

Post-market Review of medicines for smoking cessation

Plain language summary

Background

Post-market Reviews (PMRs) are routinely recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). PMRs contribute to:

- Ensuring the ongoing viability of the Pharmaceutical Benefits Scheme (PBS).
- A better understanding of medicine use in the Australian health care setting.
- Assessing the ongoing cost-effectiveness of PBS-listed medicines.
- Overall improvements to the quality use of medicines and education for patients and health professionals.

Input from expert technical advisers and consultation from consumers, industry and healthcare professionals are part of the PMR process. This provides an opportunity to share experiences, expertise and knowledge when making decisions on medicine access and funding.

The PBAC recommended a PMR of medicines for smoking cessation ('the Review') in March 2018. The final terms of reference (ToRs) were approved by the Minister for Health in February 2020. Outcomes of the Review became publicly available in June 2022.

The Review

The Review aimed to evaluate the usage, effectiveness, safety, and cost-effectiveness ('value for money') of PBS-listed medicines for smoking cessation.

The Review's ToRs considered the following:

ToR 1 - Treatment guidelines: How do the most recent clinical guidelines for smoking cessation medicines compare to the current PBS restrictions?

ToR 2 - Medicine use: How are smoking cessation medicines used in different patient groups? For example, how long are people on treatment, how many are combining treatments and which medicine combinations are being used?

ToR 3 - Medicine effectiveness and safety: How do the various smoking cessation treatments compare concerning safety and effectiveness, including those not included on the PBS as combination treatments?

ToR 4 - Value for money: Based on the findings of the previous questions, are smoking cessation medicines providing value for money?

Smoking cessation medicines included in the Review

- Bupropion [Zyban®]
- Varenicline [Champix®]
- Nicotine replacement therapy (NRT) – various brands (patch, gum, and lozenge form)

Review key findings

The key findings from the Review are summarised below for each of the four ToRs.

ToR 1 – Treatment guidelines

Australian and international smoking cessation treatment guidelines generally aligned with PBS restrictions and dosing for these medicines. However, there were some differences:

- Treatment guidelines recommend the use of two forms of NRT at once however the current PBS restrictions do not.
- Treatment guidelines recommend longer courses of NRT compared to the 12 weeks permitted by the PBS.
- NRT 'double-patching' (using two NRT patches at once) and 'cut-down to quit' dosing (using NRT to reduce cigarette smoking or prepare to quit) were recommended in treatment guidelines but are not possible with the current PBS quantities and repeats.

The current PBS restriction that requires a six-month gap between starting one quit attempt with bupropion followed by another quit attempt with varenicline (or vice versa) is not reflected in the guidelines. Overall, guidelines differed in their recommendations for the use of bupropion and varenicline in combination (the United Kingdom guidelines advise against this) and the combination of either of these medicines with NRT.

ToR 2 – Medicine use

The Review found that 265,544 people (1.2% of the Australian population) were dispensed 542,492 PBS prescriptions for smoking cessation medicines in financial year 2019/2020, at a cost to the Commonwealth of \$36 million. Varenicline was the most prescribed of the PBS medicines (56%) followed by NRT (43%) and bupropion (1%).

In 2019, PBS-subsidised NRT accounted for 7% of all NRT use, the majority (94%) of these being nicotine patches. The remaining use of NRT was primarily nicotine gum products that were purchased privately from over-the-counter (OTC) access.

In 2019, approximately 52,000 people (1.8% of smokers aged 14 years and over) contacted Quitline. This suggested a low uptake of counselling services compared to the number of people accessing smoking cessation medicines on the PBS (approx. 266,000).

ToR 3 – Medicine effectiveness and safety

When used alone ('monotherapy') in people who had not taken the medicine previously, all medicines included in the Review were more effective but less safe (caused more adverse events) compared to no treatment (placebo). In people who had taken the medicine previously, only varenicline was more effective than placebo.

All medicines included in the Review appeared to have similar safety however, varenicline was likely to be more effective than bupropion and NRT. Short acting forms of NRT (gum and lozenges) appeared to have similar effects and safety to NRT patches.

When used in combination, varenicline combined with NRT patch was more effective than varenicline alone¹ with similar safety. Combination NRT appeared to have higher efficacy and similar safety compared to placebo, bupropion and NRT alone. Combination NRT appears to be less effective but safer compared to varenicline monotherapy.

ToR 4 – Value for money

Combination NRT was found to provide better value for money than varenicline and NRT in combination. The estimated additional cost to the PBS for both these treatments was within the range of \$60 million to \$70 million for the first five years post-PBS listing.

PBAC recommendations

The PBAC considered the reports addressing ToRs 1-4 of the PMR and overall accepted the Review findings.

¹ New evidence emerged after this finding which identified that combination varenicline and NRT was not as effective as suggested under ToR 3 of the Review. This new evidence was included in the value for money assessment under ToR 4.

The PBAC made the following recommendations to the Minister for Health:

- Extend the PBS restrictions for NRT to allow an additional 12 weeks of PBS-subsidised NRT in a 12-month period.
- Extend the PBS restrictions for NRT to allow up to two different forms of NRT to be prescribed together (combination NRT) on the PBS.

The PBAC supported the prospect of an education campaign targeting prescribers to raise awareness of the improved effectiveness of smoking cessation medicines when provided in combination with support and counselling.

Further information on the PBAC's comments and recommendations from the Review can be found in the [Outcomes](#) for this meeting. The full PBAC minutes are published along with the PMR report on the [Review webpage](#).