

Technical Alert

Permitted Indication Determination No. 1 of 2018 & associated guidance. Listed Medicine Applications with Permitted Indications available from today.

The *Therapeutic Goods (Permissible Indications) Determination No.1 of 2018* made under subsection 26BF(1) of the *Therapeutic Goods Act 1989* has now been registered on the Federal Register of Legislation.

The full Determination and the Explanatory Statement can be downloaded [here](#).

Guidance for Permitted Indications is now available on the TGA website [here](#).

Indications can be searched using the TGA Business Services website [here](#), under the “Indications for Listed Medicines” tab.

The Listed Medicine application system through the TGA’s electronic Business Services will be available from **today, 8 March 2018**.

Sponsors have **3 years** to transition ARTG entries to permitted indications. For the first **18 months**, this will not incur a fee.

Please advise CMA if there are indications (or lack thereof) that are causing difficulties for your listings. Note that permitted indications can be combined for the purposes of labelling and marketing, for example, symptom indications can be combined with condition indications. Please check if combined indications satisfy your indication requirements. CMA is collating a list of indications to request for the next version of the Permitted Indication Determination in June. Please email technical@cmaustralia.org.au to add indications to our list.

Questions on how to use applications with permitted indications can be directed to the Listed Medicines helpdesk on **1800 773 312**. Please advise CMA if there are implementation difficulties and enough interest we can request specific training sessions.

ENDS