CHANGES TO PRESENT (OR RECOMMENDED) PBS AVAILABILITY

When the PBAC makes a recommendation under section 101(3) of the *National Health Act 1953* ("the Act") in relation to a drug/medicinal preparation which it considers should be made available as a pharmaceutical benefit under Part VII of the Act, it is also required to consider whether the drug/medicinal preparation should be made available only in certain circumstances (see section 101(3C) of the Act). Where the PBAC considers that the drug/medicinal preparation should be made available only in certain circumstances, it specifies the circumstances in its recommendation under section 101(3).

At its meeting on **6 May 2022**, the PBAC in making its recommendation under section 101(3) of the Act, decided to recommend a change to the circumstances under which nicotine (in patch, gum, and lozenge form) is made available as a pharmaceutical benefit under Part VII of the Act.

A note of the PBAC's decision follows.

9.02 Post-market Review of medicines for smoking cessation

1 Purpose of item

That the PBAC:

1.1 **Consider** the draft report for the Post-market Review (PMR) of medicines for smoking cessation ("the Review") addressing Review terms of reference (ToRs) 1-3.

1.2 **Note** the [redacted] submission (and associated economic model) along with the evaluation commentary**.**

1.3 **Consider** the *Cost-effectiveness Review of Specified Combinations of Smoking Cessation Medicines and Estimates for the Pharmaceutical Benefits Scheme* (PBS) report conducted under ToR 4 of the Review.

1.4 **Note** the Drug Utilisation Sub-Committee (DUSC) and Economics Sub-Committee (ESC) advice from the June 2021 and February 2022 meetings.

1.5 **Note** the sponsor pre-sub-committee responses (PSCRs) from the June 2021 and February 2022 meetings.

1.6 **Note** the sponsor pre-PBAC response**.**

1.7 **Note** stakeholder input to the PMR.

1.8 **Comment** on the Review 'options' proposed by the Review reference group (refer to pages 38-44 of the *Report summary and 'options' for PBAC consideration*) and provide

advice on any recommendations to change the current PBS listings for varenicline (VAR) and/or nicotine replacement therapy (NRT).

1.9 **Note** the draft PBS restrictions to allow combination use of VAR and/or NRT on the PBS.

2 Background

2.1 There are currently three pharmacological interventions for smoking cessation available on the PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS): NRT (in patch, gum, and lozenge form), VAR and bupropion (BUP). These medicines are presented in Table 1.

Table 1: Medicines for smoking cessation listed on the PBS/RPBS

Brand, strength [pack size]	Sponsor	PBS Item number	DPMQ
NRT – Patch			
Nicorette 16hr Invisipatch®, 25mg/16 hours [28]	Johnson & Johnson Pacific Pty Limited	10076H	$49.96
Nicotinell Step 2®, 14mg/24 hours [28]	Orion Laboratories Pty Ltd	5572G	$49.96
Nicotinell Step 1®, 21mg/24 hours [28]	Orion Laboratories Pty Ltd	3414Q 5571F	$49.96
Nicabate P®, 21mg/24 hours [28]	GlaxoSmithKline Australia Pty Ltd	5465P	$49.96
Nicotinell Step 3®, 7mg/24 hours [28]	Orion Laboratories Pty Ltd	5573H	$49.96
QuitX® 21mg/24 hours [7] [a]	Alphapharm Pty Ltd	4573Q	$58.68
QuitX® 14mg/24 hours [7] [a]	Alphapharm Pty Ltd	4572P	$55.72
QuitX® 7mg/24 hours [7] [a]	Alphapharm Pty Ltd	4571N	$52.56
NRT – Lozenge			
Nicotinell®, 2mg [216]	Orion Laboratories Pty Ltd	11617K	$49.96
Nicotinell®, 4mg [216]	Orion Laboratories Pty Ltd	11619M	$49.96
NRT – Chewing gum			
Nicotinell®, 2mg [216]	Orion Laboratories Pty Ltd	11618L	$68.90
Nicotinell®, 4mg [216]	Orion Laboratories Pty Ltd	11612E	$49.96
Varenicline – Tablet			
Champix®, 500microgram tablet [11] (&) varenicline 1mg tablet [42] [b]	Pfizer Australia Pty Ltd	9128K	$87.24
Champix®, varenicline 1mg [56] [c]	Pfizer Australia Pty Ltd	5469W	$100.69
		9129L	$193.16
Bupropion – Modified release tablet			
Zyban®, 150mg [30]	Aspen Pharmacare Australia Pty Limited	8465M	$63.52
Zyban®, 150mg [90]	Aspen Pharmacare Australia Pty Limited	8710K	$169.11

As of 13 May 2022. DPMQ = Dispensed Price for Maximum Quantity [a] Repatriation Care items [b] Initiation Pack [c] Continuation Pack

2.2 In July 2017, the PBAC deferred a major submission for the listing of NRT in the form of gum and lozenges (2 mg and 4 mg strengths) on the PBS. The PBAC noted that the efficacy of nicotine lozenges and gum significantly improved when used in combination with nicotine patches, but that no evidence was provided in the submission about the cost-effectiveness of combination NRT.

2.3 In March 2018, the PBAC recommended the listing of nicotine gum and lozenges as monotherapies on the PBS for treating nicotine dependence. The PBAC considered that a broader review of PBS-listed nicotine dependence treatments, in the context of the current clinical guidelines, would help inform whether the current subsidy arrangements should be altered to better support smoking cessation.

2.4 The final ToRs for the PMR of medicines for smoking cessation were approved by the Minister for Health on 24 February 2020 as follows:

1. Collate the current clinical guidelines for medicines for smoking cessation and compare these to the Therapeutic Goods Administration (TGA) and PBS restrictions for these medicines.
2. Review the utilisation of PBS-listed medicines for smoking cessation including but not limited to patient demographics, time on treatment, and the proportion using PBS-subsidised combination treatment.
3. Review the efficacy and safety of NRT, VAR and BUP for smoking cessation including combination therapies not currently PBS-subsidised.
4. Subject to the findings of ToRs 1, 2 and 3, review the cost-effectiveness of medicines for smoking cessation.

Note: E-cigarette devices and nicotine liquids were out of scope of this PMR.

2.5 The department commissioned two independent contractors, the Centre for Health Economics Research and Evaluation (CHERE) and the University of South Australia (UniSA), to undertake research to inform the Review findings for ToRs 1-3. The CHERE was contracted to provide a report addressing ToRs 1 and 3 and UniSA provided a report addressing ToR 2.

2.6 An independent reference group was established to guide and provide advice to the Review. The reference group provided advice on issues raised by stakeholders, considered the evidence provided addressing each ToR, and guided the development of the draft report.

2.7 In line with the published PMR framework, there were several opportunities for stakeholder consultation including:

- to comment on the draft ToRs
- a public submission process addressing the Review and the final ToRs
- a stakeholder forum held via webinar on 3 December 2020
- to comment on the draft report.

2.8 Stakeholder comments are published in full on the Review's public consultation page. Stakeholder feedback is also summarised in the final Review report as follows:

- Report summary – pages 11, 14, 33-34 and 36-37
- Background report – pages 8-9
- ToR 1 report – page 7
- ToR 2 report – pages 6-7
- ToR 3 report – pages 24-25
- ToR 4 report – page 16.

2.9 The following areas of the department were consulted during the formulation of the Review's draft ToRs and on the draft report:

- Tobacco Control Section - Alcohol, Tobacco and Other Drugs Branch
- Tackling Indigenous Smoking Program: Child and Family Health Section - Health Plan, Early Years and Engagement Branch
- Supply Programs Section – Pharmacy Branch
- the TGA.

2.10 In June 2021, the DUSC and ESC considered the PMR of medicines for smoking cessation draft report including the key findings and the 'options' proposed by the reference group. In addition, the ESC was asked to consider if a cost-effectiveness review (CER) of medicines for smoking cessation should be progressed under ToR 4 of the PMR and if considered necessary, advise on the approach to be undertaken and potential medicine comparisons to be evaluated.

2.11 The ESC provided the following advice on a potential future CER under ToR 4 of the PMR:

- In considering options 2 and 3, the ESC advised that a cost-effectiveness analysis of combination NRT (NRT+NRT) *versus* NRT monotherapy, and varenicline and NRT in combination (VAR+NRT) *versus* VAR monotherapy, should be progressed under ToR 4 of the Review.
- The ESC considered a confidential submission to the Review [redacted] that included a cost-effectiveness analysis of [redacted]. The ESC noted that the [redacted] cost-effectiveness submission had not been evaluated by an external evaluation group.
- The ESC suggested that the evaluation commentary of the [redacted] submission and any additional modelled comparisons should be provided to the ESC and the PBAC for consideration at a future meeting.

2.12 The ESC also provided specific comments on the Review options:

- Option 1: The ESC noted that while longer durations and additional courses per 12-month period of PBS-subsidised NRT were supported by sponsors, stakeholders

and in clinical guidelines, there was limited evidence from the ToR 3 report to support this option.

- Option 2: The ESC noted that there was some evidence to clinically support combination NRT (option 2a) however, the evidence to support double patching (option 2b) was limited and varied according to the different strengths compared. The ESC therefore supported PBS-subsidised combination NRT provided it was found to be cost-effective.
- Option 3: The ESC noted the report findings that VAR+NRT had greater efficacy than VAR monotherapy and therefore supported option 3 (PBS-subsidised VAR+NRT) subject to a finding of acceptable cost-effectiveness.
- Option 4: The ESC supported option 4.
- Option 5: The ESC noted that while option 5 (the PBS listing of NRT inhaler/inhalator and/or mouth spray) was supported by stakeholders, the evidence from ToR 3 showed that there was no statistically significant difference in efficacy between NRT inhaler/inhalator and placebo and that these products were available over-the-counter (OTC).
- Option 6: The ESC supported option 6.

2.13 In August 2021, the department engaged the services of the Centre for Health Economics (CHE), Monash University to undertake an economic evaluation of the [redacted] submission and prepare an evaluation commentary for consideration by the ESC and the PBAC. The commentary raised several concerns regarding the cost-effectiveness analysis and noted several model inputs were outdated. The submitted model's base case incremental cost-effectiveness ratio (ICER) was estimated to be [redacted] per quality-adjusted life-year (QALY) for [redacted] over a [redacted] time horizon.

2.14 Due to the issues raised in the evaluation commentary of the [redacted] submission, the CHE, Monash University was contracted to conduct a *CER of specified combinations of medicines for smoking cessation and estimates of the cost to the PBS* under ToR 4 of the Review. The purpose of the CER was to provide the PBAC with information on the cost-effectiveness of PBS-listed therapies (VAR and NRT), administered either as monotherapy or combination therapy.

2.15 The CER assessed the cost-effectiveness of the following comparisons of medicines for smoking cessation:

- VAR *versus* NRT
- VAR+NRT versus VAR
- VAR+NRT versus NRT
- NRT+NRT versus VAR
- NRT+NRT versus NRT
- VAR+NRT and NRT+NRT versus VAR+NRT.

And thus, provided evidence on the cost-effectiveness of the potential PBS listing of the following scenarios:

1. VAR+NRT only
2. NRT+NRT only
3. both VAR+NRT and NRT+NRT.

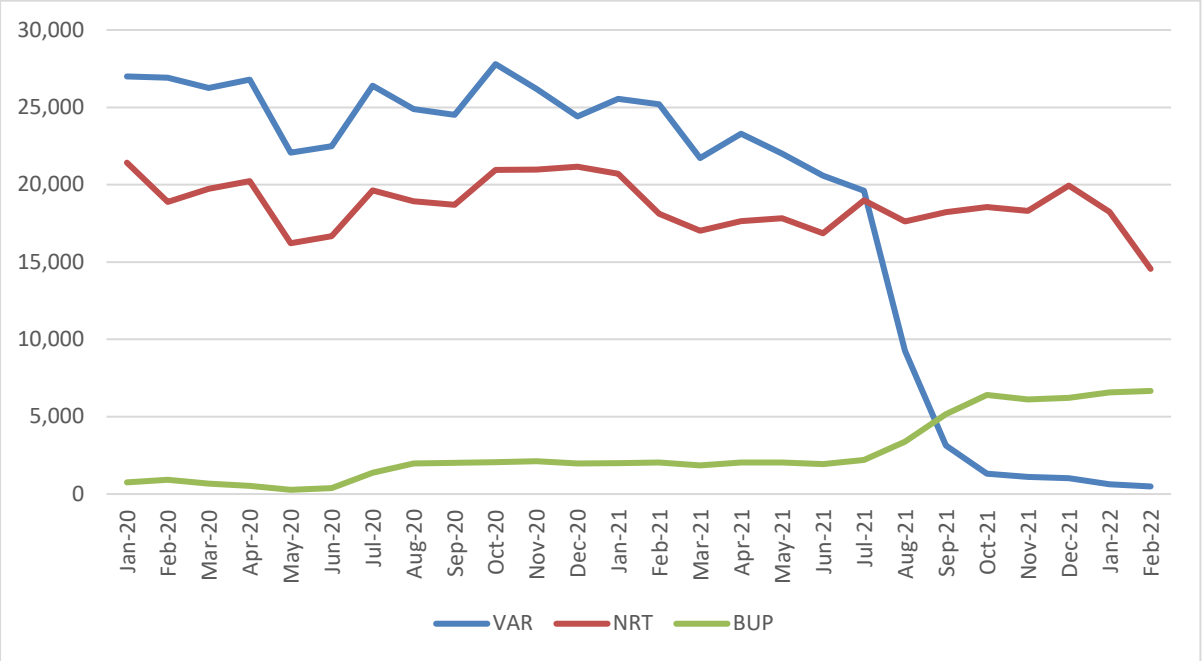
The research also provided estimates of the likely financial implications to the PBS of such listings.

Varenicline shortage

2.16 There is currently one PBS-listed brand of VAR (i.e., Champix) which has been under a supply shortage since 4 June 2021. This is expected to persist until 31 October 2023.

2.17 Figure 1 below shows that utilisation of VAR on the PBS has declined from approximately 22,000 scripts per month, before the shortage of VAR, to approximately 500 scripts per month in February 2022; whilst use of BUP has increased from approximately 2,000 scripts per month to approximately 6,500 scripts per month over the same period.

Figure 1: Services (scripts) from Services Australia data - based on date of processing



Note: NRT service numbers include both PBS and RPBS items.

2.18 In March 2022, the PBAC recommended the listing of a section 19A product (VAR, 1 mg tablet, APO-Varenicline (Canada)) at the requested price for the duration of the section 19A approval (expiry date: 28 February 2023), as an alternative brand to Champix (VAR, 1 mg tablet). The Section 19A product would have the same PBS restrictions as the registered Champix product in shortage. The PBAC noted that the

section 19A approval applied only in respect to the continuation pack and that the section 19A product would only be accessible to patients who had received treatment with the initiation pack, as required under the current PBS restrictions.

Queensland Quitline: 'Intensive Quit Support Program'

2.19 As part of Review option 6, the department contacted Queensland (QLD) Health in January 2022 regarding the evaluation of its *Intensive Quit Support Program*. The department was advised that evaluation of the regional, rural, and remote hospital and health services cohort was completed in 2021 however, the report would not be made available. QLD Health advised that further investigation was being undertaken in relation to several findings within the report, particularly around the provision of NRT. QLD Health would be collaborating with the QLD University of Technology (QUT) on this project.

3 Proposed listings

3.1 The department provided proposed PBS listings for NRT and VAR, to align with options 1, 2 and 3, for PBAC consideration. These are outlined on pages 26-29 of the ToR 4 report.

3.2 The proposed amendments to the PBS listings sought to increase the number of treatment attempts for non-Indigenous patients from one 12-week course to two 12-week courses of PBS-subsidised NRT per 12-month period. This was intended as either NRT monotherapy (in a single form) or as combination therapy (i.e., with another NRT product or in combination with VAR). Allowing 24 weeks of PBS NRT per 12-month period would bring the current NRT listings for the general population into line with the current NRT listings for the Aboriginal and Torres Strait Islander population, who already have access to 24 weeks of PBS-subsidised NRT in a 12-month period.

3.3 Double patching, as combination NRT therapy, under option 2b was not proposed. However, the PBAC was asked to consider whether increases in the maximum quantity of the same NRT patch should be permitted on the PBS.

4 Review report key findings and 'options' for the PBAC

4.1 The Review report provided several key findings for ToRs 1-4 (refer to pages 9-37 of the *Report Summary*).

4.2 Review options were developed by the reference group following consideration of the available evidence and stakeholder input (refer to pages 38-44 of the *Report Summary*). These options were provided to assist the PBAC and its sub-committees in their consideration and formulation of recommendations and advice to government.

5 Key findings of the cost-effectiveness review

5.1 The costs, health outcomes and ICERs for each of the stated comparisons, with a discount rate of 5%, are presented in Table 2 below. The first reported comparison compared the two major usual care options currently available, VAR *versus* NRT as the first line therapy, which resulted in an ICER between $55,000 to < $75,000 per QALY. The estimated ICERs for VAR+NRT *versus* these usual care comparators, VAR and NRT, were within the range of $35,000 to < $45,000; whilst the estimated ICERs for NRT+NRT *versus* VAR and NRT were within the range of $15,000 to < $25,000 and $25,000 to < $35,000 respectively. The scenario of listing both VAR+NRT and NRT+NRT compared to listing VAR+NRT alone was found to be both costlier and less effective (i.e., was dominated).

Table 2: Main cost-effectiveness analysis results (5% discount rate)

Comparison	Costs ($AU)			Health outcomes (QALYs)			ICER ($ per QALY)
	Proposed treatment	Comparator treatment	Diff.	Proposed treatment	Comparator treatment	Diff.	
(VAR) vs (NRT) [a]							
(VAR+NRT) [b] vs (VAR)							
(VAR+NRT) [b] vs (NRT)							
(NRT+NRT) [b] vs (VAR)							
(NRT+NRT) [b] vs (NRT)							
(VAR+NRT & NRT+NRT) [b] vs (VAR+NRT) [b]							

[a] This only considered the use of NRT *versus* VAR on the first attempt. The assumed use of NRT and VAR for subsequent attempts was assumed to be the same in both cases.

[b] Assumptions were also made about how the listing of these new combinations would also impact on the use of products in subsequent quit attempts. These results were produced by simulating 600,000 patients through each possible scenario for 50 years. 600,000 patients were used to minimise the Monte Carlo error.

6 Budgetary impact

6.1 Table 3 below presents the estimated financial implications to the PBS/RPBS, Medicare Benefits Schedule (MBS), and the health system combined in each financial year to 2026-2027 for the three listing scenarios: VAR+NRT only (Scenario 1), NRT+NRT only (Scenario 2) and both VAR+NRT and NRT+NRT (Scenario 3). Under the base case assumptions, the estimated incremental cost to the PBS for the first five years was approximately $60 million to < $70 million for Scenario's 1 and 2 and $90 million to < $100 million for Scenario 3.

6.2 The proposed additional listings first increased costs given the substitution to more expensive combination therapy, but the more effective therapies were then assumed to reduce the need for future assisted quit attempts. Also, it was assumed that substitution to the newly listed therapies would increase over time as more clinicians changed their standard of care.

Table 3: Estimated incremental net cost to the PBS/RPBS (less co-payment) and MBS under the proposed listing scenarios relative to the current PBS restrictions

	2022-2023	2023-2024	2024-2025	2025-2026	2026-2027
Scenario 1 (VAR+NRT listed on the PBS)					
PBS/RPBS net cost (less co-pay) VAR NRT BUP MBS net cost Health budget net cost					
Scenario 2 (NRT+NRT listed on the PBS)					
PBS/RPBS net cost (less co-pay) VAR NRT BUP **MBS net cost** **Health budget net cost**					
Scenario 3 (both VAR+NRT and NRT+NRT listed on the PBS)					
PBS/RPBS net cost (less co-pay) VAR NRT BUP **MBS net cost** **Health budget net cost**					

Source: *ToR 4: Cost-effectiveness review of specified combinations of smoking cessation medicines and estimates for the Pharmaceutical Benefits Scheme* report (p15)

6.3 A significant proportion of the additional costs to the PBS were likely to come from those currently making attempts using OTC products or those who were already using combination products by adding OTC products to their PBS-subsidised regimen. Further subsidising quit attempts may encourage adherence which may also increase successful quitting.

6.4 The financial estimates relied heavily on the extent of the substitution away from existing products and whether these existing products were accessed OTC or on the PBS. Assuming higher rates of substitution such that combination therapy replaces most monotherapy on the PBS, or where twice as many patients switch from OTC to PBS therapy, increased the estimates by 20% to 75%. There is also a risk that the financial implications may be considerably greater than those estimated above should the proposed listings of combination therapy encourage patients to make additional assisted quit attempts.

6.5 The financial estimates above did not account for the financial implications that would arise due to the current shortage of VAR. A sensitivity analysis accounting for this market shock found that the impact on the incremental costs depended on the extent that other PBS-listed therapies (NRT and BUP) would substitute for VAR when unavailable. Monthly PBS utilisation data for VAR, NRT and BUP from January 2020 to February 2022 are provided in Figure 1 above.

7 PBAC outcome

7.1 The PBAC noted stakeholder submissions to the Review, sponsor PSCRs, one pre-PBAC response, and ESC and DUSC advice.

7.2 The PBAC considered the Review report for the PMR of medicines for smoking cessation and the *CER of Specified Combinations of Smoking Cessation Medicines and Estimates for the PBS* report and overall, accepted the key findings.

7.3 The PBAC considered the six options proposed by the Review reference group and made the following comments and recommendations.

7.4 **Option 1a: Allow an additional 12 weeks of PBS-subsidised NRT therapy in a 12-month period for non-Indigenous patients, for the re-treatment of patients who had an unsuccessful quit attempt.**

AND

Option 1b: Allow an additional 12 weeks of PBS-subsidised NRT therapy in a 12-month period for non-Indigenous patients, who have ceased smoking during the initial 12 weeks of therapy to prevent relapse.

Note: Aboriginal and Torres Strait Islander persons already have access to 24 weeks of PBS-subsidised NRT in a 12-month period.

7.5 The PBAC recommended options 1a and 1b.

7.6 The PBAC noted that options 1a and 1b aligned with clinical guidelines and were supported by sponsors and stakeholders.

7.7 The PBAC noted that there was limited evidence from the ToR 3 report to support longer durations of treatment with NRT. However, the PBAC supported removing

barriers to people accessing smoking cessation products and providing greater flexibility for clinicians, by allowing longer durations of NRT or multiple assisted attempts at stopping smoking within the same year.

7.8 The PBAC noted that the ToR 2 report showed that only 12% of consumers prescribed NRT filled prescriptions for the full 12 weeks duration of therapy, suggesting that uptake (via the PBS) of longer durations of therapy may be low.

7.9 **Option 2a: Remove the requirement for nicotine patch, lozenge, or gum to be used as monotherapy to allow for combinations of NRT patch + short acting formulations to be used concomitantly on the PBS.**

AND

Option 2b: Remove the requirement for nicotine patch, to be used as monotherapy to allow for combinations of NRT patch formulations to be used on the PBS, to allow for double patching (e.g., two 21 mg/24-hour patches daily, 21mg + 14mg/24-hour patches daily) as second line therapy under an authority required restriction. Alternatively, double patching could be achieved by allowing increased quantities to be approved via a phone or online authority.

7.10 The PBAC recommended option 2a, but where multiple forms of NRT are prescribed, subsidy be limited to up to two different forms.

7.11 The PBAC noted that option 2a was consistent with clinical guidelines and was supported by sponsors and stakeholders.

7.12 The PBAC noted that the Review report showed that combination NRT was superior to NRT monotherapy in terms of efficacy. In terms of safety, there were no statistically significant differences in cardiac adverse events, serious adverse events, or withdrawals due to treatment.

7.13 The PBAC considered that the estimated ICERs for NRT+NRT *versus* the usual care comparators (VAR and NRT) were within acceptable cost-effectiveness thresholds that were typically considered reasonable value for money.

7.14 The PBAC agreed with the DUSC that there were several areas of uncertainty regarding the estimated financial impact to the PBS of the three listing scenarios. However, the PBAC considered the estimated incremental cost to the PBS for the listing of combination NRT ($60 million to < $70 million over the first five years) acceptable.

7.15 The PBAC noted that the scenario of listing both VAR+NRT and NRT+NRT compared to VAR+NRT alone was found to be both costlier and less effective (i.e., was dominated). The PBAC agreed with the ESC that an indirect comparison of ICERs suggested that NRT+NRT was a more cost-effective option than VAR+NRT. The PBAC considered that given a choice between recommending VAR+NRT or NRT+NRT, and in the context of the current shortage of VAR, NRT+NRT was the most appropriate choice at the present time.

7.16 The PBAC did not recommend option 2b.

7.17 The PBAC noted that advice from the reference group and several guidelines suggested that double patching may be useful for heavily dependent smokers. The PBAC agreed with the ESC however, that the evidence to support option 2b (double patching) was limited and varied according to the different strengths compared.

7.18 The PBAC agreed with the reference group that PBS restrictions should not allow multiple NRT patches as first line treatment and that clinicians should first trial standard doses of NRT to avoid unnecessary treatment withdrawal and wastage.

7.19 The PBAC recommended that the department explore options for the PBS subsidy of double patching via an authority required level of restriction to be considered by the committee at a later date.

7.20 **Option 3: Remove the requirement for VAR to be used as monotherapy, to allow for use in combination with NRT on the PBS.**

7.21 The PBAC did not recommend option 3.

7.22 The PBAC noted that two national guidelines and one international guideline recommended the use of VAR in combination with NRT, as an alternative to VAR alone.

7.23 The PBAC agreed with the ESC that given the limited and variable evidence for VAR+NRT there was still considerable uncertainty regarding whether this treatment was more effective than VAR monotherapy (RR=1.21, 95%CI 0.88, 1.66).

7.24 The PBAC noted that the estimated ICER for VAR monotherapy *versus* NRT monotherapy was $55,000 to < $75,000/QALY and considered that this was significantly higher than the ICERs that were typically accepted by the committee. The PBAC considered that a price reduction for VAR may be justified to bring the ICER for VAR *versus* NRT into an acceptable range.

7.25 The PBAC noted that the estimated ICERs for VAR+NRT *versus* VAR and NRT as monotherapy were both between $35,000 to < $45,000/QALY and considered that this was above the cost-effectiveness thresholds for primary preventative treatments that were commonly considered reasonable value for money.

7.26 The PBAC recommended that the department contract an external evaluation group to explore the impact of different pricing options to reduce the ICER for VAR *versus* NRT and VAR+NRT *versus* VAR to between $25,000 to < $35,000/QALY and negotiate with the sponsor of VAR once supply is re-instated.

7.27 **Option 4: Recommend an education campaign targeting prescribers to raise awareness of the improved effectiveness of smoking cessation pharmacotherapies when provided in combination with comprehensive support and counselling and enable prescribers to support best practice in recommending or providing comprehensive support and counselling services.**

7.28 The PBAC supported option 4.

7.29 The PBAC noted that evidence from the ToR 3 report showed that smoking cessation rates improved with proactive telephone counselling and clinical guidelines considered that any smoking pharmacotherapy combined with behavioural support was more effective than pharmacotherapy alone.

7.30 The PBAC noted the ESC advice that the evidence from the ToR 2 report suggested low uptake of counselling services compared to the population accessing PBS medicines for smoking cessation; despite the requirement that people accessing PBS-subsidised smoking cessation therapy "must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program."

7.31 **Option 5: Consider the PBS listing of nicotine inhaler* and/or nicotine mouth spray.**

*Nicotine inhaler products do not include electronic cigarettes or e-liquids which were excluded from the PMR of medicines for smoking cessation.

7.32 The PBAC noted stakeholder feedback that all forms of NRT should be subsidised under the PBS because some formulations may not be clinically appropriate for certain patients. The PBAC noted however, that evidence from the ToR 3 report showed no statistically significant difference in efficacy between NRT inhaler/inhalator and placebo and that these products are available OTC.

7.33 The PBAC supported increasing the range of PBS-listed NRT formulations to provide additional treatment options for consumers and prescribers. The PBAC advised that it would remain open to submissions from sponsors to list these formulations on a cost-minimisation basis to the currently listed gum and lozenge.

7.34 **Option 6: That the department follow-up with QLD Quitline following its evaluation of the 'Intensive Quit Support Program' and to explore if there are other effective ways of providing access to government funded NRT in addition to the current PBS and section 100 arrangements.**

7.35 The PBAC noted that access to NRT should not be contingent on specific government programs and considered that whilst the program evaluation by QLD Health may be informative, it would not limit other forms of access for consumers.

Outcome:
Recommended (as above)

8 Recommended listing

8.1 Amend current nicotine listings that have two restriction summaries (one for Aboriginal and Torres Strait Islander persons and one for non-Indigenous Australians) as follows:

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts.**	**Available brands**
NICOTINE					
nicotine 4 mg lozenge, 216	11619M	1	216	2	Nicotinell
nicotine 25 mg/16 hours patch, 28	10076H	1	28	2	Nicorette 16hr Invisipatch
nicotine 2 mg chewing gum, 216	11618L	2	432	1	Nicotinell
nicotine 4 mg chewing gum, 216	11612E	1	216	2	Nicotinell
nicotine 2 mg lozenge, 216	11617K	1	216	2	Nicotinell
nicotine 21 mg/24 hours patch, 28	5465P	1	28	2	Nicabate P

Delete Restriction Summary 5140 / Treatment of Concept: 5140	
Concept ID (for internal Dept. use)	~~**Category / Program:** GENERAL – General Schedule (Code GE)~~
	~~**Prescriber type:** ☒Medical Practitioners ☒Nurse practitioners~~
	~~**Restriction type:** ☒Restricted benefit~~
8619	~~**Indication:** Nicotine dependence~~
8621	~~**Population criteria:**~~
8620	~~Patient must be an Aboriginal or a Torres Strait Islander person~~
	~~**AND**~~
7890	~~**Clinical criteria:**~~
7889	~~The treatment must be the sole PBS-subsidised therapy for this condition~~
9293	~~**Administrative Advice:**~~ ~~Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.~~ ~~Benefit is improved if used in conjunction with a comprehensive support and counselling program.~~
7606	~~**Administrative Advice:** No increase in the maximum quantity or number of units may be authorised.~~
7607	~~**Administrative Advice:** No increase in the maximum number of repeats may be authorised.~~
Edit Restriction Summary 6848 / Treatment of Concept: 6848	
8619	**Indication:** Nicotine dependence
11245	**Clinical criteria:**
11244	The treatment must be as an aid to achieving abstinence from smoking
	AND
7890	**Clinical criteria:**
Remove 7889	~~The treatment must be the sole PBS-subsidised therapy for this condition~~
Insert New CC1	*The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation*
	AND
Insert	***Clinical criteria:***
New CC2	*The treatment must, in terms of the number of forms/presentations prescribed, be limited to up to 2 (e.g., patches plus gum is permitted, but not patches plus gum plus lozenges)*
	AND

8625	**Clinical criteria:**
8624	Patient must have indicated they are ready to cease smoking
	AND
9296	**Clinical criteria:**
Remove 9295	~~Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period~~
Insert New CC2	*Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period*
	AND
20605	**Treatment criteria:**
20604	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
9299	**Prescribing Instructions:** Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.
7606	**Administrative Advice:** No increase in the maximum quantity or number of units may be authorised.
7607	**Administrative Advice:** No increase in the maximum number of repeats may be authorised.

8.2 Amend current nicotine listings that have one restriction summary to appear as follows:

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№. of Rpts.**	**Available brands**
NICOTINE					
nicotine 14 mg/24 hours patch, 28	5572G	1	28	2	Nicotinell Step 2
nicotine 7 mg/24 hours patch, 28	5573H	1	28	2	Nicotinell Step 3
nicotine 21 mg/24 hours patch, 28	3414Q	1	28	2	Nicotinell Step 1

Edit Restriction Summary 6848 / Treatment of Concept: 6848	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL – General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒Restricted benefit
8619	**Indication:** Nicotine dependence
11245	**Clinical criteria:**
11244	The treatment must be as an aid to achieving abstinence from smoking
	AND
7890	**Clinical criteria:**
Remove 7889	~~The treatment must be the sole PBS-subsidised therapy for this condition~~
Insert New CC1	*The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation*
	AND
Insert	***Clinical criteria:***
New CC2	*The treatment must, in terms of the number of forms/presentations prescribed, be limited to up to 2 (e.g., patches plus gum is permitted, but not patches plus gum plus lozenges)*
	AND
8625	**Clinical criteria:**
8624	Patient must have indicated they are ready to cease smoking
	AND
9296	**Clinical criteria:**
Remove 9295	~~Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period~~

Insert New CC2	*Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period*
	AND
20605	**Treatment criteria:**
20604	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
9299	**Prescribing Instructions:** Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.
7606	**Administrative Advice:** No increase in the maximum quantity or number of units may be authorised.
7607	**Administrative Advice:** No increase in the maximum number of repeats may be authorised.

There was no PBAC recommendation pertaining to PBS item codes relating to the Repatriation Pharmaceutical Benefits Scheme.

This restriction may be subject to further review. Should there be any changes made to the restriction sponsors will be informed.