

Technical Alert

Regulatory Reform Implementation Dates

The TGA has confirmed the implementation dates for the changes introduced by the *Therapeutic Goods Amendment Bill No. 1 of 2017*. Dates are expected to be announced on the TGA website soon.

15 March 2018

May be pushed back one or two days if legislation is delayed.

- **Permitted Indications introduced**
 - The three-year transition period begins. During the first 18 months, free updates to indications within ARTG entries will be allowed. Multiple free updates to the ARTG indications may be made within this period.
- **Applications for Listed Assessed medicines begin.**
 - CMA has developed a completely ANONYMOUS, 1-minute survey to collect the approximate number of applications for the new pathway. This number will be provided to the TGA to assist in their resource planning so that they can be in a position to meet industry's needs and timeframes.

Please complete the anonymous, 1-minute survey at:
https://s.surveyplanet.com/HkduW6g_f

- **Other reforms begin, including the 2-year protection period for newly approved new complementary medicine ingredients.**

1 July 2018

- CRP abolished
- All advertising complaints are assessed by the TGA only.
- The new/updated Advertising Code is expected to come into effect.

1 July 2020

- **Ending pre-approvals of advertisements in specified media.**
 - Pending a review of the advertising system at 18 months (late 2019/early 2020).
 - This was an amendment made to the Bill by agreement between the two major political parties.
 - This will allow time to develop familiarity with the new Advertising Code.

ENDS