

20 April 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By online submission

Dear Sir/Madam

Re: Consultation on the Management and Communication of Medicines Shortages

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to contribute to the Therapeutic Goods Administration (TGA) consultation regarding the management and communication of medicines shortages in Australia. The RANZCP represents over 4000 qualified psychiatrists in Australia, many of whom have specific experience with medicine shortages. As such, we strongly support the purpose of the reforms and welcome the opportunity to contribute.

The RANZCP considers access to adequate and appropriate prescription and non-prescription medication to be a critical element of providing high-quality health care. Medication treatment in psychiatric disorders can be crucial in assisting recovery, permitting other psychological healing and allowing for adjustment processes to occur.

Most importantly, the RANZCP notes the need for continuity and stability of supply of medicines for consumers. At present, when a medicine shortage occurs, it is expected that a health professional prescribes substitute medicines or therapeutic alternatives. However, in the case of psychiatric medicines, the selection and provision of an alternate medicine can needlessly impact on medicine effectiveness and consumer outcomes. These situations may provoke acute and substantial decompensations in patients, which at times are life threatening. This is particularly concerning with medications where there are few or no practical alternatives for particular patients and the transition time and risk period is substantial if there is any available alternative. In addition, often the interactions of multiple medicines need to be considered.

It is the RANZCP's view that mandatory reporting of all medicine shortages to the TGA and mandatory public reporting of extreme or high 'patient impact' shortages, as outlined in the consultation paper, are sensible and productive measures. The current medicine shortage notification system, whereby notification of shortages is voluntary, provides limited warning or information on shortages, and may be a source of concern for psychiatrists and consumers.



A more robust warning system, which provides accurate and timely information will allow psychiatrists to more effectively consider and enact alternate arrangements for consumers where necessary. The RANZCP would encourage, where practical, that the TGA further flag extreme or high patient impact shortages on the PBS website, at a pharmacy level and if possible directly with relevant medical professionals and consumers.

The RANZCP considers the definition of a medicine shortage that would trigger mandatory reporting to the TGA, and the proposed scope for covered medicines, to be clear and appropriate. Periodic evaluation of the proposed 'Medicines Watch List' is supported to ensure that it remains clinically relevant and up to date. The RANZCP notes that the World Health Organisation (WHO) Model List of Essential Medicines, on which the proposed 'Medicines Watch List' is partially based, includes a number of medicines for mental and behavioural disorders that are not included on the proposed 'Medicines Watch List'.

If you would like to discuss any of the points raised in this letter, please contact [REDACTED], Policy and Partnerships via [REDACTED] or by phone on [REDACTED].

Yours sincerely

[REDACTED]

[REDACTED]
[REDACTED]

Ref: 1080o