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Tuesday 04 Jul 2017

SAS notification broadened

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

Today's issue of PD

RACGP slams Amcal pathology move

THE Royal Australian College of General Practitioners (RACGP) has blasted the new pathology testing services offered by Sigma's Amcal chain (*PD* 26 Jun 2017).

"Pharmacists add value when it comes to giving advice and information about medicines, but ordering a test through a pharmacy rather than your local GP creates risks for patients including fragmentation of care, unnecessary duplication of tests, confusion about the interpretation of the results, and increased out of pocket costs," the doctors' group said. Go to racgp.org.au for more.

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THE Therapeutic Goods

Administration (TGA) has published an update about the Special Access Scheme (SAS), introducing Category C, a new accelerated notification pathway to drug access.

Category C allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval.

The goods will be specified in a list along with their indications and the type of health practitioner authorised to supply them.

There are separate lists for medicines, medical devices and biologicals, each with their own set of rules defining who is authorised and under what conditions. In addition, the TGA has

developed more guidance on access to medicinal cannabis products along with an SAS guidance tool for access to unapproved therapeutic goods, SAS guidance for health practitioners and sponsors and an SAS FAQ section together with new forms for each category.

Consent to treatment and indemnity for use forms are also included and information around importing controlled substances.

NIP expansion

EFFECTIVE 01 Jul the National Immunisation Program (NIP) is being expanded by the Federal Government to include more catchup vaccines for people, including immigrants, to protect them against vaccine preventable diseases.

The expansion aims to improve the quality of the community's herd immunity which is critical to protect those too young or too sick to be immunised with a focus on preventable diseases like measles, mumps, meningococcal, polio, whooping cough, chickenpox and Human Papillomavirus (HPV).

There are currently more than 467,000 Australians aged between 10 and 19 years who are not fully immunised, the government said. Pharmacist arrested

THE Western Australian Corruption and Crime Commission has published its report on Schedule 8 drugs resulting from the investigation of a pharmacist who had become highly addicted to a potent opioid drug (hydromorphone).

The pharmacist subsequently circumvented controls on various Schedule 8 drugs at two hospitals so as to steal the drugs for his personal use, the report said. As a consequence,

recommendations were made to WA Health to prevent further such abuse of S8 access, including regular compliance checks, enhancing automated systems and introducing automated Electronic Storage and Supply Unit systems. Visit ccc.wa.gov.au for more.

Fluorouracil a-flagged

APOC-5FU (fluorouracil 5% w/w cream) from Apotex is now listed on the RPBS effective 01 Jul as a-flagged and interchangeable with iNova Pharmaceuticals' Efudix for the treatment of solar and senile keratoses as well as Bowen's disease, the company has said.

APOC-5FU is the only generic fluorouracil available in pharmacy.



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Dispensary Corner

SOMETIMES Viagra can be expensive, according to Norway's Eigersund Mayor Odd Stangeland. The hapless mayor is facing

down a \$20,000 bill to restore the

famous tourist magnet, the "penis rock" or trollpikken (loosely, the

"troll dick") to its former glory. Vandals had truncated the erection using powerful drilling equipment, police believe, but so far there are no suspects.



Local contractor Sverre Garpestad is quoted as saying that with the aid

of helicopters, it would take about an hour to drill new supports, add bolts and mortar, and replace the landmark, or in his own words, "We have the Viagra it takes."

The cost is being crowd-funded to support local tourism.

HERE'S a fascinating statistic men who have children when they are older tend to have "geekier sons," according to a new study released by King's College London.

The researchers devised a 'Geek Index' based on a combination of non-verbal IQ, ability to focus on a subject, and "social aloofness" - and those who had a high score went on to do better at school.

They speculated a range of reasons for the phenomenon, including the fact that geekier dads took longer to find a mate and start a family - and passed on those traits to their children.

TWC inaugural Expo success



MORE than 350 people, including hundreds of pharmacy owners and pharmacy staff, came together for business development and networking at the inaugural TerryWhite Chemmart (TWC) Suppliers and Strategic Partners Expo held recently at the Adelaide Convention Centre.

The event has been running under the Chemplus banner since 2008, but this was the first time it was held for the merged TerryWhite Chemmart network.

The expo also provided members with an update on the business, including the launch of the TerryWhite Chemmart Baby Diaries App, which has been likened to a 'one-stop-shop' for new parents. TWC ceo Anthony White said the Expo was a "key event on the calendar for South Australian members and available to all members nationwide."

He said the event gives pharmacists direct access to suppliers and industry partners to ask questions and learn more about new products on the market.

OTC Training Academy

NICHOLAS Hall and Xpotential will be exhibiting at the 2017 World Self Medication Industry General Assembly and running a one-day OTC Training Academy Workshop, to be held in Sydney on 20 Oct.

CLICK HERE for more information.

WIN WITH **DESIGNER** BRANDS

This week *Pharmacy Daily* and Designer Brands are giving away each day three of their DB Cosmetics Longwear Lipsticks.

These smooth, creamy lipsticks deliver all-day wear and opaque colour. Easy to apply, the DB Cosmetics Longwear Lipstick glides onto the lips without dragging or pulling. With super-strong pigments for a rich, intense colour that lasts. **CLICK HERE** to see more

To win, be the first person from QLD to send the correct answer to the question to **comp@pharmacydaily.com.au**

Does DB Cosmetics test on animals?



MOST community pharmacies across Australia participate in the voluntary Return of Unwanted Medicines (RUM) program.

Guild

The program began in 1998 as a Commonwealth Government program aiming to give all Australians access to a free and convenient method of disposing of expired and unwanted household medicines.

The success of the program can be seen from its initial collections of some 100 tonnes of unwanted medicines to the current 700 tonnes a year.

Collected medicines are taken to a high temperature incinerator for safe and environmentally friendly disposal.

The need to properly dispose of unwanted or expired medicines is to prevent residuals of the medicines being recirculated into the environment and food chains.

Interestingly, the data from collection of unwanted medicines also can prove valuable.

Monash School of Pharmacy reviewed a representative sample of the returned bins and found the bins were more than 93% full on average, with 44% of the returned medicines not expired.

Insulin, salbutamol, paracetamol, frusemide and glyceryl trinitrate were the top five medicines returned.



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MIMS

New Products

- Ibrance (palbociclib) is a small molecule inhibitor of cyclin dependent kinases (CDK) 4 and 6. Testing of palbociclib in a panel of molecularly profiled breast cancer cell lines revealed high efficacy against luminal breast cancers, particularly estrogen receptor (ER) positive breast cancers. Ibrance is indicated for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer in combination with: an aromatase inhibitor as initial endocrine based therapy; fulvestrant in patients who have received prior therapy. Ibrance is supplied as capsules containing 75 mg, 100 mg or 125 mg of palbociclib in packs of 21.
- Naglazyme (galsulfase (rch)) is a normal variant form of the polymorphic human enzyme, N-acetylgalactosamine 4-sulfatase. Galsulfase (rch) is a lysosomal enzyme that catalyses the cleavage of the sulfate ester from terminal N-acetylgalactosamine 4-sulfate residues of glycosaminoglycans (GAG), chondroitin 4-sulfate and dermatan sulfate. GAG substrate accumulation throughout the body leads to widespread cellular, tissue and organ dysfunction. Naglazyme is indicated as long-term enzyme replacement therapy in Mucopolysaccharidosis VI (MPS VI, N-acetylgalactosamine 4-sulfatase deficiency, Maroteaux-Lamy syndrome). Naglazyme is supplied in vials containing 5 mg galsulfase (rch) per 5 mL solution in packs of 1.

New Indications

- Halaven (eribulin mesilate) is now indicated for the treatment of unresectable liposarcoma in patients who have received prior chemotherapy for advanced or metastatic disease.
- Keytruda (pembrolizumab (rch)) is now indicated for the first-line treatment of metastatic non-small cell lung carcinoma (NSCLC) in patients whose tumours express PD-L1 with a ≥ 50% tumour proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumour aberrations.

Keytruda is now indicated for the treatment of advanced NSCLC in patients whose tumours express PD-L1 with $a \ge 1\%$ TPS as determined by a validated test and who have received platinum containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received prior therapy for these aberrations prior to receiving Keytruda.

Keytruda is now indicated for the treatment of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum containing chemotherapy.

New Contraindications

- Codeine (Panamax Co, Prodeinextra (paracetamol/codeine phosphate hemihydrate), Mersyndol, Panalgesic (paracetamol/codeine phosphate hemihydrate/doxylamine succinate)) is now contraindicated in the event of impending childbirth or in case of risk of premature birth.
- Phenobarbitone Injection (Aspen Pharma) (phenobarbital (phenobarbitone)) is now contraindicated in acute intoxication with alcohol, hypnotics or analgesics or intoxication with stimulants or depressant psychotropic agents.
- Pregnyl (human chorionic gonadotrophin) is now contraindicated with abnormal (not menstrual) vaginal bleeding without a known/ diagnosed cause.
- Serenace (haloperidol), in common with other neuroleptics, has the potential to cause rare prolongation of the QT interval. Use of haloperidol is therefore contraindicated with clinically significant cardiac disorders, history of ventricular arrhythmia or torsades de pointes, and uncorrected hypokalaemia. Haloperidol should not be used concomitantly with other QT prolonging drugs.
- Varilrix and Varilrix HSA-Free (varicella vaccine, live attenuated) are contraindicated with severe humoral or cellular immunodeficiency.
- Viekira Pak Combination Therapy Pack (paritaprevir/ritonavir/ombitasvir and dasabuvir) is now also contraindicated in moderate hepatic impairment (Child-Pugh B) due to risk of potential toxicity.

This list is a summary of only some of the changes that have occurred over the last month. Before prescribing, always refer to the full product information.