pharmacy businesses in Victoria will visit their pharmacies regularly.

See pharmacy.vic.gov.au.

Narcotic Act review

HEALTH Minister Greg Hunt has appointed Professor John McMillan to review and report on the operation of the Narcotics Drug Act 1967.

The Act establishes a framework to both prevent abuse and diversion of controlled narcotics and to ensure the availability of such drugs for medical and research purposes.

In Oct 2016 the Act was also extended to provide for the regulation of cannabis cultivation and production in Australia "to enable a sustainable supply of safe medicinal cannabis products for therapeutic purpose".

The review is required as soon as possible after the second anniversary of the commencement of the 2016 amendments, with a report to be tabled in Parliament by 29 Oct 2019.

Hunt said a public consultation process would form part of the review, and this is expected to commence early next year.

Afluria Quad approval

THE Pharmaceutical Benefits Advisory Committee has recommended the expansion of availability of Afluria Quad (inactivated quadrivalent influenza vaccine) to people aged 5-17 under the National Immunisation Program.

The full list of recommendations from the Nov 2018 PBAC meeting is online at pbs.gov.au.

Welcome to Pharmacy Daily's weekly comment feature. This week's contributor



is Peter Marshall, Managing **Director - Pharmacy Solutions** Australia.

Buying the right **Pharmacy**

WHETHER buying your first pharmacy or your fifth, your thought process should be similar – does this business suit my skill set and where can I add value? Does the pharmacy you wish to purchase give you scope to utilise your skills?

I have sold the same pharmacy within 2 years on many occasions because the purchaser either didn't understand what they were best at (or enjoyed most) about retail pharmacy, or they settled for a pharmacy because they felt some sort of external pressure to buy it.

Medical centre pharmacies do not suit all personalities, pharmacies with a heavy retail focus likewise do not lend themselves to everyone. If you are buying a business that needs to be relocated, doctors co-located or poor lease to be re-negotiated – these can be difficult to achieve and not everyone has the necessary acumen.

I would suggest that to truly understand where you or your company's skills lie, you should seek an opinion from a trusted business advisor or mentor. Having people around you that have industry experience and are trusted is a massive step in the right direction for any business professional, no matter how small or large.

Win with SkinB5

This week Pharmacy Daily & SkinB5 are giving away each day the NEW SkinB5's Clear Skin Superfood Booster valued at \$63.90.

Clear Skin Superfood Booster is an innovative nutritional approach to skin wellness for blemish and acne prone skin, using specially selected ingredients to supply the body with key vitamins, minerals, essential fatty acids, amino

acids, digestive enzymes, probiotics & prebiotics. Available from Sigma PDE CODE PD301911. Watch the YouTube video here for more.

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

> How many ingredients are in the Clear **Skin Superfood Booster?**

Check here tomorrow for today's winner.



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