

Consultation on complementary medicine reforms: TGA response and submissions received

Today the TGA has published its response and submissions received to the February 2017 public consultation 'Reforms to the regulatory framework for complementary medicines: Assessment pathways'.

A total of 60 submissions were received, which comprised:

- 24 submissions from industry and peak industry bodies
- 18 submissions from consumer, healthcare and other professional bodies
- 2 submissions from academic institutions
- 6 submissions from practitioners
- 7 submissions from individuals
- 3 submissions from government agencies

CMA would like to thank all members for contributing to the industry response. The CMA submission to this consultation can be found [here](#).

TGA Response

Submissions received in response to the consultation showed broad stakeholder support for the proposed approaches to implement these reforms. However, some modifications were proposed, particularly in relation to the evidence requirements and protection of efficacy data for products assessed through the new listing pathway. The TGA will continue to review implementation options to address these concerns.

Stakeholder feedback has informed the TGA's position going forward and the upcoming changes to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*. Changes resulting from the feedback are summarised in the [Outcome Summary](#), noting further targeted feedback will be sought in some cases.

Main changes resulting from this public consultation include:

- A new listing pathway to be introduced that will sit between the current listed (lowest risk) and registered (higher risk) pathways.
- Implementation of the permitted indications list
- The ability to use an efficacy 'claimer' for pre-market assessed complementary medicines
- A mechanism to allow for a 2 year market exclusivity period for new complementary medicine ingredients approved for use in listed medicines.

Further information on implementation arrangements and guidance documentation for reforms in this consultation will be included on the TGA website in the coming months.