Australian Government
Department of Health
Therapeutic Goods Administration

Complementary medicines reforms

16 December 2013

The Therapeutic Goods Administration (TGA) has started work on a series of reforms to complementary medicines that seeks to improve community confidence in the safety and quality of these medicines.

This will be achieved by:

- ensuring that the TGA effectively informs the community of its role in providing timely access to the therapeutic goods that Australians need, and that they meet appropriate standards of quality, safety and efficacy
- clarifying requirements for sponsors of complementary medicines
- improving the Australian community's understanding of the TGA's regulatory processes and decisions for complementary medicines
- strengthening the integrity and transparency of the regulatory framework for complementary medicines
- enhancing the complementary medicine regulatory framework to ensure that it remains adaptable to community and industry expectations.

The reforms are part of the *TGA reforms: A blueprint for TGA's future (/about/tga-reforms-blueprint.htm)* ("the Blueprint"), including a number of recommendations from the *Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines (http://www.anao.gov.au/Publications/Audit-Reports/2011-2012/Therapeutic-Goods-Regulation-Complementary-Medicines)* ("the Auditor-General's Report").

The reforms will initially focus on the recommendations from the Auditor-General's report; the recommendations will be implemented through the following projects:

- Key regulatory guidance materials (/industry/cm-reforms-key-guidance-materials.htm)
- Standard indications (/industry/cm-reforms-standard-indications.htm)
- Publishing outcomes of listing compliance reviews (/industry/cm-reforms-publish-reviews.htm)
- Using risk profiles in listing compliance reviews (/industry/cm-reforms-risk-profiles.htm)
- Investigation processes for advertising breaches (/industry/cm-reforms-advertising-breaches.htm)

Additional recommendations included in the Blueprint also impact upon complementary medicines regulation and will lead to further projects in the future.

Consultation

In considering how to action the Auditor-General's recommendations, the TGA held discussions with an Informal Working Group. This group, consisting of representatives from consumer groups, healthcare professionals and complementary medicine industry associations, provided advice to the TGA on aspects of implementation.

The TGA will conduct consultation with consumers, health professionals and sponsors in relation to aspects of the projects where they have an impact on individuals and/or organisations outside of the TGA.

To ensure that you receive email notification of new consultations, please ensure that you subscribe to email updates (/newsroom/subscribe.htm).

Reform timeframe and progress

Reform activity	Progress	Future activity
Update key regulatory guidance document on the evidence a sponsor should hold in support of indications for listed medicines	The TGA has completed two rounds of public consultation (/newsroom/consult-cm-closed.htm). The first consultation (/newsroom/consult-cm-evidence-listed-medicines-120423.htm) closed 25 May 2012. The second consultation (/newsroom/consult-cm-evidence-listed-medicines-120827.htm), on a revised version of the evidence document, closed on 22 October 2012. The TGA hosted Road Shows in Melbourne, Sydney and Brisbane in July and August 2013.	The TGA will conduct further workshops with industry organisations in November and December 2013. The updated evidence document will be published in early 2014. In the future, the evidence document will be revised as required.

Update to the Australian Regulatory Guidelines for Complementary Medicines (ARGCM)	A four-stage public consultation for the revised ARGCM was conducted over a period of nine months. The industry submissions (/newsroom/consult-cm-argcm-submissions.htm) and TGA response (/newsroom/consult-cm-argcm-tga-response.htm) have been published on the TGA website. The final revised ARGCM (/industry/cm-argcm.htm) was published on 13 December 2013.	In the future, the ARGCM will be reviewed as required.
Permitted (coded) indications project	The TGA completed a public consultation (/newsroom/consult-cm-closed.htm) on the permitted (coded) indications project on 15 March 2013. The TGA published the 27 consultation submissions (/newsroom/consult-cm-permitted-indications-130114-submissions.htm) on the TGA website 19 June 2013.	A revised list of proposed indications will be published on the TGA website in early 2014. The new indications will be added to the listed medicines electronic application portal.
Update of the listed medicines electronic application portal	The online listed medicines application and submission portal has been updated to improve its useability. The new portal (https://www.ebs.tga.gov.au/) was launched in August 2013, together with a user guide (/industry/ebs-elf-userguide.htm). The TGA hosted Road Shows in Melbourne, Sydney and Brisbane in July and August 2013 to assist with the introduction of the new portal.	The new permitted indications list will be added to the listed medicines application portal.
Publishing outcomes of listing compliance reviews	The listing compliance review framework was implemented and published in September 2012. In October 2012, the TGA began publishing information on products which have been cancelled (/industry/cm-cancellations-cr.htm) from the ARTG as a result of a compliance review.	Information regarding listed complementary medicines that have been cancelled from the ARTG as a result of compliance reviews will continue to be reported on TGA website: Complementary medicines: Cancellations from the ARTG following compliance review (/industry/cm-cancellations-cr.htm). Next year, information on the outcomes of all compliance reviews will be published on the TGA website.
Enhancing post-market monitoring	Data that is collected from listing compliance reviews performed by the TGA are being used to develop risk profiles.	The TGA will continue to collect data from listing compliance reviews to prioritise reviews based on risk profiling.
Investigation processes for advertising breaches	A standard operating procedure for investigating advertising breaches is now being used by the TGA. An internal workflow is being developed to manage advertising complaints and facilitate reporting. Appropriate timeframes for the completion of investigations into advertising breaches are being refined by the TGA.	The TGA will finalise a workflow system for complaints handling and to facilitate reporting of non-compliance with advertising requirements.

Contact

For further information about the complementary medicines regulatory reforms, contact the Office of Complementary Medicines (/industry/cm.htm#contacts).

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