The Royal Australian & New Zealand College of Psychiatrists

Your Health in Mind

16 December 2016

MMDR consultation: Criteria for comparable overseas regulators
Reform Coordination and Support
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email to: MMDR.Consultation@tga.gov.au

Dear Sir/Madam

Re: Criteria for comparable overseas regulators

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide feedback to the Therapeutic Goods Administration's (TGA) consultation regarding *Criteria for comparable overseas regulators*. The RANZCP supports the efforts of the TGA to streamline its assessment and registration processes to improve timely access by Australian consumers to new medicines. However, the RANZCP notes the need to maintain the rigor of streamlined processes in order to ensure the safety of approved medicines.

The Expert Panel conducting the *Review of Medicines and Medical Devices Regulation*, to which the RANZCP made a submission in January 2015, found that on average Australian patients had to wait 5 months longer than patients in the US or Europe for anti-cancer medicines, 7 months longer for cardiovascular medicines and up to 15 months longer for nervous system medicines (Sansom et al., 2015). Given these findings, the RANZCP considers it crucial that the TGA works to ensure that its processes for assessing and registering medicines are efficient.

The RANZCP is pleased to see the Stage 1 criteria that would be used to identify comparable overseas regulators. In particular criterion 1, which specifies the need for the comparable overseas regulator to have a similar regulatory framework to the TGA, for example, conducting full *de novo* assessments and similar pre- and post-market regulatory activities, including pharmacovigilance programs; and criterion 3, which states that comparable overseas regulators must use similar international standards and guidelines in their assessments.

However, the RANZCP is concerned that despite these robust criteria, accepting the assessment reports of comparable overseas regulators may compromise consumer health care, well-being and safety. The Government points to the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as examples of potential comparable overseas regulators (Department of Health, 2015). Whilst the FDA and the EMA both represent institutions with significant expertise, neither have unblemished track records. The FDA has been strongly criticised in the past for not effectively protecting the American public from the risks posed by certain drugs (Institute of Medicine, 2010). More recently, concerns have been raised over the safety and efficacy of fast-tracked drugs and that more post-marketing monitoring is needed (American Association for the Advancement of Science, 2014; United States Government Accountability Office, 2015).

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Similarly, the European Ombudsman has conducted a number of inquiries into the EMA in recent years over its refusal to publish clinical trial data (European Ombudsman, 2010; 2014).

The TGA is a trusted national institution which works to safeguard the well-being of consumers by ensuring that medicines have been rigorously tested, that levels of risk are communicated clearly and that information is updated as knowledge develops. Lessons learned from the past would indicate that the exercise of a good deal of caution would be beneficial to the community at large. The RANZCP encourages careful consideration of the proposed changes to the current system in the context of how they will impact on the quality and safety of medicines in Australia.

If you would like to discuss any of the issues raised in the submission, please contact Rosie Forster, Senior Department Manager, Practice, Policy and Partnerships via rosie.forster@ranzcp.org or by phone on (03) 9601 4943.

Yours sincerely

Professor Malcolm Hopwood
President

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