

AUSTRALIAN ASSOCIATION OF CONVENIENCE STORES

CONSULTATION PAPER SUBMISSION

THE THERAPEUTIC GOODS ADMINISTRATION
POTENTIAL REFORMS TO THE REGULATION OF NICOTINE VAPING PRODUCTS

13 JANUARY 2023

Overview

The Australian Association of Convenience Stores (AACCS) is the representative body of more than 7,000 convenience stores across Australia, who employ close to 100,000 Australians and generate \$10 billion in store sales (excluding fuel). Our membership consists of national retailers such as Ampol, Viva Energy, 7-Eleven Australia, BP Australia, and many small, often family-owned businesses who support local communities in both metropolitan and regional areas across Australia.

The current prescription regulatory model for nicotine vaping products has disadvantaged legitimate convenience stores, who are unable to sell these products legally and in a regulated manner as they currently do for tobacco products and other quit smoking aids. As outlined in the Consultation paper, this has resulted in a black market for these products which is being accessed by children. It may also be obstructing access to these products by adults.

Background

Against the recommendations made by AACCS at the time, the former Federal Government introduced the current prescription model for nicotine vaping products (NVPs) in an attempt to restrict access to children.

Analysis commissioned by AACCS and conducted by Roy Morgan Research¹ and Convenience Measures Australia (CMA)² in 2022 shows that the current model has regrettably resulted in the growth of a black market which targets children and bypasses any proper safety and ingredient regulations. The introduction of the prescription model on 1 October 2021 has resulted in:

- Over 1.2 million Australian adults (6.1% of the adult population) now vape each month (Roy Morgan, August 2022);
- 88% of NVPs being purchased through the black market (CMA research, June 2022); 12% only of NVP consumers are using the prescription model as intended
- The creation of a lucrative black market, bypassing all regulatory controls and allowing children to access vapes freely, with no age identification measures imposed;
- The imposition of unnecessary costs on Australian governments, through the Medicare rebate, costly and futile enforcement initiatives and unclaimed GST; and
- Lawful businesses facing significant declines in foot traffic and loss of supplementary purchases with over a million Australian adults purchasing their vaping products from black market retailers.

¹ Roy Morgan Single Source, October 2021 – September 2022

² CMA Consulting, Nicotine Vaping Product Usage & Change, June 2022

Policy Solution

It is clear the current regulatory model has not met its stated objectives and the government has lost control of the NVP market, affecting Australian parents, schools, children, healthcare providers, retailers and consumers. No amount of enforcement under the current regulatory model is likely to contain the spread of the illicit market for NVPs.

To reduce youth access to NVPs, the government must effectively control the NVP market. Without control of the illicit market, illegal black-market operators will continue to sell unregulated NVPs to children. The only solution to fix the current prescription model policy failure is to implement regulatory reform that controls the whole market by providing Australia's 1.2 million adult vapers a controlled pathway to lawfully purchase NVPs in the same way tobacco or alcohol products are sold. This can be achieved through the following three measures:

1. Regulated retail sales of nicotine vaping products;
2. Product standards of nicotine vaping products; and
3. Uniform licensing scheme for retailers.

Regulated retail sales of nicotine vaping products

The current prescription-only model requires consumers to have a prescription for all purchases of nicotine vaping products, requiring a GP visit and restricting sales to pharmacies or overseas retailers.

Many doctors do not understand how to prescribe, and many pharmacies don't supply vapes. These hurdles in obtaining vapes, particularly for people who want to quit smoking, have led to the emergence of a large-scale black market. Illicit operators sell to willing adults but also target young people and children through social media.

Product standards of nicotine vaping products

The current policy settings and enforcement measures have failed. Australia needs to look at other successful regulatory models currently operating in New Zealand, the United Kingdom and Canada.

Similar to the purchase of tobacco products, a new model could permit adults to buy regulated vapes with strict electrical safety and ingredient standards from responsible retailers upon age identification. This would support informed product choice by consumers and reduce the reach of the growing black market which targets children, bypasses health controls and the tax system.

Uniform licensing scheme for retailers

Rather than fueling an illegal black-market trade in unregulated vaping products, adults should be able to purchase these products from responsible, legitimate retailers - who have safely retailed other nicotine products for decades.

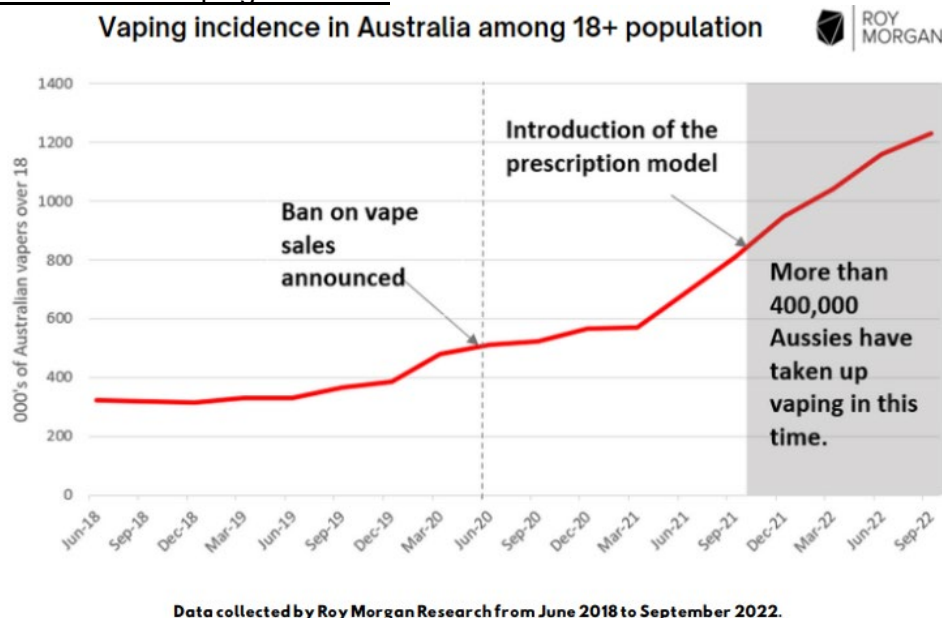
AACS supports a Responsible Retailer Code, to demonstrate how retailers can fulfil a crucial role in ensuring vapes are not being sold to underage Australians. Allowing retailers to sell vaping products would benefit both business owners and the Australian Government.

Once GST, import taxes and corporate taxes are applied to the sale of these products this revenue would contribute to the funding of schools, hospitals, infrastructure and other important government initiatives.

The Australian NVP Market

Research conducted by Roy Morgan this year highlighted that vaping in Australia has grown by 285% in the last 5 years – with 1.2 million adult Australians now using nicotine vaping products³. This number has grown at a pace of approximately 1,000 adult Australians per day in the period since the introduction of the new regulations in October 2021.

Figure 1 – Australian Vaping Incidence



The recently commissioned survey from Convenience Measures Australia showed only 12% of NVP purchases are being made legally with a prescription – meaning that 88% are using the black market to purchase nicotine vaping products and evading Australia’s NVP control framework and tax system.

³ Roy Morgan Single Source, October 2021 – September 2022

Tobacco and NVP Control Funding Opportunity

In a recent publication from The Australian newspaper in October 2022⁴, the sale of regulated adult consumer NVPs was estimated to raise around \$200 million in new GST revenues per year. At a prevailing rate of 10%, this would equate to retail sales of approximately \$2.2 billion annually.

Data published in recent financial statements from publicly listed retailers indicate that around 30% of retail sales is retained as retailers' gross margin⁵. On the assumption that 30% is the assumed margin, this would result in retailers receiving approximately \$660 million in annual margins from the sales of vaping products. The financial statements indicate major retailers see 11% of this as profit and at the corporate tax rate of 30% this would equate to almost \$21.8 million in company tax receipts.

Subtracting the \$660 million in retailer's margins from the \$2.2 billion in total sales, leaves an estimated \$1.54 billion of vaping products being sold by wholesalers. If a conservative estimate of 10% is used, this would equate to wholesale margin on vaping products to be \$154 million annually.

The financial statement from a publicly listed wholesaler indicates that its profits account for a far higher share of its margins than the retail sector mentioned above – approximately 21% in 2022⁶. Using a conservative estimate of 21% applied across the entire wholesale sector, this would deliver wholesale profits of \$32.3 million, equating to \$9.7 million in company tax at the prevailing rate of 30%.

As there are currently no large NVP manufacturers in Australia, nearly the entire value of the good sold would be imported into Australia. Removing the wholesale and retail margins from the consumer spend on vaping products, leaves an imported value of goods equal to \$1.39 billion.

Vapour products containing nicotine (e.g. liquids, cartridges and disposable) should be classified under customs tariff HS code 2404.12.90 upon importation into Australia. This customs tariff code triggers a 5% Most-Favoured-Nation customs duty rate. Consequently generating \$69.3 million in import duties. Further, with the proper regulation of NVPs, approximately \$30 million per year of corporate taxation revenues can be generated for the Australian Government.

The result of the proper regulation of NVPs as an adult consumer good in Australia would mean the generation of at least \$300 million per year or \$1.2 billion over forward estimates for the Australian Government to use to fund tobacco and NVP control programs.

⁴ The Australian, Vaping blitz an \$800m 2022 budget lift, 25 October 2022

⁵ Coles reported a gross margin of 33.4% in 2021 while Woolworths reported a gross margin of 29.7% in 2022

⁶ Metcash Annual Report 2022

Population Health Benefit

In the recently updated Cochrane Review in November 2022⁷, a University of Oxford led team, concluded that nicotine vaping products increased quitting rates compared with other forms of smoking cessation.

The Cochrane Review further found that nicotine vaping products were more effecting in aiding quitting smoking than behavioural support such as counselling, and other common methods including Nicotine Replacement Therapy in the form of patches or gum. The Cochrane Review's analysis of data from 22,000 participants in 78 studies provided the "strongest evidence to date on the benefits of using vaping as a smoking cessation aid.

Dr Sarah Jackson, Principal Research Fellow, UCL Tobacco and Alcohol Research Group in the Cochrane Review stated, "*These findings follow a recent review of the harms of e-cigarettes, which show clear evidence that vaping poses only a small fraction of the health risks of smoking. Take together, these reports should provide reassurance to smokers that e-cigarettes are much safer to use and can increase your chances of quitting.*"⁸

The Cochrane Review is considered the gold standard for any publication and provides a strong basis for consideration with regard to any policy approach made toward nicotine vaping products.

A recent report from the Centre for Economics and Business Research (Cebr) found the potential net healthcare saving if 50% of United Kingdom smokers switched to vaping to be £698 million⁹. The healthcare budgets of countries who have regulated NVPs as adult consumer products are benefiting greatly. With the United Kingdom Government stating "*vaping devices such as e-cigarettes have played a major role in the decrease in smoking prevalence in the UK*"¹⁰.

Latest data from the New Zealand Government also reveals a rapid decrease in smoking rates to record lows since the introduction of adult consumer regulations for NVPs with the New Zealand Action for Smokefree 2025 Director stating "*The influence of safer alternatives to smoking such as vaping, efforts by grassroots smoking cessation programmes and the investment going into communities to stop people smoking are all working.*"¹¹

As the TGA would be aware, healthier citizens contribute more to the economy by working and living longer, and by reducing pressures on the Australian healthcare system. As cigarettes are the number one cause of preventable death and disease in Australia, tools such as nicotine vaping products are a powerful mechanism to help people quit smoking and boost both health and economic outcomes.

⁷ Cochrane Database of Systematic Reviews, Electronic cigarettes for smoking cessation, 17 November 2022

⁸ Science Media Centre, Expert Reaction to Cochrane Review, 17 November 2022

⁹ Cebr, Economic impact assessment of the vaping industry, September 2022

¹⁰ UK Office for National Statistics, Adult smoking habits in the the UK: 2021, 6 December 2022

¹¹ ASH, Health Survey Shows NZ On Track To Achieve Smokefree 2025, 17 November 2022

TGA Reform Options

Australia's growth in adult consumption of NVPs has occurred even though there has been a prohibition on lawful retail sales and the introduction of the prescription model that prohibited adults from lawfully purchasing NVPs without a prescription. Acknowledging this growth in adult consumer demand notwithstanding the consumer prohibition controls in place, AACCS strongly recommends the TGA reconsider the recommend options put forward in the consultation paper to consider establishing a pathway for the regulated controlled sale of NVPs through lawful and experienced retailers.

Proceeding with the preferred options recommend by the TGA in the consultation paper to continue to regulate this category as a prescription medicine will simply be destined to another policy and health failure. Adult consumer demand being serviced by the black market will remain, even if taxpayer dollars are spent on additional enforcement measures.

In contrast, if adults are given the choice to buy these products legally, these adult consumers are more likely to discard their purchasing habits from the black market and move into the legitimate lawful market which can be underpinned by quality standards and youth access prevention measures in retail stores.

Most importantly, this will see less availability for minors seeking products. This policy can work and has been proven to work in New Zealand - where after introducing legislation to strictly control vaping products as an adult consumer good, New Zealand's youth vaping rate in 2022 has started to decline. The policy crisis of youth access can only be addressed if the government regulates where supply meets the adult consumer demand.

In the context of the NVP market's adult consumer dynamic, AACCS recommends the Australian Government's regulatory priority be the establishment of a controlled and regulated NVP market that enables the lawful sale of products to adult consumers. AACCS has provided comments in response to the four areas of reform proposed by the TGA to the prescription model, however AACCS reiterates that without the introduction of a pathway for adult consumers to purchase NVPs from lawful retailers, the TGA's proposed reforms will not address youth access or the black-market trade. Similar to the success Australia has had in driving youth smoking to record lows from an effective tobacco control framework, the Australian Government will not be able to effectively address this issue without control of the NVP market.

The Australian Government will not be able to control youth access unless the Government can control the whole NVP market. Government control of the NVP market will only be possible by introducing strict adult consumer regulations that shifts demand from the black-market to lawful responsible retailers.

Changes to border controls for NVPs

For the retail industry, the black market created from the prescription model has come at a significant cost to foot traffic and incidental purchases at retail and convenience stores. This is because over a million adult consumers who would have otherwise purchased regulated nicotine products from lawful retailers are instead buying unregulated products from black

market operators. In addition to much tighter import controls and a ban on personal importation of NVPs, AACCS recommends the introduction of:

- An adult consumer regulatory framework to permit lawful retailers to sell NVPs on production of age identification;
- Consumer product and electrical safety standards regulated by the Australian Competition and Consumer Commission (ACCC);
- Packaging and ingredients standards set under Australian Consumer Law;
- The ban of line sales; and
- Strong penalties for sales to minors.

AACCS supports the preferred option to remove the personal importation scheme and impose tighter controls on the importation of NVPs if these measures are simultaneously implemented with the introduction of regulated adult consumer framework to address the illicit trade in NVPs.

As the consultation paper identifies *“The detection of NVPs can be difficult at the Australian border due to the physical properties of the goods. Unlike some other products, such as tobacco, liquid nicotine cannot be identified by sight and smell.”* Banning personal importation or changing import requirements alone without introducing a pathway for adult NVP consumers to lawfully purchase regulated products from licensed retailers will not stop the illegal importation of NVPs. Vaping is now completely mainstream in Australia and if you can't control the market the government will never be able to stop youth access given that 88% of the market is being serviced by black market operators who are targeting children and avoiding paying taxes on these products.

Introducing tough adult consumer regulations in combination with tightening import requirements and banning personal importation, will dry up the demand for the black market by giving adult smokers and vapers the ability to purchase vaping products from lawful retailers – like they can for nicotine patches, nicotine inhalers and nicotine gums. Permitting a legitimate lawful market, the Australian Government can control it and put in place the safety standards and youth access prevention measures which are currently effective for tobacco and alcohol.

Pre-market TGA assessment of NVPs against a product standard

AACCS supports the introduction of a pre-market notification process for NVPs sold as an adult consumer product by lawful retailers. NVP manufacturers should be required to submit certified product information that complies with set mandatory safety standards regulated by the ACCC under Australian Consumer Law.

The TGA's preferred option to establish a pathway to enable supply of unapproved NVPs that meet a quality and safety standard and a TGA-approved NVP registration in the ARTG will not

address the underlying black-market demand for NVPs by adult consumers. The black-market demand for NVPs originates from adult consumers being unwilling to purchase NVPs as a prescription product and therefore resorting to unlawfully buying unregulated products which are easily accessible from illicit suppliers.

Without providing a pathway for adult consumer to lawfully purchase NVPs from licensed retailers, Australia's 1.2 million adult vapers will continue to revert to the most convenient purchase option which will inevitably be met by black-market operators. While the TGA's consultation paper is correct in identifying consumers may be more inclined to purchase a quality assessed product over an unregulated product, the TGA does not correctly identify the underlying driver for black-market purchases – which is accessibility. The imposition of restricted access for adult smokers or former smokers who are accustomed to purchasing tobacco products from lawful retailers will override any desire to purchase a regulated product with a doctor's prescription from a pharmacy, driving the majority of these consumers to purchase unregulated products from the black market when no other lawful regulated product is available for retail purchase.

Strengthening of the product standard regarding minimum quality and safety standards for NVPs

AACS recommends the introduction of strong product standards for NVPs under Australian Consumer Law to enable the lawful purchase of regulated products from licensed retailers. The minimum quality and safety standards introduced should reflect the best-practice regulatory framework currently in place in New Zealand which permits a range of flavours, product types, and adult targeted packaging.

Acknowledging as the TGA consultation paper outlines a number of other jurisdictions have restricted or indicated an intention to restrict NVP flavours, AACS emphasises no jurisdiction has prohibited all flavours aside from tobacco, and all of these jurisdictions have adult consumer regulatory frameworks in place with much greater control over their NVP markets.

Restricting NVPs to a single tobacco flavour as proposed will only drive more consumers from purchasing products lawfully into buying their preferred product from the black-market.

In principle, AACS supports stronger standards for labelling, packaging and ingredients under an adult consumer regulatory framework. However, implementing stronger standards within the current prescription model will be ineffective as the Australian Government controls less than 15% of the total NVP market, with over 85% of all products being supplied by the black market.

To ensure the development of effective consumer regulations under Australian Consumer Law that will meet the adult demand currently being serviced by the black-market, AACS proposes the Australian Government hold a National Vaping Summit. A National Vaping Summit will enable input from key stakeholders, including health professionals, teachers and law enforcement, to develop a world-lead best practice consumer regulatory framework.

Clarifying the status of NVPs as ‘therapeutic goods’

The current classification of NVPs as a therapeutic good has resulted in the Australian Government losing complete control of the NVP market. Instead of clarifying the status of NVPs as a therapeutic good, the Government must implement regulatory reform that treats vaping products as controlled adult consumer products.

Australia is considered a laggard on vaping internationally. In contrast, New Zealand and the United Kingdom have successfully implemented policies permitting the sale of vaping products to adults and ensuring age identification requirements.

Regulation will put the Government back in control. By setting ingredient and electrical standards, and introducing mandatory age identification, Australia can break the black market business model. Introducing licensing and regulating adult retail sales of e-cigarettes will remove the incentive for consumers to purchase from the black market and ensure products have:

- Clear and accurate labelling;
- Strong and consistent product standards; and
- Are only sold to adults by responsible retailers.

Yours sincerely,

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