

Smoking Cessation Therapy: PBS/RPBS utilisation

Drug utilisation sub-committee (DUSC)

February 2016

Abstract

Purpose

To report on the utilisation of smoking cessation therapies subsidised on the Pharmaceutical Benefits Scheme (PBS) or Repatriation Pharmaceutical Benefits Scheme (RPBS). DUSC requested the analysis consider the impact of Nicotine Replacement Therapy (NRT) products changing from Authority Required to Authority Required (STREAMLINED) on 1 December 2013.

Date of listing on the Pharmaceutical Benefits Scheme (PBS)

1. Bupropion: 22 August 2000
2. NRT: 1 May 2000 (Repatriation only)
1 December 2008 (Aboriginal and Torres Strait Islander population)
1 February 2011 (general population)
3. Varenicline: 1 January 2008

Data Source / methodology

Data were extracted from the DUSC and Department of Human Services (DHS) prescription databases from the earliest available data and continuing to September 2015. It includes data on the item supplied, the quantity, cost to Government, de-identified personal identification number (PIN) and patient date of birth.

Key Findings

In calendar year 2014:

- There were 373,934 people supplied R/PBS subsidised smoking cessation therapies.
- 88,527 of those people made their first attempt at quitting with R/PBS subsidised smoking cessation therapy.
- There were 15,828 R/PBS prescriptions supplied for bupropion; 136,556 for NRT and 335,088 for varenicline.
- \$47.8 million in R/PBS benefits was paid for smoking cessation therapy.

The change in restriction to NRT did not significantly impact the utilisation trends of R/PBS smoking cessation therapies.

Purpose of analysis

According to the 2013 National Drug Strategy Household Survey (NDSHS) conducted by the Australian Institute of Health and Welfare (AIHW), the average number of people who smoke daily has declined significantly over 2010-2013 period (from 15.1% to 12.8%).¹ Despite this, tobacco remains a significant cause of death and disability in Australia. Around 3.3 million Australians still smoke and an estimated 15,000 people die each year of smoking-related illness.² There are three pharmacological interventions for smoking available on the Pharmaceutical Benefits Scheme (PBS): nicotine replacement therapy (NRT), varenicline and bupropion.

A number of changes to the PBS restrictions for these products have occurred since DUSC last reviewed NRT in October 2012. These changes include that the PBS listings for NRT were changed from Authority Required to Authority Required (STREAMLINED) on 1 December 2013.

The purpose of this analysis is to report the utilisation of R/PBS subsidised smoking cessation therapies and to consider the impact of NRT products changing from Authority Required to Streamlined on 1 December 2013.

Background

Pharmacology

Varenicline

There are nicotine receptors in the brain. When cigarette smoke is inhaled, nicotine attaches to these receptors. This sends a message to a different part of the brain to release a chemical called dopamine. Dopamine gives a feeling of pleasure which only lasts for a short time. The body wants to repeat this feeling reinforcing the need to keep smoking. It is believed that varenicline works as a partial nicotine agonist by activating these receptors and blocking nicotine from attaching to them.^{3,4}

Nicotine Replacement Therapy (NRT)

NRT has been designed to slowly allow nicotine to be absorbed by the body to offset the physical withdrawal symptoms of smoking cessation. It is easier to withdraw off NRT than cigarettes due to the lower levels of nicotine present [CMI]. Short-acting forms of NRT (gum, inhalation cartridge, lozenge, oral spray and sublingual tablet) give a rapid increase in blood nicotine concentration, similar to that associated with smoking, and may be helpful

¹ Australian Institute of Health and Welfare 2014. National Drug Strategy Household Survey detailed report 2013. Drug statistics series no. 28. Cat. no. PHE 183. Canberra: AIHW. Available from www.aihw.gov.au Accessed 26 Oct 2015

² Intergovernmental Committee on Drugs 2012. National Tobacco Strategy 2012-2018. Canberra: Department of Health and Ageing. Available from <http://www.nationaldrugstrategy.gov.au/> Accessed 28 Oct 2015.

³ Varenicline (Champix®) Consumer Medicine Information. Available from <https://www.ebs.tga.gov.au>, Accessed 16 Oct 2015

⁴ Therapeutic Guidelines 2011. Available from <http://online.tg.org.au/complete/> Accessed 16 Oct 2015

for the more nicotine-dependent smokers. Nicotine patches do not produce this rapid increase, which people trying to quit may crave.⁴

Bupropion

Bupropion is a non-nicotine oral therapy (originally developed as an antidepressant) with similar efficacy to NRT in aiding smoking cessation. It is effective for smokers with depression, cardiac or respiratory diseases, and also to improve short-term abstinence rates for people with schizophrenia.⁴ Bupropion is believed to interact with chemicals called noradrenaline and dopamine in the brain; however, the exact mechanism of action is not fully understood. It is a medicine prescribed for short-term treatment to help stop smoking with appropriate counselling. Bupropion reduces withdrawal symptoms and the urge to smoke.⁵

Therapeutic Goods Administration (TGA) approved indications

Varenicline

Varenicline is indicated as an aid for smoking cessation in adults over the age of 18 years. In December 2008, the TGA released this bulletin:

“To October 2008, we have received 339 adverse reaction reports with varenicline, 255 (72%) of which describe psychiatric symptoms including depression, aggression, agitation, abnormal dreams, insomnia, hallucination and anger. There have also been reports of suicidal/self-injurious ideation or behaviour. We have also received 15 reports of seizures in patients using varenicline. It is not known how many of these had a prior history or risk of a seizure disorder and there is no experience from clinical trials of varenicline in patients with epilepsy. Therefore prescribers are also advised to exercise caution when prescribing varenicline to patients with a history of seizure disorder.”⁶

In August 2010, the TGA released this statement:

“To May 2010 the TGA had received 1025 reports of suspected adverse reactions to varenicline, 691 (67%) of which describe psychiatric symptoms such as depression, agitation, anxiety, altered mood and aggression. There were reports of 206 suicide-related events in people taking varenicline, including 15 completed suicides.”⁷

In December 2015, the TGA announced an update to the PI to highlight safety information regarding the risk of psychiatric symptoms and potential interaction with alcohol. This information relates to the risks of psychiatric symptoms and potential interaction with alcohol. Psychiatric symptoms can involve changes in behaviour, thinking or mood and may include depression, anxiety, agitation, aggression, mood swings, self-harm, thoughts of self-harm, or seeing, hearing or sensing things that are not there. The information was

⁵ Bupropion (Zyban®) Consumer Medicine Information. Available from <https://www.ebs.tga.gov.au>, Accessed 16 Oct 2015

⁶ Therapeutic Goods Administration 2008. Available from <https://www.tga.gov.au/publication-issue/australian-adverse-drug-reactions-bulletin-vol-27-no-6> Accessed 4 November 2015.

⁷ Therapeutic Goods Administration 2010. Available from <https://www.tga.gov.au/publication-issue/medicines-safety-update-no4-2010> Accessed 4 November 2015.

previously provided in the PI, but is now listed in bold text at the beginning of the Precautions section under the heading 'Psychiatric Symptoms'.⁸

NRT

NRT is indicated for treatment of nicotine dependence, as an aid to smoking cessation. The 21 mg/24 hour (Step 1) patches may also be used by people who smoke 20 or more cigarettes per day for two weeks prior to quitting smoking.

Bupropion

Bupropion is indicated as a short-term adjunctive therapy for the treatment of nicotine dependence in those who are committed to quitting smoking, when used in conjunction with counselling for smoking cessation/abstinence. On the 5 September 2001, the TGA released this safety alert notice:

“The very high usage of bupropion in a short time has highlighted several possible adverse effects, some of which may be severe. Since November 2000, the Adverse Drug Reactions Advisory Committee (ADRAC) has received 1237 Australian reports of suspected adverse reactions in connection with the use of Zyban SR[®]. In 1215 of these, Zyban SR[®] was implicated as the sole suspected drug. The profile of the drug is dominated by hypersensitivity reactions and neurological and psychiatric effects.”⁹

⁸ Therapeutic Goods Administration 2001. Available from <https://www.tga.gov.au/alert/varenicline-champix> Accessed December 10 2015.

⁹ Therapeutic Goods Administration 2001. Available from <https://www.tga.gov.au/alert/bupropion-zyban-sr>. Accessed 4 November 2015.

Dosage and administration

Table 1: Dosage and administration of varenicline and bupropion

Brand name and sponsor	Dose and frequency of administration
Varenicline (Champix®) Pfizer	<p>1 mg and 0.5 mg/1 mg combination pack tablets</p> <p>0.5 mg once daily for 3 days, then 0.5 mg twice daily for 4 days, then 1 mg twice daily for 11-23 weeks, as tolerated.</p> <p>The patient should set a date to stop smoking. Champix dosing should start 1 – 2 weeks before this date. Alternatively, a flexible approach to quitting smoking may be adopted. Patients can begin varenicline dosing and then quit smoking between days 8 and 35 of treatment. Champix tablets should be swallowed whole with water, with or without food. Patients should be treated with Champix for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with Champix at 1 mg twice daily is recommended to further increase the likelihood of long term abstinence. Patients who are motivated to quit and who do not succeed in stopping smoking during prior varenicline therapy, or who relapse after treatment, should be encouraged to make another attempt once factors contributing to the failed attempt have been identified and addressed.¹⁰</p>
Bupropion (Zyban®) GlaxoSmithKline Australia Pty Limited	<p>150 mg modified release tablet</p> <p>Initially, 150 mg once daily in the morning for 3 days, then 150 mg twice daily (doses at least 8 hours apart) for 7–9 weeks.</p> <p>It is recommended that treatment is started while the patient is still smoking and a "target stop date" set within the first two weeks of treatment with Zyban, preferably in the second week. Discontinuation should be considered if the patient has not made significant progress towards abstinence by the seventh week of therapy, since it is unlikely that they will stop smoking during that attempt.¹¹</p>

Source: Product Information accessed on TGA website

¹⁰ Varenicline (Champix®) Product Information. Available from <https://www.ebs.tga.gov.au>, Accessed 21 Oct 2015.

¹¹ Bupropion (Zyban®) Product Information. Available from <https://www.ebs.tga.gov.au>, Accessed 21 Oct 2015.

Table 2: Dosage and administration of R/PBS listed NRT products

Brand name and sponsor	Dose	Frequency of administration
Nicotinell® Perrigo Australia Pty Limited	7 mg/24 hours patch, 14 mg/24 hours or 21mg/24 hours	Apply one patch to the skin once a day. Treatment should not exceed 12 weeks.
Nicabate P® and Nicabate CQ 21® GlaxoSmithKline Australia Pty Limited	21 mg/24 hours patch	
QuitX® Alphapharm Pty Limited	7 mg/24 hours, 14 mg/24 hours and 21 mg/24 hours patches	
Nicorette® Johnson & Johnson Pty Limited	5 mg/16 hours, 10 mg/16 hours, 15 mg/16 hours patches	Apply one patch to the skin upon waking and remove at bedtime. Treatment should not exceed 12 weeks.
Nicorette Invisipatch® Johnson & Johnson Pty Limited	25 mg/16 hours patch	

Source: Product Information accessed on TGA website¹²

Table 3: Dose for 24 hours patches by step, duration of treatment and brand name

Step	Dose	Duration based on brand name
Step 1	21 mg/24 hours patch	Nicabate P®: 6 weeks (if smoking less than 10 cigarettes/day, have cardiovascular disease or weigh less than 45kg, start with Step 2 for 6 weeks)
		QuitX® and Nicotinell®: 4 weeks (if smoking less than 20 cigarettes/day, start with Step 2 for a total of 8 weeks then Step 3 for 4 weeks)
Step 2	14 mg/24 hours patch	Nicabate®: 2 weeks
		QuitX® and Nicotinell®: 4 weeks
Step 3	7 mg/24 hours patch	Nicabate®: 2-4 weeks
		QuitX® and Nicotinell®: 4 weeks

Source: Product Information accessed on TGA website¹³

¹² Nicotine (Nicotinell®, Nicabate P®, Nicabate CQ®, QuitX®, Nicorette® and Nicorette Invisipatch®) Product Information. Available from <https://www.ebs.tga.gov.au>, Accessed 21 Oct 2015.

¹³ Nicotine (Nicotinell®, Nicabate P®, Nicabate®, QuitX®, Nicorette®) Product Information. Available from <https://www.ebs.tga.gov.au>, Accessed 22 Oct 2015.

Table 4: Dose for 16 hours patches (Nicorette®) by step and duration of treatment

Step	Dose	Duration of treatment
Step 1 - Invisipatch	25 mg/16 hours patch	8 weeks (If smoking 15 cigarettes or more per day)
Step 2	15 mg/16 hours patch	4 weeks (May progress to Steps 3 and 4 when patient has fewer cravings for a total treatment duration of 12 weeks)
Step 3	10 mg/16 hours patch	As required
Step 4	5 mg/15 hours patch	As required

Source: Product Information accessed on TGA website¹⁴

Clinical situation

According to the 2013 National Drug Strategy Household Survey (NDSHS) conducted by the Australian Institute of Health and Welfare (AIHW), the average number of people who smoke daily has declined significantly over 2010-2013 period (from 15.1% to 12.8%). Younger people are delaying the take up of smoking. The age at which 14–24-year-olds smoked their first full cigarette increased from 14.2 in 1995 to 15.9 years in 2013. Furthermore, smokers reduced the average number of cigarettes smoked per day; from 15.8 cigarettes in 2010 to 13.7 in 2013. There was variation in the number of cigarettes smoked per day between age groups. A heavy smoker is considered to be someone who smokes 20 or more cigarettes per day. In 2013, 3 in 10 (33%) smokers were considered heavy smokers and heavy smoking was highest among people aged 50–69 with more than 4 in 10 (44%) smoking 20 or more cigarettes per day.¹⁵

The NDSHS 2013 survey was the first time that respondents were asked about their use of battery operated electronic cigarettes. They are devices for creating aerosols which contain nicotine and/or flavouring agents, the aerosol then being inhaled. The visual, physio-sensory and behavioural aspects of electronic cigarettes simulate the act of tobacco smoking. In 2013, 1 in 7 (14.8%) smokers aged 14 or older had used battery-operated electronic cigarettes in the last 12 months.¹⁵

As smoking rates continued to decline, people were less likely to view tobacco as a drug that causes the most deaths (decreasing from 36% in 2010 to 32% in 2013) or thought that tobacco was of most concern to the general community (declining from 15.4% in 2010 to 14.5% in 2013). Support for policies aimed at reducing the harm that tobacco causes remained high in 2013. In particular, there were rising levels of support for a rise in tax on tobacco products to pay for health education and to contribute to treatment costs. Smokers were the least likely to support policies aimed at reducing tobacco-related harm,

¹⁴ Nicotine (Nicorette®) Product Information. Available from <https://www.ebs.tga.gov.au>, Accessed 22 Oct 2015.

¹⁵ Australian Institute of Health and Welfare 2014. National Drug Strategy Household Survey detailed report 2013. Drug statistics series no. 28. Cat. no. PHE 183. Canberra: AIHW. Available from www.aihw.gov.au Accessed 26 Oct 2015.

particularly for measures related to increases in taxes on tobacco products, but, along with non-smokers, showed strong support for measures relating to minors.¹⁵

The National Tobacco Strategy 2012-2018 developed by the Intergovernmental Committee on Drugs (IGCD) Standing Committee on Tobacco, has the aim of reducing the national smoking rate to 10% of the population, and halving the Indigenous smoking rate by 2018. The strategy has been developed with input from a range of stakeholders, including governments, health groups, community-based organisations, industry organisations and the public. All health ministers endorsed the strategy at the 9 November 2012 meeting of the Standing Council on Health.¹⁶

The National Tobacco Strategy states that mass media campaigns are highly effective components of tobacco control programs, second only to price increases. The media environment in Australia is changing rapidly and campaigns must adapt to a range of communication challenges and opportunities such as the rapid growth in the number of free-to-air channels and the increasing importance of subscription television, the internet and social media.¹⁶

The NDSHS indicated that the majority of smokers attempted to make a change to their smoking behaviour in the last year. Smokers trying to quit or change their smoking behaviour tried mainly due to costs and concern for their health.¹⁵ In March 2012, a survey on quit smoking habits found that around 40.1% of smokers report attempts to quit in a given year with an average of 2.1 attempts. Based on free recall, this translates to an average annual quit attempt rate of 0.82 attempts per smoker. Estimates derived only from the preceding month to adjust for recall bias indicate an annual rate of approximately one attempt per smoker. There is a high prevalence of quit-related activity, with more than a third of smokers reporting thoughts or actions related to quitting in a given month. More than half the surveyed smokers eventually succeeded in quitting for at least 1 month, and a majority of these for over 6 months. Smokers think a lot about stopping and make many unsuccessful quit attempts. Many have been able to last for extended periods and then relapsed.¹⁷

PBS listing details (as at December 2015)

PBS listing details are available at Appendix A.

Restriction

For details of the current PBS listing refer to the [PBS website](#).

¹⁶ Intergovernmental Committee on Drugs 2012. National Tobacco Strategy 2012-2018. Canberra: Department of Health and Ageing. Available from <http://www.nationaldrugstrategy.gov.au/> Accessed 28 Oct 2015.

¹⁷ Borland R, Partos TR, Yong HH, Cummings KM, Hyland A. How much unsuccessful quitting activity is going on among adult smokers? Data from the International Tobacco Control 4-Country cohort survey. *Addiction* 2012; 107(3): 673-682.

Date of listing on PBS

Bupropion: 22 August 2000

NRT: 1 May 2000 (Repatriation only)

1 December 2008 (Aboriginal and Torres Strait Islander population)

1 February 2011 (general population)

Varenicline: 1 January 2008

Changes to listing

Changes to the listings of PBS smoking cessation therapies are extensive and have been included in Appendix B. Current PBS listing details are available from the PBS website.

Relevant aspects of consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)

NRT

At the March 2010 meeting, the PBAC recommended the listing of nicotine transdermal patches releasing 15 mg /16 hours (Nicorette®) on the PBS for the general population as an Authority Required listing as an aid to cessation of smoking in patients who have entered or are entering a comprehensive support and counselling program in the context of a public health priority area. The PBAC recommended that the listing of nicotine patches be limited to a maximum of 12 weeks treatment in a 12 month period.

For further details, refer to the Public Summary Document from the March 2010 PBAC meeting.

At the November 2011 PBAC meeting, the PBAC recommended listing a 25 mg/16 hour nicotine transdermal patch (Nicorette®) on the PBS as an Authority Required benefit under the same listing conditions as 21 mg/24 hour nicotine transdermal patches (Nicabate P®, Nicotinell Step 1®).

Subsequently, two additional lower strength patches were added to the PBS (5572G, 5573H) on 1 January 2012.

In December 2012, the PBAC noted the findings of the October 2012 Drug Utilisation Sub-Committee (DUSC) review of NRT utilisation showed a lower than expected utilisation for the period 1 February 2011 to 31 December 2011. The PBAC considered that the data supported the streamlining of listings for nicotine transdermal patches. The PBAC considered that streamlining of nicotine transdermal patches would not significantly change the pattern of utilisation of these products on the PBS.

The PBAC agreed that streamlining would serve to reduce prescriber burden, and was not likely to be associated with any major safety issues.

Varenicline

The PBAC recommended listing varenicline at its July 2007 meeting. The PBAC noted the DUSC advice that the sponsor's utilisation estimates may have overestimated usage, and requested the DUSC monitor usage.

For further details, refer to the Public Summary Document from the July 2007 PBAC meeting.

In October 2009, the DUSC conducted a twelve month utilisation analysis which determined that whilst there were greater than expected numbers of patients initiating varenicline, there were high discontinuation numbers before treatment completion.

In March 2014, the PBAC recommended a change to the listing of varenicline to allow an additional course within a twelve month period for patients who have been unsuccessful in achieving abstinence from smoking during or after a course of PBS-subsidised varenicline. This recommendation was made on the basis of acceptable cost effectiveness to placebo, bupropion and NRT. The PBAC considered that repeated courses of varenicline within a twelve month period were of acceptable safety based on the currently known safety profile of varenicline, which incorporates worldwide usage, and the information provided in the submission. The PBAC accepted that varenicline is of superior efficacy to placebo, bupropion and NRT, and no worse in terms of safety to bupropion. The PBAC noted that no claim was made with respect to comparative safety to placebo or NRT. The PBAC considered that varenicline is of inferior safety to placebo and NRT.

For further details, refer to the Public Summary Document from the March 2014 PBAC meeting.

Bupropion

The PBAC recommended listing bupropion on the PBS at its September 2000 meeting as an Authority Required listing for use within a comprehensive treatment program in those who have unsuccessfully attempted to stop smoking with nicotine replacement therapy or in whom nicotine replacement therapy is contraindicated. At the time of listing, there were no other PBS subsidised treatment options available for smoking cessation and as such the perspective taken was that of the savings to the health care system arising from the prevention of smoking-related morbidity.

For further details, refer to the Public Summary Document from the September 2000 PBAC meeting.

Previous reviews by the DUSC

The DUSC Secretariat conducted a review of NRT utilisation for the DUSC October 2012 meeting and the key findings were as follows:

- Fewer numbers of patients than expected at the time of listing were initiated on nicotine patches (NRT).

- About a quarter of a million prescriptions were filled for NRT in 2010 which was less than expected.
- The actual use of varenicline (Champix®) since NRT was PBS listed for the general population has decreased. The number of patients starting varenicline was about 25% lower than the previous 12 months and PBS benefits for treatment with varenicline was around 26% lower than the previous 12 months. The apparent reduction is likely to be a combination of reduced demand and listing of NRT. Immediately prior to listing of nicotine there was a major media campaign and a change in excise for cigarettes. Published evidence has shown that these programs have a significant but short lived impact on people seeking to quit. The peak in supply of varenicline just prior to listing of NRT shows the impact of the media and excise measures on utilisation of smoking cessation aids. It is difficult to determine the likely extent of any substitution as the utilisation of both NRT and varenicline are highly variable.
- The uptake of NRT in its first year of listing has been gradual and for most of the year follows a similar pattern to varenicline utilisation. The pattern for both these drugs is different to bupropion which had a high peak at listing, attributed to it being the first PBS subsidised product for smoking cessation, followed by a decline that has stabilised at a low level.

DUSC noted that the utilisation of NRT was lower than expected but considered that to some extent this may be due to previous supply shortages. Nonetheless, DUSC was encouraged by the number of patients attempting to quit smoking. DUSC observed that utilisation of smoking cessation therapies varies throughout the year, influenced by media campaigns and seasonal factors. DUSC noted PBAC concerns when recommending NRT for PBS listing in 2010 that utilisation and total costs were highly uncertain. Given that use has been well within the bounds expected, DUSC recommended that the PBAC consider removing the requirement for a telephone authority approval from the PBS restriction for NRT.¹⁸

Methods

Data for NRT, varenicline and bupropion were extracted from the DUSC and Department of Human Services (DHS) prescription databases from the earliest available data.

The DUSC database contains an estimate of under co-payment prescriptions (Guild Survey) prior to April 2012; and contains actual under co-payment data from April 2012. The DUSC database also contains a private prescription estimate to August 2012; use of this estimate in the analysis is indicated by a footnote to the figure or table. It includes data on the item supplied, the quantity and cost to Government.

For the patient level analysis, de-identified data were extracted from the DHS Supplied Prescriptions database by date of supply for the calendar years 2000 - 2015 inclusive for all smoking cessation Anatomic Therapeutic Classification (ATC) codes. These data include

¹⁸ Drug Utilisation Sub Committee Outcome Statement October 2012. Available at <http://www.pbs.gov.au/industry/listing/elements/dusc-meetings/dos/dusc-dos-oct-2012-v2.0.pdf> Accessed 24 Nov 2015

patient date of birth, which allows for analyses based on patient age, and the de-identified personal identification number (PIN), which allows for analyses of the number of people supplied smoking cessation therapies of same day supply, and reattempts to smoking cessation therapy. While supply on the same day of multiple R/PBS subsidised therapies is likely to underestimate the extent of co-administration of extended release products, it provides, with reasonable certainty, a low estimate of co-administration.

For the purpose of determining the coverage time of a prescription in patient level analyses, a treatment course has been defined as 12 weeks. This coincides with the PBS treatment criteria for smoking cessation therapy. Note that varenicline can be extended for a further 12 weeks (to a total of 24 weeks of therapy) under the PBS, to improve the likelihood of long term abstinence, if tolerated and at the discretion of the prescriber. A “reattempt” at smoking cessation was defined as being a subsequent supply of any smoking cessation therapy, after a gap of more than twelve weeks since completion of a treatment course of any smoking cessation therapy. The cut off point for reattempts was 30 September 2015.

As this analysis uses date of supply prescription data, there may be small differences compared with publicly available DHS Medicare date of processing data.¹⁹ The publicly available DHS Medicare data only includes subsidised R/PBS prescriptions with prescriptions under the patient co-payment not included. The DHS Medicare data used in this report includes under co-payment prescriptions from 1 April 2012.

There are special PBS supply arrangements for clients of eligible remote area Aboriginal Health Services (AHSs). AHSs are able to receive bulk supplies of PBS medicines through an approved community or hospital pharmacy. Data on items supplied to AHSs include the item and quantity supplied, month of supply, the name of the AHS, State and cost to Government. The supply data relate to the pharmacy supplying the items to the AHS. For medicines supplied to AHSs, there are no data on whether the products were supplied to patients or any other patient-level data. Data on the number of packs supplied to AHSs are presented in a separate table (Table 9).

¹⁹ PBS statistics. Australian Government Department of Human Services Medicare. Canberra. Available from <<http://www.medicareaustralia.gov.au/provider/pbs/stats.jsp>>.

Results

Analysis of drug utilisation

Overall utilisation

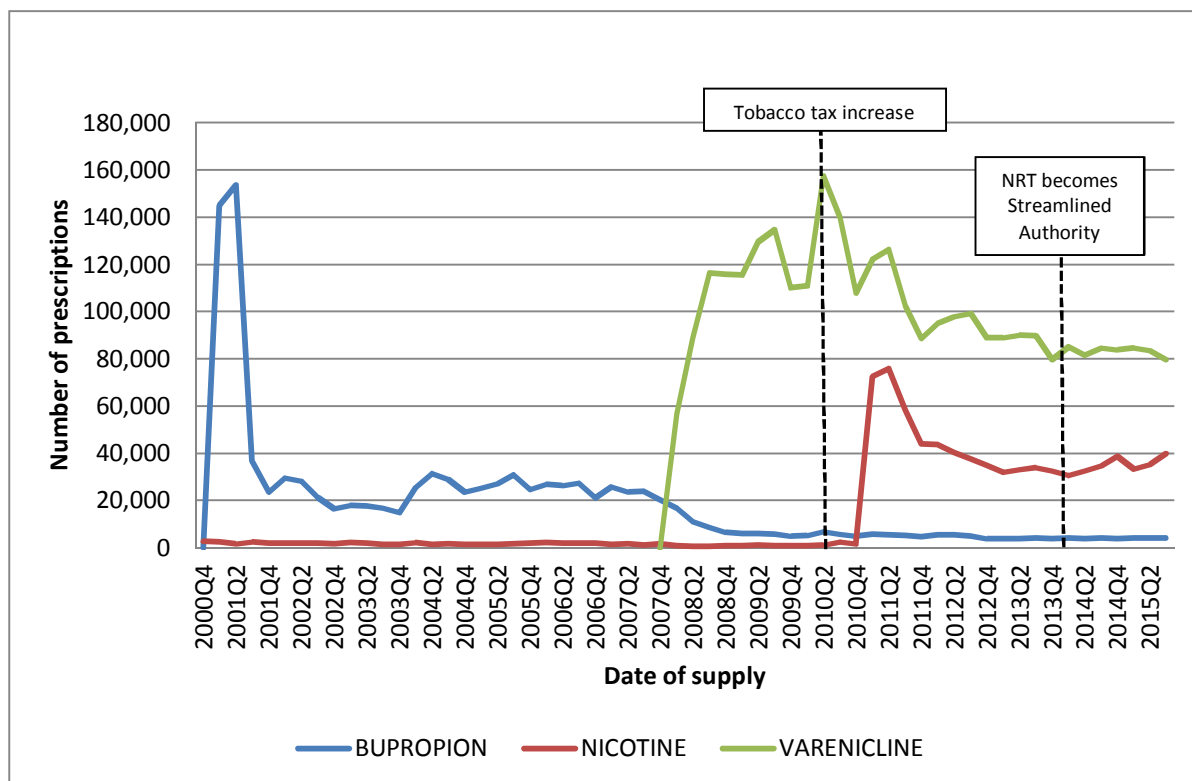


Figure 1: Drug utilisation for R/PBS listed smoking cessation therapy per quarter from July 2000 to September 2015.

Prescriptions by date of supply. Includes under co-payment estimate and actual. Includes private estimate. Source: DUSC database accessed November 2015.

Table 5: Number of R/PBS subsidised smoking cessation prescriptions supplied

Year	Number of R/PBS Prescriptions
2013	495,928
2014	487,472

Prescriptions by date of supply. Includes under co-payment estimate and actual. Source: DUSC database, November 2015.

In 2014, the overall use of R/PBS smoking cessation therapies was 487,472 prescriptions, down by 1.7% from 2013 (n=495,928) (Table 5).

Figure 1 depicts varenicline as the most utilised smoking cessation therapy on the R/PBS since its listing in January 2008 with NRT as the second most utilised since its listing. Bupropion had a substantial initial uptake when it was listed in August 2000 as the sole subsidised therapy; however, its utilisation has declined and not changed markedly over the study period.

There was a peak in the utilisation of varenicline in Quarter 2 of 2010 (Figure 1), which may have been due to the 25% increase in tobacco tax on 30 April 2010.²⁰ As mentioned earlier in this report, the National Tobacco Strategy states that price increases to tobacco products are the second most highly effective components of tobacco control programs after mass media campaigns.¹⁶

Subsidised use of these three therapies has remained stable since 2012. NRT went from Authority Required to streamlined authority in December 2013. Figure 1 depicts no major change in utilisation of NRT at the time of this change in restriction. In September 2015, NRT became Restricted Benefit. The effect of this change is yet to be determined.

People supplied smoking cessation therapy

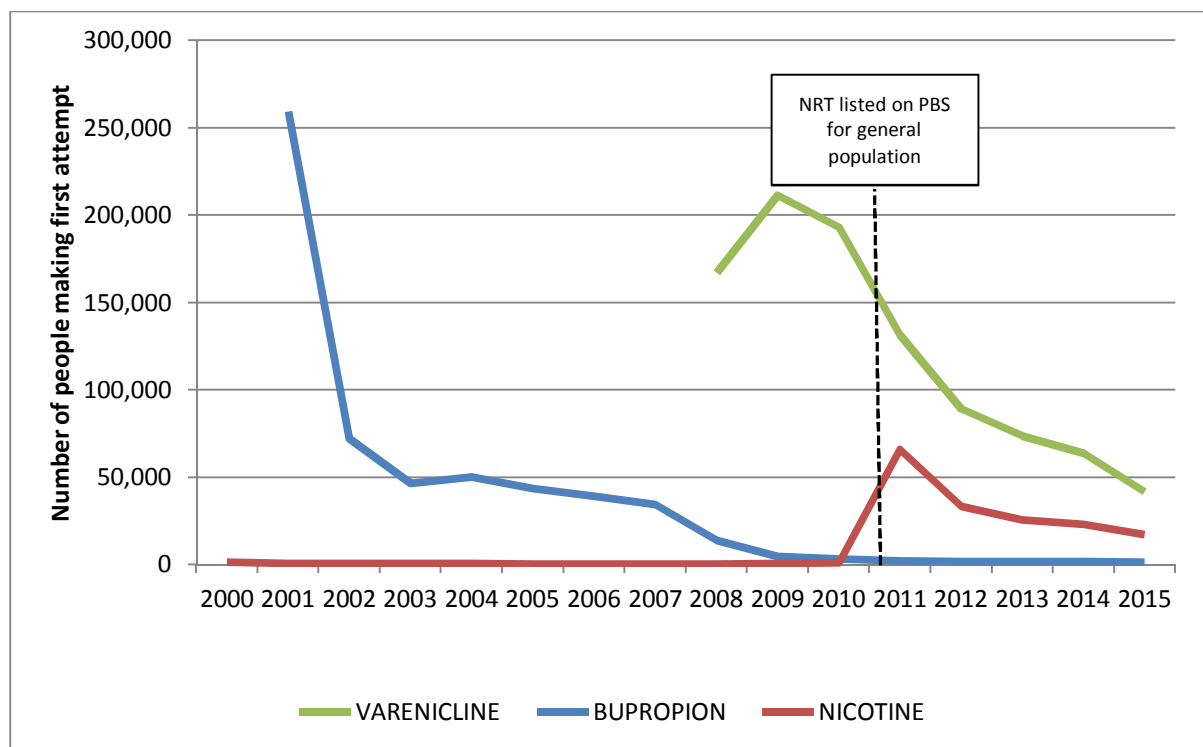


Figure 2: Smoking cessation therapy choice for people receiving their first R/PBS supply by year

For the purpose of this study, “first attempt” has been defined as no prior supply of PBS subsidised smoking cessation therapy since May 2000, to coincide with the listing of bupropion.

Source: DHS Medicare Database, November 2015.

Figure 2 shows that the number of first attempts peaked with the introduction of each new subsidised therapy then declined over time.

²⁰ Dunlop S, Cotter T, Perez D. Impact of the 2010 tobacco tax increase in Australia on short-term smoking cessation: a continuous tracking survey. Medical Journal of Australia 2011; 195(8): 469-472.

First and subsequent smoking cessation therapy choice

Tables 6-8 show the sequence of smoking cessation therapies supplied.

Table 6: R/PBS subsidised smoking cessation therapy choice for people who made their first quit attempt in 2012

First attempt	Reattempting drug therapy	Secondary reattempting drug therapy	Tertiary reattempting drug therapy	Number of people	% of total people in cohort
Varenicline	-	-	-	62091	49.8%
Nicotine	-	-	-	20531	16.5%
Varenicline	Varenicline	-	-	15749	12.6%
Varenicline	Varenicline	Varenicline	-	3806	3.1%
Nicotine	Nicotine	-	-	2975	2.4%
Varenicline	Nicotine	-	-	2435	2.0%
Nicotine	Varenicline	-	-	2292	1.8%
Nicotine	Nicotine (repeat) [†]	-	-	2227	1.8%
Bupropion	-	-	-	1387	1.1%
Varenicline	Varenicline	Varenicline	Varenicline	740	0.6%
Total people in top 10 most common sequences				114233	91.7%
Total people using other sequences				10405	8.3%
Total people attempting smoking cessation therapy				124638	100%

Source: DHS Medicare Database, November 2015.

[†] A repeat prescription was used to obtain the supply.

Table 7: R/PBS subsidised smoking cessation therapy choice for people who made their first quit attempt in 2013

Initiating Drug	Reattempting drug therapy	Secondary reattempting drug therapy	Tertiary reattempting drug therapy	Number of people	% of total people in cohort
Varenicline	-	-	-	56172	55.5%
Nicotine	-	-	-	17339	17.1%
Varenicline	Varenicline	-	-	11221	11.1%
Nicotine	Nicotine	-	-	2160	2.1%
Varenicline	Nicotine	-	-	1730	1.7%
Varenicline	Varenicline	Varenicline	-	1659	1.6%
Nicotine	Nicotine (repeat) [†]	-	-	1648	1.6%
Bupropion	-	-	-	1494	1.5%
Nicotine	Varenicline	-	-	1425	1.4%
Varenicline	Bupropion	-	-	331	0.3%
Total people in top 10 most common sequences				95179	94%
Total people using other sequences				6033	6%
Total people attempting smoking cessation therapy				101212	100%

Source: DHS Medicare Database, November 2015.

[†] A repeat prescription was used to obtain the supply.

Table 8: R/PBS subsidised smoking cessation therapy choice for people who made their first quit attempt in 2014

Initiating Drug	Reattempting drug therapy	Secondary reattempting drug therapy	Tertiary reattempting drug therapy	Number of people	% of total people in cohort
Varenicline	-	-	-	54140	61.1%
Nicotine	-	-	-	17440	19.7%
Varenicline	Varenicline	-	-	6620	7.5%
Bupropion	-	-	-	1699	1.9%
Nicotine	Nicotine (repeat) [†]	-	-	1674	1.9%
Nicotine	Nicotine	-	-	1414	1.6%
Varenicline	Nicotine	-	-	1034	1.2%
Nicotine	Varenicline	-	-	756	0.9%
Varenicline	Varenicline	Varenicline	-	451	0.5%
Varenicline	Nicotine	-	-	318	0.4%
Total people in top 10 most common sequences				85546	96.6%
Total people using other sequences				3020	3.4%
Total people attempting smoking cessation therapy				88566	100%

Source: DHS Medicare Database, November 2015.

[†] A repeat prescription was used to obtain the supply.

All drugs presented in Tables 6-8 are from original prescriptions, unless indicated otherwise as a repeat prescription.

For each yearly cohort, the most frequent scenario was that people tried varenicline as their first R/PBS subsidised quit attempt, then had no subsequent R/PBS subsidised quit attempts up to the most recent data (September 2015). This scenario occurred for around half of people in each cohort (Tables 6-8).

The next most frequent drug regimen in each cohort was NRT supplied as first R/PBS quit attempts with no reattempts made since the initial date of supply (Tables 6-8). Whether this is indicative of treatment success or relapse with no reattempt cannot be deduced.

It is possible that people have used non-subsidised smoking cessation therapies, which are not included in these data. As each cohort was followed to the most recent available data (September 2015), the people in the earlier cohorts had more opportunity to reattempt smoking cessation therapy.

Instances of same day supply

Patients were observed from the date of their first quit attempt via R/PBS subsidised smoking cessation therapy to see whether they obtained multiple forms of therapy on the same day. Over the period of 2012-2015, very few people were supplied bupropion, NRT and varenicline, or a combination thereof, on the same day. There were 20 patients who received both bupropion and NRT; one patient who received bupropion and varenicline; and 126 patients who received NRT and varenicline on the same day.

Utilisation by age

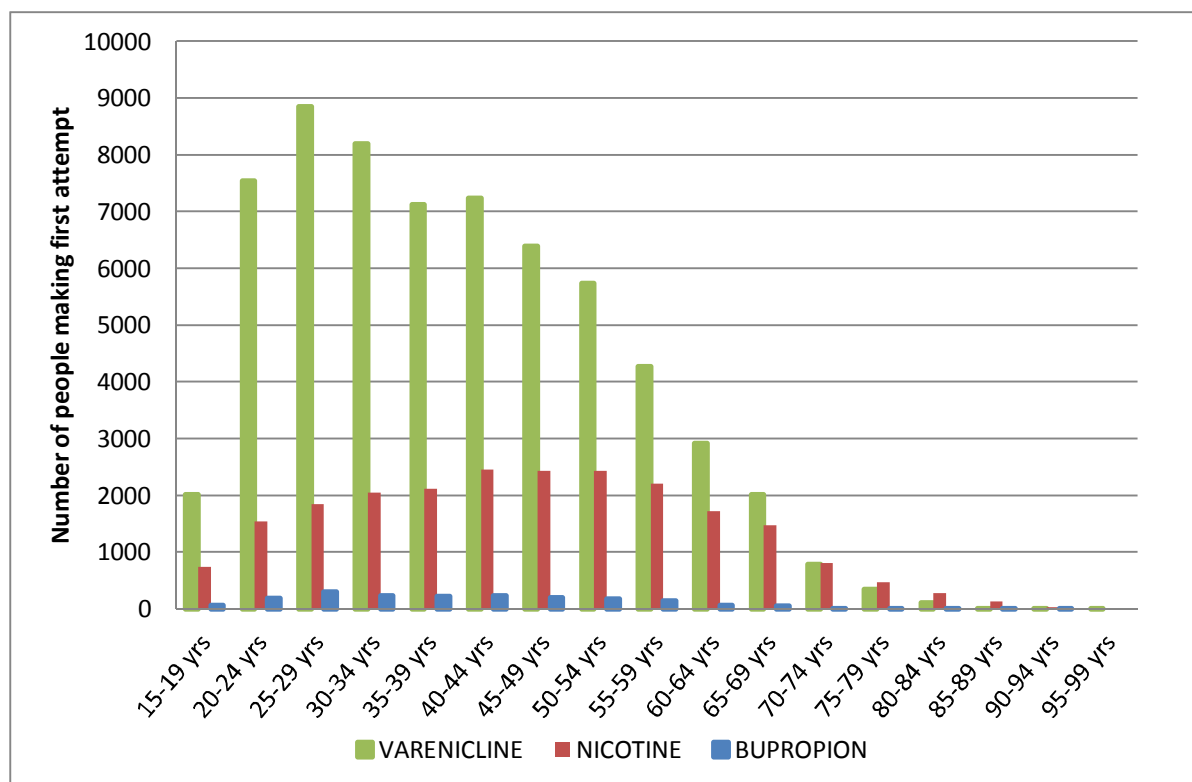


Figure 3: Age distribution of people making their first R/PBS subsidised quit attempt in the calendar year 2014

For the purpose of this study, “first attempt” has been defined as no prior supply of PBS subsidised smoking cessation therapy since May 2000, to coincide with the listing of bupropion.

Source: DHS database, November 2015.

In 2014, varenicline was the most frequently used first R/PBS smoking cessation therapy in most age groups, apart from older people (over 75 years of age) where the use of NRT was more common. NRT was used more frequently as a person’s first R/PBS smoking cessation therapy in middle aged people than in other age groups. Bupropion usage was low across all the age groups (Figure 3).

Aboriginal health services supply

Table 9: Number of packs of smoking cessation therapy provided by aboriginal health services (AHS)

Year	Drug			Total
	Bupropion	NRT	Varenicline	
2011	154	2,030	1,831	4,015
2012	129	2,682	1,915	4,726
2013	98	2,797	1,869	4,763
2014	87	3,342	1,807	5,236
2015	41	1,851	1,027	2,919
Grand Total	508	12,702	8,449	21,659

AHS data: September 2015. AHS data is at item level by date of processing.

The total number of packs for all smoking cessation therapy through AHS in 2014 was 5236; which is 1% of the number of smoking cessation therapies supplied through the PBS over the same year (n=487,472) (Table 9).

Utilisation of NRT

Table 10: People supplied their first PBS subsidised NRT by duration of therapy

Weeks of coverage	Year of first attempt				
	2011	2012	2013	2014	2015 [†]
4	64,320 (47.7%)	33,985 (54.3%)	25,990 (55.8%)	22,940 (56.3%)	21,104 (68.5%)
8	26,479 (19.6%)	11,726 (18.7%)	8,625 (18.5%)	7,197 (17.7%)	5,097 (16.5%)
12	41,976 (31.1%)	16,257 (26%)	10,744 (23.1%)	7,612 (18.7%)	3,554 (11.5%)
16	1,517 (1.1%)	437 (0.7%)	677 (1.5%)	1,308 (3.2%)	563 (1.8%)
20	433 (0.3%)	138 (0.2%)	255 (0.5%)	653 (1.6%)	236 (0.8%)
24	236 (0.2%)	59 (0.1%)	209 (0.4%)	619 (1.5%)	172 (0.6%)
28	6 (<0.1%)	6 (<0.1%)	39 (0.1%)	164 (0.4%)	53 (0.2%)
32	2 (<0.1%)	-	22 (<0.1%)	112 (0.3%)	24 (0.1%)
36	3 (<0.1%)	-	19 (<0.1%)	113 (0.3%)	11 (<0.1%)
Total number	134,972	62,608	46,580	40,718	30,814

People have been excluded if patient category is repatriation or Closing The Gap (CTG).

[†] Data from 2015 is part year and available until 30 September.

Source: DHS Medicare Database, November 2015.

General and concessional beneficiaries are permitted up to 12 weeks' supply of subsidised NRT each year. Table 10 highlights in red the cohorts of people using NRT as permitted in the PBS restriction. Four weeks coverage correlates to one prescription being supplied; eight weeks correlates to two prescriptions (whether it be a repeat or a second original) and 12 weeks to three prescriptions (whether repeats or subsequent original prescriptions).

Table 10 indicates that the vast majority of people comply with the restriction requirement of a maximum of 12 weeks of NRT therapy. However, the proportion of people who received greater than 12 weeks of therapy was highest in 2014 after the restriction changed from Authority Required to streamlined authority. Across the five years, the majority of people have four weeks supply of R/PBS subsidised NRT, with the percentage increasing slightly each year. More people are only using NRT for four weeks (i.e. were supplied one prescription). Whether this is indicative of treatment success or attempt failure cannot be determined.

Note that people who are supplied NRT under the Closing The Gap (CTG) scheme, are permitted two courses every twelve months, and the RPBS has no restriction on the number of courses permitted per year, therefore both have been excluded from the data in Table 10.

Analysis of expenditure

Table 11: R/PBS benefits for smoking cessation therapy

Year	Total
2011	\$63,855,217
2012	\$52,642,220
2013	\$48,811,717
2014	\$47,810,310
2015 [†]	\$23,704,182
Grand Total	\$236,823,645

Source: DHS Medicare Pharmacy Claims database using date of supply, which may be slightly different to publicly available Medicare Australia date of processing data, accessed September 2015.

[†]2015 data incomplete. Only available to September 2015.

Analysis of actual versus predicted utilisation of NRT

Table 12: Actual versus predicted estimates of people using R/PBS subsidised NRT

Estimates	Year				
	2011	2012	2013	2014	2015
Predicted					
Actual	140,708	93,853	80,388	77,442	64,546 [†]
Difference					
Actual as % of Predicted					

Source: DHS Medicare Pharmacy Claims database using date of supply, which may be slightly different to publicly available Medicare Australia date of processing data, accessed September 2015.

[†]2015 data incomplete. Only available to September 2015.

Table 13: Actual versus predicted estimates of R/PBS subsidised NRT prescriptions

Estimates	Year				
	2011	2012	2013	2014	2015
Predicted					
Actual	251,106	156,973	131,947	136,556	68,303 [†]
Difference					
Actual as % of Predicted					

Source: DHS Medicare Pharmacy Claims database using date of supply, which may be slightly different to publicly available Medicare Australia date of processing data, accessed September 2015.

[†]2015 data incomplete. Only available to September 2015.

Table 14: Actual versus predicted estimates of cost of NRT to R/PBS

Estimates	Year				
	2011	2012	2013	2014	2015
Predicted					
Actual	\$10,709,998	\$6,531,620	\$5,635,363	\$5,931,070	\$2,887,798 [†]
Difference					
Actual as % of Predicted					

Source: DHS Medicare Pharmacy Claims database using date of supply, which may be slightly different to publicly available Medicare Australia date of processing data, accessed September 2015.

[†]2015 data incomplete. Only available to September 2015.

The actual use of NRT has been lower than predicted in terms of the number of people, prescriptions supplied and cost in each year since listing. The reasons for these lower than estimated numbers cannot be deduced. NRT products are also available over the counter; the utilisation of which is outside the scope of this analysis.

Discussion

According to the latest National Drug Strategy Household Survey (NDSHS) published in 2013, the average number of people who smoke daily declined significantly over the 2010-2013 period (from 15.1% to 12.8%).¹⁵ A gradual decline in the utilisation of R/PBS subsidised smoking cessation therapy occurred over the same time period (Figure 1). Whether this is indicative of the declining smoking rate cannot be deduced. The NDSHS indicated that the majority of smokers attempted to make a change to their smoking behaviour in the year before the report was published. Smokers trying to quit or change their smoking behaviour tried mainly due to costs and concern for their health.¹⁷ The Australian Government announced a tobacco tax increase in April 2010, the first tax increase of its kind in a decade. A study conducted by the Medical Journal of Australia, indicated a significant increase in the number of people who made a quit attempt in 2010 after the tax announcement.²⁰ A peak in the utilisation of varenicline in Quarter 2 of 2010 may have been due to increased quit attempts with the sudden increase in the cost of cigarettes (Figure 1).

The utilisation of R/PBS subsidised smoking cessation therapies was not significantly impacted by NRT products changing from Authority Required to Streamlined on 1 December 2013 (Figure 1).

In March 2012, a survey on quit smoking habits found that smokers think a lot about stopping and make many unsuccessful quit attempts.¹⁷ In most cases people who reattempted R/PBS smoking cessation therapy used a subsequent original rather than a repeat prescription (Tables 6-8). Obtaining a new prescription from a doctor could indicate greater doctor-patient interaction, which may reinforce quitting habits. However, this practice may also indicate reattempts after more than one year.

There are a number of alternative means of quitting other than long-acting R/PBS subsidised therapies. They include gum, lozenges, sublingual sprays and will power. R/PBS subsidised smoking cessation therapies are all extended release formulations, in that they are used once or twice daily. The extent of same day supply of R/PBS subsidised smoking cessation therapies was low. However, the use of non-subsidised immediate release products is recommended to reduce cravings whilst using the extended release products.⁴ It is also possible to purchase NRT over the counter, which does not appear in PBS data.

According to the Royal Australian College of General Practitioners (RACGP), NRT is considered a clinically suitable option for many people attempting to quit and has a

different safety profile compared to varenicline and bupropion.²¹ NRT is PBS subsidised for one 12 week course of therapy each year for general and concessional beneficiaries. Table 11 depicts the coverage of therapy obtained by those people, for 12 months since their initial supply. Those that have coverage beyond 12 weeks are not complying with the PBS restriction. These numbers are low; however, it may indicate NRT being used for smoking reduction as opposed to cessation. It may also suggest that patients are reattempting quitting regularly throughout the year, which is within normal quitting practice.¹⁵ It cannot be determined from PBS data whether patients are compliant with therapy or using it as prescribed.

DUSC consideration

DUSC noted that the reduced prevalence of smoking may be contributing to the reduction in the use of smoking cessation products. These products may also be being used as smoking reduction tools as opposed to cessation. Whilst the R/PBS subsidised therapies are indicated for smoking cessation, DUSC discussed that smoking reduction has a positive impact on health.

DUSC noted there was a demand for R/PBS subsidised smoking cessation therapies and considered that General Practitioners are successfully encouraging people to quit smoking. DUSC acknowledged the initial uptake in use of each therapy as each was listed on the R/PBS. Varenicline was the most commonly prescribed therapy and DUSC discussed whether a proportion of this was patient requests. DUSC also noted that there was a trend for people who tried bupropion to then not attempt it again. DUSC noted the high number of first quit attempts by the younger populations (Figure 3).

Over the period of 2012-2015, very few people were supplied bupropion, NRT and varenicline, or a combination thereof, on the same day. DUSC discussed the effects of using both varenicline and NRT concomitantly. DUSC also noted the view presented by an NRT sponsor in their pre-sub-committee response regarding the use of immediate release oral NRT to improve successful quitting and maintaining long term abstinence.

DUSC noted the number of packs of smoking cessation therapy provided through Aboriginal Health Services was low, although this is a subset of use in the Aboriginal and Torres Strait Islander population. People who received PBS smoking cessation therapy through community pharmacies under the closing the gap (CTG) programme were not included in these figures (Table 9). DUSC noted that where there were previously separate streamlined authority codes for NRT listings for Aboriginal and Torres Strait Islander persons, now that the listings are Restricted Benefit it is no longer possible to distinguish. The National Tobacco Strategy 2012-2018 developed by the Intergovernmental Committee on Drugs (IGCD) Standing Committee on Tobacco, has the aim of halving the Indigenous smoking rate

²¹ The Royal Australian College of General Practitioners 2011. Supporting smoking cessation: a guide for health professionals [Updated July 2014]. Available from <http://www.racgp.org.au/download/Documents/Guidelines/smoking-cessation.pdf> Accessed 15 December 2015.

by 2018.¹⁶ DUSC discussed the importance of reducing the prevalence of smoking in the Indigenous community.

The use of NRT specifically has been lower than predicted in terms of the number of people, prescriptions supplied and cost in each year since listing. DUSC considered the usage of over the counter smoking cessation therapies may have contributed, as these are more accessible than obtaining a prescription from a doctor. DUSC noted that there was no major change in the use of smoking cessation therapies with the streamlining of the NRT restriction in December 2013.

DUSC noted an article published in January 2016 by the Journal of the American Medical Association that found no significant differences in biochemically confirmed rates of smoking abstinence between varenicline and NRT.²² DUSC referred the information to the PBAC.

Overall, DUSC considered that it is difficult to interpret the trends in terms of cause and effect, as there are multiple contributing factors. It is not possible to capture OTC or private prescription use of smoking cessation therapies from the PBS data. It is also not possible to tell whether people who stop smoking cessation therapy have quit smoking. However, DUSC considered it positive that the average number of people who smoke daily has declined and noted the clinical place for smoking cessation therapies among the available options to assist people who want to quit smoking.

DUSC actions

DUSC requested that the report, stakeholder responses and DUSC minutes be provided to the PBAC.

DUSC noted an article published in January 2016 by the Journal of the American Medical Association that found no significant differences in biochemically confirmed rates of smoking abstinence between varenicline and NRT.²² DUSC referred the information to the PBAC.

Context for analysis

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

²² Baker et al. Effects of nicotine patch vs varenicline vs combination nicotine replacement therapy on smoking cessation at 26 weeks. JAMA January 2016 (315): 4.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

Sponsors' comments

Pfizer: Pfizer acknowledges that the DUSC Review provides a comprehensive assessment of the current use of smoking cessation therapies in Australia. In its conclusion, the DUSC report noted one article published in January 2016 by Baker et al which was not reviewed or discussed earlier in the report. Pfizer does not believe that this single publication is reflective of the body evidence which compares varenicline with NRT therapy. Pfizer agrees with DUSC that there is a clinical place for smoking cessation therapies, including varenicline, among the available options to assist people who want to quit smoking.

Perrigo: Perrigo would like to thank DUSC for their time in preparing this submission; we support further discussion that could lead to an increase in smoking cessation benefits for the Australian Community. We look forward to reducing the overall health burden that smoking related disease creates.

GlaxoSmithKline Australia Pty Ltd, Johnson & Johnson Pty Ltd, Alphapharm Pty Ltd: No comment received.

Disclaimer

The information provided in this report does not constitute medical advice and is not intended to take the place of professional medical advice or care. It is not intended to define what constitutes reasonable, appropriate or best care for any individual for any given health issue. The information should not be used as a substitute for the judgement and skill of a medical practitioner.

The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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Appendices

Appendix A: Listing details for R/PBS subsidised smoking cessation therapy

Table 15: PBS listing of varenicline and bupropion

Item	Name, form & strength, pack size	Max. quant.	Rpts	DPMQ	Brand name and manufacturer
5469W	Varenicline 1 mg tablet, 56 AUTHORITY REQUIRED	1	2	\$114.06	Champix® Pfizer
9128K	Varenicline 500 mcg [11 tablets] 1 mg [42 tablets]; 53 AUTHORITY REQUIRED	1	0	\$98.33	Champix® Pfizer
9129L	Varenicline 1 mg tablet, 56 AUTHORITY REQUIRED	2	0	\$218.65	Champix® Pfizer
8465M	Bupropion 150 mg modified release tablet, 30 AUTHORITY REQUIRED (STREAMLINED)	1	0	\$61.86	Zyban® GlaxoSmithKline Australia Pty Limited
8710K	Bupropion 150 mg modified release tablet, 90 AUTHORITY REQUIRED (STREAMLINED)	1	0	\$164.73	Zyban® GlaxoSmithKline Australia Pty Limited

Source: Accessed on 22 Oct 2015 from the PBS website

Table 16: PBS listing of NRT products (Restricted Benefit)

Item	Name, form & strength, pack size	Max. quant.	Rpts	DPMQ	Brand name and manufacturer
3414Q	Nicotine 21mg/24 hours patch, 28	1	2	\$54.72	Nicotinell® Step 1, Perrigo Australia Pty Limited
5572G	Nicotine 14mg/24 hours patch, 28	1	2	\$54.72	Nicotinell® Step 2, Perrigo Australia Pty Limited
5573H	Nicotine 7mg/24 hours patch, 28	1	2	\$54.72	Nicotinell® Step 3, Perrigo Australia Pty Limited
10076H	Nicotine 25mg/16 hours patch, 28	1	2	\$54.72	Nicorette 16 hr Invisipatch® Johnson & Johnson Pty Limited

5465P	Nicotine 21mg/24 hours patch, 28	1	2	\$54.72	Nicabate P® GlaxoSmithKline Australia Pty Limited
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Source: Accessed on 22 Oct 2015 from the PBS website.

Table 17: PBS listing of NRT products for Aboriginal or Torres Strait Islander Persons (Restricted Benefit)

Item	Name, form & strength, pack size	Max. quant.	Rpts	DPMQ	Brand name and manufacturer
10076H	Nicotine 25mg/16 hours patch, 28	1	2	\$54.72	Nicorette 16 hr Invisipatch® Johnson & Johnson Pty Limited
5465P	Nicotine 21mg/24 hours patch, 28	1	2	\$54.72	Nicabate P® GlaxoSmithKline Australia Pty Limited
5571F	Nicotine 21mg/24 hours patch, 28	1	2	\$54.72	Nicotinell® Step 1, Perrigo Australia Pty Limited

Source: Accessed on 22 Oct 2015 from the PBS website.

Table 18: RPBS listing of NRT products (Restricted Benefit)

Item	Name, form & strength, pack size	Max. quant.	Rpts	DPMQ	Brand name and manufacturer
4571N	Nicotine 7mg/24 hours patch, 7	2	2	\$50.91	QuitX® Alphapharm Pty Limited
4572P	Nicotine 14mg/24 hours patch, 7	2	2	\$54.07	QuitX® Alphapharm Pty Limited and Nicabate CQ 21® GlaxoSmithKline Australia Pty Limited
4573Q	Nicotine 21mg/24 hours patch, 7	2	2	\$57.03	QuitX® Alphapharm Pty Limited and Nicabate CQ 21® GlaxoSmithKline Australia Pty Limited
4576W	Nicotine 5mg/16 hours patch, 7	2	2	\$50.31	Nicorette® Johnson & Johnson Pty Limited
4577X	Nicotine 10mg/16 hours patch, 7	2	2	\$54.29	Nicorette® Johnson & Johnson Pty Limited
4578Y	Nicotine 15mg/16 hours patch, 7	2	2	\$59.11	Nicorette® Johnson & Johnson Pty Limited

Source: Accessed on 22 Oct 2015 from the PBS website.

Appendix B: Changes to Listing for R/PBS subsidised smoking cessation therapy

Table 19: Changes to Listing for NRT

Date	Change to Listing
November 2011	<p>Addition to Restriction and associated Notes for Nicabate P® (5465P) and Nicotinell® Step 1 (3414Q):</p> <p>Authority required</p> <p>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application;</p> <p>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.</p> <p>Note</p> <p>A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.</p> <p>Authority required</p> <p>Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.</p> <p>Note</p> <p>Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised. Benefit is improved if used in conjunction with a comprehensive support and counselling program.</p>
January 2012	<p>Two lower strengths of NRT added to the PBS: Nicotinell® Step 2 (5572G) and Step 3 (5573H).</p>
January 2012	<p>Change to Notes for Nicotinell® Step 1 (3414Q) to include statement: Applications for increased repeats, up to a maximum of 2, may be authorised.</p>
July 2013	<p>Addition to Notes for Nicabate P® (5465P) and Nicorette® Step 2 (9198D): <i>[Notes have been altered to address an error in the PBS Schedule which has been the subject of an errata]:</i></p> <p>Authority required</p> <p>Nicotine dependence in an Aboriginal or a Torres Strait Islander person as the sole PBS-subsidised therapy.</p> <p>Note</p> <p>Only 2 courses of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised. Benefit is improved if used in conjunction with a comprehensive support and counselling program.</p> <p>Authority required</p> <p>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the initial authority application.</p> <p>Note</p>

Date	Change to Listing
	<p>A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.</p> <p>Authority required</p> <p>Short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who is entering a comprehensive support and counselling program during the consultation at which this authority is requested. Details of the program must be specified in the initial authority application.</p> <p>Note</p> <p>A maximum of 12 weeks of PBS-subsidised nicotine replacement therapy will be authorised per year. No applications for increased maximum quantities and/or repeats will be authorised.</p>
December 2013	NRT patches became Authority Streamlined.
April 2014	Nicorette 16 hr Invisipatch® (10076H) added to the PBS.
July 2014	Nicorette® Step 2 (9198D) 28 patches deleted from the PBS (remains on RPBS as 4578Y with 7 patches)
September 2015	NRT restriction altered to Restricted Benefit.

Table 20: Changes to Listing for varenicline

Date	Change to Listing
February 2011	<p>Varenicline (5469W) added to PBS to allow for continuation of therapy with one box of 56 tablets and two repeats (Note that 9129L already listed for continuation of therapy with 112 tablets and nil repeats).</p> <p>Changes to Notes for 9129L:</p> <p>Note</p> <p>The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.</p> <p>Authority required</p> <p>Continuation of short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.</p>
October 2014	<p>Additions of treatment phases and clinical criteria.</p> <p>Varenicline (5469W) Change to Restriction:</p> <p>Authority required</p> <p>Treatment Phase: Completion of a short-term (24 weeks) course of treatment Clinical criteria: The treatment must be as an aid to achieving abstinence from smoking, AND The treatment must be the sole PBS subsidised therapy for this condition, AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment, AND Patient must have ceased smoking following an initial 12 weeks of PBS subsidised treatment with this drug in the current course of treatment. Treatment criteria: Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</p> <p>Varenicline (9129L) Change to Restriction:</p> <p>Authority required</p>

Date	Change to Listing
	<p>Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment Clinical criteria: The treatment must be as an aid to achieving abstinence from smoking, AND The treatment must be the sole PBS subsidised therapy for this condition, AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment. Treatment criteria: Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</p> <p>Varenicline (9128K) Change to Restriction: Authority required Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment. Clinical criteria: The treatment must be as an aid to achieving abstinence from smoking, AND The treatment must be the sole PBS subsidised therapy for this condition, AND Patient must have indicated they are ready to cease smoking. Treatment criteria: 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 the Authority application is requested. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.</p>
April 2015	Varenicline Restriction for 5469W altered to include a statement about a patient being in the process of ceasing smoking as opposed to must have already ceased smoking.

Table 21: Changes to Listing for bupropion

Date	Change to Listing
August 2004	<p>Change to 8710K Restriction to include the statements: Commencement of treatment as short-term adjunctive therapy for nicotine dependence to facilitate the goal of achieving abstinence in patients who have indicated that they are ready to cease smoking and who have entered a comprehensive support and counselling program.</p> <p>Change to 8465M Restriction (as above) with addition of: Details of the program must be specified in the authority application.</p>
April 2005	Addition to 8465M Restriction to also include a statement about a patient being in the process of entering a comprehensive support and counselling program during the consultation at which the authority is requested. Details of the program must be specified in the authority application.
March 2008	Addition to 8465M and 8710K Restrictions to specify that bupropion must be the sole PBS subsidised smoking cessation therapy allowed for a patient.
October 2015	<p>Bupropion becomes Authority Streamlined.</p> <p>Additions of treatment phases and clinical criteria to 8465M: Treatment Phase: Commencement of a short-term (9 weeks) course of treatment. Clinical criteria: * The treatment must be the sole PBS-subsidised therapy for this condition, AND * Patient must have indicated they are ready to cease smoking, AND * Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND * Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p>

Date	Change to Listing
	<p>Additions of treatment phases and clinical criteria to 8710K: Treatment Phase: Completion of a short-term (9 weeks) course of treatment. Clinical criteria: * The treatment must be the sole PBS-subsidised therapy for this condition, AND * Patient must have previously been issued with an authority prescription for this drug during this current course of treatment, AND * Patient must be enrolled in a comprehensive support and counselling program, AND * Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.</p>