Technical Alert

Consultation: draft list of permitted indications and evidence qualifiers

Today the draft list of permitted indications and a list of associated evidence qualifiers were made available on the TGA website. Members now have the opportunity to review, comment and propose additional indications and evidence qualifiers, at no cost, until **31 October** prior to the permitted indications reform coming into effect **1 January 2018**.

A Criteria Factsheet and a Permitted indications assessment tool have also been provided to assist you to understand how the list will work and how the regulatory requirements for listed medicines will change. More information about the implementation of the list of permitted indications is provided on the Frequently Asked Questions page.
For more information on timing, please see the Timeline for implementation.

ACTION: Members are invited to send any comments and proposals for new indications or new evidence qualifiers through to the TGA via: complementary.medicine.reforms@tga.gov.au. You are also encouraged to copy the CMA in your response at submissions@cmaustralia.org.au so that we can gauge the extent and level of feedback being provided and to contribute to the industry response regarding the project.

Please note: it is advised that sponsors not make regulatory decisions based on this preliminary information, as changes may occur before finalisation and implementation of the supporting legislation.

Background
In September 2016 the Government announced that the TGA will introduce a list of permitted indications that must be used by listed medicine sponsors to enter their product indications in the ARTG. The purpose of establishing the list of permitted indications is to:

- ensure that listed medicines can only make low level indications that are suitable for medicines that do not undergo pre market assessment
- provide transparency for sponsors on what indications are suitable for listed medicines to help prevent inadvertent non-compliance
- avoid consumers being potentially misled by inappropriate indications on listed medicine labels.

Options for implementing this reform were proposed in the recent Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways. This consultation has resulted in the preferred way to implement this reform.

If you have any further questions about the permitted indications project please contact CMA on 02 6260 4022 or email: Emma.Burchell@cmaustralia.org.au

ENDS

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