Think tank

Regulatory reforms & their impact on the Australian Complementary Medicines Industry

Benefits of the current reform:

- Increased transparency, predictability and safety

- Reduced regulatory burden and encouragement of innovation

Timeline of events:

October 2014
Ministry of Health announces Expert Panel Review of Medicines and Medical Devices Regulation

Second half of 2015
Department of Health undertakes targeted consultation on recommendations made in the Review.

September 2016
Australian Government releases Samson Review

2016-2017
Department of Health to commence design phase of reform implementation

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Implementation of reforms to the medicines regulatory framework has been the focus of many recent discussions within the pharmaceutical industry.

The Expert Panel Review of Medicines and Medical Devices Regulation has highlighted the importance of the provision of safe therapeutic goods to consumers while improving access to therapeutic goods and encouraging innovation.

In response to the Review, the Department of Health, in consultation with health-care professionals, consumers and other industry representatives, has provided their comments on each of the 58 recommendations made. Also known as the Samson Review, this response '*presents a strategic and systems-based approach to achieve long-term sustainable reform to the regulation of therapeutic goods in Australia*'. It also '*identifies ways to remove unnecessary red tape for industry*'.

With the exponential increase in consumption of complementary medicines over the last few years, consumers have been given an opportunity to take control of their own health. The current regulatory reforms therefore aim to provide consumers with evidence-based information on the safety and efficacy of the medicines they are taking, further supporting consumer health decisions.

Increased transparency between the industry and consumers will be seen with the implementation of a 'Permitted Indications' list and the subsequent removal of the 'free text' function on the listing application. **Its purpose:** to remove the potentially misleading and ambiguous therapeutic claims made on listed medicines.

Additionally, an increase in the number of post-market reviews will ensure continuing sponsor compliance and adherence to legislative requirements. It's benefits will also be seen in industry with a reduction in administrative costs.

Another significant recommendation made in this Review was the introduction of new pathways in the complementary medicines regulatory framework. These pathways will allow sponsors to make claims of efficacy by providing evidence-based information for assessment by the Therapeutic Goods Administration (TGA). Sponsors will be able to use these claims on their promotional materials.

The TGA is an internationally recognised regulatory body known for its high quality assessment and evaluation of regulatory submissions and for ensuring timely access to safe and efficacious therapeutic goods. The current regulatory reforms support the alignment of the regulatory framework to risk-based approaches and indicate the push towards an internationally harmonised framework for medicines and medical devices.

References:

1. Therapeutic Goods Administration (TGA). (2016). Reforms to the medicines regulatory framework: questions and answers. [online] Available at: https://www.tga.gov.au/reforms-medicines-regulatory-framework-questions-and-answers.

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