Technical Alert

NIIM Leadership Update
Updated Permitted Indications Determination

The National Institute of Integrative Medicine Leadership Update

Mr Steven Bunce, the inaugural CEO of the National Institute of Integrative Medicine (NIIM), will resign from his position, effective Friday 1st of March 2019. Mr Bunce has lead the growth and progression of NIIM since its inception in 2005. In that time NIIM has expanded beyond the flagship Melbourne clinic to a national network of integrative medical clinics, ground-breaking research facility and high-potential Education provider.

CMA and Carl Gibson wish to commend Mr Bunce on his commitment, leadership and innovation, which has moved NIIM from clinical practice into research, development and more recently, education. His contribution has allowed the NIIM centres to impact patients and practitioners across Australia as well as contribute positively to the profile of integrative and complementary medicine.

Update to Permitted Indications

The first Permitted Indications Determination was made in March 2018 after consultation with industry on lists of proposed indications. Since that time, the TGA has received feedback regarding issues related to the existing list.
Accordingly, the list of indications will be updated with a new instrument, *Therapeutic Goods (Permissible Indications) Determination No. 1 of 2018* (the 2018 Determination) in February 2019.

The announcement of these changes on the TGA website, also includes tables detailing additions or removal of indications, corrections or changes to existing indications, additional requirements and changes to label statements. All of these are listed on the website accompanied by reasoning for the change.

Transition arrangements

Any new listing will need to comply with the 2019 Determination, as soon as it comes into force.
For existing medicines, the TGA understands that businesses have already been working to bring products into compliance with the 2018 changes. Therefore the TGA will be taking a pragmatic approach. For example minor issues such as required label statements, will attract a reminder of the requirements, and no regulatory action.

The transition period for permitted indications ends on 8 March 2021.
All medicines are expected to be compliant with the new requirements by this time. A fee-free transition period is in place until 8 September 2019 to amend ARTG entries.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.