Pharmacy DAILY
Tuesday 09 Apr 2013 PHARMACYDAILY.COM.AU

Virility pill finding

THE Therapeutic Goods Administration has ordered that a retraction notice appear on websites promoting so-called "Virility Pills" in Australia.

The move follows a complaint about the product's advertising which implied it was clinically proven, effective in all cases and cannot cause any side effects.

WIN A PLUNKETTS PRIZE PACK

Every day this week ***PD*** is giving two lucky readers the chance to win a **Plunketts** prize pack, valued at over $26 each.

Each prize pack contains Plunketts Vita-E Natural Vitamin E Cream 100g, Plunketts 99% Pure Aloe Vera Gel 75g and Plunketts Sorbolene Concentrated Moisturiser 100g.

To win, simply be one of the first two people to send in the correct answer to the question below to: comp@pharmacydaily.com.au.

How much Vitamin E is in every gram of Vita E?

Hint! Visit www.plunketts.com.au

Congratulations to yesterday's lucky winner, **Adeleye Erinle** of **Broken Hill Base Hospital**.

Dextropropoxyphene win

DI-GESIC and Doloxene will continue to be available to Australian pain sufferers, after a decision last Fri by the Administrative Appeals Tribunal (AAT) that medications containing dextropopoxyphene should remain on the Australian Register of Therapeutic Goods.

It's the culmination of a long-running saga initiated more than 12 months ago (***PD*** 24 Nov 2011) when the Therapeutic Goods Administration decided to cancel the registration of Capadex, Doloxene, Paradex and Di-Gesic effective from 01 Mar 2012.

At the time the decision was based on a TGA review of "available evidence" which showed the compound can affect the electrical activity of the heart, potentially increasing the risk of arrhythmia.

Aspen Australia, which supplies Di-Gesic and Doloxene, claimed the TGA had relied on a flawed study of just six patients, describing the data as "questionable".

Early last year Aspen applied for a stay of the suspension from the ARTG (***PD*** 17 Feb 2012), and then in Jun the Administrative Appeals Tribunal issued a decision which referred the matter back to the Therapeutic Goods Administration.

The TGA once again decided to suspend the medications, with Aspen subsequently launching a further AAT case (***PD*** 13 Sep).

Aspen said as part of that appeal that there would be patients left without satisfactory pain relief if the medications were removed from the market.

A final hearing was set down for Feb this year (***PD*** 09 Nov 12) after the TGA confirmed that it had considered various proposals put forward by the sponsors of the medicines which would allow them to stay on the ARTG.

However the TGA said it "was not satisfied that the proposals would address the safety issues identified".

In this latest decision the Tribunal has now decided that both Di-Gesic and Doloxene should remain on the ARTG, subject to the implementation of conditions to promote the safe use of the drugs.

"The AAT's decision was made after considering the evidence of scientific and medical experts put forward by both the Therapeutic Goods Administration and Aspen over the course of a week during 2012, and a further hearing in February 2013," according to a statement issued by Aspen yesterday afternoon.

Aspen said it would provide further details of the conditions that will be implemented, in further communications to pharmacists.

"Doctors may continue to prescribe both products after carefully considering the indications, warnings and contraindications in the Product Information and Consumer Medicines Information for these products," the company said.

Di-Gesic is currently available at community pharmacies while info on the availability of Doloxene, which is currently out of stock, will be provided shortly.

Mildura hospital pharmacy restructure

PHARMACISTS working at Mildura Base Hospital in Victoria have been told their positions are being made redundant, with the hospital pharmacy being outsourced to another company within the Ramsay corporation.

The 146-bed hospital was built by Ramsay Health Care in a 2000 privatisation arrangement with the Victorian govt, and a group called Reclaim Mildura Base Hospital (RMBH) is agitating for it to return to public management.

According to RMBH, existing hospital pharmacy staff at Mildura are being required to reapply for their positions in the new "privately managed public hospital pharmacy department".

Roche Isis deal

ROCHE has announced a new alliance with US-listed Isis Pharmaceuticals to develop treatments for Huntington's disease, based on Isis' 'antisense oligonucleotide' (ASO) technology.

Roche will combine its proprietary 'brain shuttle' technology with ASO in the hope that a successful treatment would allow systemic administration of antisense drugs to treat asymptomatic patients.

Three pages today

TODAY'S issue of ***Pharmacy Daily*** has three pages of all the latest industry news, including our regular Tuesday Guild Column on **page two** and the April monthly medicines update from MIMS on **page three**.

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Guild Update

Workplace Relations tip: Record keeping

Community pharmacy employers who engage employees under federal workplace relations laws have a legal responsibility to ensure accurate and complete time and wages records are kept, and pay slips are issued to each employee. These record-keeping and pay slip obligations are designed to ensure that employees receive their correct wages and entitlements.

Maintaining accurate employment records is not only required, but also of real benefit to a pharmacy businesses.

• Documentation justifies employment actions, from recruitment and selection to resignation, retirement or termination.

• Training and development and compensation and benefits are parts of employee documentation as well.

• Maintaining accurate and complete documentation supports human resources objectives, such as succession planning and promoting from within.

• Employee documentation, when prepared carefully, confidentially and according to company policies, can reduce the chance of litigation.

• Employee documentation is good business practice and part of QCPP accreditation.

So make sure those records are up to date.

The Pharmacy Guild of Australia

APC committee members

THE Australian Pharmacy Council (APC) has called for applications and nominations for membership of its governing Council as well as its Examining Committee and Accreditation Committee.

Under the National Registration and Accreditation Scheme, APC is designated as the independent accreditation agency for pharmacy schools in Australia until July 2018.

There are two Councillor positions available from 01 July this year, with the appointments initially for a three year term.

There are also two new roles available on the Examining Committee - one for an early career pharmacist and the other for a specialist in statistics/ psychometrics or assessment.

Two academic members are being sought for the Accreditation Committee from the second half of 2013, with applicants able to self-nominate or be nominated by their organisation.

An overview of the positions and selection criteria are currently available on the APC website - **CLICK HERE** for details.

Applications are due by midnight on Sunday 21 April 2013, by email to admin@pharmacycouncil.org.au.

Plan B for Plan B

GIRLS of all ages in the USA will be able to access the so-called "morning after" pill, after a decision by a US Federal Judge which overturned a ruling by the Health Secretary limiting over-the-counter purchases to those aged 17 and up.

Levonorgestrel, sold under the brand name Plan B, will now no longer require a prescription for girls 16 and under, with Judge Edward Korman describing the previous arrangement as "arbitrary, capricious and unreasonable".

The US FDA had previously approved levonorgestrel for those of all ages, but this was overruled by Health and Human Services Secretary Kathleen Sebelius.

A spokesperson for the Department of Justice said this week's was being reviewed, with the government "considering its options".

Support for McKeon

THE Complementary Healthcare Council of Australia has endorsed the McKeon report into medical R&D in Australia (***PD*** yesterday), with CHC executive director Wendy Morrow saying the organisation supports the review's aspirational aim of having the world's best health-card system within 10 years.

"We support the Review's suggestion of embedding research into healthcare, as well as fostering a culture of commercialisation into research," Morrow said.

Research Australia, which is an alliance of 170 member groups advocating for health and medical research in Australia, also strongly backed the report, with md Elizabeth Foley urging Treasury "to make an appropriate allocation in next month's Federal budget to drive the implementation of the McKeon review recommendations".

Pharmacist ATM?

CONTROVERSIAL Northern Territory pharmacist Rollo Manning says that the current system of dispensing medicines in Australia could be done from an automatic teller machine, "for all the value that pharmacists add to their supply function".

Writing on theconversation.com last month, Manning said the retail pharmacy industry in Australia "has successfully acquired a monopoly on supplying medicines paid for by the government or consumers".

He said the main issue is that there's no requirement for the pharmacies receiving taxpayers' money to do anything more than the simple task of dispensing.

"A signature by the consumer to say they received the medicine is all that's required for the Commonwealth to pick up the bill... there is no more accountability for the $2 billion to be paid out by the PBS," Manning wrote.

It's part of a series of articles on the website about the pharmacy sector - **CLICK HERE** to view.

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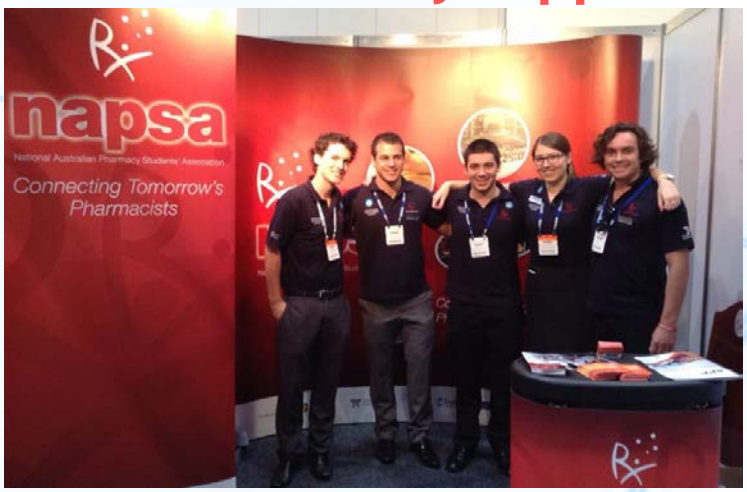
Students survey suppliers



ABOVE: Representatives from the National Australian Pharmacy Students' Association (NAPSA) conducted a survey of industry suppliers at the recent Pharmacy Guild of Australia APP conference on the Gold Coast.

The NAPSA Industrial Affairs Committee spoke to exhibitors at the APP trade show, with results currently being compiled and initial indications showing that "the pharmacy profession has a lot of support for NAPSA and also values the contribution pharmacy students can make to the workplace".

APP also provided an opportunity for members of the NAPSA executive to meet face to face and make plans for the organisation over the upcoming months.

Pictured above on the NAPSA stand are, from left: Chris Braithwaite, Luke Vrankovich, Xavier Agostino, Ellen Pedler and Matthew Tam.

Pregnancy database

THE Therapeutic Goods Administration has updated its "Prescribing Medicines in Pregnancy" database, which aims to provide information for health professionals planning the medical management of pregnant patients or patients intending to become pregnant.

The database allows medications to be searched by generic name or active ingredient, or by classification level, but does not include all therapeutic goods because certain types of drugs are usually exempt from pregnancy categorisation.

B&L FDA approval

BAUSCH + Lomb has been granted US Food and Drug Administration approval forits Prolensa (bromfenac opthalmic solution) 0.07%.

It's a new once daily NSAID eyedrop indicated for treatment of postoperative inflammation and reduction of ocular pain following cataract surgery.

Prolensa will be available in the US in 1.6ml and 3ml bottle sizes.

DISPENSARY CORNER

HERE'S some healthy ageing.

A 74-year-old pensioner in the UK manages to keep himself fit by waterskiing twice a week.

And while that's impressive for any septuagenarian, Peter Sheath effectively does it with his eyes closed, because he's been blind for more than 40 years.

Sheath said he believes that being blind actually makes it easier because it "removes the fear factor" from waterskiing.

A man has been sentenced in court for driving while intoxicated - not on alcohol or drugs, but under the influence of loud music.

The *Bristol Post* reported the unusual case which saw 25-year-old Aaron Cogley allegedly driving erratically, running red lights and almost hitting other motorists.

After he was pulled over officers found that he was listening to a style of music known as "drum and bass," and he eventually pleaded guilty to reckless driving.

April MIMS Monthly Medicine Update

NEW PRODUCTS

AndroForte 2 and AndroForte 5 **(testosterone)** is a transdermal drug delivery system. It is indicated as testosterone replacement therapy in symptomatic testosterone deficient males, including confirmed primary hypogonadism, secondary hypogonadism and late-onset hypogonadism. Testosterone is contraindicated in men with known or suspected carcinoma of the prostate, known or suspected carcinoma of the breast, known or suspected androgen-dependent neoplasia, nephrotic syndrome or hypercalcaemia. AndroForte has not been evaluated in women and is contraindicated in pregnancy and while breastfeeding. The product is not suitable for children. AndroForte 2 and AndroForte 5 are available as a cream containing 20 mg/mL and 50 mg/mL testosterone respectively in a 50 mL boxed tube.

Caprelsa **(vandetanib)** is a tyrosine kinase inhibitor that inhibits vascular endothelial growth factor (VEGF)-stimulated VEGF receptor-2 tyrosine kinase. In addition, vandetanib inhibits epidermal growth factor (EGF)-stimulated EGF receptor tyrosine kinase. Caprelsa is indicated for the treatment of patients with symptomatic or progressive medullary thyroid cancer in patients with unresectable, locally advanced or metastatic disease. It is contraindicated in patients with congenital long QT syndrome. Caprelsa is available as 100 mg and 300 mg tablets in blister packs of 30's.

Extavia **(interferon beta-1b (rbe))** is indicated for the treatment of patients with a single clinical event suggestive of multiple sclerosis (MS) and at least two clinically silent magnetic resonance imaging (MRI) lesions characteristic of MS, if alternative diagnoses have been excluded. It is also indicated for the treatment of ambulatory patients with relapsing-remitting MS characterised by at least two attacks of neurologic dysfunction over a two year period followed by complete or incomplete recovery. Extavia is also indicated for the reduction of frequency and severity of clinical relapses, and for the slowing of progression of disease in patients with secondary progressive MS. Extavia is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta. Extavia is available as a powder for injection.

Priorix-Tetra **(measles (Schwarz), mumps (Jeryl Lynn, RIT 4385 strain), rubella (Wistar RA 27/3) and varicella zoster (OKA strain))** is a live virus vaccine for immunisation against measles, mumps, rubella and varicella. Priorix-Tetra is indicated for active immunisation against measles, mumps, rubella and varicella from 9 months of age. Priorix-Tetra is contraindicated in pregnancy. If vaccination of postpubertal women occurs, pregnancy should be avoided for three months. Priorix-Tetra is contraindicated in subjects with known hypersensitivity to neomycin or to any other component of the vaccine (e.g. egg allergy). Priorix-Tetra is contraindicated in subjects having shown signs of hypersensitivity after previous administration of measles, mumps, rubella and/or varicella vaccines. Priorix-Tetra should not be given to subjects with impaired immune function. These include patients with primary or secondary immunodeficiencies, those with untreated malignant disease and those receiving immunosuppressive or X-ray therapy or high dose steroids (equivalent to 2 mg/kg/day prednisolone). Priorix-Tetra is available as a powder for injection.

SAFETY RELATED CHANGES

Felodur ER and Plendil ER **(felodipine)** are now contraindicated in haemodynamically significant cardiac valvular obstruction and dynamic cardiac outflow obstruction.

The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunization series of Infanrix IPV **(combined diphtheria, tetanus, acellular pertussis (DTPa) and inactivated poliovirus vaccine)** to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

Pradaxa **(dabigatran etexilate)** use is now contraindicated with prosthetic heart valve replacement.

Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding with the use of Premarin **(conjugated oestrogens)**.

Vfend **(voriconazole)** is now indicated as prophylaxis in patients who are at high risk of developing invasive fungal infections. The indication is based on studies including patients undergoing haematopoietic stem cell transplantation.

When using Logynon ED, Levlen ED, Triquilar ED **(ethinyloestradiol, levonorgestrel)** following a natural cycle, following first trimester abortion, following childbirth or second trimester abortion, when changing from a progestogen only method (minipill, injection, implant) or from a progestogen releasing intrauterine system (IUS), additional non-hormonal contraceptive methods are necessary for the next 14 days.

When using Diane-35 ED and Juliet-35 ED **(ethinyloestradiol, cyproterone acetate)** with no preceding hormonal contraceptive use (in the past month), changing from a progestogen only method (minipill, injection, implant) or from a progestogen releasing IUS, following first trimester abortion, after childbirth or a second trimester abortion, additional non-hormonal contraceptive methods are necessary for the next 14 days.

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.