Pharmacy Daily
Thursday 13 Sep 2018

S3 sildenafil rejected

THE Therapeutic Goods Administration's (TGA's) Advisory Committee on Medicines Scheduling (ACMS) has knocked back an application to make erectile dysfunction drug sildenafil available over-the-counter as a pharmacist-only medicine.

The ACMS said sildenafil did not satisfactorily meet the criteria for a Schedule 3 medicine because erectile dysfunction is a symptom with an underlying cause that requires diagnosis by a doctor.

The anonymous application had argued that easier access to the drug would encourage more men to seek treatment and lead to earlier and more frequent interaction with health professionals.

It also claimed that making it pharmacist-only would "destigmatise" erectile dysfunction and raise awareness of its association with diabetes and cardiovascular disease.

However the TGA's committee said "the use of sildenafil at established therapeutic dosage levels may mask the symptoms or delay diagnosis of cardiovascular disease, [which] cannot be diagnosed by a pharmacist".

It's the second time the ACMS has rejected an application to downschedule sildenafil.

The committee also rejected an application to increase the pack size for S3 paracetamol/ibuprofen combinations to 50 dosage units, saying a larger pack could potentially see consumers delay seeking further advice from a health practitioner and encourage off-label treatment of chronic pain.

Qld council "no benefit"

ESTABLISHING a Pharmacy Council in Queensland to enforce ownership restrictions and regulate pharmacy premises would cost up to $11 million over a 10 year period and would not provide any net benefit to the Qld community.

That is the key conclusion of a report by the Queensland Productivity Commission which was tabled late last month as part of the current Parliamentary Inquiry into pharmacy ownership in the state.

The economic evaluation looked at a cost-benefit analysis of establishing a pharmacy council in Queensland.

Costs were based on the direct institutional requirements of setting up such a body, but the report also noted there may be other costs as a result in terms of consumer choice and prices.

A range of possible benefits were considered, including service quality and availability, improved policy advice and education and training by pharmacies.

"Based on the available data, the Commission found no evidence that other Australian states with pharmacy councils have better outcomes..than Queensland," the report summarised.

It also found there was no evidence that existing premises regulation in Qld was resulting in unsafe conditions within pharmacies, nor that more intensive enforcement of the ownership restrictions would provide greater consumer benefits.

"The Commission has found that any of the possible impacts it has identified from forming a pharmacy council are unlikely to produce a material benefit," it concluded.

A range of regulations are already operating to achieve the objectives sought from the ownership rules, the report noted, saying administering things more intensively - such as by creating a pharmacy council - "is unlikely to produce material benefits...rather it simply adds to the general cost of regulation.

"Overall the results suggest the Queensland community will be unambiguously worse off," the report summary states.

See parliament.qld.gov.au.

Walgreens patient data purchase

AMERICAN pharmacy giant Walgreens has confirmed the US$165 million purchase of pharmacy patient prescription files relating to 185 stores operated by competitor Fred's Pharmacy.

The deal is part of efforts to improve the financial performance of Fred's which is undergoing a turnaround plan and is seeking to monetise non-core assets.

Once the deal settles Fred will be left with just 162 pharmacies in a number of general merchandise stores - a far cry from plans last year by Fred to bulk up its pharmacy presence by the purchase of 865 Rite Aid stores.

Fred's move was blocked by authorities, with Walgreens ending up buying almost 2,200 Rite-Aid stores instead.

TGA-evaluated CMs

COMPLEMENTARY Medicines (CMs) that have been evaluated by the Therapeutic Goods Administration (TGA) have been listed on the TGA website.

They include iron and folic acid supplements, phosphates, tea tree oil, vitamin D and calcium preparations, probiotics, head lice solutions and fibre tablets.

See the full list at tga.gov.au.

$10m clinical trials

THE Federal Government is investing $10 million to fund six new rare cancer and rare disease clinical trials focused on improving survival rates with new treatments.

The six new clinical trials will target pancreatic cancer, traumatic brain injury, rare skin tumours, myeloma, myelofibrosis and a pioneering treatment for high mortality cancers, such as glioblastoma, with some having a five year survival rate as low as 8%.

Ramsay misses pharmacy targets

RAMSAY Health Care failed to achieve its goals for Ramsay Pharmacy and its franchise business during the last financial year.

The company's annual report, released yesterday, noted that growth in the Ramsay Pharmacy and its franchise business was one of the strategic objectives listed as contributing to the short term incentive for Ramsay ceo Craig McNally, who did not receive all of his possible bonus because pharmacy targets were not reached.

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NPSA urges more action

THE National Pharmaceutical Services Association (NPSA) has warned that despite improvements in legislation designed to manage medicine shortages (***PD*** 12 Sep), patients continue to be placed at risk because of "loopholes in the supply chain" for pharmaceuticals.

The peak wholesaler body welcomed the passage of the *Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018* because it will help doctors and pharmacists minimise the impact on patients in the event of medicine shortages.

"More action is needed, however, to extinguish avoidable risks," said NPSA chairman Mark Hooper, ceo of Sigma Pharmaceuticals.

"Exclusive direct supply from manufacturers to pharmacies creates a dangerous dependency on sole distribution for the medicines they carry, with no redundancy of supply.

"If there is a supply interruption, for whatever reason, then patients would potentially be denied access to their medication," Hooper said.

He noted the high standards for availability of PBS items under the Community Service Obligation (CSO).

"If one CSO distributor cannot supply a drug, another is available to meet the shortfall...that system works when every PBS medicine is available to every CSO distributor," Hooper said.

The NPSA urged the government to "take the logical next step in managing medicine shortages and plug this regulatory loophole by ensuring all PBS listed medicines are made available to CSO distributors at equivalent prices".

UK family busted for fake drugs

A BRITISH family that produced home-made drugs in a cement-mixer has been convicted, with a man, his wife and his brother pleading guilty to producing and supplying unlicensed medicines and money laundering.

The defendants ran an online business that sold supplements to the body-building community, however many of the products included "powerful drugs used to treat conditions ranging from severe acne to cancer".

The UK Medicines and Healthcare products Regulatory Agency prosecuted the trio after seizing more than 112,000 tablets and almost 2,000 bottles of injectable liquids from premises they used.

The arrests followed a probe triggered by suspicions based on their lavish lifestyle and unexplained wealth.

FDA ticks new naloxone combo

THE US Food and Drug Administration has approved Teva Pharmaceuticals' Cassipa (buprenorphine and naloxone) sublingual film for the maintenance treatment of opioid dependence.

The move provides for a new dosage strength (16mg/4mg) of buprenorphine and naloxone, which is approved in both brand name and generic versions.

"There is an urgent need to ensure access to, and wider use and understanding of, medication-assisted treatment for opioid use disorder," the FDA said.

SME WA workshop

THE Therapeutic Goods Administration has announced a free "Meeting Your Obligations" workshop for small to medium enterprises (SMEs), start-ups and researchers.

The event is presented by SME Assist, aiming at beginners who are unfamiliar with therapeutic goods regulation in Australia.

It will take place from 9am to 5pm on Fri 26 Oct at Clifton's Parmelia House, 191 St Georges Terrace, Perth WA 6000.

RSVPs are due by Fri 12 Oct - for more information or to register see the website at tga.gov.au.

DuPont has the right ingredient

DUPONT Nutrition & Health is celebrating after its "Howaru Shape" probiotic won the Ingredient of the Year category at NutraIngedients-Asia Awards which took place in Singapore last Mon.

The awards aim to recognise "true innovation and cutting edge research" in healthy foods, supplements and nutrition.

Howaru Shape is the product of "outstanding gold standard science and extensive global consumer research," DuPont said, and is a brand new probiotic and prebiotic that appeals to consumers seeking to control their weight and improve their body shape, without changes in daily diet or exercise.

The company said a series of safety and efficacy studies along with a clinical trial had demonstrated that Howaru Shape can deliver a "clinically significant reduction in total body fat mass, trunk fat and waist circumference".

DuPont cited consumer insight research indicating that so-called "Weight Strugglers" are an important segment among health and wellness shoppers who are concerned about weight related health issues, but who cannot seem to overcome barriers that prevent attaining a healthy weight.

The company has a significant presence in microbiome science and pre- and pro-biotics, and works with manufacturers to help develop new products, brand growth and differentiation.

The award was accepted on behalf of DuPont by Andrew Henriksson, principal application specialist, who said he was "extremely proud of the entire DuPont team on working together on the submission".

For more information see www.danisco.com/Shape.

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Dispensary Corner

WELL this is a little awkward.

A cholera outbreak in the northern region of Ethiopia is being blamed on contaminated holy water in some of the area's monasteries.

The epidemic has tragically seen at least ten people die in the last two weeks, while more than 1,200 victims have contracted the disease, reports the *BBC*.

Authorities say poor hygiene and drinking of unsafe water is to blame, with the monasteries unfortunately believed to be taking water from rivers carrying the awful disease.

The local government has taken the controversial step of interfering in religious affairs by ordering the temporary cessation of holy water use.

FEELING stressed at work?

Perhaps you should take note of the latest craze sweeping South Korea, which has seen the launch of a host of new 'Stress Cafes' according to *The Atlantic*.

Guests are welcomed with slippers, dim lights, soothing tea, board games, massage chairs, beanbags and hammocks, while some outlets also offer esoteric add-ons - which could be classified as professional services - like oxygen generators and mental health counselling.

One of the chains, with the catchy title of "Mr Healing" has opened more than 100 outlets since 2015.

There's probably an interesting research project studying the correlation of the rise of the public havens with the recent nuclear sabre-rattling of North Korean neighbour Kim Jong Un.

Opioid pack size review

THE Therapeutic Goods Administration (TGA) has commenced a review of opioids commonly used to treat acute pain in the home setting, to consider whether registered pack sizes align with the requirements for their intended short-term use.

The plan is one of the outcomes of the TGA's consultation on opioids (***PD*** 23 Jan 2018) which saw almost 100 submissions received from government bodies, industry suppliers, health professionals and other organisations.

The TGA said there was "strong and consistent support" for four of the proposed options in the consultation paper, including the pack size review, looking at indications for opioid products used to treat pain, reviewing label warnings and Consumer Medicines Information, as well as working to raise health professional and consumer awareness about pain management guidelines and non-opioid alternatives for chronic pain.

If suitable pack sizes for post-surgical or injury acute pain treatment are not available, the TGA said it would work with sponsors to support them in registering smaller pack sizes of these products.

"Importantly, this review is not considering restriction of larger pack sizes for products that are registered to treat chronic pain, including cancer pain," the TGA said.

A review of the Product Information for opioid products is also under way, with a focus on the currently approved indications taking into consideration current clinical guidelines, responses to the public consultation and warnings provided in comparable overseas medicines information documents - particularly relating to Fentanyl which has been identified as an opioid of particular concern for abuse and misuse.

Consumer Medicines Information documents for opioids are also under review, focusing on how clearly the risks of addiction and overdose are conveyed, while the TGA has also flagged the creation of a plan to raise awareness and educate health professionals about pain management guidelines.

Travel Specials

WELCOME to *Pharmacy Daily*'s travel feature. Each week we highlight a couple of great travel deals for the pharmacy industry, brought to you by *Cruise Weekly*.

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