

Cancer Council Australia's submission to the *Public consultation on the post-market review of medicines for smoking cessation draft Terms of Reference*.

Cancer Council is Australia's peak non-government cancer control organisation, involved in all cancer types and all areas of cancer control, and provides advice to Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

We understand that Quit Victoria have also made a submission to the public consultation. As such, Cancer Council Australia has focused this feedback on high level considerations and defer to the Quit Victoria submission for more granular detail.

Cancer Council Australia is strongly supportive of the proposed post-market review of medicines to ensure that more people who smoke can be supported to quit and stay smoke free. Changes to subsidies have the potential to reduce smoking-related inequities through increased access to cessation support that is better suited to people who have complex health or psycho-social needs and smoke.

We ask that the following be considered as the Terms of Reference are finalised.

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.

Currently there is a lack of current clinical guidelines for medicines for smoking cessation, with the only nationally recognised clinical guideline being the Royal Australian College of General Practitioners *Supporting smoking cessation: a guide for health professionals*¹. While this guideline is relevant to the general practice and primary care setting, it has limited applicability for health professionals working in other settings and is generally limited to TGA indications.

As such, a potential unintended consequence of this term may be to limit the evidence reviewed to that included in this guideline which may not necessarily reflect best practice tobacco dependence treatment.

Cancer Council Australia recommends seeking the expert opinion of health professionals, smoking cessation experts, and include the review of current health service guidelines (such as evidence-based guidelines for NRT use that enable best practice prescribing developed by Quit Victoria and Alfred Health), to identify where smoking cessation medicines are being appropriately used beyond the scope of clinical guidelines and the TGA.

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.

However 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.^{ii,iii}

As such, 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.*

This amendment would ensure the review aligns with current PBS clinical criteria for smoking cessation medicines that: *“Patient must have entered a comprehensive support and counselling program”* and *“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.”*

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

Cancer Council Australia is aware that people who smoke often do not use adequate dosages of smoking cessation medicines, nor do they take the medicines for an adequate length of time. 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 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^{iv}, resulting in an increase in quit rates of 15-36% compared with monotherapy.^v However current restrictions include *“The treatment must be the sole PBS-subsidised therapy for this condition”* which does not enable best practice prescribing of combination NRT, and instead limits prescribers to opting for a single NRT product (where a subsidy applies). This restriction is likely to create inequalities in terms of access to best practice tobacco dependence treatment and thus perpetuate tobacco-related inequities.

Additionally, tobacco dependence is a chronic, relapsing condition. People who smoke will make a quit attempt many times before succeeding.^{vi} Currently 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 Aboriginal and Torres Strait Islander patients, the criteria states: “*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)^{vii}, research suggests that the rate of relapse among people who smoke and have a mental illness can be reduced with longer use of pharmacotherapy.^{viii} 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.^{ix,x,xi}

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

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 with the medicines. We recommend that any opportunities to implement an opt-out (and proactive) referral to behavioural intervention services (like Quitlines) when prescribing smoking cessation medicines on the PBS should be explored.

Thank you for your consideration of this submission.

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