



Australian Self-Medication Industry Inc  
Suite 2203, Level 22, 141 Walker Street,  
North Sydney NSW 2060  
PO Box 764, North Sydney NSW 2059  
Ph +61 2 9922 5111 Fax +61 2 9959 3693  
Email: [info@asmi.com.au](mailto:info@asmi.com.au) [www.asmi.com.au](http://www.asmi.com.au)  
ABN 55 082 798 952

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# MEDIA STATEMENT

## ASMI response to TGA reform blueprint

The Australian Self-Medication Industry (ASMI) today welcomed the announcement of a series of significant reforms to the Therapeutic Goods Administration (TGA) and the regulation of non-prescription products.

The measures will impact areas including product advertising and promotion, regulation of complementary medicines, and the transparency of TGA decision-making.

The Executive Director of ASMI, Dr Deon Schoombie said: "We are generally pleased with the thrust of the blueprint and the very strong commitment to industry consultation, but in a document of this magnitude, there are inevitably areas where we are disappointed."

In regard to advertising reforms, ASMI welcomes the moves toward a strengthened framework for advertising controls, including expanded pre-approval processes for advertising, as well as appropriate sanctions, penalties and complaints handling.

ASMI is also pleased that Pay TV has been included in the pre approval process.

"We support these measures and have worked with all stakeholders to pursue a clear and consistent framework to guide all aspects of advertising. We strongly support an approach that retains the existing self-regulatory process within a broader co-regulatory framework," Dr Schoombie said.

The issue of ethical promotion of therapeutic goods to healthcare professionals has been the subject of a comprehensive process of industry consultation. ASMI has been a member of the working group that prepared recommendations to government earlier this year.

"We are disappointed that the government has not accepted the findings of the working group because this would have established a very clear and consistent approach right across the industry, binding both those who belong to industry associations as well as those who don't.

"This was a missed opportunity to implement changes that would have prevented renegades from continuing to bring the industry into disrepute," Dr Schoombie said.

The TGA also announced changes to the regulatory framework for complementary medicines.

ASMI is pleased that the TGA has decided to proceed with reforms that flow from the recent report of the Australian National Audit Office (ANAO) into the complementary medicines sector.

ASMI has consistently called for the implementation of key recommendations of the Expert Committee on Complementary Medicines in the Health System, established in 2005.

ASMI supports a further strengthening of the framework to ensure greater compliance through increased post-market surveillance. The TGA currently undertakes both random and targeted surveillance, and this should be extended to ensure early detection of non-compliance.

Penalties and sanctions should be in place to act as an effective deterrent against non-compliance.

“There is a need for more accurate and timely information on complementary medicines, and for measures to protect the credibility of those products that are proven and evidence-based.”

The TGA also considered the issue of labelling of complementary medicines, including measures to identify those products where the TGA does not assess evidence to support efficacy.

ASMI believes that the use of the product label to educate about regulatory processes has not yet been demonstrated as an effective means to help consumers to better understand complementary medicines. It would be more helpful to undertake comprehensive consumer research to test the most effective and efficient means of communicating this information to consumers.

We are pleased with the government’s recommendation on working with stakeholders to scope and develop these options.

The TGA also announced changes to improve clarity and awareness of regulatory decision-making, arising out of the recent review, chaired by Professor Dennis Pearce AO.

“The non-prescription products industry welcomes these measures which aim to increase the flow of information, improve certainty and clarity, and produce more timely TGA decisions,” Dr Schoombie said.

“Our key concern is the need to balance this transparency with protection of commercially confidential information

“There has been a good deal of industry frustration with the lack of clarity from the TGA about important regulatory decisions. We look forward to seeing these measures implemented to help reduce red tape and improve transparency on how and why decisions are made by the TGA,” he said.

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About ASMI: The Australian Self-Medication Industry (ASMI) is the peak industry body for the Australian self care industry representing consumer healthcare products including over-the-counter medicines and complementary medicines. ASMI’s mission is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the broad national health strategy. [www.asmi.com.au](http://www.asmi.com.au)

**Media contact:** Bob Bowden, Foresight Communications (02) 9241 2811, 0412 753 298