25th November 2019

Review Secretariat
Pharmaceutical Benefits Scheme
Department of Health

Dear Sir/Madam,

Quit Victoria ("Quit") and the Australian Council on Smoking and Health (ACOSH) welcome the opportunity to make a submission to the *Public consultation on the post-market review of medicines for smoking cessation draft Terms of Reference.*

Quit is the peak tobacco control body in Victoria and drives the development and implementation of smoking cessation policy and programs in that state. It also has a leadership role in knowledge transfer and policy development related to smoking cessation across the Cancer Council nationally. Quit develops, evaluates and delivers smoking cessation services, principally through the Victorian Quitline, in partnership with academic collaborators. ACOSH works through advocacy and collaboration to create comprehensive strategies to reduce the health consequences of smoking. ACOSH aims to reduce overall smoking rates in Western Australia, including within groups with a high prevalence of smoking, through targeted campaigns.

Quit and ACOSH are strongly supportive of the proposed post-market review of medicines to ensure that more people who smoke can be supported to become tobacco free. Changes to PBS subsidies have the potential to reduce tobacco-related inequities through increased access to cessation support that is better suited to people who have complex health or psycho-social needs and also smoke.

Quit and ACOSH would like the following key points under each Term to be considered. In addition, we recommend an amendment be made to Term two.

1. ***Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Good Administration (TGA) and PBS restrictions for these medicines.***

There is a dearth of current clinical guidelines for medicines for smoking cessation. The only nationally-recognised clinical guideline for smoking cessation is The Royal Australian College of General Practitioners *Supporting smoking cessation: a guide for health professionals*, which, while highly relevant to the general practice setting, has limited applicability for health professionals working in other settings and is generally limited to TGA indications.[1] At the time of writing, an update of the guidelines is currently underway (with anticipated release in early 2020), which Quit is aware has undergone extensive revision to incorporate new evidence. While consideration of current clinical guidelines and TGA indications is certainly crucial, it is important to acknowledge that these may not necessarily reflect best practice tobacco dependence treatment.

[1] Zwar N, Richmond R, Borland R, Peters M, Litt J, Bell J, Caldwell B, Ferretter I. Supporting smoking cessation: a guide for health professionals. Melbourne: The Royal Australian College of General Practitioners, 2011.

PBAC should also seek the expert opinion of health professionals, smoking cessation experts, and conduct a review of health service guidelines, in developing and addressing the proposed Terms of Reference. In the absence of National Health and Medical Research Council (NHMRC) clinical practice guidelines for smoking cessation, Quit and ACOSH recommend PBAC additionally seek the expert opinion of health professionals, smoking cessation experts, and include the review of current health service guidelines, to identify where smoking cessation medicines are being appropriately used beyond the scope of clinical guidelines and the TGA. Quit and Alfred Health have worked with a number of Victorian health services and a large PHN to develop evidence-based guidelines for NRT use that enable best practice prescribing.

2. ***Review the utilisation of PBS-listed medicines for smoking cessation including patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment.***

We commend the intent of this Term as we believe it is critical to understand whether the use of PBS-listed medicines is acting to reduce or exacerbate tobacco-related inequities. Particularly whether there are barriers to access for Aboriginal and Torres Strait Islander people and people with low incomes.

We recommend an amendment to this term, such that it reads *Review the utilisation of PBS-listed medicines for smoking cessation* ***combined with comprehensive support and counselling****, including patient demographics, time on treatment, and the proportion using PBS subsidised combination treatment*

Best practice tobacco dependence treatment is a combination of smoking cessation medicines and multi-session behavioural intervention, such as that offered through Quitlines. Combining these approaches has the most significant positive impact on the success of quit attempts.[2,3]

The PBS currently specifies the following clinical criteria for smoking cessation medicines:

"Patient must have entered a comprehensive support and counselling program"

"Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated."

Despite the inclusion of these criteria, there is significant discordance between PBS prescribing of smoking cessation medicines and the enrolment of patients in behavioural intervention services such as Quitline, as indicated by the number of referrals to Quitline from health professionals.

For example, in Victoria in 2018, there were approximately five prescriptions of NRT for every 1000 persons. This equates to an estimated 32,000 NRT prescriptions.[4] On this basis, a corresponding

[2] Kotz D, Brown J, West R. Prospective cohort study of the effectiveness of smoking cessation treatments used in the "real world". *Mayo Clin Proc.* Oct 2014;89(10):1360-1367.
[3] West R, Raw M, McNeill A, et al. Health-care interventions to promote and assist tobacco cessation: a review of efficacy, effectiveness and affordability for use in national guideline development. *Addiction (Abingdon, England).* Sep 2015;110(9):1388-1403.
[4] Pharmaceutical Benefits Scheme database statistics. Available from: http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp

number of health professional Quitline referrals would be expected (or in fact a higher number, considering bupropion and varenicline carry the same restrictions). However, in 2018, the Victorian Quitline received 1,555 health professional referrals, which is significantly lower than the number of PBS NRT prescriptions. Anecdotally, health professionals may be satisfied they have "made a referral" and met the PBS criteria, having simply advised the patient to call Quitline and having provided the patient with the phone number. This is not sufficient. Quit advocates that referrals to Quitline *must* be made proactively – whereby the health professional completes a referral form and submits this to Quitline, either by fax or online. There is evidence that proactive referrals result in a 13-fold increase in enrolment in treatment, compared to simply advising the patient to call.[5]

Conversely, for Aboriginal and Torres Strait Islanders, enrolment in a smoking cessation counselling program is *not* part of the clinical criteria for NRT products. Instead, the following statement is included as an additional note after the population and clinical criteria:

"Benefit is improved if used in conjunction with a comprehensive support and counselling program."

This is contrary to evidence-based treatment and may be contributing to higher smoking rates in Indigenous communities.

3. Review the efficacy and safety of PBS-listed medicines and guideline-recommended medicines for smoking cessation, including those not currently PBS subsidised.

The efficacy and safety of smoking cessation medicines has been well-established, however we are aware that people who smoke often do not use adequate dosages or duration of smoking cessation medicines. This results in a perception that these medicines are ineffective and, in turn, discourages further or repeated use of medicines to support quit attempts. Given smoking is a chronic relapsing condition and that the use of medicines can greatly increase the success of a quit attempt, this has the potential to ensure people smoke for significantly longer periods of time with direct health consequences.

Ideally, this Term should recognise the importance of tailoring smoking cessation medicine dosing to individuals, and that many will benefit from higher doses, longer durations, and (in most cases) combination nicotine replacement therapy (NRT). Quit and ACOSH would also like to see that this Term addresses a plan to disseminate and communicate this safety information to consumers and health professionals, to dispel myths and ensure clinically appropriate, best practice prescribing of these medicines.

PBS restrictions do not enable best practice prescribing of smoking cessation medicines, particularly in relation to NRT

Most people who smoke will require combination NRT, consisting of a patch to provide a baseline level of nicotine, in combination with a faster-acting product (mouth spray, gum, inhalator or

[5] Vidrine JI, Shete S, Cao Y, Greisinger A, Harmonson P, Sharp B, et al. Ask-Advise-Connect: A New Approach to Smoking Treatment Delivery in Health Care Settings. JAMA Internal Medicine. 2013;173(6):458-64.

lozenge) to adequately control cravings, manage triggers and prevent or ameliorate nicotine withdrawal symptoms. High quality evidence has consistently shown that people using combination NRT are more likely to quit than those using monotherapy[6], resulting in an increase in quit rates of 15-36% compared with monotherapy.[7]

The following restrictions are in place for nicotine products listed on the PBS (patch, gum and lozenge):

"*The treatment must be the sole PBS-subsidised therapy for this condition"*

These restrictions do not enable best practice prescribing of combination NRT, and instead limits prescribers to opting for a single NRT product (where a subsidy applies). This has significant implications for patients, who must either (a) purchase an additional full-priced product, with a cost impost or (b) use only a single NRT product, which is suboptimal treatment. For people with low incomes, cost is a significant barrier to NRT use.[8] This PBS restriction is likely to create inequalities in terms of access to best practice tobacco dependence treatment and thus perpetuate tobacco-related inequities.

Faster-acting NRT products currently available in Australia include the oral spray, inhalator, gum and lozenge. The inclusion of the gum and lozenge on the PBS were welcome additions, but these products will not be clinically appropriate for all patients, nor will they be preferable to all patients. The inclusion of the inhalator and oral spray added to the list of available faster-acting products eligible for a PBS subsidy is important to provide greater patient choice.

Some individuals, particularly those with complex health and/or psychosocial needs or high dependency on nicotine, will need to use NRT products for a duration longer than that permitted by current PBS restrictions

Tobacco dependence is a chronic, relapsing condition. People who smoke will make a quit attempt many times before succeeding.[9]

For the general population, PBS clinical criteria pertaining to NRT products state:

"Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period."

And for the Aboriginal and Torres Strait Islander population, the criteria states:

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[6]Shah SD, Wilken LA, Winkler SR, Lin SJ. Systematic review and meta-analysis of combination therapy for smoking cessation. J Am Pharm Assoc (2003). 2008;48(5):659-65.

[7] Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Review. 2019. Available from: https://doi.org/10.10 02/14651858.CD013308

[8] Bryant J, Bonevski B, Paul C, O'Brien J, Oakes W. Developing cessation interventions for the social and community service setting: A qualitative study of barriers to quitting among disadvantaged Australian smokers. BMC Public Health, 2011;11:493.

[9] Chaiton M, Diemert L, Cohen JE, Bondy SJ, Selby P, Philipneri A et al. Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers. BMJ Open. 2016;6:e011045.

"Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period."

While a recent Cochrane review did not find a statistically significant increase in quit rates with longer durations of NRT use (both combination NRT and patch alone)[10], people with complex health and/or psychosocial needs are likely to require more intensive tobacco dependence treatment, and for longer durations than specified above. For example, research suggests that the rate of relapse among people who smoke and have a mental illness can be reduced with longer use of pharmacotherapy.[11] The restriction on duration of use may serve to perpetuate inequities by not enabling repeat NRT prescriptions for the people who are likely to need them the most. Reassuringly, evidence has consistently shown that longer term use of NRT is safe and serious adverse events are very rare.[12,13,14]

Quit is also aware of anecdotal evidence that the inclusion of a 12-week timeframe in the PBS criteria has created the perception that a single 12-week course of an NRT product is all that is required to aid successful quitting; for some individuals this is not necessarily the case.

4. ***Review the cost-effectiveness of PBS-listed and guideline-recommended medicines for smoking cessation.***

Tobacco smoking remains the leading cause of preventable death and disease in Australia[15], with a report released earlier this year estimating the tangible and intangible costs of tobacco use as close to $137 billion annually. Nearly $7 billion is directly related to healthcare costs.[16] There is no doubt that a comparatively miniscule investment to optimise PBS-subsidisation of smoking cessation medicines will be cost-effective. The question, rather, is just how large will the return on investment be in terms of cost-savings to the health system?

It is important to note that investment in PBS-subsidised smoking cessation medicines is not being optimised unless there is a way to ensure patients are using behavioural intervention concurrently

[10] Lindson N, Chepkin SC, Ye W, Fanshawe TR, Bullen C, Hartmann-Boyce J. Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Review. 2019. Available from: https://doi.org/10.10 02/14651858.CD013308

[11] Tidey JW, Miller ME. Smoking cessation and reduction in people with chronic mental illness. BMJ. 2015;351:h4065.

[12] Schnoll RA, Goelz PM, Veluz-Wilkins A, Blazekovic S, Powers L, Leone FT, Gariti P, Wileyto EP, Hitsman B. Long-term nicotine replacement therapy: a randomised clinical trial. JAMA Internal Medicine. 2015;175(4):504-511.

[13] Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P. Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis. BMJ. 2009;338:b1024.

[14] Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database of Systematic Reviews. 2018:CD000146. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000146.pub5/full

[15] Australian Institute of Health and Welfare 2019. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no.21. Cat. No. BOD 20. Canberra: AIHW.

[16] Whetton S, Tait RJ, Scollo M, Banks E, Chapman J, Dey T et al. Identifying the social costs of tobacco use to Australia in 2015/2016. National Drug Research Institute, Curtin University. 2019. Western Australia: NDRI.

with the medicines. Any opportunity to mandate a proactive referral to behavioural intervention services (Quitlines) when prescribing smoking cessation medicines on the PBS should be explored.

If you require further information, please contact Dr Jasmine Just (Health Systems Project Lead, Quit Victoria) at jasmine.just@cancervic.org.au

Thank you for your consideration of this submission.

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