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The role of self-medication with Nicotine Replacement Therapy
in making smoking history
and opportunities for further collaboration between
Government and Industry

Submission to the Preventative Health Taskforce

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BETTER HEALTH THROUGH RESPONSIBLE SELF CARE



The role of self-medication with Nicotine Replacement Therapy (NRT) in making smoking history and the opportunities for Government/Industry collaboration

Executive Summary

ASMI and its members strongly support the Taskforce's goal to reduce the smoking prevalence in Australia to 9% by 2020. Australia's tobacco control record is world class and for more than a decade an integral part of this policy has been the progressive de-scheduling of nicotine replacement therapies (NRT). It is important that as public health policy evolves that it does so in a manner that does not compromise the key elements of a system that is working.

A viable self-medication NRT market benefits:

- (i) consumers, with easy access to affordable therapies, new ways to quit, and education on how to quit
- (ii) government, with a no-cost strategy for reducing smoking prevalence and its associated public health gains
- (iii) industry, with a financially sustainable market that supports ongoing investment in innovation, and awareness creation through advertising and promotion.

The *National Preventative Health Taskforce Technical Report 2 Tobacco Control in Australia: making smoking history* proposes "Increased use of NRT" and "Commissioning a study on the pros and cons, feasibility and benefits for various possible options for the subsidy of NRT in Australia". ASMI fully endorses this proposal. ASMI believes the issue of subsidisation of NRT should be approached with considerable caution. Current evidence suggests that subsidised NRT may encourage smoking cessation but the most appropriate subsidy models need to be developed.

ASMI would like to propose close collaboration between the Taskforce and industry to develop suitable subsidy models that would deliver the desired outcomes in terms of reducing the prevalence of smoking without impacting negatively on industry's ability to innovate and raise anti-smoking awareness.

The goal of further reducing the prevalence of smoking is achievable and can be advanced through collaboration with industry and other key stakeholders. Other strategies to further reduce smoking include:

- Using NRT for harm minimisation
- Endorsing the first-line role of NRT in smoking cessation
- Removing barriers to NRT use, e.g. removing references to nicotine on cigarette packaging

The role of self-medication with Nicotine Replacement Therapy in making smoking history and the opportunity for collaboration

When considering public health policy on tobacco control, the key elements are (i) how to prevent the uptake of smoking and (ii) how to assist current smokers to quit. The submission by ASMI focuses on the latter, which involves both motivating and enabling smokers to quit.

Australia's tobacco control record is world class

The best conventional tobacco control strategies have been shown to reduce smoking prevalence by around 0.5% per year¹ and Australia is performing at this level and has done so since 1991 (see table 1). While the goal of accelerating the decline in smoking prevalence is admirable, it is critical that new initiatives do not compromise the current quitting dynamics that are delivering world class reductions in prevalence of smoking.

Table 1: Smoking prevalence in countries of focus

Country	Prevalence of daily smoking (year)	Rate of decline of smoking prevalence
Australia ²	17.4% (2004)	0.48% (1991 to 2007)
USA ³	15.6% (2004)	0.45% (1995 to 2007)
UK	24% (2005) ⁴	0.4% ⁵ (1999-2002 following reimbursed NRT)
New Zealand ⁶	23.4% (2004)	0.32% (1990 to 2004)

Australia benefits from a viable over-the-counter (OTC) NRT market

The progressive de-scheduling of NRT in Australia from prescription medication to General Sale in 2006⁷ has been met with increased utilisation with each stage of increased access, for example the first full year of advertised Schedule 3 (Pharmacist Only) NRT resulted in an 53% increase in unit growth, with each subsequent level of gain being essentially sustained.⁸

¹ Tobacco Advisory Group of the Royal College of Physicians, Ending tobacco smoking in Britain. 2008 September Royal College of Physicians

² Australian Institute of Health and Welfare 2008. 2007 National Drug Strategy Household Survey: first results. Drug Statistics Series number 20. Cat. no. PHE 98. Canberra: AIHW. <http://www.aihw.gov.au/publications/phe/ndshs07-fr/ndshs07-fr-no-questionnaire.pdf>

³ Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Data. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2007. <http://apps.nccd.cdc.gov/brfss/display.asp> Accessed 8/12/08

⁴ National statistics, UK snapshot http://www.statistics.gov.uk/cci/nugget_print.asp?ID=866

⁵ Jarvis MJ. Monitoring cigarette smoking prevalence in Britain in a timely fashion. *Addiction*. 2003;98(11):1569-74.

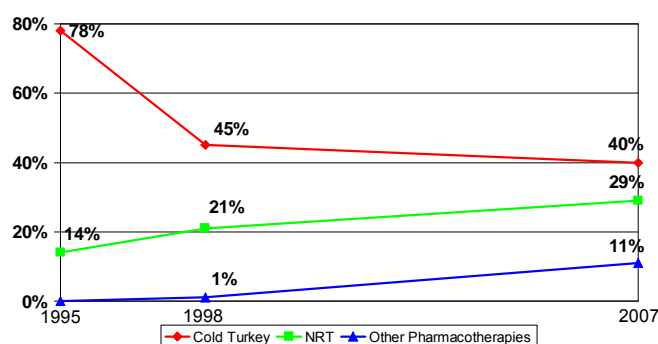
⁶ Ministry of Health. Tobacco Facts 2005. Wellington. Ministry of Health

⁷ Bittoun R. A decade of over-the-counter therapeutic nicotine in Australia. Its contribution to improving quit rates and saving lives. Smoking Cessation Research Unit. University of Sydney.

⁸ IMS Australian Pharmaceutical Index, Units Oct 1997 to September 2008

Australian survey data indicate that the OTC availability of NRT has been associated with increased use of NRT by successful quitters (Figure 1).⁹

Figure 1. Treatments used by successful quitters in the past and present



This is consistent with research from the US that demonstrated that relative to prescription availability, the OTC availability of NRT would result in more successful quitters, fewer-smoking attributable deaths and increased life expectancy for current smokers.¹⁰

A viable OTC NRT market represents a win for consumers, government and industry, in that:

- Consumers benefit with easy access to affordable, effective cessation therapies. Easy access to NRT is critical as research indicates that about half of all quit attempts are put into action immediately and these unplanned quit attempts are more likely to succeed than planned quits (odds ratio 2.6).¹¹
- Government benefits with a no-cost, effective means for ongoing decreases in smoking prevalence and associated public health benefits
- Industry benefits from continuing to have a financially sustainable market that supports ongoing investment in innovation and creating awareness through advertising and promotion.

Innovation is an important factor in reducing smoking prevalence, as each innovation represents “new hope” which can motivate smokers to make new quit attempts. The Australian OTC NRT market has benefited from innovation through

- new products such as lozenges, microtabs, inhalers, clear patches, and
- new indications, such as cut down then stop, PreQuit patches and combination NRT.

Creating awareness about therapeutic solutions and products is another critical element of industry viability. The investment in above the line advertising of NRT has been substantial over the past decade and has often exceeded Quitline advertising. The positive contribution of NRT advertising is acknowledged in formal evaluation of the National Tobacco Campaign¹², for example an analysis by the Cancer Council Victoria determined that in 2004-2005, two thirds of all anti-smoking TV advertising in

⁹ Bittoun R. A decade of over-the-counter therapeutic nicotine in Australia. Its contribution to improving quit rates and saving lives. Smoking Cessation Research Unit. University of Sydney.

¹⁰ Lawrence WF et al. Does over-the-counter nicotine replacement therapy improve smokers’ life expectancy? Tobacco Control 1998;7(4):364-8

¹¹ West R, Sohal T. “Catastrophic” pathways to smoking cessation: findings from national survey. BMJ 2006;332:458-60

¹² Summary of findings of National Tobacco Campaign – Evaluation Report Volume II, www.quitnow.info.au?internet/quitnow/publishing.nsf/conent/evaluation-summary accessed 9/12/08

Victoria was done by manufacturers of NRT.¹³ In addition to above the line advertising, the industry has made similar levels of investment in below the line activities, such as quitting promotions, healthcare professional education and market research. It is estimated that current annual investment by industry promoting smoking cessation is approximately \$20 million.

As both government and industry have a common goal in reducing smoking prevalence, there are many opportunities to collaborate, such as (i) sharing consumer research to develop even more effective campaigns, (ii) collaborating with media scheduling so that Quitline advertising that is focused on WHY STOP SMOKING and industry advertising that is focused on HOW TO STOP can be synchronised to work more efficiently together (iii) sharing information on targeting low socio-economic groups.

Subsidised NRT

In the discussion paper, “Australia: The Healthiest Country by 2020”, the Taskforce proposes providing subsidised NRT for various disadvantaged groups and callers to the Quitline. Internationally, various methods of subsidising NRT have been implemented and evaluated. Several randomised controlled studies have demonstrated that reducing patients’ out-of-pocket costs for smoking cessation therapies (including NRT) is associated with increased utilisation of these medications^{14,15,16,17}. While in most studies increased use has translated into increased cessation rates^{18,19,20}, this has not been universal²¹. Similarly community-based efforts involving the distribution of free NRT, such as the programmes in New York²² and Minnesota²³ have demonstrated increased programme usage and abstinence rates.

However like the randomised clinical trials, results have not always been positive. For example the provision of free NRT in addition to ongoing behavioural smoking cessation program offered through a local health department, found the quit rate

¹³ Brennan E, et al. Victorian current and former smokers’ quitting activity, and the impact of cessation aids, services and anti-smoking campaigns. CBRC Research Paper Series No. 29. Melbourne, Australia: Centre for Behavioural Research in Cancer, The Cancer Council Victoria, August 2007

¹⁴ Hughes JR, et al. Effect of cost on the self-administration and efficacy of nicotine gum: A preliminary study. *Preventive Medicine* 1991; 20:486-496.

¹⁵ Curry SJ, et al. Use and cost effectiveness of smoking cessation services under four insurance plans in a health maintenance organization. *New England Journal of Medicine* 1998; 339:673-679.

¹⁶ Schauffler HH, et al. Variations in treatment benefits influence smoking cessation: Results of a randomized controlled trial. *Tobacco Control* 2001; 10:175-180.

¹⁷ Hays JT, et al. Over-the-counter nicotine patch therapy for smoking cessation: Results from randomized, double-blind, placebo-controlled, and open label trials. *American Journal of Public Health* 1999;89:1701-1707.

¹⁸ Hughes JR, et al. Effect of cost on the self-administration and efficacy of nicotine gum: A preliminary study. *Preventive Medicine* 1991; 20:486-496.

¹⁹ Curry SJ, et al. Use and cost effectiveness of smoking cessation services under four insurance plans in a health maintenance organization. *New England Journal of Medicine* 1998; 339:673-679.

²⁰ Schauffler HH, et al. Variations in treatment benefits influence smoking cessation: Results of a randomized controlled trial. *Tobacco Control* 2001; 10:175-180.

²¹ Hays JT, et al. Over-the-counter nicotine patch therapy for smoking cessation: Results from randomized, double-blind, placebo-controlled, and open label trials. *American Journal of Public Health* 1999;89:1701-1707.

²² Cummings KM, et al. Reach, efficacy, and cost-effectiveness of free nicotine medication giveaway programs. *J Public Health Management Practice* 2006a;12(1):37-43.

²³ An LC, et al. Increased reach and effectiveness of a statewide tobacco quitline after the addition of access to free nicotine replacement therapy. *Tobacco Control* 2006;15:286-293.

amongst smokers provided free nicotine patches to be 53% lower at the 18-month follow-up compared with smokers participating in the program prior to the incorporation of free nicotine patches (6.7% vs. 14.3%).²⁴

The two countries where distribution channels for pharmaceuticals are closest to that in Australia are the UK and New Zealand. In both these markets subsidised NRT is available, however with distinct differences. In the UK, NRT was listed on the NHS in 2001 at prices that related to the current OTC pricing, while in New Zealand, subsidised NRT was provided via a tender system via Quitline vouchers. Although both systems are considered successful by their respective governments, the New Zealand system has significantly reduced the ability for branded NRT business to invest in this market, such that the industry has not supported research and development, introduced innovation nor does it significantly invest in advertising and promotion. In contrast, in the UK the OTC NRT market has remained viable and the industry continues to invest in research, innovation and advertising, thus the public benefits from both subsidised NRT and accessible OTC NRT.

Although the rate of decline in smoking prevalence cannot be linked to a single factor, it is of interest to note that the rate of decline is greater in the UK (0.4%) than New Zealand (0.32%) but both of these are declining at a slower rate than Australia (0.48%) (see table 1).

When considering disadvantaged groups it is important to recognise that although there may not be access to subsidised NRT, there is access to other subsidised cessation aids. Hence any proposal for NRT subsidy should be preceded by gaining a clear understanding of the successes and failures of these subsidised interventions as well as motivational factors that have an impact on the ability to quit.

Subsidised NRT may be of merit, but collaboration is required to develop a model that will not compromise existing OTC market, and its associated investment in innovation, advertising and promotion, that is already delivering strong public health benefits.

Subsidised NRT for disadvantaged groups

Table 2: Disadvantaged groups and access to subsidised cessation aids.

Group	Subsidy access	Comment
Indigenous	PBS access to NRT patches from Dec 08, and PBS access to bupropion/varenicline	Should access to NRT be expanded beyond patches, as all forms of NRT are equally effective ²⁵ ?
Mental illness	PBS access to bupropion/varenicline but co-morbidities may limit their use. If institutionalised access to NRT can be gained with existing hospital tender system.	Even though cessation is the ultimate goal, harm minimisation may be an alternative strategy for people who smoke very heavily.
Correctional services, juvenile justice	Access to NRT can occur within the existing tender system.	

²⁴ Alberg AJ, et al. The influence of offering free transdermal nicotine patches on quit rates in a local health department's smoking cessation program. *Addictive Behaviors* 2004;29:1763-1778.

²⁵ Stead LF, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. *Cochrane Database Syst Rev* 2008;(1):CD000146.

Homeless	PBS access to bupropion/varenicline	What proportion of the homeless have mental illnesses limiting the use of bupropion/varenicline?
Blue-collar and low SES groups	PBS access to bupropion/varenicline	An alternative strategy would be to encourage employer funded workplace cessation initiatives, via tax incentives to employers in predominantly blue collar industries.

Based on the above it appears that there is an opportunity to increase access to NRT for people with mental illness in institutional care.

Learnings from California

California is cited as an example of best-practice in tobacco control. In 1989, the state legislature passed a cigarette tax increase, and a portion of the tax was dedicated to supporting efforts to reduce smoking in the state. Throughout the early 1990s those programmes were created and implemented.^{26,27} They included aggressive media campaigns, telephone quit lines, support for local advocacy efforts, and tobacco-related scientific research.²⁸ In addition, the state continued to increase the tax on cigarettes and implemented the first smoke-free state law that eliminated smoking in public places, including workplaces.

In 1996, NRT became available as an OTC product and research confirmed that its wider availability was associated with increased use of NRT for abstinence.^{29,30} For the minority who had access to subsidised NRT, population effectiveness studies suggest that subsidies should target highly motivated smokers who have already taken behavioural action, such as making their home smoke-free, as these people are more likely to be successful than people who had not taken any behavioural action.³¹

The primary focus of Californian initiatives has been on motivating people to stop smoking rather than subsidising pharmaceutical aids. This suggests that the primary focus of the Preventative Health Taskforce should be making cigarette smoking even more socially unacceptable, thus motivating existing smokers to quit and undertake appropriate behavioural change.

²⁶ Bal DG, et al. Reducing tobacco consumption in California. Development of a statewide anti-tobacco use campaign. JAMA 1990; 264: 1570-4.

²⁷ Bal DG, et al. California as a model. J Clin Onc 2001; 19: 69s-73s.

²⁸ Bal DG, et al. California as a model. J Clin Onc 2001; 19: 69s-73s.

²⁹ Reed MB et al. The effect of over-the-counter sales of the nicotine patch and nicotine gum on smoking cessation in California. 1: Cancer Epidemiol Biomarkers Prev. 2005;14(9):2131-6.

³⁰ Al-Delaimy WK et al. When California smokers use nicotine replacement therapy, most are trying to quit smoking. Tobacco Control 2005;14:359-60

³¹ Gilipn EA et al. Population effectiveness of pharmaceutical aids for smoking cessation: what is associated with increased success? Nicotine Tob Res. 2006;8(5):661-9.

Forecast cost of subsidised NRT

On page 49 of the *NPHT Technical Report 2 Tobacco Control in Australia*, there is a brief discussion of the potential cost of subsidising NRT that appears to be based on the PBS history of bupropion. These calculations are likely to be an underestimation of what would occur as the decline in demand for bupropion was driven by adverse publicity about safety and ultimately a lack of consumer awareness of the product. In addition, this forecast appears to be inconsistent with the goals of the Taskforce. If we are to achieve a smoking prevalence of 9% by 2020, this is unlikely to be achieved by one or two peak years of NRT use. A more realistic scenario would be increased NRT use that is sustained, followed by a decline that matches the reduction in the prevalence of smoking.

Australian consumer research indicates that reimbursing NRT based on the New Zealand voucher model would increase the number of total quit attempts using any form of pharmacotherapy by 6%³². However the majority of the people who would use reimbursed NRT are those who would have purchased it for themselves as an OTC therapy. The forecast increase in use of NRT was not income dependent and the incremental quit attempts would come from people with a lower commitment to quitting.

Overall the evidence suggests that subsidised NRT is beneficial to smoking cessation, but the potential benefits are not guaranteed. ASMI believes industry collaboration in investigating NRT subsidy models is essential and that any proposed model should not compromise the OTC NRT market, as this cessation strategy has delivered positive public health benefits for more than a decade and continues to deliver health benefits.

Other opportunities to accelerate the reduction of tobacco smoking in Australia

Harm minimisation

People smoke because they are addicted to nicotine, but nicotine itself is not hazardous, it is the other constituents in tobacco smoke that cause harm.³³ For many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible.³⁴ Harm reduction strategies, such as using NRT to reduce the number of cigarettes smoked per day without the specific intention to quit, have been advocated to reduce the prevalence and health impacts of tobacco smoking.³⁵ A Cochrane analysis on harm reduction found that NRT approximately doubled the odds of reducing the number of cigarettes per day by 50% or more, and nearly doubled the odds of quitting.³⁶

³² GlaxoSmithKline data on file TLE32633

³³ Zwar N et al. Nicotine and nicotine replacement therapy – the facts. *Aust Pharmacist* 2006;25(12):969-73

³⁴ Stratton K et al. Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine. National Academy Press Washington, D.C.2001 http://www.nap.edu/openbook.php?record_id=10029&page=R1

³⁵ Tobacco Advisory Group of the Royal College of Physicians, Ending tobacco smoking in Britain. 2008 September Royal College of Physicians

³⁶ Stead LF, Lancaster T. Interventions to reduce harm from continued tobacco use. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD005231. DOI: 10.1002/14651858.CD005231.pub2.

ASMI believes that the potential merits of this strategy should be considered by the Taskforce as it may benefit smokers (and their families) who can not be motivated to quit.

NRT as first-line cessation therapy

The Taskforce clearly advocates the wider use of NRT as a way to assist more people become ex-smokers. It advocates that all smokers be offered NRT³⁷ and acknowledges that NRT can be used by “virtually any smoker”³⁸. An initiative that can be undertaken to assist achieving this goal is to formally acknowledge and support the first-line role of NRT.

For example, the Quitnow website does not directly discuss the use of clinically proven cessation aids at all appropriate opportunities, such as on the “getting help” page of its consumer website, where currently there is no reference to pharmacotherapies.³⁹ Similarly, a survey on GP advice on smoking cessation found that cutting down was the most frequently recommended method of quitting ahead of NRT⁴⁰, suggesting the need for ongoing GP education.

Barriers to NRT use - removing references to nicotine on cigarette packaging

A survey of Australian smokers found that 25% believed that NRT was just as harmful as smoking cigarettes and an additional 40% of smokers did not know whether this was true or false. These misperceptions result in a significant number of smokers both delaying quit attempts and quitting unassisted.⁴¹ This barrier could be removed by removing all references to nicotine from the packaging of cigarettes, so that the link between nicotine and harm is no longer reinforced. In the long-term this should enable smokers to be more receptive to using NRT to assist quitting rather than incorrectly believing that therapeutic nicotine is harmful to their health.

³⁷ Tobacco Working Group. Technical Report No 2. Tobacco in Australia: Making Smoking History pviii

³⁸ Tobacco Working Group. Technical Report No 2. Tobacco in Australia: Making Smoking History p36

³⁹ Quitnow, <http://www.quitnow.info.au/internet/quitnow/publishing.nsf/Content/getting-help>, Accessed 8/12/08

⁴⁰ Germain D. Doctors' advice to their patients about smoking: 2004. CBRC Research Paper Series No. 26. Melbourne, Australia: Centre for Behavioural Research in Cancer, The Cancer Council Victoria, June 2007.

⁴¹ Zwar N et al. Nicotine and nicotine replacement therapy – the facts. Aust Pharmacist 2006;25(12):969-73