The Royal Australian & New Zealand College of Psychiatrists
New South Wales Branch

06 June 2025

Project Team
Review of the Poisons and Therapeutic Goods Act
Pharmaceutical Services Transformation Unit
Legal and Regulatory Services
NSW Ministry of Health
1 Reserve Rd,
St Leonards NSW 2065

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Dear Project Team,

Re: Proposal to remove daily dose limits imposed on the prescribing, supply and administration of Schedule 8 psychostimulants

The NSW Branch of The Royal Australian and New Zealand College of Psychiatrists (RANZCP) appreciates the opportunity to submit a response to this proposal by the NSW Secretary of Health to remove daily dose limits currently imposed on the prescribing, supply, and administration of Schedule 8 psychostimulants.

The RANZCP also appreciates the New South Wales Pharmaceutical Services Unit's (PSU) interest in removing the regulatory burden associated with the prescribing, supply and administration of Schedule 8 psychostimulants on stakeholders, and the due diligence taken to understand the risks that these changes may present to public health.

The RANZCP response to this proposal was developed in consultation with members of the RANZCP Faculty of Addiction, the Faculty of Child and Adolescent Psychiatry, the NSW Branch Committee and the Attention Deficit Hyperactivity Disorder (ADHD) Network Subcommittee who have considered the impact of the changes and the potential risk to public health.

The RANZCP position statement, ADHD across the lifespan emphasises the need to apply evidence-based precautions when prescribing stimulant medications to ensure the safety of patients and the community. The statement recommends prolonged assessment phases, staged supply and close follow-up supervision as extra precautions that should be applied when prescribing stimulant medications and increasing to higher doses of stimulant medications (1).

The RANZCP guidance for the use of stimulant medications in adults with ADHD and narcolepsy cautions on the risk of interactions with other medications used in these conditions, and that particular consideration should be given to other possible diagnosis or

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conditions. Such conditions include acquired brain injury and neurological conditions. Substance use, anxiety, eating and mood disorders are also common in adults with ADHD and usually require treatment in their own right (2).

Supporting data

The six months of Safescript data referred to in the discussion paper is insufficient evidence of there being no substantial risk to public health and safety from these proposed legislative changes.

In addition to our concerns about the insufficient and brief period of data collection, other data provided in the discussion paper raises the following questions which should be addressed before considering any changes to the current dose limits.

1) The data suggests that 85% of practitioners who prescribed higher doses of dexamfetamine were a relevant specialist, leaving 15% of higher dose prescribers who were not relevant specialists. Who were the other prescribers and if the current restrictions are lifted, would the rate of prescribers who are not relevant specialists also increase?
2) The data shows that 'higher doses' were only prescribed in four percent of cases. If the current restrictions are removed would the consequence be an increase in the rate of higher dose prescribing?
3) While the six months of data collected by Safescript proves that the prescribing of S8 psychostimulant medicines above the current dose limits is very low over that six-month period, would data collected over a longer period, like 12 months, produce a different result?

Risks associated with the removal of daily dose limits

The discussion paper argues that any changes to dose limits would not increase the risk associated with the supply of these medicines, however some of our members take a contrary view. They believe that dose limits act as an added precaution against the risk of S8 psychostimulants diverting to the illicit market and the potential for abuse, misuse and physical and psychological dependence.

Their position is consistent with one of the National Drug Strategy 2017-2026 pillars of harm minimisation (supply reduction) (3). There is also evidence that high dosages of stimulants observed in cases of substance abuse increase the risk of psychosis (4).

They also believe that the risks associated with the removal of dose limits is not mitigated by the additional controls imposed on the supply of these medicines by 'State and Territory medicines and poisons regulatory agencies' as stated in the discussion paper.

Furthermore, the recent decision in NSW allowing General Practitioners to provide ongoing prescriptions for children and adults who are on stable doses of ADHD medication, without needing to refer to a specialist, may increase the quantity of psychostimulants in the community and potentially impact the level of abuse and misuse.

RANZCP members who were consulted on this proposal made the following observations:

1) The current regulations are consistent with Therapeutic Goods Administration (TGA) approval process.
2) People requesting higher doses are almost always experiencing comorbidity and very few benefit from higher doses.
3) Applying a maximum dose authority only to a "patient with a substance dependence" is stigmatising to people with substance use issues who already have difficulty in finding treatment for comorbid ADHD.
4) If a person is not responding at the higher authorised dose, there is limited benefit for increasing the dose for treatment of recognised conditions.
5) Dose limits are both evidence-based and a sound guide for prescribers.
6) Higher doses are associated with a higher risk of psychosis and hospital admissions (4).

Recommendations

1) The Safescript Data collection period should be extended to 12 months before any decision on the removal of daily dose limits of S8 psychostimulant medication is considered.
2) If the NSW Government proceeds with the removal of daily dose limits, 12 months of subsequent data collection should be commissioned to monitor and review the effect of the regulatory change.
3) Dose limits are both evidence based and a sound guide for prescribers, therefore when exceeding the manufacturer's recommended dose prescribers should undertake a new clinical assessment of their patient to understand their patient's response to the previously prescribed dose.
4) Prescribers exceeding the manufacturer's recommended dose should seek a second opinion from another relevant specialist before prescribing a higher dose.
5) For increased safety of prescribing and monitoring, there must be uniformity of regulations across states and territories, including:
    a. uniformity of doctors' registration (AHPRA registration and College registration), uniformity of prescribing regulations
    b. uniformity of monitoring with SafeScript software and Pharmaceutical Benefits Scheme (PBS) regulations

We thank you for the opportunity to respond to this proposal. Please do not hesitate to contact me via the RANZCP NSW Branch Policy and Advocacy Advisor, Richard Hensley, at Richard.hensley@ranzcp.org or by phone on 93523609 if you require further information.

Yours sincerely,

Dr Pramudie Gunaratne
Chair, NSW Branch Committee

References

1. The Royal Australian and New Zealand College of Psychiatrists. ADHD across the lifespan 2023 [Available from: https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/adhd-across-the-lifespan.
2. The Royal Australian and New Zealand College of Psychiatrists. Guidance for the use of stimulant medications in adults 2015 [Available from: https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/use-of-stimulant-medications-in-adults.
3. Australian Government Department of Health 2017. National Drug Strategy 2017-2026.
4. Lily Hechtman. ADHD medication treatment and risk of psychosis. The Lancet Psychaitry.6(8):632-3.