



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines Minutes on Item 3.03

Antidepressants and youth suicide

Sponsors: multiple

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BY THE DEPARTMENT OF HEALTH

October 2021

Contents

Medicine details	3
Documents submitted for ACM consideration	4
Delegate's Overview	4
Delegate's summary of issues	4
Delegate's Preliminary View	4
Advice sought by Delegate of the Secretary of Department of Health	5
ACM discussion	5
General comments	5
ACM advice to the Delegate	5

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Medicine details

Active ingredient	Innovator brand	Sponsor*
Citalopram	Cipramil	Lundbeck Australia Pty Ltd
Escitalopram	Lexapro	Lundbeck Australia Pty Ltd
Fluoxetine	Prozac	Eli Lilly Australia Pty Ltd
Fluvoxamine	Luvox	Viartis Pty Ltd
Paroxetine	Aropax	Aspen Pharmacare Australia Pty Ltd
Sertraline	Zoloft	Viartis Pty Ltd
Desvenlafaxine	Pristiq	Pfizer Australia Pty Ltd
Duloxetine	Cymbalta	Eli Lilly Australia Pty Ltd
Venlafaxine	Efexor	Viartis Pty Ltd
Mianserin		
Mirtazapine	Avanza	Organon Pharma Pty Ltd
Amitriptyline		
Clomipramine	Anafranil	Novartis Pharmaceuticals Australia Pty Ltd
Doxepin		
Dosulepin	Dothep	Alphapharm Pty Ltd
Imipramine	Tofranil	Amdipharm Mercury Australia Pty Ltd
Nortriptyline	Allegron	Arrow Pharma Pty Ltd
Phenelzine	Nardil	Link Pharmaceuticals
Tranlycypromine	Parnate	Amdipharm Mercury Australia Pty Ltd
Agomelatine	Valdoxan	Servier Laboratories Australia Pty Ltd
Moclobemide	Aurorix	Viartis Pty Ltd
Reboxetine	Edronax	Pfizer Australia Pty Ltd
Vortioxetine	Brintellix	Lundbeck Australia Pty Ltd

* Other sponsors: Accord Healthcare, Alembic Pharmaceuticals Australia, Alphapharm, Amdipharm Mercury Australia, Amneal Pharma Australia, Apotex, Arrow Pharma, Aspen Pharmacare Australia, Avallon Pharmaceuticals, Boucher & Muir, Cipla Australia, CNS Pharma, Dr Reddys Laboratories Australia, Eli Lilly Australia, Generic Health, Generic Partners, Ipca Pharma (Australia), Link Pharmaceuticals, Lundbeck Australia, Lupin Australia, Medis Pharma, Micro Labs, Novartis Pharmaceuticals Australia, Organon Pharma, Pfizer Australia, Pharmacor, Sandoz, Servier Laboratories Australia, Southern Cross Pharma, Strides Pharma Science, Sun Pharma ANZ, Viatrix.

Documents submitted for ACM consideration

The ACM considered the following documentation:

- NPS MedicineWise. MedicineInsight Report: Epidemiology of mental health conditions and antidepressant utilisation in people aged less than 25 years attending general practice. Sydney: NPS MedicineWise, June 2021.
- Ratified minute of ACM 22 (August 2020) on Antidepressants and youth suicide.

Delegate's Overview

Delegate's summary of issues

The TGA published a review on the issue of antidepressants and youth suicide in December 2020¹ including ACM advice sought at the August 2020 meeting (updated report published April 2021).²

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.

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.

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:

1. An analysis of the NPS 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.
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.

Delegate's Preliminary View

Given the finding of increasing trends in mental health conditions in this population, the Delegate considers that the MedicineInsight analysis supports the previous advice of the ACM. In particular, any regulatory action to limit prescriber or Pharmaceutical Benefits

¹ <https://www.tga.gov.au/alert/antidepressant-utilisation-and-risk-suicide-young-people> (9 December 2020)

² <https://www.tga.gov.au/resource/antidepressant-utilisation-and-risk-suicide-young-people> (28 April 2021)

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. The Delegate's proposed actions are:

1. Publish the findings of the MedicineInsight 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).

Advice sought by Delegate of the Secretary of Department of Health

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?***

ACM discussion

General comments

The ACM expressed concern on growing rates of depression and anxiety in young people.

The ACM would welcome an opportunity to review the findings of the National Integrated Health Services Information investigation, when available.

ACM advice to the Delegate

The ACM advised the following in response to the Delegate's specific request for advice:

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?***

The ACM noted the NPS MedicineInsight analysis with interest and noted that overall, this analysis does not indicate an association between use of antidepressants and rates of youth suicide in Australia.

Key findings of the MedicineInsight report were that 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 2018–2019, and about 6% of all patients aged less than 25 years had at least one antidepressant prescription recorded during 2018–2019. The ACM noted that this indicated use of non-pharmacotherapy treatment options, including mental health treatment plans.

Very few suicides were recorded in this dataset. However, the recorded rates of suicide attempt, suicide ideation and self-harm in patients have increased at least 3-fold over a 10-year period.

Co-prescribing was reassuringly low: in 2018–2019 an antidepressant was uncommonly prescribed on the same day as an antipsychotic (8.7% of the patients), benzodiazepine/z-drug (7.1%) or ADHD stimulant (2.6%).

The ACM noted that for children 14 years and younger, initial and maintenance prescribing of antidepressant was most likely by a specialist paediatrician than by a GP. The low prescribing rate of antidepressants in children 14 years and younger in the GP database used in the NPS MedicineInsight report may underestimate the actual prescribing rate in the youngest age cohort (ascertainment bias).

The MedicineInsight report includes 2020 data. The various impacts of the COVID-19 pandemic on mental health, demand for services, and availability of telehealth services, is not yet known.

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?*

The ACM did not identify additional risk minimisation measures that should be undertaken at this time. The ACM agreed with the Delegate that while the MedicineInsight analysis provides additional information about trends and utilisation of antidepressants in young people, this analysis has not identified a clear need for further regulatory action.

The ACM continued to support prescriber and consumer education, as described in the earlier ACM advice on this issue (see ACM 22, item 3.01). Healthcare professionals need to provide education on the risk of suicidal ideation especially in the first month of therapy, and the benefit-risk of pharmacotherapy, to patients and family members.

Any increased restriction on prescribing would further disadvantage children and adolescents, especially in areas where access to specialist prescribers and alternative treatment modalities is already limited.

3. *Does the Committee recommend any additional actions from the TGA on this issue?*

No additional actions were recommended by the ACM.

Ratified and provided to Delegate on 15 October 2021.

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