



6 February 2024

Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

Email: [Medicines.Scheduling@health.gov.au](mailto:Medicines.Scheduling@health.gov.au)

Dear Advisory Committee on Medicines Scheduling (ACMS),

**Re: Consultation: proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, March 2024. 1. Proposed amendments referred for scheduling advice to ACMS meeting #43 1.1 Cytisine.**

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

General practitioners (GPs) are the first point of contact for most Australians seeking healthcare, with almost 90% of the population seeing a GP at least once each year.<sup>i</sup> 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.

Cytisine has long been used for smoking cessation in herbal form and is currently marketed in 18 countries throughout eastern and central Europe and Central Asia.<sup>ii</sup> Its availability as an over-the-counter product for smoking cessation has more recently extended to Canada, Portugal, Spain, Italy and the UK.

Cytisine is now approved for use in the UK by the Medicines and Healthcare Products Regulatory Agency and is subsidised by the National Health Service.<sup>iii</sup>

Despite calls for wider availability of cytisine, accessibility to date has been limited by market forces, with little incentive of return on investment by pharmaceutical companies.<sup>iv, v</sup> Hence the current application for scheduling presents an important opportunity for Australian smokers and health professionals to benefit greatly from an additional first-line medicine for smoking and vaping cessation.

There is moderately certain<sup>vi</sup> 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.<sup>vii</sup>

Increasing the available options of approved first-line medicines indicated for nicotine dependence is strongly supported by the RACGP.

**Recommendation:**

The RACGP recommends the scheduling of cytisine for the treatment of nicotine dependence.

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, Practice Management, Standards & Quality Care on (03) 8699 0544 or at [Stephan.groombridge@racgp.org.au](mailto:Stephan.groombridge@racgp.org.au)

Yours sincerely



**Dr Nicole Higgins**  
**RACGP President**

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

<sup>ii</sup> Tutka P et al. Cytisine for nicotine addiction treatment: A review of pharmacology, therapeutics and an update of clinical trial evidence for smoking cessation. *Addiction*. 2019;114:1951-69.

<sup>iii</sup> West R et al. Cytisine. National Centre for Smoking Cessation and Training (NCSCT). Available from: <https://www.ncsct.co.uk/library/view/pdf/Cytisine.pdf> 2024

<sup>iv</sup> Walker N et al. Getting cytisine licensed for use worldwide: A call to action. *Addiction*. 2016;111:1895-8.

<sup>v</sup> Walker N et al. Public Submission to the 23rd WHO expert committee on the selection and use of essential medicines, Geneva: 21 June to 2 July 2021 Geneva: WHO; 2021. Available from: [https://cdn.who.int/media/docs/default-source/essential-medicines/2021-eml-expert-committee/public-comments/a38\\_varenicline\\_walker.pdf?sfvrsn=91db4be2\\_5](https://cdn.who.int/media/docs/default-source/essential-medicines/2021-eml-expert-committee/public-comments/a38_varenicline_walker.pdf?sfvrsn=91db4be2_5) 2021.

<sup>vi</sup> 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 from: [https://www.cochrane.org/CD006103/TOBACCO\\_can-medications-varenicline-and-cytisine-nicotine-receptor-partial-agonists-help-people-stop-smoking](https://www.cochrane.org/CD006103/TOBACCO_can-medications-varenicline-and-cytisine-nicotine-receptor-partial-agonists-help-people-stop-smoking)

<sup>vii</sup> 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