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## **New orphans on TGA**

THE TGA has added to the list of designated orphan drugs: Xgeva (denosumab), propranolol hydrochloride, Fixtera (recombinant factor IX), and Carbaglut (recombinant human coagulation factor IX Fc fusion protein (rFIXFc), carglumic acid).

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# **EMA** investigates Roche

**SERIOUS** shortcomings in Roche's pharmacovigilance processes have led to European Medicines Agency to launch an infringement procedure against the company.

The action marks the first time the EMA has launched infringement procedures against a drug manufacturer.

The shortcomings were picked up by UK Medicines and Healthcare products Regulatory Agency (MHRA) during a pharmacovigilance inspection carried out in May this year.

According to the allegations, Roche failed to properly report the side effects of 19 of its centrally authorised EU medicines, including Avastin, Herceptin, Tarceba, Xeloda, and Tamiflu.

These failures included the 80,000 reports for medicines marketed by Roche in the US which had been collected through a Roche-sponsored patient support program, but which had not been evaluated to determine whether or not they should be reported as suspected adverse reactions to the European Union (EU) authorities.

According to the MHRA, these reports included 15,161 reports of death of patients, however it is not known whether the deaths were due to natural progression of the disease or had a causal link to the medicine.

Other issues caught by the MHRA related to the evaluation and reporting to national medicines agencies of suspected adverse reactions from their

reporting systems (around 23,000) and clinical trials (around 600).

Despite launching the procedures, the EMA has moved to quell concern, saying that there is no evidence that the drugs in question posed a risk for patients, but rather that the agency's concern was the shortfall in the reportage of side effects.

The EMA will report the outcome of its investigation to the European Commission in around 18 months time.

Should Roche be found guilty the European Commission may force it to pay a fine of up to 5% of its EU revenue for 2011, or to make periodic penalty payments.

# **Eylea on the PBS**

FROM 01 December Evlea (aflibercept) will be available on the Pharmaceutical Benefits Scheme for the treatment of neovascular (wet) Age-related Macular Degeneration.

Eylea is a novel recombinant fusion protein which works by trapping excess vascular endothelial growth factor (VEGF) in the eye and has a higher binding affinity for VEGF than natural receptors have.

Trapping excess VEGF limits the growth of abnormal blood vessels and hence reduces leakage.

### Pharmacist of the Year

**DEIRDRE** Criddle has been named as the Pharmacist of the Year in the PSA's Excellence Awards announced at PAC12.

Criddle was lauded for her tireless efforts in HMR services, hospital discharge and formulary and health practice education.

# **WIN A BOSISTO'S SOLUTION PACK**



**PD** has teamed up with Bosisto's this week and is giving five lucky readers the chance to

win a Bosisto's Solutions prize pack.

Bosisto's has the "Solution" to a chemical-free home! From cleaning, killing germs and natural first aid to foot care and helping with sleep and relaxation, the Bosisto's Solutions range is the key to a naturally healthy home for you and your family.

Visit www.fgb.com.au for more information!

To win, simply be the first person to send in the correct answer to the auestion below to: comp@pharmacydaily.com.au.

Which Bosisto's Solutions is the perfect natural first aid?

Congratulations to yesterday's lucky winner, Rebecca Segrott from The Pharmacy Guild of Australia.

# PHARMACIES FOR SALE

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### 1523— Sydney Northern Beaches —NSW

Back on the market. Located in a premier tourist Sydney beach enclave, T/O \$3.22m, Be quick for the tourist season. G P 39%, good lease. Price \$2,995,000

#### 1536— East of Perth - WA

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# Health, Beauty and New Products

Welcome to our weekly feature with all the latest health, beauty and new products for pharmacy!

Suppliers wanting to promote products in this feature should email advertising@pharmacydaily.com.au.



## Rose-Hip for nourished skin

Rose-Hip Vital's Australian certified organic cold pressed Rosehip Oil contains naturally occurring bioflavonoids which act as potent anti-oxidants, helping to reduce free radical damage in the skin. Enriched with essential fatty acids (Omega 3, 6 & 9) the oil is perfect for thirsty, stressed skin, keeping it hydrated, moisturised and nourished. The oil, which is extracted without using heat, solvents or chemicals, is also rich in anti-ageing Vitamins A and C; as well as anti-inflammatory Vitamin E and antioxidants lycopene & beta-carotene. The product is suitable for use on the face and body, and aids in reducing the appearance of stretchmarks and scars, promoting skin elasticity and texture, and

maintaining skin hydration and softness.

RRP: \$19.95 (30ml), \$29.99 (50ml)

**Stockist:** 1800 851 888

Website: www.rosehipvital.com.au

# Draw crowds with magnetic nails

Designer Brands' new 3D nail lacquers, Magnetic Nails, contain magnetic particles which create unique shapes. The shapes are created when users hover the Magnetic Nails magnet over the nail to move the particles. The look takes 5-10 seconds per nail to create. The range is perfect for quirky summer looks, and includes magnetic designs such as: Hypnotic Circles, Starlight Talk, Diagonal Lines, Star Treatment, Tidal Waves, and Pointed Arrow.

RRP: \$7.99 for Magnetic Polish + Magnet, \$2.50 per Magnet, \$14.99 for an all in one Steel and Rage Kit containing three Magnets, two Magnetic Polishes and one top-coat

Stockist: 1300 765 332 Website: www.tbn.com.au



## Old style art for the face

Laura Mercier's summer collection is inspired by the early 1900's Art Nouveau artistic movement, and features a plethora of sugary, happy tones in sheer textures. The range includes a Turquoise Caviar Eye Stick for a smokey eye look, a Bleu Long Lash Mascara in navy which extends and separates hard-to-reach lashes by scooping up and lengthening each lash with the brush. The range also includes a high-shine

Orange Tulip Lip Glace designed to create the illusion of fuller lips; as well as a Nude Pink Creme Lip Print which is crafted to give the "just bitten" look, and features a velvety matte finish.

RRP: \$39 (Turquoise Caviar Eye Stick), \$39 (Bleu Long Lash Mascara), \$30 (Orange Tulip Lip Glace), and \$30 (Nude Pink Creme Lip Print)

**Stockist:** 02 9663 4277

Website: www.adorebeauty.com.au

### Smell like you're riding a horse at night

The new scent from Annick Goutal, Nuit Étoilée, is a unisex fragrance inspired by "distant and fond memories of nightly escapades under a starry night on horseback". The perfume is crafted with sweet orange, tonka bean and citron, as well as peppermint oil, Siberian pine and balsam fir. The scent also comes in his and her bottles, with the ladies scoring a ribbed bottle with a blue moiré taffeta ribbon, whilst for gentlemen, the scent comes in a square bottle with a midnight blue label.

**RRP:** \$130 (50ml), \$150 (100ml square bottle), \$190 (100ml ribbed bottle)

Stockist: 02 9663 4277

Website: www.annickgoutal.com



# **DISPENSARY** CORNER

**DON'T** ask about its origin.

A US police officer faced a stiff penalty after dipping his head into an 18-litre bucket of urine.

The officer, Phil Croucher, was off-duty at the time, and took on the dare after, what we assume was an afternoon of alcohol consumption and football watching, resulted in the germination of a very dumb idea.

Now one might wonder what price Croucher put on dignity, and the answer to that is that his friends pooled their funds and enticed him to take the plunge for \$450.

Unfortunately for the officer the stunt was captured on video by his friends, and found its way onto his Police Chief's desk.

Shortly after the "airing" Croucher was suspended on 'medical leave'.

The leave was more of a wrist slap than anything, with the Chief saying he expected more of his officers, and reinstating Croucher soon after.

The YouTube reactions to the 'stunt' have been varied, with some praising the dunk, others revolted, and others, like Brandon Stroud, a little in both camps, saying "on one hand he's earning almost \$500 for less than a second of work, but on the other, dude, how did your life end up here?".

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