



ARTG cancellations

THE TGA has announced the cancellation from the Australian Register of Therapeutic Goods of Inner Health Candex and Myadec Primetime 50+ Formulation, due to "insufficient evidence to support the indications for the products".

TGA consults on PI, CMI

THE Therapeutic Goods Administration has launched a public consultation on possible new mechanisms to "maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)".

The major move is one of the outcomes of the 2010 TGA Transparency Review, which found that the TGA needs to explore a mechanism of maintaining the currency of the information, "including consideration of links to other information providers".

The consultation document raises a number of issues, including the potential publication of PI and CMI for all over-the-counter medicines, including S2 and S3 items, as well as considering a requirement that CMI be available to the public for all registered medicines.

There's also consideration of proposed changes to the ordering of information on the PI document, to place clinically relevant information about indications, contraindications, warnings and precautions earlier in the document.

"The current PI does not highlight this information and therefore the TGA is considering whether re-formatting of the PI would assist healthcare professionals with appropriate prescribing," according to the consultation document.

The TGA has also raised concerns that PI and CMI are not kept up-to-date once the initial approval process has occurred and the medicine has been registered.

This could be addressed by a

range of mechanisms including providing an archive of previous versions in the public search facility, as well as establishing linkages between the ARTG, PI/CMI and AusPAR search facilities.

The consultation document is now online at the TGA website, and interested parties are invited to provide feedback by 13 June.

Workshops will also take place this month to consult with peak bodies representing consumers, health professionals and suppliers, as well as providers of therapeutic goods information.

More info at tga.gov.au.

SHPA records history

THE Society of Hospital Pharmacists has enshrined the achievements of some great Australian pharmacists on the internet, as part of SHPA's Pharmacy History Week.

SHPA volunteers have written biographies of award-winning pharmacists, which have been uploaded to the Wikipedia website.

Subjects so far include Lance Jeffs, Bill Hayes, Fred J. Boyd, Mavis Sweeney, and Edward (Nikk) Phelan, all of whom had notable roles in the development of the profession in Australia.

The SHPA website also includes a series of interviews with long-time members to hear their views of how the profession has developed, including Lloyd Sansom, Anne Leversha, Bill Thomson and Gwynneth Petrie.

See www.shpa.org.au.

RGH E-Bulletin

THIS week's edition of the RGH Pharmacy E-Bulletin focuses on the rarer adverse effects of blood glucose lowering medications such as DPP-4 inhibitors (gliptins) and GLP-1 analogues - to view the bulletin [CLICK HERE](#).

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Guild Update

Budget time

THE Guild is on high alert with the Federal Budget to be brought down by Treasurer Swan at 7.30 tonight.

In normal times, one would think that pharmacy remuneration is safe from the usual Budget cycle, with the Community Pharmacy Agreement and the Price Disclosure Memorandum of Understanding still in force.

However these are not normal times with the Prime Minister recently proclaiming that "all bets are off" in terms of budgetary commitments.

She also spoke of the need for grave and urgent Budget decisions being necessary.

The Guild has not been told that the Budget contains any hits on community pharmacy, but it would be foolhardy to be complacent in the current climate.

Our view is that the PBS is tracking at sustainable levels, and both pharmacy and the broader pharmaceutical sector have already delivered significant savings to the Commonwealth.

The Guild will provide a comprehensive summary of relevant Budget measures to members after the delivery of the Budget.



**The Pharmacy
Guild of Australia**

Phebra plant GMP licence

THE TGA yesterday granted a formal licence to the new Sydney-based sterile manufacturing plant operated by Australian pharmaceutical firm Phebra.

Phebra ceo Mal Eutick said it was a "great day for the company," which has worked on the project for the last three years.

The move follows stringent assessments of the Lane Cove plant including a series of product validations, and confirms Phebra's compliance with Good Manufacturing Practice guidelines.

"The plant is testament to Phebra's investment in the future of the local manufacturing industry," Eutick said.

He said the new facility would

allow the company to significantly boost its research and production capability, with products to be made there including emergency injectables, antidotes and other small volume injections.

Eutick added that Phebra would expand its capability to conduct "all-important development programs now and into the future, providing skills development and employment for Australian scientists and medical researchers".

'New to market' move

THE Therapeutic Goods Administration is considering a "new-to-market risk communication scheme for therapeutic goods," in which consumers would be advised that particular items have been recently put on the market.

Benefits of the proposal include transparency, supporting quality use of medicines by indicating to health professionals to consider 'newness' and potential uncertainty when weighing the benefits and risks of a product for an individual.

The plan would also help encourage health professionals and the public to submit reports to the TGA about adverse events associated with new products.

A month-long consultation period has launched, with possible methods including placing a symbol next to the name of a product when it appears in certain information sources.

For more information on the proposals **CLICK HERE**.

Plibersek vaccine push

HEALTH minister Tanya Plibersek has flagged a "rigorous nationally consistent policy for schools to assess and document immunisation for all new enrolments, as a way of identifying children who have slipped through the immunisation net," as an item to be discussed by the Standing Committee on Health.

WA, NSW, Vic, Tas and the ACT all have school entry legislation for immunisation, but other than WA "the laws are not usually enforced," Plibersek added.

A national policy could require parents to present schools with Child Immunisation History statements, which are available from Medicare and are linked to the Personally Controlled eHealth Record System.

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DISPENSARY CORNER

HERE'S a novel way to quit smoking - hit a cop in the face.

Etta Mae Lopez from Sacramento, California hung around outside the local prison until a uniformed deputy came out - at which stage she walked up to him and slapped him.

She was immediately handcuffed and locked up, with the officer saying he told her "she knew if she assaulted a deputy she would go to jail and be inside long enough to quit her smoking habit".

The policeman said that his colleagues now call him by his "new Irish name: Nick O'Derm" in reference to Nicoderm nicotine patches sold in the USA.

WIN AN INNOXA PRIZE PACK



This week **PD** is giving five lucky readers the chance to win

an **Innox** beauty essentials pack including classic and new products across the Innox range.

NEW Innox Anti-Ageing & Firming facial serum - improves skin complexion to promote radiant looking skin. Specially formulated with anti-ageing ingredients to help fight signs of ageing.

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

**In which country
is Innox Skincare
made?**

Congratulations to yesterday's lucky winner, Deborah Caldera of Jardine's Chemmart Pharmacy.