

27 November 2019

Post Market Review Secretariat  
Pharmaceutical Evaluation Branch  
Pharmaceutical Benefits Division, Australian Government Department of Health

### [Review Secretariat](#)

Dear Review Secretariat,

The Royal Australian College of General Practitioners (RACGP) thanks the Department of Health for the opportunity to comment on the Terms of Reference for the Post-market review of medicines for smoking cessation.

The RACGP is a strong advocate for smoking cessation and has invested considerable resources in this area. As such we wish to draw your attention to the second edition of the RACGP guide *Supporting smoking cessation: A guide for health professionals*, due for release in January 2020. First published in 2011, the update now reflects advances in the field of smoking cessation and addresses many contemporary challenges identified by healthcare professionals. These include e-cigarettes, combination pharmacotherapies, higher dose nicotine replacement therapy, and high prevalence and special needs groups.

The updated guide now targets a broader audience, having input from a multidisciplinary expert advisory group with representation from general practice, pharmacy, addiction psychology, respiratory medicine, public health and nursing. The RACGP commissioned the Joanna Briggs Institute (JBI) and the JBI Adelaide GRADE Centre to conduct an evidence review to develop the guideline recommendations. In keeping with international best practice of guideline development, the new guide was developed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) process.

As such, the RACGP guidelines are based on the best available evidence, and relevant to a broader range of Australian health care professionals. It would therefore be prudent for the review to include these guidelines in their review process.

With regard to the draft Terms of Reference relating to PBS restrictions for smoking cessation medicines, the RACGP wishes to emphasise the importance of appropriate dosing strategies, particularly for nicotine replacement therapy (NRT). It is noted that current dosing strategies for NRT differ markedly from the Therapeutic Goods Administration (TGA) recommendations and Pharmaceutical Benefits Scheme (PBS) restrictions for these medications. In particular, the RACGP urges that more consideration is given to combination therapies which are more effective than monotherapy, however, which require more flexible prescribing options for PBS listed smoking cessation medicines. Current PBS arrangements prevent adequate prescribing for combination therapy. Cost can be a major barrier to using pharmacotherapy for smoking cessation.

It will be critical to re-assess the use of PBS-listed smoking cessation medications by patient demographic, particularly as it is well established that smoking rates are inversely related to socio-economic status. Certain demographic and cultural groups with specific needs are particularly vulnerable and experience higher smoking prevalence. These groups require flexible access to PBS-listed medicines to support more effective combination therapies (e.g NRT patch plus acute form such as spray, gum, inhalator or lozenge).

The RACGP supports the breadth of the Terms of Reference as set out by the Department of Health. In addition to these questions, we suggest that the post-market review consider the following areas and population groups:

1. Nicotine replacement therapy –

- Combination NRT – concurrent availability of two forms of PBS-subsidised smoking cessation medication is needed
- Higher dose NRT – best practice differs to current dosing recommendations
- Use of NRT during pregnancy
- Currently a maximum 12 weeks of PBS-subsidised NRT is available per 12-month period - consider extending this time for high prevalence groups.

2. Varenicline –

- Availability of PBS-subsidised varenicline for combination therapy

3. High prevalence groups –

- Aboriginal and Torres Strait Islander people
- Culturally and linguistically diverse groups
- Populations with special needs –
  - Pregnant and breastfeeding women
  - Adolescents and other young people
  - People with mental illnesses
  - People with other substance use disorders
  - People in prison
  - People with smoking related diseases
  - People who smoke and are in hospital

Yours sincerely



**Dr Harry Nespolon**  
President