



Australian Government

Department of Health
Therapeutic Goods Administration

REQUEST FOR ACM ADVICE

ACM Meeting 2021/5; ACM 29
Agenda Item and Title 3.02 Pharmacovigilance matter for advice – Antidepressants and youth suicide – UPDATE

Medicine	Antidepressant medicines – see attachment 1
Sponsor(s) Indication	See attachment 1
Summary of Issues	<p>Background and updates since last consideration by ACM</p> <p>The TGA published a review on the issue of antidepressants and youth suicide in December 2020 including ACM advice sought at the August 2020 meeting.</p> <ul style="list-style-type: none"> The review found that while the increasing use of antidepressants in young people is a concern, the current available evidence was not sufficient to conclude that a causal relationship exists between prescribing of antidepressants and rates of youth suicide. <p>As a result of the review, and advice from ACM, the TGA corresponded with the Royal Australian College of General Practitioners, the Royal Australian and New Zealand College of Psychiatrists, and the Royal Australian College of Physicians to recommend the development of joint clinical guidance for use in the primary care setting to support the safe and appropriate prescribing of antidepressants to children and adolescents.</p> <ul style="list-style-type: none"> The RANZCP responded to the Department on 18 December 2020 seeking advice on the availability of government funding for guidelines development. The RANZCP expressed its support for the request and noted the need for significant time and resources to develop guidance that is sufficiently comprehensive and relevant to apply across professional groups. <p>The TGA also partnered with the Drug Utilisation Sub-Committee (DUSC) and the Quality Use of Medicines (QUM) team from the Technology Assessment and Access Division of the Department of Health. Together, two additional investigations were commissioned:</p> <ol style="list-style-type: none"> An analysis of the MedicineInsight dataset to assess the prevalence of antidepressant prescribing, mental illness and other relevant conditions for young people under the age of 25 years visiting their general practice. The final version of this report was agreed between the TGA, DUSC, QUM and National Prescribing Service on 20 September 2021. This report is the subject

of the current issue before ACM and is presented in attachment 1. The findings of the report will also be considered by the DUSC in October.

2. An analysis of the National Integrated Health Services Information (NIHSI) dataset to estimate the change in suicide risk in young people (18-25 years old) associated with taking antidepressants. The Australian Institute of Health and Welfare (AIHW) advisory committee approved the NIHSI data linkage project on 10 May. As of 20 September 2021, the DUSC Secretariat is in the process of being granted access to the NIHSI dataset in Health's Enterprise Data Warehouse. Subject to data approvals, the analysis is expected to be completed by January 2022 with a report available for consideration by the DUSC, ACM and PBAC in February/March 2022.

MedicineInsight analysis

MedicineInsight data was used to assess the prevalence of antidepressant prescribing, mental illness and other relevant conditions for young people under the age of 25 years visiting their general practice. Key findings:

- One in ten (10.8%) young people aged less than 25 years had either a past history of, or current, depression and/or anxiety recorded in 2018–19.
- About 6% of all patients aged less than 25 years had at least one antidepressant prescription recorded during 2018–2019.
- Both annual prevalence of mental health conditions and the prescribing rate of antidepressants increased significantly across the 10-year study (2011–2020).
- Findings of the study suggest that the number of suicides recorded in MedicineInsight is very low.

Delegate's commentary

Whilst this MedicineInsight analysis provides important additional information about trends and utilisation of antidepressants in young people, this analysis has not identified a clear need for further regulatory action at this time.

Given the finding of increasing trends in mental health conditions in this population, this evaluator considers that the analysis supports the previous advice of the ACM. In particular, any regulatory action to limit prescriber or Pharmaceutical Benefits Scheme eligibility criteria is not justified on the strength of the current evidence and would further disadvantage children and adolescents, especially in regional, rural and remote areas where access to psychiatrists, paediatricians and psychological therapy is limited.

Delegate's Recommendations:

1. Publish the findings of this report, including an updated TGA safety alert regarding appropriate dosing in the paediatric and adolescent populations.
2. Share this report with the relevant medical colleges including the Royal Australian College of General Practitioners and the Royal Australian and New Zealand College of Psychiatrists. This may assist in the production of prescriber education material and clinical guidelines.
3. Await the findings of the National Integrated Health Services Information investigation (currently underway, final report due January 2022).

<p>Advice sought</p>	<p>The committee is asked to provide advice on the following specific issues:</p> <ol style="list-style-type: none"> 1. Can the committee comment on the MedicineInsight analysis including the strength of evidence for an association between use of antidepressants and rates of youth suicide in Australia? 2. Can the committee comment on whether additional risk minimisation measures are warranted and would be effective to address any potential risk of suicide amongst children, adolescents, and young adults prescribed antidepressant medications? 3. Does the Committee recommend any additional actions from the TGA on this issue? <p>The committee is also welcome to provide advice on any other issues that it thinks may be relevant to a decision on this matter.</p>
<p>Attachments</p>	<ol style="list-style-type: none"> 1. Epidemiology of mental health conditions and antidepressant utilisation in people aged less than 25 years attending general practice (D21-3112590). 2. Previous ACM advice on this issue (D21-3112590).

Dr Catherine Brogan [electronically signed]

20 September-2021

Delegate of the Secretary under regulation 35A
of the *Therapeutic Goods Regulations 1990*

Date

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