



22 August 2024

Proposed Amendments to the Poisons Standard

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Email: Medicines.Scheduling@health.gov.au

Dear Advisory Committee on Medicines Scheduling (ACMS),

Re: Public consultation on interim decisions to amend the Poisons Standard – ACMS, ACCS & Joint ACMS-ACCS March, 2024 - scheduling of cytisine

The Royal Australian College of General Practitioners (RACGP) thanks the Department of Health and Aged Care / Therapeutic Goods Administration for the opportunity to provide a submission on the proposed amendments to the Poisons Standard / scheduling of cytisine.

Every year more than 22 million Australians visit a GP for their essential health care, making GPs the most accessed health care provider in the country. Further, GPs are most often the first point of contact for most Australians seeking healthcare, with almost 90% of the population seeing a GP at least once each year.ⁱ

GPs play a key role in supporting patients to quit smoking. The RACGP is currently updating its flagship resource [Supporting smoking cessation: A guide for health professionals](#) which includes evidence-based guidance about prescribing pharmaceuticals for smoking cessation, and more recently, vaping cessation. This guidance will now be revised to include cytisine for nicotine dependence.

RACGP welcomes the decision to make cytisine available in Australia. There is moderately certain ⁱⁱ evidence supporting the efficacy of cytisine for smoking cessation and while it can cause some mild gastrointestinal symptoms, it has a very low risk of serious adverse effects.ⁱⁱⁱ

However, whilst risk of adverse events is low, we do not support pharmacy prescribing. Enabling access to this low cost first-line medicine must be balanced by mitigating the risks of possible contraindications, drug interactions and fragmented care.

The contraindications of cytisine include common patient comorbidities and pharmacists do not have adequate access to patient medical histories. This issue may be compounded by patients frequently not being fully aware of or understanding their medical conditions. For instance, patient awareness of chronic kidney disease (CKD) is low, with only 1 in 4 patients aware of a low estimated glomerular filtration rate (eGFR) ^{iv} and coded diagnosis rates for CKD in Australia are low ^v. As noted by the TGA application, there is limited clinical experience for cytisine use in individuals with kidney or liver impairment and as such, cytisine may not be suitable for these patient groups.



The RACGP notes the TGA application states that cytisine may interact with some commonly used medicines such as streptomycin, theophylline, clozapine, ropinirole, and hormonal contraceptive pills reducing their effectiveness. It will therefore be important to ensure that people seeking a pharmacy prescription are appropriately advised if they are taking these medicines.

The schedule 3 listing of cytisine (oral / oromucosal 9 mg) does not provide enough safeguards to mitigate these risks. Additional safeguards should be considered:

- a private consultation area is provided so that patients can be properly counselled and advised of possible risks and offered behavioural support
- full protocols in place to exclude possible contraindications and/or drug interactions
- information about the use of cytisine sent back to the patient's GP to facilitate continuity of care.

Vaping cessation

The RACGP supports increasing the available options of approved first-line medicines indicated for nicotine dependence. There is a dearth of strong evidence supporting *any* pharmacological approaches to managing vaping cessation and the RACGP supports the cautious prescribing of cytisine to assist with vaping cessation, in conjunction with behavioural support.

The RACGP recommends the interim decision on the schedule 4 listing of cytisine for the treatment of nicotine dependence to include vaping cessation.

The RACGP thanks the Department of Health and Aged Care for the opportunity to provide this feedback. If you have any queries regarding this submission, please contact Mr Stephan Groombridge, National Manager, e-Health, Quality Care & Standards on (03) 8699 0544 or at Stephan.groombridge@racgp.org.au

Yours sincerely

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RACGP President

ⁱ Department of Health. Annual Medicare statistics: Financial year 1984–85 to 2019–20. Canberra: DoH, 2020

ⁱⁱ Livingston-Banks J, Fanshawe TR, Thomas KH et al 2023. Can medications like varenicline and cytisine (nicotine receptor partial agonists) help people to stop smoking and do they cause unwanted effects? Available



RACGP
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from: https://www.cochrane.org/CD006103/TOBACCO_can-medications-varenicline-and-cytisine-nicotine-receptor-partial-agonists-help-people-stop-smoking

iii Courtney R, McRobbie H, Tutka P et al. Effect of cytisine vs varenicline on smoking cessation: A randomised controlled trial. *JAMA*. 2021;326(1):56-64. doi:[10.1001/jama.2021.7621](https://doi.org/10.1001/jama.2021.7621)

iv Chu CD, Chen MH, McCulloch CE et al. 2021 Patient awareness of CKD: A systematic review and meta-analysis of patient-oriented questions and study setting. *Kidney Med* 3(4);573-585 e1
doi: [10.1016/j.xkme.2021.03.014](https://doi.org/10.1016/j.xkme.2021.03.014)

v Radford J, Kitsos A, Stankovich J et al. 2019. Epidemiology of chronic kidney disease in Australian general practice: National Prescribing Service MedicineWise Medicine Insight dataset. *Nephrology (Carlton)* 24(10);1017-1025 doi: [10.1111/nep.13537](https://doi.org/10.1111/nep.13537)