



AUSTRALIAN MEDICAL
ASSOCIATION

ABN 37 008 426 793

T | 61 2 6270 5400

F | 61 2 6270 5499

E | info@ama.com.au

W | www.ama.com.au

42 Macquarie St Barton ACT 2600

PO Box 6090 Kingston ACT 2604

AMA submission – TGA proposed provisional approval pathway for prescription medicines (registration and monitoring)

MMDR.Consultation@tga.gov.au

The AMA supports the TGA's proposals for how the new provisional approval pathway for prescription medicines will operate and be managed to minimise the inherent risks to public safety. The proposals appear sensible and achievable, and are based on similar systems operating in the EU and Canada.

Specifically, the AMA supports the TGA's proposed conditions of registration, enhanced risk minimisation and communication activities, and the tracking and enforcement of registration conditions.

The AMA has no comments on processes and administration details in the consultation discussion paper applying to sponsors, i.e. the proposed application and assessment process, fees and charges, and timeframes and appeals avenues.

APRIL 2017

Contact

Georgia Morris
Senior Policy Advisor
Medical Practice Section
Ph: (02) 6270 5466
gmorris@ama.com.au