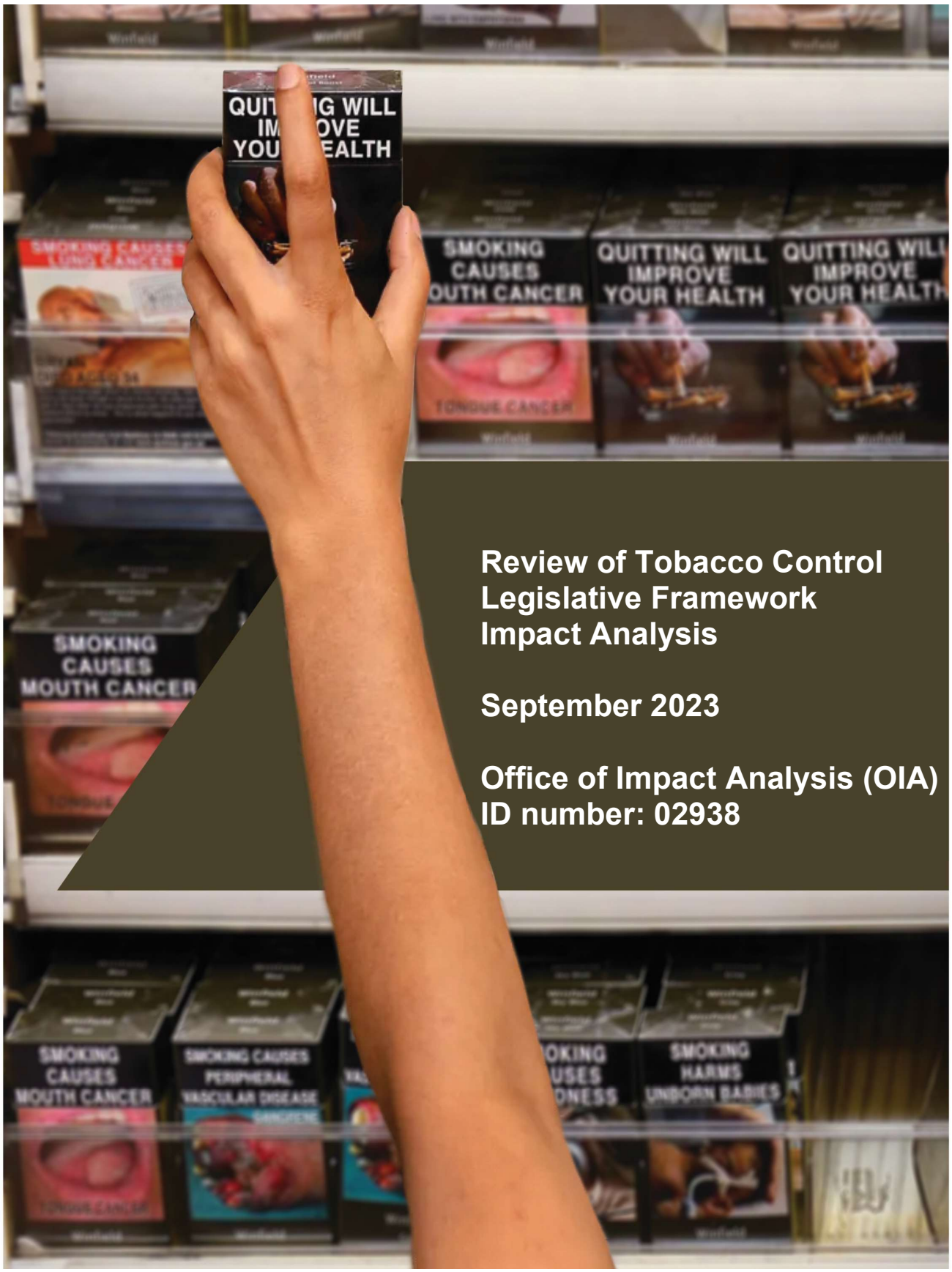

Review of Tobacco Control Legislative Framework Impact Analysis

September 2023

Office of Impact Analysis (OIA)
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Acknowledgements

The Department of Health and Aged Care acknowledges the Traditional Custodians of the land we work on and the communities that we work with. We acknowledge their history, culture, and Elders past, present and emerging.

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Glossary

ACCC Australian Competition and Consumer Commission	**RYO** Roll your own
Health warnings Means any message, information, graphic or other thing that is required to appear on the retail packaging of tobacco products by a relevant standard made under the *Competition and Consumer Act 2010.*	**SHS** Second-hand smoke
HPI Health Promotion Inserts	**TAP Act** *Tobacco Advertising Prohibition Act 1992* (Cth)
IA Impact Analysis	**The Department** Australian Government Department of Health and Aged Care
Industry The definition of 'industry' used is drawn from Article 1 of the WHO FCTC, which defines 'tobacco industry' as tobacco manufacturers, wholesale distributors and importers of tobacco products. For the purposes of this document, retailers are not included in the definition of industry. In certain circumstances, the e-cigarette industry may be considered alongside the tobacco industry. This will be specifically included and referenced.	**Thematic Review (the Review)** A review of a number of separate pieces of legislation that have similar themes as a package instead of being assessed individually. In this case, the Review considered the *Tobacco Advertising Prohibition Act 1992* (Cth), *Tobacco Advertising Prohibition Regulation 1993* (Cth), *Tobacco Plain Packaging Act 2011* (Cth), *Tobacco Plain Packaging Regulations 2011* (Cth).
Information Standard *Competition and Consumer (Tobacco) Information Standard 2011* (Cth)	**TPP Act** *Tobacco Plain Packaging Act 2011* (Cth)
NPHS National Preventive Health Strategy	**WHO** World Health Organization
NTS National Tobacco Strategy 2023-2030	**WHO FCTC** World Health Organization Framework Convention on Tobacco Control

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Executive Summary

In Australia, tobacco use is a leading cause of preventable death and disease and is a key health risk factor.[1] The Australian Government is committed to reducing the prevalence of tobacco use and associated costs, consistent with its obligations as a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC).[2]

The regulatory reforms and non-regulatory measures implemented by Australian Governments over the past 50+ years has contributed to Australia's smoking prevalence being amongst the lowest in the world. However, there is more that can be done to further reduce the preventable death and disability caused by tobacco product use and to reduce the tobacco industry's ability to undermine tobacco control measures.[3]

The National Tobacco Strategy 2023-2030 (NTS) and National Preventive Health Strategy (NPHS) 2021-2030 include the following targets in respect to tobacco control:

- achieve a national daily smoking prevalence[i] for adults (≥18 years) of less than 10 per cent by 2025, and 5 per cent or less by 2030; and
- reduce the daily smoking rate among First Nations peoples (≥15 years) to 27 per cent or less by 2030.[4] [5]

The NTS is a component of the National Drug Strategy 2017-2026 and sets out a national policy framework for the Commonwealth, state and territory governments to work together, in collaboration with non-government organisations (NGO), to improve the health of all Australians by reducing the prevalence of tobacco use and its associated health, social, environmental and economic costs and the inequalities it causes.[6] The NTS underwent two rounds of public Consultation, with outcomes highlighting the need for ongoing regulation and additional tobacco control measures. The NTS was endorsed by all Australian governments and released on 2 May 2023.

Current settings and tobacco control investments are unlikely to achieve the smoking targets outlined in these national strategies. Despite Australia's success in tobacco control, further regulatory measures and increased program investments are required to meet these targets.[7] Achieving the Government's targets for a national daily smoking prevalence requires a 7 per cent reduction in the number of daily smokers (approximately 150,000 people) in Australia in the next two years, and a 53 per cent reduction in the next eight years (approximately 1.2 million people).

The primary objectives of government action are to reduce the daily smoking prevalence by discouraging uptake among people who do not smoke and increasing cessation among people who do smoke. Secondary objectives have also been identified that have less direct impact on smoking prevalence but would support measures to meet the primary objectives. These include ensuring Australia's tobacco control regulatory framework aligns with international best practice and international precedents, and the receipt of more sales and advertising information to increase transparency and inform policy development.

In line with Australian Government guidance, this Impact Analysis (IA) examines options (including evidence, data, and analysis of the broader costs and benefits) to address the following inefficiencies and limitations of the Commonwealth's tobacco control framework and to drive a continued reduction in smoking prevalence in Australia:

A. There are multiple pieces of legislation governing tobacco control within Australia, which creates ambiguity regarding compliance, and duplication of reporting and enforcement. This is proposed to be addressed through a range of measures to:

i As tobacco smoking remains the predominant form of tobacco use in Australia by a wide margin, all prevalence estimates in this document refer to tobacco smoking unless stated otherwise.

1. Consolidate existing legislation to reduce red tape and the possible duplication of portfolio responsibility for policy and enforcement.
2. Update and improve health warnings on tobacco products to better inform consumers on the effects of tobacco use.
3. Improve coverage, enforcement, and compliance for tobacco control through updating advertising restrictions, definitions, and movement to a civil penalties regime.
4. Expand advertising prohibitions to reduce the public's exposure to the advertising and promotion of e-cigarettes and other novel and emerging products, particularly in young and vulnerable people.

B. The current tobacco framework does not effectively respond to changes in the market and products which considerably influence consumer behaviour and seek to undermine existing tobacco control measures. This is proposed to be addressed through a number of measures, including to:
    5. Standardise tobacco product size (pack, pouch, and cigarette stick sizes) as this product differentiation makes a product more attractive to consumers, including youth.
    6. Restrict the use of additives that enhance the attractiveness and palatability of tobacco products.
    7. Regulate product design features that make tobacco products more attractive to consumers, including crush balls and novel filters.
    8. Prohibit the use of brand and variant names falsely implying reduced harm.
    9. Require Health Promotion Inserts to encourage and empower people who smoke to quit.
    10. Require mandatory disclosure of sales volumes and pricing (10A), disclosure of tobacco advertising and, promotion expenditure (10B) to support policy development, implementation, and evaluation of tobacco control initiatives.
    11. Protect tobacco control policy from commercial and other vested interests.
    12. Require dissuasive measures on factory-made-cigarettes to reduce appeal of smoking, reduce smoking uptake and increase cessation.

The Department of Health and Aged Care's (the Department's) tobacco control regulations are due to sunset on 1 April 2024.[ii] In accordance with the *Legislation Act 2003,* the Department undertook a review of its tobacco control legislation to ensure it remains fit-for-purpose, kept up to date, and is in force as long as it is needed.[8] This review is referred to as the Thematic Review (the Review).

The Review applies to the following legislation:

- *Tobacco Advertising Prohibition Act 1992 (TAP Act)*
- *Tobacco Advertising Prohibition Regulation 1993 (TAP Regulation)*
- *Tobacco Plain Packaging Act 2011 (TPP Act)*
- *Tobacco Plain Packaging Regulations 2011 (TPP Regulations).*

In 2019, two broad consultations were undertaken to inform the Review: an online public consultation (January-May 2019) followed by a series of stakeholder workshops (May-July 2019).[9] Feedback from these consultations established that regulatory improvements should be made and that there is a need for ongoing regulation to achieve the Australian Government's objectives with respect to tobacco control. These consultations informed the development of the proposed

ii As part of the *Legislation Act 2003*, the Australian Government introduced changes to the sunsetting arrangements for legislative instruments so that they automatically cease to apply, unless an active decision has been made to retain them. The aim of the arrangements is to ensure that legislative instruments are kept up to date and only remain in force so long as they are needed.

Exposure Draft of the Public Health (Tobacco and Other Products) legislation package (Exposure Draft). The legislation package comprises:

- Public Health (Tobacco and Other Products) Bill 2023 (the Bill);
- Public Health (Tobacco and Other Products) Regulations 2023;
- Public Health (Tobacco and Other Products) Consequential and Transitional Bill 2023; and
- Public Health (Tobacco and Other Products) Consequential and Transitional Regulations 2023.

The Exposure Draft was released for public comment between 31 May 2023 and 14 July 2023, on the Department's engagement platform, Consultation Hub. In addition, targeted consultation sessions were conducted by external consultants, Allen and Clarke Consulting, with public health experts and First Nations representatives to understand the impact of the Exposure Draft. Tobacco industry representatives also attended targeted consultation sessions with Allen and Clarke Consulting, to understand implementation considerations of the Exposure Draft (consistent with Article 5.3 of the WHO FCTC).

Feedback on the Exposure Draft was received from a wide array of stakeholders, including public health non-government organisations, academics, government agencies, industry peak bodies, private businesses and individuals.

In general, submissions followed a number of key themes:

- non-industry related stakeholders were supportive of the proposed Exposure Draft, whilst also providing additional areas to strengthen to better promote health objectives, and introduce greater restrictions on tobacco and e-cigarette industry engagement.
- Industry stakeholders had different views on the impact of the Exposure Draft's implementation, but generally raised concerns about how it may impact the illicit market.
- A key area of agreement across industry/non-industry stakeholders related to the need for greater support for compliance and enforcement to implement the legislation. They also considered the effectiveness of the Exposure Draft towards achieving its stated objectives will be dependent on effective compliance and enforcement by the Australian Government.
- There were divergent views on the timing of implementation of reforms amongst key stakeholders. Industry stakeholders considered they needed more time to implement the measures, such as removing the proposed prohibited ingredients from their products, making adjustments to tobacco packaging, providing for the addition of inserts to product packages, and establishing reporting regimes. In contrast, public health stakeholders and First Nations' peoples considered that the proposed tobacco control measures build on the success of Australia's tobacco control measures, should go further and be introduced at the earliest possible opportunity.

The IA commenced following public consultation undertaken in 2019 to inform the thematic review of tobacco control legislation in Australia and to identify opportunities for regulatory changes.

Drawing on the public consultation, the reviews conducted as part of the development of the NTS,[10] international best practice and the evidence base, the Department developed the proposed measures outlined in this IA to respond to the identified problems.

In July 2021, a draft Regulation Impact Statement was provided to the then Office of Best Practice Regulation for consideration and was considered well developed for the stage of policy development and suitable to inform an early policy decision.

On 30 November 2022, taking into account a further draft IA which had received a formal early assessment compliant rating from the Office of Impact Analysis (OIA), the Minister for Health and

Aged Care, the Hon Mark Butler MP announced the Government's proposal to develop new legislation to reduce smoking rates. The draft IA addressed questions 1 to 4 of the 7 IA questions.

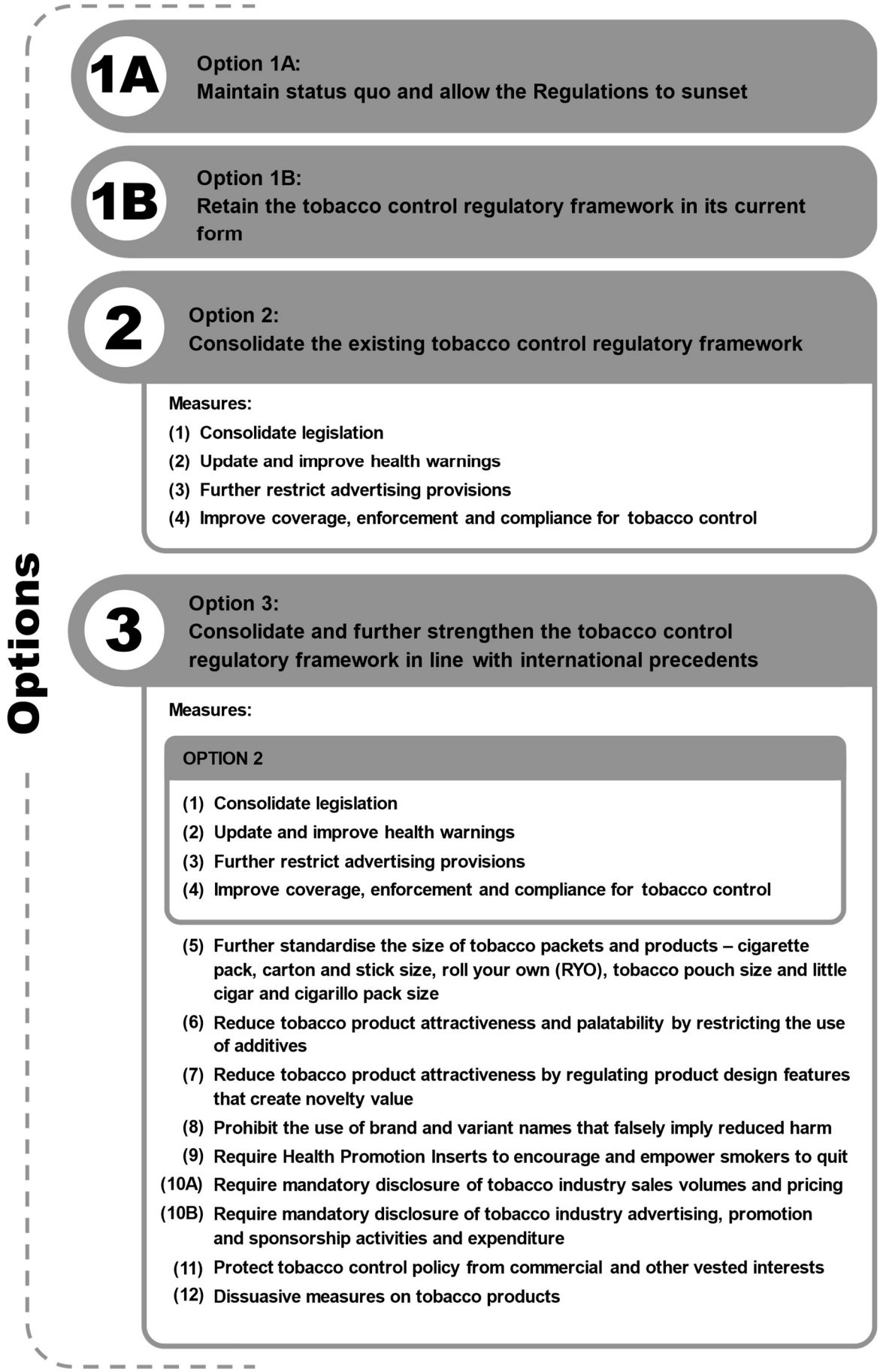
The release of the exposure draft of the Public Health (Tobacco and Other Products) legislation for public consultation on 31 May 2023 informed the further development of this IA including consideration of IA questions 5 to 7. The consultation also informed amendments to the draft legislation for consideration by Parliament. The OIA was engaged throughout the policy development process, including receiving informal drafts of the IA. At each step, the OIA noted that the IA was 'well developed' for the relevant stage in the policy development process.

In assessing the impact of the proposed options, compliance costs to industry were estimated for the purposes of this IA, using a Regulatory Burden Measurement Framework that follows the guidelines provided by the OIA, and are considered to have a relatively low regulatory impact on industry with significant public health benefit.

The options outlined in this IA are summarised in Figure 1 below. Option 3 has been identified as the preferred option which would deliver on the public health objectives of:

- **reducing uptake** among people who do not smoke
- **increasing cessation** among people who smoke
- **informing regulators** of trends in marketing, use and compliance within the tobacco control framework to contribute toward achieving the Australian Government's targets in respect to tobacco control.

Figure 1: Detailed policy options outlined in the IA



Background

The Australian Government is committed to reducing the prevalence of tobacco use and associated costs, consistent with its obligations as a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC). Tobacco use remains a leading cause of preventable death and disease and is a key health risk factor in Australia and causes more deaths than all other external risk factors put together. Tobacco use contributes to nine out of the ten diseases with the highest total disease burden in Australia.[11] Tobacco use has been estimated to account for 8.6 per cent of the national burden of disease, including more than one in every eight deaths (13 per cent),[12] and 1.7 million smoking-related hospital inpatient episodes in Australia in the 2015/16 financial year.[13]

Australia's tobacco control framework comprises numerous evidence-based measures to prevent and reduce tobacco use. However, around 2 million Australians are smoking daily,[14] and an estimated 20,500 people die each year in Australia of a smoking related illness.[15] A recent study has estimated that cigarette smoking will cause more than 250,000 cancer deaths in Australia between 2020 and 2044.[16]

The *Tobacco Plain Packaging Act 2011* (***TPP Act***) and *Tobacco Advertising Prohibition Act 1992* (***TAP Act***) are key legislative pieces in Australia's tobacco control framework. However, they are over a decade old. Evidence shows that comprehensive advertising bans are an effective means to reduce the prevalence and uptake of smoking.[17] Through the TAP Act, advertising restrictions are already in place in Australia, but there are some limitations. Similarly, Australia's plain packaging requirements under the TPP Act have made it harder for the tobacco industry to promote its products to consumers via packaging and branding design features, however tobacco companies continue to find novel ways to advertise and market their products.[18]

In accordance with the *Legislation Act 2003,* all legislative instruments are subject to sunsetting. This ensures that legislative instruments are reviewed by the responsible agency at least every 10 years. The following tobacco related legislative instruments are due to sunset on 1 April 2024: [iii]

- *Tobacco Advertising Prohibition Regulation 1993* (***TAP Regulation***)
- *Tobacco Plain Packaging Regulations 2011* (***TPP Regulations***).

Consistent with the Attorney-General's Department guidance for the sunsetting of instruments, the Department has undertaken a Thematic Review (the Review) of these instruments, their enabling Acts, and other related tobacco control legislation. This type of review is where two or more instruments that share a common theme, are reviewed together to determine if the sunsetting instruments remain fit-for-purpose, necessary and relevant, and whether they can be simplified and streamlined such that they are clearer and do not impose unnecessary regulatory burden through the First Principles Review.[iv] The Review therefore, also includes:

- *Tobacco Plain Packaging Act 2011* (***TPP Act***)
- *Tobacco Advertising Prohibition Act 1992* (***TAP Act***)
- *Court Enforceable undertakings with tobacco companies (Philip Morris, British American Tobacco Australia and Imperial Tobacco Limited) issued in 2005* (***2005 Undertakings***)
- *Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008* (***Fire Risk Regulations***)

[iii] As part of the *Legislation Act 2003*, the Australian Government introduced changes to the sunsetting arrangements for legislative instruments so that they automatically cease to apply, unless an active decision has been made to retain them. The aim of the arrangements is to ensure that legislative instruments are kept up to date and only remain in force so long as they are needed.

[iv] Findings or issues that could not be resolved through the thematic review would contribute to the work for the first principles review that would take a more fundamental look at tobacco control legislation and regulations, their objectives, the interface with other regulatory areas, and how the arrangements were implemented to ensure they were fit-for-purpose.

- *Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods* (**Oral Tobacco Ban**)
- *Competition and Consumer (Tobacco) Information Standard 2011* (***Information Standard***).[19]

In addition, the Review facilitated an opportunity for the Department to consider further health and tobacco control objectives and position the Department to undertake risk-based enforcement activity.

Three broad consultations were undertaken to inform the Review: an online public consultation (January-March 2019) followed by a series of stakeholder workshops (May - July 2019), and consultation on the Exposure Draft legislation (July 2023). Feedback from these consultations established that regulatory improvements can be made and that there is a need for ongoing regulation to achieve the Australian Government's objectives with respect to tobacco control.[20] In addition, two rounds of public consultation have occurred to support the development of the National Tobacco Strategy (NTS) 2023-2030, with outcomes highlighting the need for ongoing regulation and additional tobacco control measures.

The burden of tobacco-related harm

Whilst daily smoking prevalence continues to decrease, tobacco continues to be the leading cause of preventable death and disability in Australia. Up to two-thirds of deaths in people who smoke can be attributed to smoking and on average, people who smoke aged 45 and over are estimated to die 10 years earlier than people who do not smoke.[21] In any year, for every person who smokes who dies early, at least 30 more will be living with one or more of the many debilitating diseases caused by smoking.[22] These include cancer, chronic lung and heart disease, diabetes, infections, dental problems, breathing problems and chronic respiratory conditions, hearing and vision loss, fertility problems, osteoporosis, and early menopause in women.[23]

For people who do not smoke, exposure to second-hand smoke (SHS) is a significant cause of preventable death and disability.[24] SHS has been causally linked to cancer, respiratory and cardiovascular diseases, and to adverse effects on the health of infants and children.[25]

Tobacco use also contributes to and compounds existing health and social inequalities in Australia. It is the greatest contributor (23 per cent) to the health gap between First Nations and non-First Nations peoples.[26] Smoking causes over one-third of all deaths in First Nations populations.[27]

In comparison to the general population, the smoking rate in Australia among First Nations peoples remains very high. In 2017-18, 13.3 per cent of people aged 15 years and older in the general population reported daily smoking,[28] whilst 37.4 per cent of First Nations peoples aged 15 years and older reported daily smoking in 2018-19.[29] Additionally, the proportion of First Nations people who smoke remains higher for those living in remote areas (49.3 per cent) than in non-remote areas (34.6 per cent).[30] Similar percentages of First Nations men and women smoke daily (39.1 per cent compared to 35.9 per cent).[31] For First Nations peoples the age range with the highest proportion of smoking attributable deaths was among those aged 45 to 64 (49.8 per cent). This is compared to 82 per cent being aged 65 years and over among non-First Nations peoples.[32] First Nations peoples are also overrepresented in the hospital separations data (related to episodes of care in hospitals), accounting for 5.9 per cent of smoking attributable hospital separation costs and 7.2 per cent of the hospital separations cost amongst females.[33]

Smoking rates remain much higher than the general population among people from low socioeconomic groups with 18.1 per cent of people in the most disadvantaged areas smoking, compared to 5 per cent of those in the least disadvantaged areas smoking.[34] Research also suggests a link between smoking and increasing financial stress in low-income households. For example, B Nyakutsikwa, J Britton, T and Langley (2021) found tobacco (and alcohol) expenditure exacerbated poverty for households in the lowest income decile.[35]

Further, those who are unemployed, homeless, imprisoned, have a mental illness, or have an alcohol or other drug dependency also have higher smoking rates than the general population.[36] Smoking is reported as the largest contributory factor in the 10-20 year difference in life expectancy between those with mental health conditions and those without.[37]

There is also growing evidence that smoking contributes to poor mental health outcomes and can increase the risk of anxiety, depression, psychotic disorders and the risk of suicidal behaviour.[38] Further, foetal and adolescent exposure to nicotine may have long-term and damaging consequences for brain development, potentially leading to learning and mood disorders.[39] There is also evidence that smoking cessation improves mental health and can reduce depression, anxiety, and stress compared to people who continued to smoke.[40]

Compared to the general population, smoking rates are approximately 9 per cent higher among lesbian, gay and bisexual people.[41]

Tobacco use also has tangible costs including the reduction in economic output due to premature mortality, costs arising from workplace absenteeism, and spending on tobacco by people dependent on smoking.[42] Intangible costs include the value of life lost, pain and suffering both from premature mortality and from the lost quality of life of those experiencing smoking attributable ill-health.

A systematic review and meta-analysis published in 2019 found robust evidence that smoking increases both the risk and number of sick days in working populations, regardless of study location, gender, age, and occupational class. Smoking was associated with a 31 per cent increase in risk of sickness absence, and with 2.89 more sickness absence days per year, compared to non-smoking.[43]

The importance of reducing uptake and increasing cessation

The prevalence of tobacco use is reduced by lowering uptake and increasing cessation. This, in turn, reduces the burden of tobacco related harm.

Smoking prevalence among young people in Australia has experienced a long-term decline. Between 1984 and 2017, the proportion of teenagers smoking at least once in the previous week has declined from over 30 per cent to 9 per cent among 16–17 year-olds, and from 20 per cent to 3 per cent among 12–15 year-olds.[44] The 2019 National Drug Strategy Household Survey also shows that the average age Australians smoked their first full cigarette increased from 16.4 years in 2016 to 16.6 years in 2019.[45] Although significant progress has been made to reduce the prevalence of smoking among youth and to increase the average age of initiation of tobacco products, it is important to continue to prevent and further reduce the uptake of smoking by young Australians.

Tobacco smoking by youth and young adults has immediate adverse health consequences and accelerates the development of chronic diseases across the full life course. It can lead to nicotine addiction that causes young people to continue smoking for longer, further causing increased physical damage.[46] Nicotine exposure during adolescence may also have damaging and long-lasting effects on brain development.[47]

The majority of people who smoke commenced smoking during adolescence, with more than 80 per cent of adults who smoke initiating smoking by 18 years of age.[48] However, delaying the age when young people first experiment with tobacco products can reduce the risk that they transition to regular or daily smoking and also increase their chances of successfully quitting if they do smoke regularly.[49] Delaying the use of tobacco products may also help reduce the duration and intensity of a person's smoking, factors strongly associated with tobacco attributable disease and premature death.[50]

Evidence shows that quitting smoking at any age reduces the risk of premature death and improves quality of life.[51] Quitting reduces the risk of at least twelve cancers (including cancers of the lung,

larynx, oral cavity and pharynx, oesophagus, pancreas, bladder, stomach, colon and rectum, liver, cervix, kidney, and acute myeloid leukemia), as well as the risk of morbidity and mortality from cardiovascular disease and stroke, and the risk of developing chronic obstructive pulmonary disease.[52] Pregnant women who quit improve their health, and that of their foetuses and newborns.[53]

More than 90 per cent of the excess mortality caused by smoking can be avoided if people quit before the age of approximately 40.[54][55] Quit attempts have been found to have increased among those aged 60 years and over, compared to other age groups which have remained stable.[56] Nonetheless, in 2021-22, daily smoking rates remained highest for the 55 to 64 age bracket, with over 10 per cent of this population group smoking daily.[57]

Encouraging and supporting people who smoke to quit remains the most effective and cost efficient- method of reducing the burden of death and disease caused by tobacco use and the associated health care costs in Australia.[58][59] Quitting smoking can be hard and people who smoke are often unaware of the best ways to quit and underestimate the benefits of the various sources of help available.[60]

In 2019, the financial cost of smoking was the most common reason given by Australian people who smoke who attempted to quit (58.3 per cent), followed by concern about health (45.4 per cent). Despite the addictive nature of smoking, almost two-thirds of Australians who have ever smoked have now quit (62 per cent of people who smoke in 2019).[61] However, ongoing tobacco control interventions are critical to ensuring that the prevalence of tobacco use in Australia continues to decline. Evidence from Australia and overseas shows that when tobacco control efforts stall, so does the decline in prevalence.[62]

The tobacco market in Australia

Factory manufactured cigarettes (cigarettes) and roll your own (RYO) tobacco remain the most popular tobacco products in Australia. In 2019 the majority of Australian people who smoke aged 14 or older (84 per cent) smoked cigarettes, while over 1 in 3 (45 per cent, up from 36 per cent in 2016) smoked RYO and 1 in 10 had smoked cigarillos (10.6 per cent).[63]

The estimated value of retail tobacco sales in Australia in 2016 was over $14 billion based on the sale of approximately 14 billion cigarette sticks.[64] The estimated value of retail sales of cigars, cigarillos, and smoking tobacco (including RYO and pipe tobacco) was just less than $3 billion, giving a total value of approximately $17 billion.[65]

All tobacco in Australia is imported as wholesale tobacco, and no tobacco products have been manufactured in Australia since 2016. The three largest tobacco companies in terms of market share are British American Tobacco Australia (BATA), Philip Morris International (Philip Morris), and Imperial Tobacco Australia Limited (Imperial Brands). These companies are wholly owned subsidiaries of their overseas parent companies. In 2018 these three companies held approximately 82.8 per cent of the market share, with smaller importers making up the remaining 17.2 per cent.[66]

WHO Framework Conventions on Tobacco Control Obligations

The WHO Framework Convention on Tobacco Control (WHO FCTC) is an evidence-based treaty providing a framework for tobacco control measures to reduce tobacco use and exposure to tobacco smoke. It is the first international treaty negotiated under the guidance of WHO. It was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. It has since become one of the most rapidly and widely embraced treaties in United Nations history.[67]

The WHO FCTC was developed in response to the globalisation of the tobacco epidemic and is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. The

WHO FCTC represents a milestone for the promotion of public health and provides new legal dimensions for international health cooperation. [68]

Australia was an original signatory to the WHO FCTC and became a Party when it came into force on 27 February 2005. Being a Party to the WHO FCTC creates obligations for Australia, including in respect to demand and supply measures. The WHO FCTC obliges Australia to take steps to protect its tobacco control policy making and implementation from interference from the tobacco industry and its interests. As a Party to the FCTC, Australia is also required to report on its progress in implementing the treaty every two years.

The WHO FCTC obligations for tobacco control are directly relevant to the scope of the Review and this IA, including requirements that Australia:

- inform people of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure (Article 4)
- develop and implement comprehensive, multisectoral tobacco-control strategies, plans and legislation to prevent and reduce tobacco use, nicotine addiction and exposure to tobacco smoke; and to ensure that these strategies are protected from the interests of the tobacco industry (Article 5)
- provide protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places (Article 8)
- regulate the contents of tobacco products (Article 9)
- require disclosure of tobacco product ingredients and other information (Article 10)
- prohibit misleading tobacco packaging and labelling, and to ensure that tobacco product packages carry health warnings and messages (Article 11)
- raise public awareness of tobacco control issues (Article 12)
- ban tobacco advertising, promotion, and sponsorship (Article 13)
- introduce demand reduction measures concerning tobacco dependence and cessation (Article 14)
- eliminate all forms of illicit trade in tobacco products (Article 15)
- prohibit the sales of tobacco products to people under the legal age for smoking, including linked measures that limit access of underage persons to tobacco products such as by setting minimum pack sizes for tobacco products (Article 16).

The Guidelines for implementation of the WHO FCTC and decisions of the WHO FCTC Conference of the Parties (COP) are intended to help Parties meet their obligations under the respective provisions. They reflect and promote best practices and standards for implementation.

WHO FCTC Article 5.3

There is a well-established body of evidence that demonstrates that the tobacco industry has operated for decades with the intention of subverting the role of governments in developing and implementing public health policies to combat the tobacco epidemic.[69]

Article 5.3 of the WHO FCTC requires public officials to protect public health policies in relation to tobacco control 'from commercial and other vested interests of the tobacco industry'.

In January 2015, the Australian Government declared its view that the WHO FCTC '…does not recognise any right to non-discriminatory treatment of the tobacco industry'. The Australian Government also declared its understanding that it '… should interact with the tobacco industry only when and to the extent strictly necessary to enable [it] to effectively regulate the tobacco

industry and tobacco products, and should ensure that any such interactions are conducted transparently'.[70]

In 2019, the Department published the *Guidance for Public Officials on Interacting with the Tobacco Industry* which contains the framework for Australian public agencies and officials under Article 5.3. The document confirms that consultation with the tobacco industry should be limited to what is necessary for public officials or agencies to enact effective tobacco control measures, including the development of law or policy that directly regulates the tobacco industry and tobacco products.[71]

During consultations on the Review in 2019, the representatives of the tobacco industry wrote to the Department regarding the lack of industry participation in workshops. The Department responded by noting the WHO FCTC Article 5.3 obligations, that industry was given an opportunity to provide input during the public submission process and advised that further consultation would occur at the time when Exposure Draft of proposed legislative amendments were made public. This occurred in July 2023.

E-cigarettes, novel and emerging products

In recent years, e-cigarettes as well as novel and emerging smoking products have also come on to the market including heated tobacco products and other tobacco and nicotine products that do not involve heating. Between 2016 and 2019, the proportion of Australians aged 14 years and over who had ever used e-cigarettes rose from 8.8 per cent to 11.3 per cent.[72]

There has been widespread expansion of e-cigarette use internationally. A strong and consistent body of evidence shows that the use of e-cigarettes by people who never smoked leads to an uptake in tobacco smoking, particularly among young people. E-cigarettes are a gateway to tobacco use for youth and young adults, including for those who would otherwise be unlikely to take up conventional smoking, as they can normalise the act of smoking and create a nicotine dependency.[73,74] There are also concerns about direct health harms associated with e-cigarette use, concurrent use of e-cigarettes and tobacco products, and the potential for their use to further contribute to nicotine addiction and tobacco use, particularly among youth.[75,76]

In October 2021, Australia's regulator of medicines, the Therapeutic Goods Administration (TGA) clarified that nicotine in vaping products should be treated as prescription only medicine. This change was made to protect young people from taking up nicotine vaping, while enabling people to access these products for smoking cessation under medical supervision.

On 23 June 2022, the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) published an updated statement on e-cigarettes based on the latest scientific evidence.[77] The updated NHMRC CEO statement concludes that:

- all e-cigarette users are exposed to chemicals and toxins that have the potential to cause harm. In addition to nicotine, more than 200 chemicals have been associated with e-liquids
- e-cigarettes containing nicotine are addictive and people who have never smoked are more likely to take up tobacco smoking
- e-cigarettes are not proven safe and effective smoking cessation aids. There are other proven safe and effective options to help people who smoke quit.

Broadly similar conclusions were made in a systematic review of e-cigarettes and health outcomes that was commissioned by the Department and published in April 2022.[78]

Strategies undertaken by industries marketing these products have the potential to undermine Australia's achievements to date in tobacco control and public health. For example, research has shown an association between flavoured e-cigarette use and increased risks of smoking among youth in the United States.[79]

The tobacco and e-cigarette industries have employed a wide range of strategies and channels to advertise and promote e-cigarettes, often using the same strategies and tactics shown to increase youth initiation of tobacco products. For example, common marketing messages have drawn on themes such as freedom, good taste, romance, sexuality, and sociability.[80] Other common marketing messages relate to themes that e-cigarettes: are safer alternatives to cigarettes; are helpful in smoking cessation; and can be used in smoke free areas.[81] Evidence is not sufficient to support any widespread promotion of e-cigarette use for smoking cessation or harm reduction.[82 83] E-cigarette marketing has been significantly associated with an increased likelihood of use among middle and high school students, and exposure has also been associated with susceptibility to use among non-users.[84]

Industry strategies that may be used to appeal to youth include, but are not limited to, introducing a wide range of e-cigarette flavours that taste like fruit, mint, and candy, as well as colourful packaging.[85] Notably, in a 2022 study on e-cigarette product preferences of Australian adolescent and adult users, adolescents were significantly more likely than other age groups to use flavoured e-liquids monthly.[86] The widespread advertising and promotion of products via digital media and other communication platforms is also being used to increase the appeal of e-cigarettes to youth.

Several studies have also found an association between e-cigarette marketing exposure and greater use of e-cigarettes.[87]

Article 5.2 of the WHO FCTC requires Parties to develop appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke, which is linked to both reducing potential nicotine addiction from e-cigarette use and preventing tobacco future use.

On 30 November 2022, the TGA released a consultation paper on further potential reforms to the regulation of nicotine vaping products. This consultation recognised that despite the regulatory changes made in 2021, e-cigarette use had been continuing to grow in Australia, particularly among young people and outside the medical model that was designed as an avenue to support smokers to quit.

Following consideration of the feedback from the public consultation, proposed reforms were announced in May 2023 to introduce new controls on e-cigarette importation, contents and packaging and to work with States and Territories to address the black market for e-cigarettes.

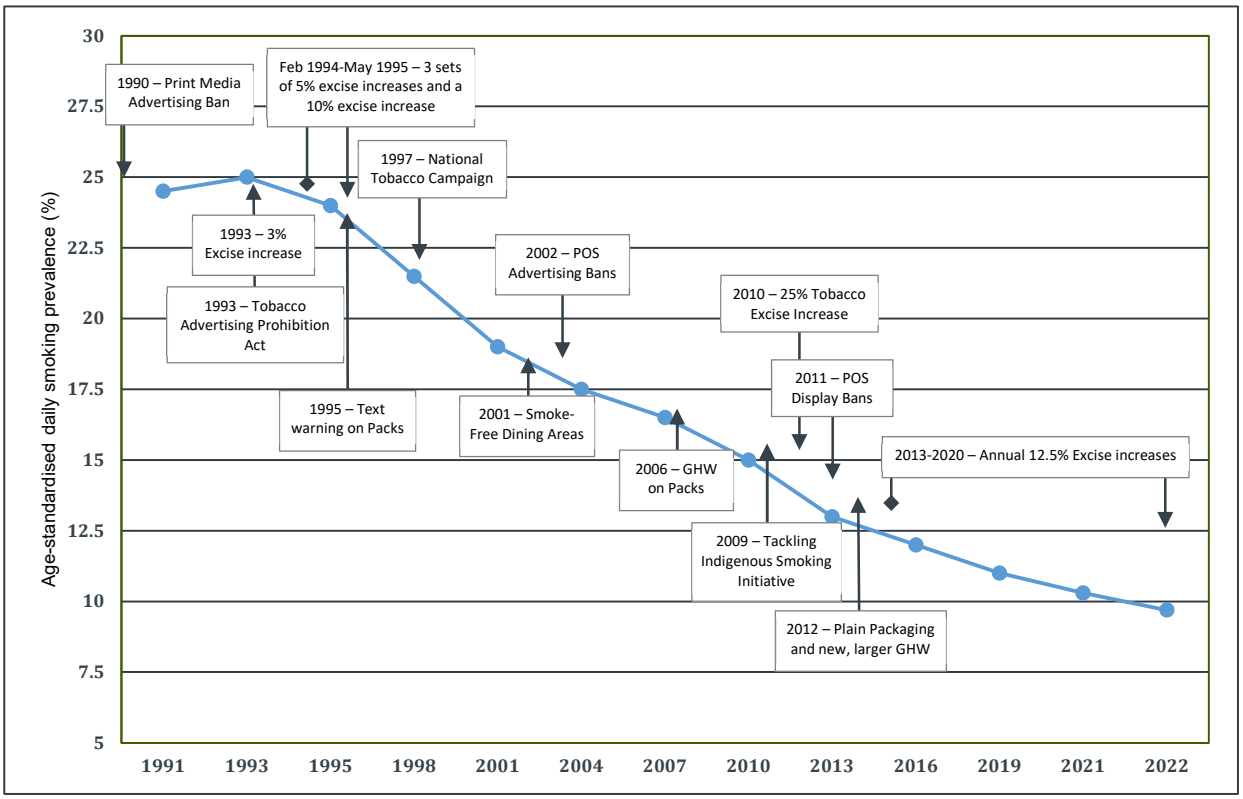
The proposed reforms outlined in this IA consider regulatory measures to to address the health risks posed by vaping and e-cigarette products by advertising and promotion of e-cigarettes. It does not consider the stronger regulation of e-cigarette availability and supply. This is being undertaken separately through the regulation of therapeutic goods and is subject to a separate Impact Analysis.

Tobacco control in Australia

Consistent with the obligations of the WHO FCTC, Australian governments at all levels have progressively implemented wide-ranging evidence-based tobacco control measures to reduce the prevalence of smoking and its associated costs. These include tobacco excise increases; education programs and campaigns; health warnings on tobacco packaging; tobacco advertising prohibitions; tobacco plain packaging; support for smoking cessation interventions; smoke-free legislation; and measures concerning illicit trade.

Australia has taken a broad approach, employing diverse tobacco control strategies to a range of tobacco products.[88] This approach has been instrumental in achieving the long-term decline in smoking prevalence in Australia. Working together, population-based strategies such as mass media campaigns, smoke-free legislation and tax increases have been shown to reduce smoking prevalence across all socio-economic groups and play a vital role in reducing smoking-related inequalities.[89 90]

Figure 2: Graph displaying daily smoking in the general population people aged 18 years and older and key tobacco control measures implemented in Australia since 1990.[91]



Current tobacco control regulatory framework

Australia's current tobacco control framework consists of a number of Acts, legislative instruments, and court undertakings at Commonwealth, state, and territory levels with the aim of reducing smoking prevalence through reducing the appeal of tobacco products and the public's exposure to smoking and tobacco products, while fulfilling its international obligations. A brief summary is provided below of the Acts, legislative instruments and court undertakings which are being considered within the Review that the Department has undertaken:

Tobacco Plain Packaging Act 2011 and Regulations

The TPP Act sets out requirements for the packaging and appearance of tobacco products. It aims to improve public health by discouraging smoking, encouraging cessation, and reducing people's exposure to SHS. It achieves this by:

- reducing the appeal of tobacco products to consumers
- increasing the effectiveness of health warnings on the retail packaging of tobacco products
- reducing the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products.

The TPP Act also aims to give effect to certain obligations Australia has as a Party to the WHO FCTC. For further discussion see Box 1. Tobacco control enforcement tools and activities development.

Tobacco Advertising Prohibition Act 1992 and *Regulation*

The objective of the TAP Act and its Regulation is to improve public health by limiting the exposure of the public to messages and images that may persuade them to start, continue smoking, or continue using tobacco products. A further discussion about the TAP Act and Regulations is provided in Box 1.

Tobacco control enforcement tools and activities development.

Court enforceable undertakings between British America Tobacco Australia; Phillip Morris Limited; and Imperial Tobacco and the ACCC

In 2005, the Australian Competition and Consumer Commission (ACCC) obtained court enforceable undertakings from BATA, Philip Morris Limited, and Imperial Tobacco (Imperial). The Undertakings related to certain descriptors which represented to consumers that certain products were in some way less harmful than others and that there were health benefits in smoking those brands. Such health claims were likely to have breached the Australian Consumer Law relating to misleading and deceptive conduct. The undertakings only apply to products manufactured by BATA, Imperial, and Philip Morris.

Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008

In 2008, the Fire Risk Regulations were made setting out a safety standard for manufactured cigarettes to reduce the risk of death or injury caused by fires which result when smouldering cigarettes inadvertently come into contact with flammable materials. Through the Treasury portfolio, the ACCC currently has policy, compliance, and enforcement responsibility for the Fire Risk Regulations.

Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods

On 4 June 1991, the then Minister of State for Justice and Consumer Affairs declared a permanent ban on chewing tobacco and snuffs intended for oral use, due to the evidence that show the link between smokeless tobacco and a variety of diseases including pancreatic cancer, oral cancer, pharyngeal cancer, and local lesions in the mouth. The ACCC within the Treasury portfolio, currently has policy, compliance, and enforcement responsibility for the Oral Tobacco Ban.

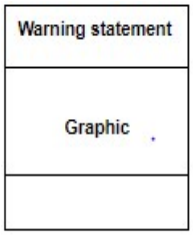
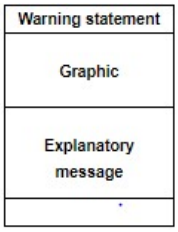
Competition and Consumer (Tobacco) Information Standard 2011

Health warnings are an important and effective component of Australia's tobacco control measures. Australian evidence shows that standardised tobacco product packaging and health warnings have reduced the appeal of smoking among young people and increased demand for cessation support.[92 93] Health warnings have also been shown to reduce smoking prevalence,[94] reduce tobacco consumption and increase quit attempts.[95 96]

The Information Standard provides the requirements of warning statements, explanatory messages, graphics, and information messages relating to tobacco products, to increase consumer knowledge of health effects and ensure the continued effectiveness of health warnings to encourage cessation and discourage uptake or relapse. As illustrated below, it requires the packaging of tobacco products to carry prescribed health warnings that comprise graphic health images, warning messages, explanatory messages, and information messages. Currently, there are 14 health warnings for cigarettes and RYO packaging and five for cigars. As per the Standard health warnings for tobacco alternate in two sets of seven warnings every 12 months.

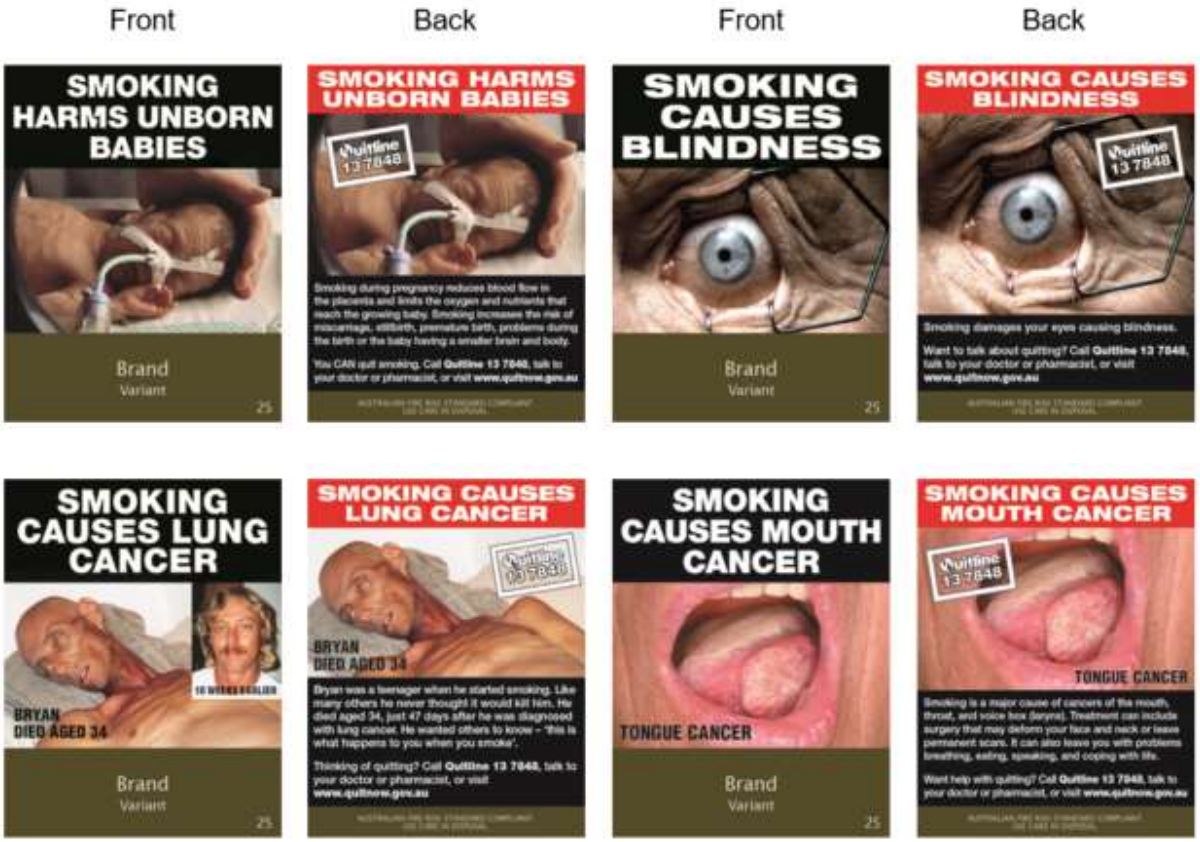
The Treasury portfolio administers the Information Standard, and it is enforced by the ACCC. The Department retains policy responsibility for tobacco health warnings and for their periodic updates to ensure that they remain effective.

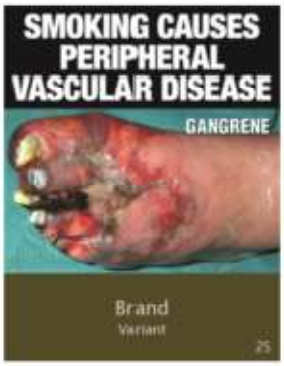
Figure 3: Information Standard Requirements for Health Warnings

	
Front outer surface of pack	Back outer surface of pack
	
Side of pack	Logo to be displayed on back outer surface

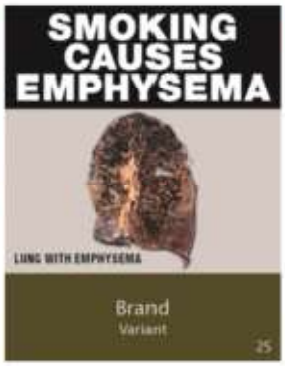
Source: *Competition and Consumer (Tobacco) Information Standard 2011* (Cth) s 1.4. Available at: https://www.legislation.gov.au/Details/F2013C00598.

Figure 4: Current Suite of Health Warnings for cigarettes and loose tobacco




SMOKING CAUSES PERIPHERAL VASCULAR DISEASE
GANGRENE
Brand
Variant
25


SMOKING CAUSES PERIPHERAL VASCULAR DISEASE
Quitline 13 7848
GANGRENE
Smoking narrows and blocks your blood vessels, reducing blood and oxygen supply to your extremities (feet, legs, hands, arms). Over time this can result in pain, open sores that don't heal and gangrene. Gangrene leads to amputation.
Want advice on quitting? Call Quitline 13 7848, talk to your doctor or pharmacist, or visit www.quitnow.gov.au


SMOKING CAUSES EMPHYSEMA
LUNG WITH EMPHYSEMA
Brand
Variant
25


SMOKING CAUSES EMPHYSEMA
Quitline 13 7848
LUNG WITH EMPHYSEMA
Smoking causes most cases of emphysema. Emphysema is the slow and permanent destruction of the airsace in your lungs. Over time it becomes harder and harder to breathe. "You slowly start to die from lack of air.
Want help with quitting? Call Quitline 13 7848, talk to your doctor or pharmacist, or visit www.quitnow.gov.au


QUITTING WILL IMPROVE YOUR HEALTH
Brand
Variant
25


QUITTING WILL IMPROVE YOUR HEALTH
Quitline 13 7848
Long term smokers can and do quit. Quitting smoking at any age has immediate and long term health benefits. Compared with a smoker, quitting today will halve your risk of:
• heart disease (after one year);
• mouth and throat cancer (after five years); and
• lung cancer (after ten years).
Thinking of quitting? Call Quitline 13 7848, talk to your doctor or pharmacist, or visit www.quitnow.gov.au


SMOKING DAMAGES YOUR GUMS AND TEETH
MALE SMOKER AGED 50
Brand
Variant
25


SMOKING DAMAGES YOUR GUMS AND TEETH
FEMALE SMOKER AGED 45
Quitline 13 7848
Smoking causes inflammation of the gum and other tissue around your teeth (periodontitis). Symptoms can include gum redness, swelling, bleeding, infection and pain. The gum, bones and other tissue supporting your teeth can be destroyed resulting in tooth loss.
Want to talk about quitting? Call Quitline 13 7848, talk to your doctor or pharmacist, or visit www.quitnow.gov.au

Figure 5: Side of pack information message example

Information messages appearing on the side of the pack are unique to each combination of warnings.

Figure 6: Current Suite of Health Warnings for cigars

Box 1. Tobacco control enforcement tools and activities

Tobacco Plain Packaging

The Department is responsible for administering and ensuring compliance with the TPP Act and TPP Regulations. Inspections and other initial field work including information visits are undertaken by the National Measurement Institute (NMI), a division of the Department of Industry, Science, and Resources. The NMI also conducts information visits to tobacco retailers to provide guidance and promote compliance with the legislation.

Compliance with the TPP Act and TPP Regulations is generally high amongst regulated, excise-paid products. However, compliance with the 'tobacco product requirements' of the TPP Act is much lower in black-market products. Where non-compliance has been detected initially, the majority of suppliers have been found to be compliant upon reinspection. Self-reporting of non-compliance and voluntary removal of non-compliant product from the market also occurs. Most outcomes in tobacco plain packaging matters include providing education and issuing notices of alleged non-compliance and warning letters.

The TPP Act triggers powers set out in the *Regulatory Powers (Standard Provisions) Act 2014* (Cth) (RP Act), which empower Authorised Officers to monitor and investigate compliance with the TPP Act. Authorised Officers are empowered to, for example, enter and search premises with consent or under warrant, ask questions and seek production of documents. Authorised Officers have monitoring and investigative powers under the TPP Act to take, test and analyse samples, and to use reasonable and necessary force in executing a warrant under the RP Act.

Without an investigative or monitoring warrant, Authorised Officers must seek the consent of the operator of the premises to conduct an inspection. In obtaining consent, the Authorised Officer must inform the operator of the premises that they have the right to refuse, limit or withdraw consent at any time.

In accordance with requirements of point-of-sale legislation administered by states and territories, tobacco products are kept out of sight of customers. Additionally, retailers are often wary of individuals viewing or handling tobacco products due to their high-cost value and will often secure or conceal tobacco products. This can present challenges for Authorised Officers in obtaining consent to exercise their powers under the RP Act to monitor compliance with the TPP Act. Enforcement options include infringement notices, enforceable undertakings, civil and criminal prosecution. The maximum penalty for a fault-based criminal offence under the TPP Act is 2,000 penalty units (as of 1 July 2023, $626,000) for individuals, or 10,000 penalty units ($3.13 million) for a body corporate.

Tobacco Advertising Prohibition

The Department is responsible for administering and ensuring compliance with the TAP Act and TAP Regulation. The TAP Act triggers a range of monitoring and investigation powers set out in the RP Act. These include powers for Authorised Officers to enter and search premises with consent or under warrant, ask questions and seek production of documents.

Enforcement options include seeking prosecution where, as of 1 July 2023, the maximum penalty for a fault-based criminal offence under the TAP Act is 120 penalty units (as of 1 July 2023, $37,560) for an individual and 600 penalty units (as of 1 July 2023, $187,800) for a corporation. Infringement notices and civil penalties are not provided for under the TAP Act.

Compliance with the TAP Act and TAP Regulation is generally very high. In September 2022, the former Minister for Health declared there had been no contraventions of the TAP Act during the 2021 year.[97]

Where noncompliance is detected, it is usually of a technical nature, rather than overt or deliberate circumvention of the relevant legislation. The Department writes to respondents to inform them of the complaint being received, with the majority of respondents becoming compliant once they are made aware of the potential contravention and, where applicable, their corporate social responsibilities. In the case of serious contraventions, the Department is reliant on prosecution as its primary enforcement tool for alleged contraventions of the TAP Act. This creates barriers to enforcement, since prosecution is often untimely, costly, and sometimes not fit for purpose for the alleged breach of the law.

What is the policy problem that you are trying to solve?

The use of tobacco products, and other novel and emerging smoking products in Australia creates health, social and economic costs. The use of e-cigarettes is regulated by the Therapeutic Goods Administration under the *Therapeutic Goods Act 1989* and therefore is not a focus of the Review or this IA, however their use is addressed in relation to advertising as evidence suggests e-cigarette advertising is a gateway for tobacco use. There is evidence that e-cigarette marketing through social media may increase the risk of e-cigarette uptake/initiation among young people. There is also evidence that e-cigarette use is a strong predictor of future tobacco use, particularly among people.[98] [99] [100]

Reducing the prevalence of tobacco use and its associated health, social, and economic costs and the inequalities it causes

As tobacco use continues to cause enormous health, social and economic costs to the Australian community, the Australian Government is committed to reducing the prevalence of tobacco use and its associated costs. The National Tobacco Strategy 2023-2030 (NTS) and National Preventive Health Strategy (NPHS) 2021-2030 include the following targets in respect to tobacco control:

- achieve a national daily smoking prevalence of less than 10 per cent by 2025 and 5 per cent or less for adults (≥18 years) by 2030
- reduce the daily smoking rate among First Nations peoples (≥15 years) to 27 per cent or less by 2030.

These targets broadly align with the WHO FCTC, WHO Global Noncommunicable Disease (NCD) targets for 2025 and United Nations (UN) Sustainable Development Goal Targets. The NTS, which complements the NPHS, sets out a national policy framework for Commonwealth, state and territory governments, and non-government organisations to work together to reduce tobacco use and its associated health, social, environmental, and economic costs, and the inequalities it causes.

The policy problems outlined in this IA are also addressed as part of the broader framework in the NTS. The objectives in the NTS are to:

- prevent uptake of tobacco use
- prevent uptake of e-cigarettes by young people and those who have never smoked
- prevent and reduce nicotine addiction
- denormalise and limit the marketing and use of e-cigarettes.
- encourage and assist as many people as possible who use tobacco to quit as soon as possible, and prevent relapse
- prevent and reduce tobacco use among First Nations peoples
- prevent and reduce tobacco use among groups at higher risk from tobacco use, and other populations with a high prevalence of tobacco use
- eliminate harmful exposure to tobacco smoke
- prevent and reduce harms associated with the marketing and use of novel and emerging products
- ensure that tobacco control in Australia is guided by focussed research, monitoring, and evaluation
- protect tobacco control policy from all commercial and other vested interests
- ensure all of the above contributes to the continued denormalisation of the tobacco industry and tobacco use.[101]

Despite progress being made to reduce tobacco use in Australia, additional tobacco control measures are necessary in order to achieve the national targets, and the objectives outlined in the NTS. The tobacco environment continues to change with novel and emerging products, and the approach to tobacco control needs to be updated to reflect this.

Without a continued comprehensive and multi-faceted approach to tobacco control, Australia's national tobacco control targets are unlikely to be achieved.[102] In 2020–21, one in twelve (8.3 per cent) people aged 18-24 years smoked daily, and this increased with age until 55-64 years where the rate peaked at 13.7 per cent.[103] In 2019, 11 per cent of Australians smoked daily, which was down from 12.2 per cent in 2016.[104]

In 2020-21, the ABS (Australian Bureau of Statistics) National Health Survey indicated that 2.1 million people aged 18 years and over were likely smoking daily (one in ten or 10.7 per cent of people aged 18 years and over).[105] To achieve the Government's aim of a national daily smoking prevalence of less than 10 per cent by 2025 and 5 per cent or less for adults (18 years and over) by 2030, would require a 7 per cent reduction in the number of people smoking daily (approximately 137,500 people) in Australia in the next two years, and a 53 per cent reduction in the next eight years (approximately 1.1 million people).

Translating the 2019 calculations of the National Drug Research Institute into 2021 prices would imply that a 137,500 reduction in the number of people smoking, in order to achieve the 10 per cent target would reduce the annual social cost of smoking to Australia by $8.4 billion.[106] Reducing the number of people who smoke by 1.1 million to achieve the 5 per cent target would represent a $67.3 billion reduction in the annual social cost of smoking.

Australia has made sound progress in reducing smoking uptake among youth; however, more can be done to prevent initiation and reduce uptake. In 2017, 1 in 20 Australian secondary students (around 79,000) were currently smoking, fewer than in 2011, and 82 per cent had never smoked.[107] Yet 13 per cent had tried e-cigarettes, and some of these students went on to try cigarettes and became current smokers.[108] RYO tobacco is becoming increasingly popular among Australian secondary students, with 29 per cent of students surveyed who had smoked in the past month in 2017 using RYO 20 or more times, compared to 24 per cent in 2014.[109] Greater focus also needs to be placed on reducing smoking prevalence amongst First Nations peoples. However, challenges to achieving this are multi-faceted and in many cases, can be location specific. For instance, in remote areas, issues can relate to underlying social determinants such as financial stress, unemployment, low education, and overcrowding.[110] In comparison to non-remote areas, tobacco control measures including smoke-free areas, media campaigns, and smoking cessation support services may also be less prevalent in remote areas. In many First Nations people's communities, strong social norms reinforce high smoking prevalence among First Nations peoples.

There has also been progress in reducing smoking rates among First Nations peoples. The combination of population level tobacco control measures and more targeted approaches that have been implemented by all Australian governments have made a strong contribution to reducing tobacco use among First Nations peoples in recent years, particularly among younger age groups and those living in non-remote settings.[111] For example, the prevalence of daily smoking among First Nations peoples aged 15 years and over decreased from 41 per cent in 2012-13 to 37.4 per cent in 2018-19. In the same period the prevalence of daily smoking among First Nations peoples 18-24 years old declined from 42.4 per cent to 35.8 per cent. In 2018-19, 51.4 per cent of First Nations people who smoke aged 15 years and over had tried to quit smoking in the previous 12 months.[112] Findings from an analysis conducted by the Australian Bureau of Statistics in 2017 also showed that specific funding for First Nations peoples tobacco control since 2008 has contributed to the decline in smoking rates among First Nations peoples.[113] In the context of Australia's approach to tobacco control, continuation of targeted investments to support culturally safe and locally relevant approaches will continue to be important for further reduced smoking prevalence among First Nations peoples.

Tobacco use also impacts related stakeholders. These include population groups that are at a higher risk of harm from tobacco use (for example pregnant women and people living with a chronic health condition) and populations with a high prevalence of tobacco use (for example people living in disadvantaged socioeconomic areas). They also include people experiencing mental illness. Smoking is associated with an increased risk of a range of mental illnesses including psychosis, schizophrenia,

anxiety, depression and bipolar disorder. In 2019, people with mental health conditions were twice as likely to smoke daily as people who had not been diagnosed or treated for mental health conditions (20% compared with 9.9%).[114] People who smoke are more likely to experience social isolation and loneliness, and cutting down smoking is associated with a reduction in suicidality and depression. People with mental illness also experience a disproportionate health and financial burden from smoking.[115] Measures to reduce smoking prevalence within these population groups will help reduce the likelihood of these negative health, social, and economic outcomes for people experiencing mental illness.

Other impacts

The impacts of a reduction in tobacco consumption affect not only smokers, but their families and broader communities. Reduced rates of smoking can be expected to lead to a range of community impacts, including significantly reduced exposure to second-hand smoke and reduced waste.

Waste from cigarette butts represent an ongoing environmental challenge for Australia. Cigarette butts were identified as the most littered object in Australia in the National Plastics Plan 2021.[116] It is estimated that about one-third of cigarettes sold each year in Australia are littered. Littered cigarette butts contain plastic and chemical residues, including from pesticides, nicotine and heavy metals (leachates), which can contaminate soil and water and can lead to bioaccumulation in the food chain. The cost of tobacco-related litter removal in Australia has been estimated at around $73 million per year.[117] Measures to reduce tobacco use will deliver environmental and economic benefits related to waste reduction.

Addressing inefficiencies and limitations of existing tobacco control regulatory framework and reducing regulatory burden

The Review has identified a number of areas where there are opportunities to modernise, simplify and streamline the current regulatory framework for tobacco control through updating and repealing redundant aspects, and consolidating related legislation.

Tobacco advertising prohibitions

Based on a comprehensive review of scientific evidence, the 2012 US Surgeon General's report concluded that advertising and promotional activities undertaken by tobacco companies have been shown to cause the onset and continuation of smoking among youth. The report also refers to evidence which '*consistently and coherently points to the intentional marketing of tobacco products to youth as being a cause of young people's tobacco use'.*[118]

Tobacco advertising is a powerful influence that increases the use of tobacco products, particularly by children and young people. Comprehensive advertising bans are an effective means to reduce the prevalence and initiation of smoking.[119] Partial advertising bans only have a minimal effect as companies transfer expenditure to media platforms where advertising is still allowed.[120] [121] This illustrates the need to maintain a comprehensive advertising ban in Australia, which includes new media platforms and other forms of promotion. It is also important that all provisions can be appropriately enforced to limit the public's exposure to such advertising and promotion, including through sponsorship acknowledgments.

To ensure that the TAP Act remains fit-for-purpose and current there is a need to modernise. The TAP Act was introduced in 1992 and amended in 2012 to extend the restrictions on tobacco advertising to the internet and other electronic media.

The Review identified that there are some inefficiencies within the TAP Act that require improvement to fully meet its objectives to limit the exposure of the public to messages and images that may persuade them to start or continue to smoke or use tobacco products. This includes strengthening the ability of the Department to monitor compliance with the TAP Act and to investigate possible breaches.

Authorised Officers would be better able to monitor compliance with the law and investigate potential violations if they also had the power to purchase material, to take, test and analyse samples, and to enter premises for compliance purposes and use reasonable force without a warrant or consent.

Additionally, the TAP Act is modelled on a criminal based enforcement scheme. Current enforcement options include seeking prosecution where, as of 1 July 2023, the maximum penalty for a fault-based criminal offence under the TAP Act is $37,560 for an individual and $187,800 for a corporation. The reliance on prosecution as a primary enforcement tool governed by the legislation reduces the ability of the Department to tailor its enforcement action to the potential or actual harm of the alleged breach of the TAP Act in instances where educative measures are insufficient.

Broader sanctions and remedies, including infringement notices, disposal of seized goods, and recall of products, would reduce reliance on prosecution and make it easier for the Department to deliver a risk-based and proportionate enforcement response to non-compliance and for businesses involved in the tobacco supply chain to know and understand their rights and responsibilities, and more readily comply with the law.

The Review found some provisions need to be either updated or repealed and definitions amended to reflect current products and advertising strategies within the market. For example, the TAP Act does not apply to new or novel smoking products that do not contain tobacco, such as e-cigarettes, or nicotine pouches. This is problematic as these products can closely resemble more traditional tobacco products. The distinction between a product that contains tobacco product (currently captured under TAP Act) and a product with nicotine only (not currently captured under TAP Act) is difficult to determine.

There are also concerns about direct health harms associated with e-cigarette use, concurrent use of e-cigarettes and tobacco products and the potential for their use to further contribute to nicotine addiction and/or tobacco use, particularly among youth.[122] [123] [124] There is now strong and consistent evidence showing that e-cigarettes are a gateway to tobacco use for youth and young adults, including for those who would otherwise be unlikely to take up conventional smoking.[125] [126] Recent Victorian research has shown that the prevalence of use of e-cigarettes has significantly increased among the Victorian adult population from 2018-19 to 2022.[127] Ever-use increased from 17 per cent to 22 per cent, current use doubled from 3 per cent to 6.1 per cent and regular use more than doubled from 1.6 per cent to 3.5 per cent.[128]

There is also growing evidence that e-cigarette products with and without nicotine pose a range of harms to human health. Evidence from observational and experimental studies has implicated the use of e-cigarettes in various harms to the heart and lungs.[129] Known carcinogens have also been found in e-cigarette aerosols, although the extent to which e-cigarette use increases the risk of cancer remains unknown.[130]

Strategies undertaken by industries marketing these products have the potential to undermine Australia's achievements to date in tobacco control and public health. Currently, the Department monitors tobacco advertising and promotion through its compliance regime. However, it has limited ability to detect and monitor novel advertising approaches or identify trends in marketing expenditure, which seek to undermine the existing tobacco control framework. This impedes the potential effectiveness of tobacco advertising prohibitions.

Tobacco Plain Packaging

The implementation of Australia's plain packaging and enhanced graphic health warnings (GHWs) in 2012 (plain packaging measure) was ground-breaking, and its impact has been significant in reducing smoking prevalence and passive smoking in Australia.[131] It also has a positive impact on reducing the appeal of tobacco products, reducing the potential for tobacco packaging to mislead consumers, and enhancing the effectiveness of GHWs.

Twenty-five international jurisdictions have since passed plain packaging laws and have built on Australia's approach, with Armenia being the latest country to require plain packaging for tobacco products from 1 January 2024.[132]

While the TPP Act and Regulations have been effective and efficient, they have not kept pace with challenges in the evolving operating environment, and they would benefit from updates and amendments. The current powers do not allow the Department to seek injunctions or enforceable undertakings for alleged contraventions of the TPP Act. Further, the powers do not enable Authorised Officers to seek monitoring warrants for the purpose of determining the requirements of the TPP Act are being complied with. They also do not effectively limit the ability of tobacco products to evoke associations and mislead consumers as to perceived value.

Tobacco Health Warnings

With an ever-growing body of evidence on the harmful effects of tobacco use on the human body, it is incumbent on government to ensure its citizens are aware of the health consequences of smoking. Article 11 of the WHO FCTC creates an obligation on Parties to use national law to mandate measures that ensure tobacco packages carry warnings that describe the harmful effects of tobacco use. Globally, tobacco GHWs have been implemented in more than 134 jurisdictions.[133]

Australia's current health warnings were last updated in 2012. New scientific research has emerged on the effects of tobacco use on health.[134] Consistent with WHO FCTC, it is important that health warnings are updated to reflect this evidence in order to adequately inform Australians of what is currently known about the health consequences of smoking. Detailed recommendations are outlined in Option 2.

The Information Standard does not currently address or incorporate several elements recommended in the *Guidelines for Implementation of Article 11*. For example, the Guidelines recommend greater coverage of product-specific warnings (requiring warnings focusing on the specific health effects related to each product) and health warnings that contain information on the addictive nature of tobacco, adverse economic and social outcomes, impact of tobacco use on significant others and provide advice on cessation.[135]

Additionally, the impact of health warnings wear out over time and changes are needed to maintain importance, enhance impact, and effectiveness.[136] [137] Evidence shows that health warnings on tobacco packaging tend to wear-out quickly.[138] [139] This is not due to diminishing effectiveness of content, but rather because of decreased attention.[140] Eye tracking studies suggest that people who smoke frequently eventually stop attending to messages.[141] [142] Even pictorial health warnings tend to start to lose effectiveness within two years.[143] As highlighted in the 2018 market research evaluation of GHWs, commissioned by the Department, there is a need to address the current wear-out and consider how to pre-empt wear-out for future health warnings.

There is also an opportunity to extend health warnings from the packaging to the product itself in order to better communicate health warnings to consumers and reduce smoking prevalence. Table 1 below outlines the awareness of Australian adults of health conditions caused by smoking.

There is clear evidence supporting changes to health warnings to adequately and effectively inform consumers of the current and extensive health effects of tobacco use, maintain importance and enhance impact and effectiveness. Despite this, the current regulatory framework does not facilitate timely updates and requires a lengthy process to affect legislative change.

Under the current regulatory framework, there is a potential misalignment between policy design and enforcement, and potential duplication in enforcement activities. This is due to the split in responsibilities between the Australian Competition and Consumer Commission (ACCC) and the Department. The ACCC currently has responsibility for enforcement of the health warnings, while the Department uses enforcement powers under the TPP Act to encourage, educate and inform tobacco suppliers of their obligations in respect to tobacco control, and undertake site inspections to ensure that compliance is met when selling stock and displaying health warnings. This regulatory oversight is potentially duplicative, creating unnecessarily high administrative costs for government.

Table 1: Awareness of Australian adult's health conditions caused by smoking

Awareness of Australian adults of health conditions caused by smoking: number who responded 'very likely' or 'likely' for each condition

		Smoking status*		
	Total	**People who never smoked**	**People who quit smoking**	**People who smoke**
Number of respondents	1806	958	471	363
Lung cancer	1646 (91.2%)	897 (93.6%)	432 (91.8%)	304 (83.9%)
Throat cancer	1615 (89.4%)	885 (92.4%)	423 (90.4%)	295 (81.4%)
Mouth cancer	1586 (87.8%)	870 (90.8%)	419 (88.9%)	286 (78.8%)
Disease of the teeth and gums	1574 (87.1%)	862 (90.0%)	411 (87.2%)	291 (80.2%)
Heart disease	1549 (85.8%)	834 (87.0%)	418 (88.8%)	288 (79.3%)
Emphysema	1546 (85.6%)	820 (85.7%)	421 (89.5%)	294 (81.0%)
Stroke	1490 (82.5%)	799 (83.5%)	411 (87.4%)	271 (74.7%)
Oesophageal cancer	1391 (77.0%)	778 (81.2%)	365 (77.5%)	243 (66.9%)
Poor outcomes after surgery	1341 (74.3%)	769 (80.3%)	359 (76.2%)	207 (57.0%)
Peripheral vascular disease	1162 (64.4%)	626 (65.3%)	330 (70.1%)	202 (55.6%)
Stomach cancer	1021 (56.5%)	577 (60.2%)	271 (57.6%)	167 (46.2%)
Pancreatic cancer	921 (51.0%)	529 (55.2%)	222 (47.1%)	164 (45.3%)
Liver cancer	912 (50.5%)	535 (55.8%)	226 (47.9%)	146 (40.1%)
Infertility in women†	899 (49.8%)	548 (57.3%)	212 (45.0%)	135 (37.2%)
Kidney cancer	864 (47.8%)	478 (49.9%)	229 (48.5%)	151 (41.6%)
Peptic ulcer	859 (47.6%)	489 (51.0%)	222 (47.0%)	143 (39.4%)
Erectile dysfunction†	808 (44.7%)	494 (51.6%)	189 (40.2%)	120 (33.1%)
Blindness	786 (43.5%)	395 (41.3%)	229 (48.6%)	159 (44.0%)
Bladder cancer	750 (41.5%)	404 (42-32.2%)	192 (40.8%)	151 (41.6%)
Diabetes	726 (40.2%)	412 (43.0%)	192 (40.8%)	118 (32.4%)
Ectopic pregnancy†	655 (36.3%)	402 (43.0%)	140 (29.7%)	101 (27.7%)
Acute leukaemia	562 (31.1%)	326 (34.1%)	141 (29.9%)	93 (25.6%)
Rheumatoid arthritis	489 (27.1%)	290 (30.2%)	109 (23.2%)	88 (24.2%)

* People who never smoked have not smoked 100 cigarettes in their lifetime, people who quit have smoked 100 cigarettes but do not currently smoke, and people who smoke said that they currently smoked daily, weekly, or less than weekly. Smoking status was missing for 15 participants. † Respondents were asked, 'How likely do you think it is that smoking increases the risk of _ _ _ ?' Bold: Harms featured on graphic health warnings in Australia in the 5 years before the survey; in September 2017, any of 14 designated health warnings could be displayed on cigarette packs. All raw numbers are weighted as described in the text.

Source of table: E Brennan, K Dunstone and M Wakefield, 'Population awareness of tobacco-related harms: implications for refreshing health warnings in Australia' (2018) *Medical Journal of Australia* 209(4):173-174.

Impact of positive reinforcement on smoking cessation

While health warnings are effective in increasing consumer knowledge of health effects relating to smoking, encouraging cessation and to discouraging uptake or relapse, there is scope to further strengthen the effectiveness of Australia's health warnings via the introduction of complementary messaging in tobacco packaging that encourages and empowers people who smoke to quit. Current health warnings create strong fear appeals and are effective at increasing cessation intentions, but have minimal impact on cessation knowledge and do not build self-efficacy for cessation.[144] This is problematic as the greatest behavioural change occurs when strong fear appeals are combined with high response efficacy messages (for example, quitting smoking averts a problem caused by smoking) and self-efficacy messages (for example, the belief that one is capable of quitting).[145] In contrast, strong fear appeals with low-efficacy messages produce the greatest levels of defensive responses (for example, the belief that a health risk is not real or only applies to others).

There is an effective and untapped opportunity to better utilise tobacco packaging to increase and enhance cessation activity through the inclusion of Health Promotion Inserts (HPIs). HPIs are small information cards included in tobacco product packets, which include messages highlighting the benefits of quitting and promote effective cessation resources and strategies. Evidence indicates that self-efficacy is critical to cessation activity;[146] and people who smoke are often unaware of how best to quit and the many sources available to help.[147]

Opportunities to strengthen the tobacco control regulatory framework to reduce impact on public health

Australia's plain packaging measure has made it harder for the tobacco industry to promote its products to consumers via packaging and branding design features. However, the tobacco industry responds to policy and regulatory changes by continually adapting product design and packaging. From a tobacco control perspective, the tobacco industry, uses product design and development as one of a number of strategies to encourage product sales and recruit new customers.

In recent years, the tobacco industry has found new and innovative ways to increase product appeal.[148] For example, there has been a proliferation of new cigarette pack and RYO pouch sizes (units/grams per pack), allowing greater product variety.[149] New product design features have also emerged, such as flavour capsules and filter innovations, which increase appeal and reduce harm perceptions, particularly for youth.[150] In addition, brand and variant names have become more evocative and descriptive, as a means to increase appeal, reduce harm perceptions and convey previous pack imagery.[151] [152]

Box 2. Tobacco product development

Product design features provide a means of product differentiation and allow the tobacco industry to enhance the appeal of its products to different market segments. Recent novelty features and innovations include:

- flavour capsules or 'crush balls' – a flavour or substance is added to the product when crushed or squeezed by the fingers
- recessed filters – a hollow tube at the mouth end
- firm filters – have the same appearance as regular filters but are much denser
- filters with visible designs.

These designs are particularly popular among young people, with a growing body of evidence suggesting that the attractiveness and appeal of cigarettes is strongly associated with physical characteristics and design features. The flavour and interactivity of 'crush balls' appeal to young people, encouraging uptake and experimentation. Meanwhile, filter innovations can create

positive associations, such as improved physical appearance and quality, effecting young people's perceptions of harm.

There is international precedent among other jurisdictions for regulation of product design features.

The Review identified areas where international jurisdictions have taken further steps to strengthen their regulatory frameworks in line with best available evidence. These steps counter tobacco industry initiatives to increase the attractiveness and palatability of their products that are not currently covered by Australia's regulatory framework.

Tobacco product sizes

In recent years, Australia has experienced a proliferation of new cigarette pack sizes and RYO pouch sizes. This allows greater product differentiation based on price and is a means to increase appeal to different market segments. In addition, cigarettes are often sold as part of multi-packs and cartons.

Larger cigarette pack size is associated with higher tobacco use which is negatively associated with smoking cessation.[153] Evidence from tobacco companies also supports a causal link between cigarette pack size and use, with larger sizes leading to increased tobacco use.[154] However, below a certain size, smaller and therefore cheaper packs, which are more easily affordable and also able to be concealed from parents and caregivers, can lower barriers to tobacco initiation and use by youth.[155] International jurisdictions, including Canada, New Zealand, Norway, Russia and Georgia have legislated to standardise the cigarette pack size to 20 or 25 cigarettes.

Whilst there is a minimum pack size of 20 cigarettes in Australia, odd pack sizes have emerged in recent years, making it more difficult for consumers to work out the price per stick at the retail counter. Some products appear to provide bonus cigarettes, for example by offering 21s and 22s for a similar price to the standard 20s pack. Some offer a '+1' range to overtly promote the bonus cigarette.

Growth in the use of RYO has been marked among youth and young adults and small pouch sizes are contributing to affordability for youth.[156] [157] Pouches as small as 10 grams are available at some retail outlets, at a cost of around $12. In 2019, 45 per cent of people who smoke used RYO, up from 36 per cent in 2016. One-third (33 per cent) of people who smoked used RYO along with cigarettes (up from 26 per cent in 2016), and 13.9 per cent used RYO only (up from 10.7 per cent in 2016). In international jurisdictions, including New Zealand, United Kingdom, France, Ireland, and Norway, RYO pouch weight is required to be a minimum of 30 grams.

Little cigars and cigarillos are currently sold in a variety of pack sizes in Australia, including in small pack sizes of 1, 3 and 5. These small packs sizes are problematic as they provide young users with a product that closely resembles the look and smoking experience of a cigarette at a low-price point for young users. For example, a single cigarillo can retail for as little as $2 in Australia.[158] Research in the United States and Canada indicates that the low cost of cigar products (due to availability in small package quantities) is a significant factor in their appeal for youth and young adults.[159] [160] Available data indicates a slow rise in usage of these products among Australian youth.[161] New Zealand has legislated that packs of little cigars or cigarillos are required to be sold with a minimum of 20 little cigars or cigarillos.

Cigarette stick size

Cigarette sticks are available in a range of sizes in Australia, with varying lengths and diameter. The sizes appeal to different market segments and convey different attributes to users in respect of appeal, taste, and harm.[162] Slim cigarettes are particularly problematic as they are perceived by young people who smoke and people who have never smoked as most appealing and least harmful.[163] [164]

There are currently no specific regulations in Australia relating to cigarette size. Cigarette packet dimensions are regulated and indirectly set the maximum length of cigarettes to fit in a pack of maximum length of 125mm.[165]

Figure 7: Example of super slim, extra-long, regular, and slim branded cigarettes available in Australia (listed top to bottom)

Box 3. Young Australians and tobacco marketing

Australia's tobacco control policies aim to reduce smoking and its associated harms by i) preventing the uptake of new smoking (particularly young people); and ii) encouraging and supporting cessation. Australia implements a suite of comprehensive measures to achieve this aim, including tobacco excise increases; smoke-free legislation; education programs and campaigns; health warnings on tobacco packaging; tobacco advertising prohibitions; tobacco plain packaging; and support for smoking cessation interventions; Conversely, the tobacco industry aims to continually recruit people to take up smoking and adapts to tobacco control policies through innovation in product design and marketing appeal. Many of these strategies are specifically targeted at young people, impacting youth beliefs about, or perceptions of harm.

Commonly held misperceptions that some tobacco products are safer than others include:

- RYO tobacco is natural and therefore safer than cigarettes
- slim cigarettes are safer than regular cigarettes
- cigarette brands and variants with certain colour descriptors or terms such a 'smooth' are safer.

Tobacco excise and pricing is the most effective tobacco control policy in minimising uptake and encouraging smoking cessation.[166] Following the introduction of plain packaging and the imposition of a 25 per cent increase in tobacco tax in late April 2010, Australia experienced a proliferation of new cigarette pack sizes and RYO pouch sizes. This has significantly increased the tobacco industry's ability to engage in price related promotion and differentiate its products. Product differentiation is a way of increasing sales through effectively targeting specific consumer groups.

Examples of pack and product differentiation the tobacco industry has introduced into the Australian market, include:

- New cigarette pack sizes of 21, 22, 23 and 26 cigarettes per pack (instead of standard 20 or 25), making it difficult for consumers to compare prices per cigarette.
- Small RYO pouch sizes, with pouches as small as 10g (instead of standard 30g) available at some outlets for $12.

- Wide variation of cigar and cigarillo pack sizes (1, 3, 5, 12, 18, 20, 21 and 25), with single cigarillos purchasable for $2.

These pricing variances can make products appear more affordable or better value for money, particularly to young people and other price sensitive consumers including those on lower incomes. In conjunction with the impact of industry strategies on youth perceptions of harm, this has led to changing patterns of youth tobacco use in Australia.

There has been a marked growth in the use of RYO among young Australians,[167] [168] with 18-24 year olds who only smoke RYO cigarettes increasing from 1 in 20 (in 2010) to 1 in 5 (in 2019).[169] Additionally, in 2017, 70 per cent of past-month people who smoke aged 12-17 years had used RYO pouches at least once, with 29 per cent using them 20 times or more.[170]

Further standardisation of product sizes and regulation of variant names is therefore necessary in limiting smoking uptake, particularly among young people.

Additives increase tobacco product attractiveness and palatability

Additives are used in tobacco products to improve flavour and aroma, mask harsh and irritating characteristics, create milder and sweeter smoke, and reduce sensory irritation.[171] [172] There is a significant body of evidence indicating that additives enhance the attractiveness and palatability of tobacco products, fostering uptake and addiction, particularly among youth.[173] [174] Australian ingredient reports indicate that many additives are present in Australian cigarettes, with the vast majority identified as having a flavouring function.[175] Some additives that enhance palatability are also known to contribute to addictiveness and/or toxicity.[176] Additives are also used to attractively colour tobacco product components, and to create the impression that products have health benefits or reduced health hazards.[177]

A 2019 report by the WHO concluded that the presence of flavourings in tobacco products is associated with a greater willingness to experiment, which in turn may promote the move from experimentation to regular use.[178] A report by Purcell Consulting found that 'reviews of tobacco industry documents confirm the importance of smoothness, mildness and sweetness when designing brands to appeal to young and inexperienced [people who smoke]'.[179]

In some international markets, the tobacco industry has released accessories that are designed to impart flavour to a tobacco product. For example, flavour cards can be inserted into tobacco packaging, or flavoured filtered tips can be used with RYO tobacco. This is problematic as these products circumvent and undermine the policy intent of current additive restrictions.

There is no comprehensive regulatory framework regarding additives that enhance attractiveness and palatability in tobacco products in Australia. All states and territories in Australia, with the exception of the Northern Territory, have legislative restrictions on the sale of fruit or confectionary flavoured cigarettes. However, there are no other restrictions.

Further, there is no legal obligation on industry to report on tobacco ingredients, Australia has a Voluntary Agreement with three tobacco companies to annually disclose and report on the ingredients in cigarettes sold in the Australian market. However, the information provided under the terms of the voluntary agreement provides minimal benefit to government, tobacco control experts and the public, and concerns have been raised regarding its accuracy and utility. It is also inconsistent with the guidelines for the implementation of Article 5.3 of the WHO FCTC, which recommend that Parties reject partnerships and non-binding or non-enforceable agreements with the tobacco industry.

Multiple international jurisdictions have implemented additive restrictions, including Brazil, Canada, European Union, the United States of America and Uruguay as a means of reducing attractiveness and palatability of tobacco products.

Novel product features increase tobacco product attractiveness

The attractiveness and appeal of tobacco products is strongly associated with their physical characteristics and design features.[180] [181] Product design features, such as crush balls or capsules (which add a flavour or substance to a tobacco product when crushed by the user) and novel cigarette filters make products more attractive to people who smoke and attract new users.

Product design features provide a means of product differentiation to enhance the appeal of different products to different market segments. Product design features can meet people's interests in respect to areas such as health, glamour, novelty, self-image, weight loss, convenience/ease of use and sensory experience.[182]

There is clear evidence that crush balls and novel cigarette filters in particular increase the attractiveness of tobacco products, particularly to youth. Crush balls are particularly popular among youth due to their flavour and interactivity and capsule cigarettes may serve as a starter product. [183] [184] Some research also indicates that the use of capsule cigarettes is associated with 'misperceptions of relative harm'.[185]

Novel cigarette filters are also a popular product design feature in Australia, with new types of filters emerging (such as recessed, firm, and charcoal filters). These modifications to cigarette filters have largely arisen in response to plain packaging as a way to increase product appeal. For broader discussion about novel product design features see Box 2. Tobacco product development.

Recessed filters feature a hollow tube at the mouth end and are described by the tobacco industry as providing 'a different look' and '…creating a smoother taste and shift[ing] the staining observed on the cigarette mouth end away from the consumer.'[186] Recent Australian research suggests that recessed and firm filters falsely reassure people who smoke about the harms of smoking, and that firm filters increase appeal.[187] These perceptions undermine other regulatory efforts for tobacco control, in that they enhance appeal and consumers may feel falsely reassured by these filters, thereby reducing the urgency of quitting.[188]

Many cigarette packages now include references to filter technology. This is problematic as such references can lead to false perceptions of reduced harm, particularly for youth.[189] Importantly, research indicates that filters do not appear to have a beneficial effect on mortality rates arising from smoking and may contribute to other detrimental health impacts.[190] Some packages also refer to crush balls and may contribute to false perceptions of reduced harm.

Filter materials and design may confer positive product associations to consumers and also influence perceptions of harmfulness. Even the choice of tipping paper colour – usually white or 'cork'– can impact perceived health risk, with white-tipped cigarettes rated by people who smoke as significantly less dangerous than cork-tipped cigarettes.[191] Whilst the colour of tipping paper used to wrap a filter tip has no meaningful impact on a cigarette or its function, it does have an impact on consumer perceptions of safety of that cigarette, which serves to undermine regulatory responses to tobacco control implemented to date.[192]

The appearance of cigarettes is currently regulated under Part 3 of the TPP Regulations. However, these regulations do not extend to the broad range of product design features, such as crush balls and novel filters.

The European Union, Turkey and Moldova specifically prohibit capsules, and Canada and New Zealand have regulated in a similar manner to the recommended approach for novel cigarette filters. Additionally, Canada requires industry to report on product design features, as part of its annual reporting requirements and New Zealand has proposed adding a regulatory power to its tobacco control legislation to speed up the prohibition of future product innovations aimed at increasing the appeal and addictiveness of smoked tobacco products.

Misleading brand and variant names can falsely imply reduced harm

Since the introduction of plain packaging, brand and variant names have become more descriptive and there are also now more variant names available under each brand.[193] Variant names have a wide range of themes and are designed to appeal to a diverse range of consumers. Some variants attempt to recreate connotations formerly aroused by visual brand imagery and aim to reassure people who smoke, deter quitting, and potentially attract new users.[194]

Brand and variant names influence expected hedonic and sensory attributes, including appeal, strength, tar level and quality.[195] [196] They can create unfounded perceptions about relative harmfulness and ease in quitting.[197] [198] This is problematic as the belief that you can reduce harm by the type of cigarette you smoke might delay or reduce smoking cessation.[199] Descriptors such as 'smooth', 'fine', 'rich', 'blue' and 'silver' continue to mislead consumers in relation to perceptions of harm.[200] [201] [202] [203]

In 2005, the ACCC found that the use of terms such as 'mild' or 'light', or displaying the nominal yield for tar, nicotine and carbon monoxide on tobacco products is misleading and contravenes the *Trade Practices Act 1974*.[204] Following the removal of these terms and yields in 2005, the tobacco industry began using colours to express the 'strength' or purported nicotine and tar content.[205] Lighter colours were used to indicate lower nicotine and tar, while bolder colours indicated higher nicotine and tar, and green would often indicate menthol.[206]

The use of colours in Winfield packs is demonstrated below in Table 2 and shows the way in which variant names are used as a descriptive term in order to circumvent regulatory controls. This has allowed people who smoke to continue to associate colours with purported 'strengths' and continue the misconception of harms related to use of particular products.

Table 2: Winfield packs sold in Australia: variant names pre and post ACCC court enforceable undertakings [207]

Package Colour	Purported nicotine	Old variant name	New variant name
	16 mg	Filters	Red
	12 mg	Extra Mild	Blue
	8 mg	Super Mild	Gold
	6 mg	Special Mild	Sky Blue
	4 mg	Ultra Mild	Grey (prev. Silver)
	2/1 mg	No old variant name	White
	8 mg (Menthol)	Menthol	Optimum Menthol

Following the introduction of plain packaging it was apparent that a number of brands not previously using a colour descriptor in the variant, altered their variant name to include a colour. This often aligned with the colour of the original packaging. Some examples of this practice include:

- 'Dunhill Infinite', which used white packaging, became 'Dunhill Infinite White'
- 'Dunhill Distinct', which used blue packaging, became 'Dunhill Distinct Blue'
- 'Dunhill Premier', which used red packaging, became 'Dunhill Premier Red'
- 'Peter Jackson Rich', which used gold packaging, became 'Peter Jackson Rich Gold'.

According to an analysis by Cancer Council Victoria, as at March 2020, 83 per cent of variant names now include a colour, compared to less than 50 per cent prior to plain packaging.[208] A number of variants have

also received further extensions, such as ‘smooth’, ‘New York Blend’ or ‘Fine’, which are intended to give the same impressions of lesser harm or of a premium product as the prohibited terms ‘mild’ or ‘light’.

Research also shows that consumers often perceive cigarettes with descriptors such as ‘organic’, ‘natural’, ‘additive-free’ or health-oriented terms as less harmful than other cigarettes[209 210 211] Further, this research indicates that such descriptors may influence intentions to purchase.[212 213]

Australian people who smoke continue to be manipulated by the persistent marketing influence of the brand and variant name. Consumer and sensory psychology literature indicates that branding can have a significant impact on sensory experience through a process called ‘sensation transfer’, in which the attributes conveyed by the brand are transferred to the product itself.[214]

The current TPP Regulations specify a maximum font size, font, text colour, location, and frequency in which the brand and variant names can appear; however, contains no further restrictions on brand and variant names.

Multiple international jurisdictions have implemented restrictions on brand and variant names including, Canada, New Zealand, European Union, United Kingdom, and Norway.

Limited industry information restricts the ability to monitor effectiveness and address industry activity, potentially undermining tobacco control

A barrier to reducing tobacco use in Australia is the opaqueness of the tobacco market, limiting the ability of the Australian Government to further target its regulatory interventions towards specific drivers for tobacco use. The Australian Government presently has limited access to data on tobacco product sales volumes and pricing, and tobacco advertising, promotion and sponsorship activities and expenditure. This limits its ability to track the effectiveness of existing tobacco control measures and tobacco industry funded activities aimed to circumvent regulation and undermine existing tobacco control measures. This outcome is inconsistent with the guidelines for implementation of Article 5.3 of the WHO FCTC, which state:

> To take effective measures preventing interference of the tobacco industry with public health policies, Parties need information about its activities and practices, thus ensuring that the industry operates in a transparent manner…Parties should require the tobacco industry and those working to further its interests to operate and act in a manner that is accountable and transparent.[215]

The government has limited access to sales information for specific brands and brand variants, which limits its ability to track trends in tobacco product usage in Australia. Available data sources do not contain desired information and tend to be available only for purchase. Some of this data may not be entirely reliable due to known linkages between the data organisation and the tobacco industry.[216 217] Direct sales data from the tobacco industry would provide the government with more reliable information on tobacco use and the effectiveness of tobacco control measures.

Comprehensive advertising bans are an effective means to reduce the prevalence and initiation of smoking.[218] Comprehensive advertising bans have been shown to reduce smoking initiation by an average of 6 per cent and smoking prevalence by an average of 4 per cent; whereas partial bans are likely to only reduce prevalence and initiation by 2 per cent. Further, empirical evidence has shown that incomplete bans result in companies transferring expenditure to media in which advertising is permitted.[219] Advertising restrictions are already in place in Australia, but there are some limitations. Tobacco companies continue to find novel ways to advertise and market their products. This can include sponsorship, funding research, making donations, and corporate hospitality gatherings at major events, as well as advertising through social media influencers.[220 221] The commercial and other vested interests of the tobacco industry also extend to individuals and organisations whose interests may be aligned with them. For instance, tobacco companies use individuals and affiliated organisations to act, directly or indirectly, on their behalf to take action to further their interests.

Whilst government monitors tobacco advertising and promotion as part of its compliance regime, it has limited ability to detect and monitor novel advertising approaches or identify trends in marketing expenditure. This impedes the potential effectiveness of tobacco advertising prohibitions. Information on tobacco advertising, promotion and sponsorship activities and expenditure would be useful to help determine regulatory needs and priorities.

The legislative framework for tobacco advertising is set out in the TAP Act, which defines the meaning of *tobacco advertisement* as well as the meaning of *publishing a tobacco advertisement.* [222]

There is currently no regulatory framework at the Commonwealth-level that requires industry disclosure of advertising, promotion and sponsorship activities or expenditure, or tobacco sales and pricing. However, there are multiple international jurisdictions which have implemented requirements for companies to disclose information to government including, Canada, New Zealand, European Union, and United States of America.

Why is government action needed?

Evidence from Australia and overseas shows that when tobacco control efforts stall, so does the decline in smoking prevalence. The Australian Government has the following targets in respect to tobacco control, as outlined in the NTS and NPHS 2021-2030:

- daily smoking prevalence of less than 10 per cent by 2025 and 5 per cent or less for adults (≥18 years) by 2030
- reduce the daily smoking rate among First Nations peoples (≥15 years) to 27 per cent or less by 2030.

The NTS is a sub-strategy of the National Drug Strategy 2017-2026. It sets out a national policy framework for the Commonwealth, state, and territory governments to work together, and in collaboration with non-government organisations, to improve the health of all Australians by reducing the prevalence of tobacco use and its associated health, social, environmental, and economic costs and the inequalities it causes.[223]

Through a multi-faceted approach to tobacco control, Australia has made significant progress in reducing smoking prevalence over many years. However, despite Australia's successes in reducing the prevalence, challenges remain.[224] Current settings and tobacco control investments are unlikely to achieve the national targets outlined in the NTS and NPHS 2021-2030, therefore further regulatory measures and increased program investments are required to meet these targets.

In 2015-2016, the costs of tobacco use borne by the Australian community were estimated to be $137 billion.[225] Tobacco use also remains the biggest contributor to Australia's preventable health burden, contributing 8.6 per cent of the total burden of disease in Australia in 2018. [226]

Achieving the aim to reduce smoking prevalence to less than 10 per cent by 2025 would reduce the annual social cost of smoking to Australia by $8.4 billion and achieving the five per cent or less target for adults by 2030 would reduce the annual social cost of smoking to Australia by $67.3 billion. This calculation is based on the National Drug Research Institute's central estimate.[v]

Australian Government action is needed to ensure that Australia complies with its obligations as a party to the WHO FCTC which aims to advance international cooperation to protect present and future generations from the preventable and devastating health, social, environmental, and economic consequences of tobacco use and exposure to tobacco smoke.

There is also a relationship between tobacco control and Australia's commitment to the United Nations (UN) Sustainable Development Goals (SDGs) which include 17 goals and 169 targets to be achieved by 2030. Many of the SDGs have a direct or indirect relation to tobacco control, and further reducing tobacco use will play a major role in global efforts to achieve the SDG target to reduce premature deaths from non-communicable diseases by one third by 2030.

Objective of Government Action

The primary, long term objective of tobacco control is to further reduce tobacco prevalence by:

- reducing uptake among non-tobacco users, with a particular focus on youth and young adults (as this is the time of tobacco initiation for the vast majority of users)
- increasing cessation among current users of tobacco products.

The medium-term objectives of the new policies are to:

- reduce the appeal and attractiveness of tobacco products to consumers

[v] This estimate is based on the National Drug Research Institute central estimate that smoking imposed an annual cost of $136.9 bn in 2015/16 (see Table 7). Accounting for an increase in people who smoke from 2.4 million in 2016 to 2.6 million in 2018 and a 7.2% increase in CPI prices from 2015/16 to 2020, translates the National Drug Research Institute estimate to $159 bn in 2020 or $61,156 per smoker.

- reduce the ability of tobacco products and the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking
- increase cessation knowledge and activity among people who smoke
- increase knowledge relating to the benefits of quitting among people who smoke.

By achieving these outcomes, the government will be furthering its intended aim to meet tobacco control targets and support future reductions in tobacco prevalence. This longer-term outcome is expected to be achieved via the following medium-term outcomes:

- limiting the exposure of the public to messages and images that may lead to tobacco use
- reducing the appeal and attractiveness of tobacco products to consumers
- reducing the ability of tobacco products and the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking
- increasing the effectiveness of health warnings on the retail packaging of tobacco products
- increasing the knowledge of health harms caused by tobacco use among people who smoke
- increasing tobacco cessation knowledge and activity among people who smoke
- increasing knowledge relating to the benefits of quitting among people who smoke.

In addition, improved access to data on tobacco sales and advertising information would help inform future policy to reduce smoking prevalence.

Reaching the primary, long-term goal to further reduce tobacco prevalence (and more specifically the NTS and NPHS 2021-2030 targets) will require a multi-faceted approach. The NTS and NPHS 2021-2030 recognise that success in reducing smoking prevalence requires combining different forms of government action with meaningful engagement from many sectors and communities.[227] They also recognise that there are a range of psychological, social, economic, and cultural factors that contribute to an increased likelihood of using tobacco and a greater difficulty in quitting. These wider determinants of health contribute to the high prevalence of tobacco use among certain population groups, including those from low socioeconomic groups and First Nations peoples.[228]

The policy options outlined in this IA would contribute to Australia's comprehensive set of tobacco control measures by targeting the medium-term outcomes above. Achievement of the long-term goals and NTS and NPHS 2021-2030 targets will be dependent on a suite of regulatory and non-regulatory measures in addition to the population-level regulatory interventions canvassed in this IA.

Reasons for Government Action

In terms of economic theory, government action is necessary to address market failures related to information asymmetry and negative externalities. This includes from the tobacco industry which has a long, proven history of trying to delay, dilute and defeat governments' attempts to prevent and reduce tobacco use. Information asymmetry occurs as consumers are unlikely to have sufficient information about the addictive nature of the products and the full extent of health harms from use and exposure to make optimal decisions around usage. This is compounded by product engineering and marketing techniques that increase the appeal and attractiveness of tobacco products and may reduce perceptions of harm. In addition, the delay between the act of smoking and negative health outcomes may impede rational choices regarding smoking and health, even with the provision of relevant information.

Negative externalities are created as tobacco use creates costs not just to producers and users, but to the broader community. This includes health harms caused by exposure to SHS, health harms caused to infants and children whose mothers smoked during pregnancy, lost productivity caused by smoking -related illnesses, forest fires, and litter and environmental damage caused by cigarette butts.

In addition, further government action is required to ensure that the prevalence of tobacco use in Australia continues to decline and the impacts on the individual and community are reduced.[229] [230] [231]

Barriers and Risks to Meeting Objectives of Government Action

As with any broad population health reform requiring behavioural change, there are a number of potential barriers to meeting the Government's objectives. To achieve success, tobacco control must be comprehensive and multi-faceted. The success of stricter tobacco control measures will be influenced by programs delivered at all levels of Government in Australia, through public health organisations such as Cancer Councils, and through clinical guidelines, support programs and communication campaigns. Stakeholder engagement and collaboration is key to ensure that all measures being implemented through Option 3 are appropriately adapted to complement the broader tobacco control environment.

In addition, tobacco use is the most significant modifiable risk factor contributing to the gap in health status between First Nations people and non-Indigenous Australians and is responsible for 12% of the total preventable health burden for First Nations people. Challenges to effective tobacco control for First Nations people are multi-faceted and include likely issues of access and appropriateness of services and support, reflecting systemic barriers to improving the health of First Nation peoples. Additional factors contributing to continued high prevalence of smoking in First Nations communities include the normalisation of smoking in many communities, reflecting the historical role of tobacco, beginning to smoke at an early age, and the underlying economic and social determinants, low socio-economic status, low levels of education, and high unemployment.

There is a well-established body of evidence that demonstrates that the tobacco industry has operated for decades with the intention of subverting the role of governments in developing and implementing public health policies. To mitigate any risk of tobacco industry influence on the implementation of the proposed tobacco control measures, consultation has been limited to that which is necessary to enact effective tobacco control measures and has been undertaken in line with Article 5.3 of the WHO FCTC.

For individuals who use tobacco products, a key barrier to successfully reducing smoking rates includes cognitive biases which distort perceptions, judgements or decision making. The tobacco industry employs these biases to influence social norms, habits and routines to encourage tobacco use.

Measures to strengthen the tobacco control framework may mean that existing stock that is currently being lawfully supplied in Australia may no longer be lawfully sold. This may increase incentives on retailers or suppliers to unlawfully sell newly non-compliant stock. While this did not occur following the introduction of plain packaging measures, any government action to strengthen tobacco control measures should be supported by an enforcement regime that allows Authorised Officers to detect and respond to the sale of non-compliant stock. Further implementation considerations are provided under How Will You Implement and Evaluate your Chosen Option.

There is the potential for some individuals to seek alternate options to maintain nicotine consumption, rather than using the tobacco products that comply with the new measures. This may include seeking new tobacco sources, such as tobacco products being sold on the black market that do not adhere to the proposed tobacco product requirements, or transitioning to the use of e-cigarette or vaping devices through either legal or illegal channels. However, there was no evidence of an increase to the trade of illicit tobacco products that occurred because of the tobacco plain packaging legislation, and that there is not anticipated to be any meaningful change to the illicit trade because of the proposed measures.

The Australian Government works with state and territory governments, law enforcement agencies and relevant taskforces, such as the Illicit Tobacco Task Force, to investigate allegations of illegal tobacco and e-cigarette supply, and assists in the enforcement of those matters.

Compliance with the proposed legislation and existing legislation relating to the sale of e-cigarettes and vaping devices will continue to be monitored under existing frameworks to limit the trade of vaping and e-cigarette devices or tobacco that does not comply with legislative requirements. Changes in smoking patterns and behaviours will also be monitored.

While the policy options in this IA seek to regulate advertising and promotion of e-cigarettes, it does not address the broader regulation of e-cigarette availability and supply. Instead, the reforms proposed under Option 3 complement the stronger regulation and enforcement of all e-cigarettes proposed by

the Australian Government. The Government has committed to separately design new controls on e-cigarette importation, contents and packaging and is working to address the black market for e-cigarettes through the therapeutic goods framework and stronger border control measures. These separate reforms are proposed to include:

- stopping the import of non-prescription vapes;
- increasing the minimum quality standards for vapes including by restricting flavours, colours, and other ingredients;
- requiring pharmaceutical-like packaging;
- reducing nicotine concentrations and volumes;
- banning all single use disposable vapes; and
- ending vape sales in convenience stores and other retail settings, while making it easier to get a prescription for legitimate therapeutic use.

Measures to increase awareness and education of harms related to the use of tobacco products need to be accurate and factual to ensure believability and resonance with consumers. This has been addressed through extensive and rigorous evidence review, market testing, and consultation with international and domestic tobacco control experts; and the inclusion of additional governance processes, such as the proposed requirement for the Chief Medical Officer to approve health warnings and health promotion inserts before regulations are made.

Infeasibility of partnerships and non-binding or non-enforceable agreements with the tobacco industry (non-regulatory options)

Under Article 5.3 of the WHO FCTC, Australia has obligations to take steps to protect its tobacco control policy setting and implementation from interference from the tobacco industry and its interests.

This obligation reflects the well-established body of evidence that demonstrates that the tobacco industry has operated for decades with the intention of subverting the role of governments in developing and implementing public health policies to combat the tobacco epidemic.[232] It also reflects the fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests.[233]

Recommendation 3.1 of the *Guidelines for Implementation of Article 5.3* states that:

> *'Parties should not accept, support or endorse partnerships and non-binding or non-enforceable agreements as well as any voluntary arrangement with the tobacco industry or any entity or person working to further its interests.'*

Recommendation 3.3 further states that:

> *'Parties should not accept, support or endorse any voluntary code of conduct or instrument drafted by the tobacco industry that is offered as a substitute for legally enforceable tobacco control measures.'*[vi] [234]

Strengthening Australia's implementation of Article 5.3 is a priority under the NTS. Priority 1 of the NTS seeks to protect public health policy, including tobacco control policies, from tobacco industry interference. There is a broader recognition of the need to protect Australia's tobacco control settings from all other commercial and vested interests. Consistent with this approach, relevant Commonwealth and state and territory Ministers have affirmed the importance of protecting public health policy from all commercial and other vested interests related to e-cigarettes, including the interests of the tobacco industry.[235] Protecting Australia's tobacco control settings from all commercial and other vested interests also accords with Australia's obligations under Article 14 of the WHO FCTC (demand reduction measures concerning tobacco dependence and cessation).

[vi] These recommendations were developed based on a large body of evidence showing that voluntary regulation with the tobacco industry has been ineffective and, in some cases, even counterproductive.

The government recognises that partnerships and non-binding or non-enforceable agreements with the tobacco industry have the potential to be problematic as they create a public perception of cooperation, which may bolster the tobacco industry's reputation and generate goodwill and public acceptance.

As such, partnerships and non-binding or non-enforceable agreements with the tobacco industry are not considered viable non-regulatory options in this IA.

There is currently a *Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes* (the Voluntary Agreement) between the Australian Government and the three largest tobacco companies in Australia. This was signed in the year 2000, prior to Australia ratifying the WHO FCTC in 2004.

Whilst the Voluntary Agreement has provided some information about contents of cigarettes and purposes of various additives, a 2008 evaluation commissioned by the department (and published online) notes that the information disclosed is not comprehensible to consumers, and has little public health value to consumers, Non-Government Organisations, scientists or government.[236] For example, it does not adequately reveal the number and purpose of additives used in individual tobacco brands as ingredients are reported as maximum quantities not exceeded. Further, concerns have also been raised about its accuracy.[237] [238] In line with Australia's obligations under Article 5.3 of the WHO FCTC and consistent with best practice recommendations, the Department is seeking to replace the Voluntary Agreement with a regulated requirement.

What policy options are you considering?

The following three options are being considered. These have been informed following consultation and research as part of the Review.

A range of different policy measures have been proposed under each option.

Figure 7: Policy options

Option 1A: Maintain status quo and allow the Regulations to sunset

Option 1A would come to pass if no action was taken. This option would mean that the following legislative instruments would sunset on 1 April 2024: [vii]

- *Tobacco Advertising Prohibition Regulation 1993* (***TAP Regulation***)
- *Tobacco Plain Packaging Regulations 2011* (***TPP Regulations***)

The *Tobacco Plain Packaging Act 2011* and *Tobacco Advertising Prohibition Act 1992* would remain in force. However, the TPP and TAP Regulations which contain the details of requirements to enable compliance with the Acts would cease to be in force.

The TPP Regulation prescribes requirements for the retail packaging and appearance of tobacco products for Part 2 of Chapter 2 of the Act. The requirements set out in the TPP Regulations include:

- Appearance and physical features of retail packaging, including colour and finish
- Trademarks or marks on retail packaging
- Brand, business, company and variant names
- Wrappers
- Inserts and onserts.

The sunsetting of the TPP Regulations would alter the current plain packaging requirements, which would have broader implications for both compliance and public health objectives. The TAP Regulation prescribes the specific requirements for advertising of tobacco products, including;

- Point of sale advertising for shops, vending machines, and internet sales. such as the size, content, format and location of tobacco advertisements; inclusion of health warnings, warnings about age restrictions on the sale of tobacco products, information about any fees, taxes and charges payable in relation to tobacco products; and age restricted access systems for access to tobacco advertisements
- Written and Oral acknowledgments of assistance or support

The sunsetting of the TAP Regulation would alter the current tobacco advertising requirements removing restrictions, which would have broader implications for both compliance and public health objectives.

[vii] As part of the *Legislation Act 2003*, the Australian Government introduced changes to the sunsetting arrangements for legislative instruments so that they automatically cease to apply, unless an active decision has been made to retain them. The aim of the arrangements is to ensure that legislative instruments are kept up to date and only remain in force so long as they are needed.

1B Option 1B: Retain the tobacco control regulatory framework in its current form

Option 1B: Retain the tobacco control regulatory framework in its current form

Option 1B would allow the TPP Regulations and TAP Regulation, to continue in their current form instead of sunsetting. Option 1B would therefore maintain the regulatory framework for the regulation of tobacco product advertising and plain packaging in its current form.

The TPP Act and TPP Regulations would continue to support the tobacco control framework to improve public health by limiting the exposure of the public to messages and images that may persuade them to start or continue smoking or to use or continue using tobacco products.

The Department would continue to administer the TPP Act and the TPP Regulations including enforcement and compliance. This option would not result in any changes for the tobacco importers, retailers, people who smoke, or the general public.

The other components of the current tobacco control regulatory framework, would remain unchanged:

- *Court enforceable undertakings between British America Tobacco Australia; Philip Morris Limited and Imperial Tobacco and the ACCC* would only apply to products manufactured by BATA, Philip Morris and Imperial.
- *Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008* would remain in force and the ACCC, through the Treasury portfolio, would continue to have policy, compliance, and enforcement responsibility for the Fire Risk Regulations.
- *Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods* would remain in force and the ACCC within the Treasury portfolio would continue to have policy, compliance, and enforcement responsibility for the Oral Tobacco Ban.
- *Competition and Consumer (Tobacco) Information Standard 2011* would remain in force and the Treasury portfolio would continue to administer the Information Standard and be enforced by the ACCC. The Department would continue to have policy responsibility for tobacco health warnings and for their periodic update.

Option 2: Consolidate the existing tobacco control regulatory framework

Option 2 presents opportunities to modernise, simplify and streamline the regulatory framework for tobacco control through updating and repealing redundant aspects, and consolidating related legislation. This option would enable current limitations and inefficiencies to be addressed, including improving monitoring, enforcement, and compliance capabilities. Further restricting advertising provisions will ensure that the TAP Act is modernised and responsive to the current marketing environment which continues to have a powerful influence on tobacco initiation. Similarly, updating health warnings will ensure they are reflective of new and best practice research about the health consequences of smoking. Improving the coverage of enforcement and compliance will also help ensure that tobacco control measures which seek to reduce tobacco consumption are implemented effectively and upheld.

No substantive new policy measures would be introduced under this option. Rather, legislation would be modernised and refined to meet current objectives.

Four measures are proposed under Option 2:

Measure 1: Consolidate Legislation

This measure is well-supported by the feedback from the consultation for the Review. However, this measure does not address feedback in relation to the need to maintain and strengthen the current multi-pronged approach to tobacco control, including by updating existing tobacco control regulation.[239]

Consistent with the government's deregulation agenda, the following legislation, regulations, instruments, and court enforceable undertakings would be consolidated into a single Act and delegated legislation:

- *Tobacco Plain Packaging Act 2011*
- *Tobacco Advertising Prohibition Act 1992*
- *Tobacco Plain Packaging Regulations 2011*
- *Tobacco Advertising Prohibition Regulations 1993*
- *Court Enforceable undertakings with tobacco companies issued in 2005*
- *Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008*
- *Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods*
- *Competition and Consumer (Tobacco) Information Standard 2011*

Consolidating the above legislation would improve the current tobacco control framework through removal of any duplicated or redundant provisions and would serve to simplify and streamline the legislation.

Tobacco Plain Packaging Act 2011 and *Regulations*

Under this measure, minor amendments would be made to reduce ambiguity for businesses and individuals. It is also proposed that the TPP Act and Regulations are used as the mechanism to incorporate the proposed options outlined in this IA. The structure and drafting style of the current TPP Act allow for the insertion of other legislation, providing a vehicle for the proposed consolidation of the tobacco control framework. Some matters, as appropriate, will be delegated to the updated Regulations.

Tobacco Advertising Prohibition Act 1992 and *Regulation*

It is proposed that the TAP Act and Regulations are consolidated into the current TPP Act and Regulations, including amendments to modernise and refine provisions to better address current and future challenges. The refinements to the TAP Act and Regulation provisions in the consolidated legislation include improving monitoring and enforcement powers and moving to a civil penalty regime – making enforcement and deterrence easier with a range of options available, such as fines and injunctions.

Consolidation of other instruments into the TPP Act and Regulations

Consistent with streamlining the tobacco control framework and reducing regulatory burden, it is proposed that the following Acts, Regulations, and instruments would be consolidated into the TPP Act and Regulations:

- Incorporating *Court enforceable undertakings between British American Tobacco Australia; Phillip Morris Limited and Imperial Tobacco and the ACCC* into the TPP Act and expanding the provisions so they apply to all tobacco products within Australia, not just those sold by Phillip Morris, BATA and Imperial.
- Incorporating the following practice regulations and standards into the TPP Act and Regulations and transferring responsibility for compliance and enforcement responsibility from the ACCC to the Department:
    - *Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008*
    - *Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods*
    - *Competition and Consumer (Tobacco) Information Standard 2011*

It is proposed that states and territories would retain current compliance and enforcement capability as currently available under the Australian Consumer Law.

Measure 2: Update and improve health warnings

Consistent with WHO FCTC obligations, the following proposed improvements and updates to the suite of health warnings would contribute to reducing uptake, increasing cessation, and improving health knowledge among people who smoke:

- expanding the scope of tobacco products that require health warnings and include product specific warnings and information for RYO tobacco, pipe tobacco, water-pipe tobacco, cigars, and bidis
- creating new and updated health warnings to better reflect the current evidence on the health effects of smoking
- creating new and updated health warnings to meet new and existing educational objectives (for example, new health warnings could include the effects of smoking on quality of life and seek to correct misperceptions of harm)

- increasing the number of health warnings to better inform consumers of the nature and extent of the health effects of smoking and to reduce the effects of wear-out
- pre-empting the problem of wear-out by incorporating increased variability and novelty in design, and on rotation (for example, changes in colour, layout, and font)
- maintaining the current schedule of rotating a set of health warnings every 12 months
- potentially requiring messaging elsewhere on the pack and in online consumer information (for example, in the explanatory message, under the lid, on the inside of the lid of the pack, or on the inside surface of the closing flap on RYO products).

Updating and improving health warnings would promote greater awareness to people who smoke of the vast range and magnitude of health risks, associated with tobacco use and exposures. It would increase the effectiveness of health warnings by increasing their noticeability, importance and impact. Health warnings would be based on evidence and undergo an iterative design and market testing process to maximise effectiveness for Australian people who smoke.

Measure 3: Further restrict advertising provision

Although Australia has significant tobacco advertising prohibitions, there are further areas where advertising is evident. Supported by the strong evidence demonstrating the influence advertising and promotion of tobacco products has on uptake and continuation of smoking, and in line with Article 13 of the WHO FCTC, it is proposed that the current advertising provisions are further restricted. The proposed restrictions would include prohibitions of acknowledgement of assistance or support from the tobacco industry and to reduce existing exceptions for publication or broadcast to prohibit any advertisements that are likely to promote tobacco products or smoking. This approach recognises that promotion of tobacco companies themselves is a form of promotion of tobacco products or tobacco use, even without the presentation of brand names or trademarks.

To continue to meet the current objective of the TAP Act to improve public health, additional regulation is required to limit the public's exposure to advertising and promotion of e-cigarettes- and other novel products.[viii] The rationale for this proposed approach reflects that public exposure to e-cigarette advertising and promotion poses a range of direct and indirect risks to tobacco control and population health.

- Exposure to e-cigarette advertising across a wide range of media is positively associated with e--cigarette use among young people. This broadly accords with earlier research showing that the advertising and promotional activities by tobacco companies have been shown to cause the onset and continuation of smoking among young people.[240]
- E-cigarette use increases the risk of nicotine addiction, particularly among young people.[241]
- E-cigarette use by people who do not smoke tobacco increases the risk of future tobacco use, particularly among young people.[242]
- E-cigarette use by people who have quit smoking may result in an increased likelihood of tobacco smoking relapse compared with people who formerly smoked tobacco who do not use e-cigarettes.[243]
- All e-cigarette users are exposed to chemicals and toxins that have the potential to cause adverse health effects.[244]

The TAP Act currently prohibits images and messages relating to smoking; however, it does not extend to images or messages relating to e-cigarettes and it is often difficult to ascertain whether an image is depicting tobacco smoking or e-cigarettes. It is proposed that the restrictions on broadcasting and publishing of tobacco messages and images are extended to e-cigarettes and other novel products. Further it would reduce ambiguity and provide greater clarity regarding advertising of products relating to smoking, in particular to media editors and publishers.

[viii] This includes all types of products that may not be wholly captured under the TAP Act at present that are capable of promoting tobacco use and/or nicotine addiction, such as e-cigarette devices and components (with and without nicotine), heated tobacco devices and components (with and without tobacco), shisha, nicotine pouches, lozenges, and gums.

Exceptions would be retained to allow content that is justified by reasons of legitimate journalistic, artistic or academic expression, or legitimate social or political commentary.

Measure 4: Improve coverage, enforcement, and compliance for tobacco control

To improve the effectiveness of the tobacco control framework, additional amendments are required to meet current objectives and contribute to reducing Australia's smoking prevalence. Consistent with a best practice regulation approach, the proposed amendments would also provide clarity and more legal certainty for tobacco retailers, importers, and wholesalers.

In particular, this measure establishes greater compliance and enforcement options for the Department as the regulator. The emphasis is on bringing greater consistency and robustness to the Department's ability to monitor compliance with the law, and to ensure its powers are tailored to the specific challenge of tobacco control. For example, at present Authorised Officers do not have powers of entry without a warrant or the expressed consent of the site operator to identify whether products are compliant with the legislation. Providing Authorised Officers with the powers to conduct inspections of a retail premise that is open to the public without having to seek the consent of the site operator will increase the ability of Authorised Officers to detect tobacco products that do not comply with the legislation.

When obtaining consent under the RP Act, the Authorised Officer must inform the site operator that they have the right to refuse, limit or withdraw consent at any time. As tobacco products are kept out of sight of the public due to the state and territory point-of-sale legislative requirements, and are often secured or concealed for security reasons, this can create challenges for Authorised Officers in obtaining consent to exercise their powers under the RP Act.

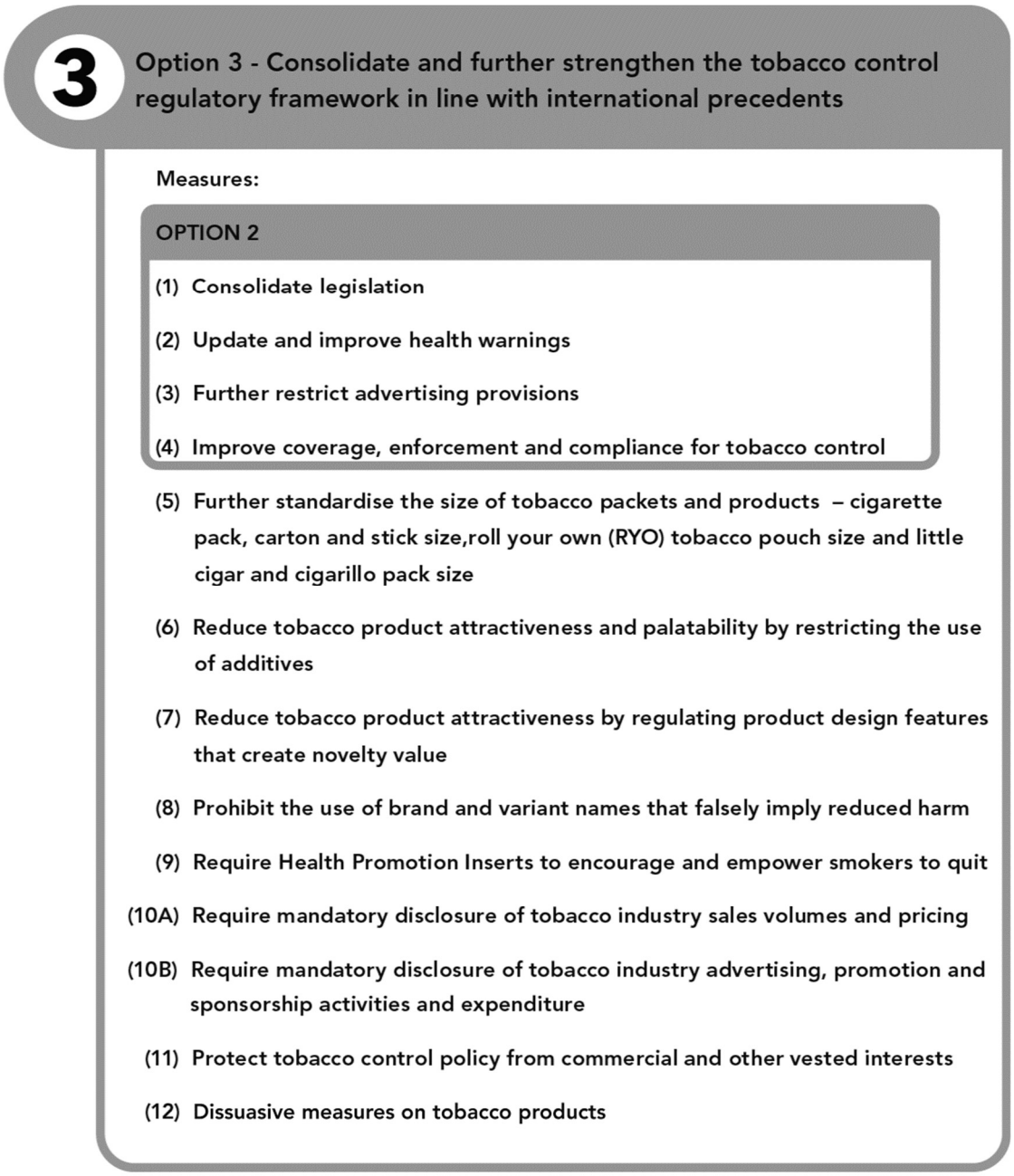
This measure is being proposed in the context of a continued problem of non-compliant tobacco production, importation, and sale within Australia. It is noted that $1.89 billion of excise duty was evaded through the sale of illicit tobacco in 2020-21.[245] This measure aims to equip Authorised Officers with a more responsive suite of enforcement tools for conducting inspections and supporting retailers to understand their rights and responsibilities. This measure will also introduce infringement notices as an enforcement tool for the TAP Act, reducing reliance on court-initiated outcomes or prosecution as a primary enforcement tool under the TAP Act.

Proposed areas for refinement are outlined below. These refinements would also address some of the issues outlined under Barriers and Risks to Meeting Objectives of Government.

- Expansion of powers to make regulations updating health messages and addressing the introduction of new tobacco product features and emerging advertising strategies
    - This will provide flexibility in the legislation to enable updates to be made to inform consumers of other health related impacts of tobacco use and to address the introduction of emerging products or features and advertising strategies which undermine the tobacco control framework.
- Expansion of investigation, monitoring, enforcement, and compliance provisions
    - The *Regulatory Powers Act (Standard Provisions) Act 2014* (RP Act) provides for a standard suite of provisions in relation to monitoring and investigation powers, as well as enforcement provisions. The TPP and TAP Acts were updated through the *Regulatory Powers (Standardisation Reform Act) 2021* to expand the circumstances in which monitoring powers may be triggered and used, and to update some descriptions.
    - However, further amendments, specific to tobacco control legislation, are required to be undertaken through the Review process. These amendments include providing for:
        - civil penalties and infringement notices for breaches of the TAP Act
        - the ability to purchase materials for compliance purposes
        - the ability to take, test and analyse samples for compliance with the TPP Act

        - powers of entry and ability to use reasonable force (for example to open a locked cabinet) in executing a monitoring or investigation warrant
        - the ability to dispose of seized goods.
- Broaden and update definitions
    - Consistent with international precedent, amendments to definitions will address current limitations, inefficiencies and provide the ability for the legislation to address emerging advertising platforms and methods.
- Update and repeal redundant clauses
    - To ensure the tobacco control framework remains fit-for-purpose and is consistent with the best practice regulation approach.
- Prescribe new cigarette packaging and dimension requirements
    - To prescribe new cigarette packaging and dimension requirements to prevent exploitation of cigarette pack size and shape as a form of promotion.
- Prescribe a font size for brand and variant names, require that they each occupy up to a specified width, and restrict the use of non-alphabetic characters
    - To prescribe new height and width requirements and restrict the use of non-alphabetic characters for brand and variant names to reduce their ability to be a form of promotion.

Option 3: Consolidate and further strengthen the tobacco control regulatory framework in line with international precedents



Option 3 includes all of the four measures outlined in Option 2, which aim to modernise, streamline, and strengthen the regulatory framework for tobacco control, and includes additional policy measures (measures 5 – 12) to further strengthen Australia's tobacco control framework and reduce prevalence. Together these measures would seek to reduce smoking rates by restricting features that make products more attractive and palatable to consumers, reducing the ability for industry to mislead consumers about the harmful effects of smoking, and increase the knowledge of consumers and government about the harms of smoking and current industry practices. Each measure reflects international best practice and is in line with the WHO FCTC. The new policy measures are summarised below in Figure 8.

The new policy measures 5 – 12 are:

Figure 8: New policy measures within Option 3

The primary objective of the new policies is to further reduce smoking prevalence by:

- reducing uptake among people who do not smoke, with a particular focus on youth and young adults (as this is the time of smoking initiation for the majority of people who smoke)
- increasing cessation among people who smoke.

A secondary objective is to provide more sales and advertising information to the Australian Government to inform future policy to reduce smoking prevalence. This objective is well supported by the WHO FCTC, including the strengthening of efforts to prevent tobacco industry interference in public health policies by ensuring that information provided by the industry is transparent and accurate (Article 5.3). It will inform the development of public awareness of the strategies and activities of the tobacco industry and its products, such as those relating to advertising, promotion and sponsorship (Article 12 and the Guidelines for implementation of Article 12 of the WHO FCTC). Requiring industry to disclose information on ingredients will support the development and implementation of relevant policies, activities and regulations, and monitoring (Article 10 and the Partial Guidelines on the Implementation of Articles 9 and 10).

The medium-term objectives of the new policies are to:

- reduce the appeal and attractiveness of tobacco products to consumers
- reduce the ability of tobacco products and the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking
- increase cessation knowledge and activity among people who smoke
- increase knowledge relating to the benefits of quitting among people who smoke.

Each of the proposed new regulatory measures is summarised in the table below and further detailed information on each measure follows.

Table 3: Policy measures in Option 3, in addition to measures in Option 2

Rationale for change	International precedent
Measure 5: Further standardise the size of tobacco packets and products – cigarette pack, carton and stick size, roll your own (RYO) tobacco pouch size and little cigar and cigarillo pack size	
Varying cigarette pack sizes and RYO pouch sizes increase product differentiation based on price and increases appeal to different market segments. Larger cigarette pack sizes are associated with increased consumption, and increased consumption makes it somewhat harder for people who smoke to quit. Small RYO pouch sizes and the availability of little cigar and cigarillos in small pack sizes provide a low price point for youth and is a key factor in observed increases in youth uptake. Varying cigarette stick sizes increases appeal to different market segments and can mislead perceptions of harm.	Cigarette pack and stick size: • Canada: excise stamps are available for pack size of 20 or 25 only, which in practice regulates sizing to 20 or 25 • New Zealand (NZ) requires cigarettes to be sold in packs of 20 or 25 • Norway requires pack size of 20 • Russia requires pack size of 20 • Singapore requires minimum pack size of 20 • Georgia requires pack size of 20. RYO tobacco pouch size: • NZ requires RYO tobacco in pouches of 30 or 50 grams • European Union (EU) requires minimum pouch size of 30g Little cigar and cigarillo pack size: NZ requires pack size of 20 or 25

Measure 6: Reduce tobacco product palatability by restricting the use of additives	
Tobacco products contain many additives that enhance the attractiveness and palatability of tobacco products, fostering uptake and addiction, particularly among youth. Additives are also used to mask the smell and visibility of second-hand smoke, to reduce concerns and complaints from people who do not smoke and relieve people who smoke of some of the social pressure to quit.[246]	• Canada restricts/prohibits ingredients that have colouring properties, prohibits ingredients that create the impression of health benefits, prohibits ingredients that are associated with energy and vitality • EU has a prohibition of tobacco products with characterising flavours, as well as prohibiting addition of vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks, caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality, additives having colouring properties for emissions • United States of America (USA) restricts additives that impart characterising flavours • Brazil prohibits tobacco products that contain sweeteners, honey, molasses or any other substance that can impart a sweet flavour, apart from sugars, as well as seasonings, herbs and spices, ingredients which may create an impression of health benefits, and additives associated with alleged stimulating or invigorating properties, including taurine, guaraná, caffeine and glucuronolactone. It also prohibits tobacco products that contain ameliorants, which are defined as "a substance that reduces irritating aspects of the smoke of tobacco products".
Measure 7: Reduce tobacco product attractiveness by regulating product design features that create novelty value	
Product design features, including crush balls and novel filters, enhance the attractiveness of tobacco products to people who smoke and new users, particularly youth. There are also misperceptions about filters that they reduce health risks and harms associated with these products. For example, filter ventilation dilutes the smoke inhaled by the smoker, appearing to the user to reduce its harshness and strength of taste. However, their use does not reduce, and may even increase health risks as some people who smoke adjust the manner they smoke cigarettes to compensate for the diluted smoke (larger or more frequent puffs, blocking filters).[247]	• Canada requires that any part of the cigarette filter that is visible must be white; and tipping paper must be white or cork. Tobacco products must have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities • EU has banned capsules containing flavours or any other substance • NZ requires that cigarette filter tips must be made of white material, be coloured plain white or imitation cork on the outside, and not contain printing or embellishment of any kind. A cigarette must be cylindrical with flat ends • In Turkey, tobacco cannot contain components like capsules that alter smell or flavour • In Moldova, tobacco product components like capsules cannot contain flavourings, and components like capsules cannot contain flavourings
Measure 8: Prohibit the use of brand and variant names that falsely imply reduced harm	
Brand and variant names promote products to consumers. Colours, names, and other signifiers represent different characteristics to consumers, increasing the attractiveness of certain products to different market segments.	To varying degrees, NZ, the EU, the United Kingdom and Norway have regulated brand and variant names. Canada prohibits certain language being used as a brand or variant. The Canadian Tobacco Products Regulations (Plain and Standardised Appearance) prohibit the use of colours or characteristics of a filter (such as identifying the filter type as a 'firm', 'taste flow', or 'flavour/crush ball' construction)
Measure 9: Require Health Promotion Inserts to encourage and empower people who smoke to quit	
Health Promotion Inserts (HPIs) – appearing as small cards inside tobacco products – are an effective and untapped means to provide people who smoke with information to encourage and empower them to quit. Being positive in tone, HPIs complement the fear-based health warnings to increase cessation.	Canada requires packs of cigarettes and little cigars to contain one of 16 health information messages on an insert

Measure 10A: Require mandatory disclosure of tobacco industry sales volumes and pricing **Measure 10B: Require mandatory disclosure of tobacco industry advertising. promotion and sponsorship activities and expenditure**	
The Australian Government currently has limited access to data on sales volumes and pricing for specific brands and products. This information is valuable for policy development, implementation, and evaluation. The Australian Government currently has limited access to information on tobacco advertising, promotion and sponsorship activities and expenditure. This limits its ability to track trends and have comprehensive advertising prohibitions.	Several jurisdictions require the tobacco industry to routinely report sales volume data, for example: • Canada (sales figures and expenditure on advertising and promotions since 2000). • USA (domestic sales figures since 1967) • NZ (sales figures for all tobacco products since 2004) • EU (various requirements since 2016) Canada and the USA require mandatory disclosure of tobacco industry advertising, promotion, and sponsorship.
Measure 11: Protect tobacco control policy from commercial and other vested interests	
New regulations to implement obligations under Article 5.3 of the WHO FCTC, will provide an opportunity to reduce industry marketing activities, reduce industry's influence on tobacco control policy development and implementation, strengthen monitoring and evaluation and increase the accountability and transparency of industry activities that do occur.	Canadian manufacturers and importers must provide Health Canada with information about their tobacco products and, where applicable, their emissions. In addition to information on sales, ingredients, manufacturing procedures, promotional activities and research activities, they must report on over 20 constituents (substances found in tobacco) and 40 emissions (substances found in smoke). Health Canada records all meetings with tobacco industry.[ix] New Zealand, since 2011, has maintained a publicly available online register of meetings with the tobacco industry.[x] The Ministry of Health also makes available on its website annual tobacco returns filed by tobacco manufacturers and importers.[xi]
Measure 12: Require dissuasive measures on tobacco products	
Dissuasive measures on tobacco products have an on-product health warning, such as 'Causes stroke', and/or are unattractively coloured. They better communicate the risks and harms of smoking, compared to a standard product, in a manner that cannot easily be avoided. Research indicates that dissuasive measures on cigarettes are perceived as significantly less appealing, more harmful, and less likely to encourage trial. They are also likely to reach a group of people who smoke less responsive to plain packaging and other health warnings.	Canada (2023) will require messages to be printed on individual cigarettes.

[ix] https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/meeting-summaries-tobacco-vaping-industry.html

[x] https://www.health.govt.nz/our-work/regulation-health-and-disability-system/smoked-tobacco-products/information-manufacturers-and-importers-smoked-tobacco-products/tobacco-annual-returns

[xi] https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/who-framework-convention-tobacco-control/meetings-and-correspondence-tobacco-industry-representatives

Measure 5: Standardise tobacco product size – cigarette pack, carton and stick size, RYO tobacco pouch size and little cigar and cigarillo pack size

This measure would set requirements in the new streamlined tobacco legislation that would standardise:

- the number of cigarettes per pack to 20 and prohibit the retail sale of cigarette multi-packs and cartons, preventing all variation in cigarette pack size
- cigarette carton size to 10 cigarette packs per carton for sale (including that the price of a cigarette carton must be equivalent to the sum of the price of the individual cigarette packs contained in the carton) to support the effectiveness of health warnings and HPIs by helping even distribution of messages in rotation ensuring that smokers are exposed to all messages
- the weight of RYO pouches to 30 grams, preventing all variation in pouch sizes
- the number of filtered and small cigars per pack to 20, preventing the sale of single units and small pack sizes of filtered and small cigars
- cigarette stick dimensions (length and diameter), preventing all variation in cigarette size.

Under this measure, tobacco companies would only be permitted to import tobacco products that met the requirements (and if tobacco product manufacture were to restart in Australia, could only manufacture products that meet those requirements). As a result, consumers would only be able to purchase products that met stick dimensions and in the pack sizes indicated.

Table 4: Rationale for proposed measure to regulate stick and pack sizes

Product	Standardisation recommendation	Rationale
Cigarette pack	20 cigarettes	This is an international standard for pack size. For example, Norway, Georgia, and Russia limit pack size to 20. While the most popular brands in Australia all come in a range of different pack sizes, many of the smaller more niche brands are only produced in 20s. In addition, larger packs sizes tend to lower the price per cigarette, promoting higher consumption.
Cigarette cartons	10 units per pack for sale	Larger pack sizes tend to lower the price per cigarette, promoting higher consumption. This is the most common carton size currently supplied. This also supports the effectiveness of health warnings and HPIs, by helping even distribution of messages in rotation and ensuring that people who smoke are exposed to all messages.
RYO tobacco pouch	30 grams	The United Kingdom, Norway and the European Union all have a minimum RYO tobacco pouch size of 30g. This size provides a price point out of reach of most teenagers at a cost of over $50 per pouch. Any bigger than 30 grams would be better value (cheaper to produce and therefore cheaper per gram) and likely promote greater consumption. Any smaller would make the pouch more affordable for youth.
Little cigars and cigarillos	20 cigars or cigarillos	This sizing is consistent with the current minimum pack size of cigarettes, and the proposed standardised pack size of cigarettes. It is also consistent with Canada's minimum pack size for little cigars/cigarillos.
Cigarette stick	7.65-8mm diameter 82-85mm length	This sizing is consistent with one of Canada's regulated sizes and would prevent slim and super slim cigarettes. Canada permits two cigarette lengths – a 'regular' and 'king'. The recommended length is as per Canada's 'king' sizing. The 'regular' sizing is not considered relevant to the Australian market, as these cigarettes are only commonly available in Canada and the Caribbean. New Zealand also regulates cigarette diameter and length.

Measure 6: Reduce tobacco product attractiveness and palatability by restricting the use of additives

Modelled on international best practice and in line with the WHO FCTC, the proposed measure would prohibit a specific list of additives that increase palatability (flavours and sweeteners), have colouring properties, create the impression of health benefits, or health effects (for example energy boosters).

This measure would also prohibit some additives that are designed to enhance palatability, that are also known to contribute to addictiveness and/or toxicity.

To improve regulatory certainty, there would be a permitted list for additives that have other functional properties (for example, preservatives or humectants). Ideally, these additives would not contribute to palatability, but in some instances, additives would have both functional and palatability properties (for example, propylene glycol and glycerol) and might need to be permitted.

Additive prohibitions would apply to all tobacco products. Tobacco accessories that impart flavour to tobacco, including flavour cards and flavoured RYO filters, would also be prohibited.

The proposed prohibited and permitted additive list is based on an assessment of Australian cigarette ingredient reports; the WHO FCTC *Partial Guidelines for Implementation of Articles 9 and 10*; the WHO Study Group on Tobacco Product Regulation;[248] the WHO Advisory Note relating to Banning Menthol in Tobacco Products;[249] as well as consideration of additives that have been prohibited in international markets. The proposed prohibited and permitted additive list has already been implemented in Canada.

Table 5: Proposed list of prohibited and permitted additives

Proposed list of prohibited additives:
Additives that have flavouring properties or that enhance flavour (excluding permitted additives) (including additives identified as flavouring agents by the Joint Food and Agriculture Organization of the United Nations/WHO Expert Committee on Food Additives in the Committee's evaluations, as published in the WHO Technical Report Series, additives identified as generally recognised as safe (GRAS) by the Flavour and Extract Manufacturers Association (FEMA) Expert Panel in its lists of GRAS substances referred to as 'GRAS 3' to 'GRAS 24' and subsequent lists of GRAS substances); menthol, including l-menthol, and menthone, including l-menthone; amino acids; caffeine; cloves; colouring agents (excluding those used to whiten the paper or the filter or to imitate a cork pattern (for cigarettes), create the alphanumeric code (for cigarettes), colour a single band around the circumference of a cigar as Pantone 448C or create marks on the band as Pantone Cool Gray 2C, or meet any requirement outlined in legislation); essential fatty acids; fruits, vegetables or any product obtained from the processing of a fruit or vegetable (excluding activated charcoal and starch); glucuronolactone; probiotics; spices, seasonings and herbs; sugars and sweeteners, excluding starch; taurine, vitamins and mineral nutrients, excluding those necessary to manufacture the tobacco product.
Proposed list of permitted additives:
Benzoic acid, butylated hydroxytoluene, carboxymethyl cellulose, citric acid, ethanol, polyoxyethylene sorbitan monolaurate, fumaric acid, glycerol, guar gum, paraffin wax, propylene glycol, glycerol esters of wood rosin, sodium acetate anhydrous, sodium alginate, sorbic acid, triacetin, n-propyl acetate and tributyl acetylcitrate.

This measure would be accompanied by a system to support regulatory compliance, similar to Canada's approach. It is proposed that tobacco manufacturers and importers would be required to submit annual reports of ingredient lists to government by brand and variant. Ingredient lists would contain prescribed information such as: the brand and variant name of the product; common, chemical and trade names of ingredients; purpose of use of ingredients; the amount of the ingredient used in the product.

Government would undertake compliance activity based on these reports and laboratory testing of tobacco product samples at accredited laboratories. Legislation could allow the option of government on-site compliance visits of the Australian based subsidiaries of tobacco manufacturers.

Measure 7: Reduce tobacco product attractiveness by regulating product design features that create novelty value

Modelled on international best practice and in line with the WHO FCTC, the proposed measure would regulate existing product design features that are known to increase the attractiveness of tobacco products. It would ban capsules, standardise the appearance of filters to remove recessed filters and filters with visible designs from the market, and standardise tipping paper colour of cigarettes to cork.

Further, it would allow the regulations to prescribe a particular product design feature to be prohibited, should it seek to enhance attractiveness of the product. This would help future proof against new product design features that might emerge and enhance the attractiveness of tobacco products.

To aid compliance and enforcement, the tobacco industry would be required to submit annual reports that would include information on research and development activities.

Measure 8: Prohibit the use of brand and variant names that falsely imply reduced harm

Modelled on international best practice (outlined below in Table 6) and in line with the WHO FCTC, the proposed measure would prohibit tobacco product packaging and labelling from promoting a tobacco product by any means that is false, misleading, deceptive, or likely to create an erroneous impression about its characteristics, health effects, risks, or emissions - including in respect to brand and variant names.

It would specifically prohibit the use of the following terms/descriptors in brand and variant names, which falsely imply reduced harm:

- terms that imply reduced harm, such as ‘low tar’, ‘light’, ‘ultra-light’, ‘mild’;
- terms that refer to quality, such as ‘extra’ and ‘ultra’;
- colours such as ‘black’, ‘blue’, ‘gold’, ‘red’ and ‘white’;
- terms that refer to a filter, such as ‘charcoal filter’, ‘recessed filter’;
- terms that refer to health effects, such as ‘organic’, ‘natural’, ‘additive-free’; and
- terms that suggest the inclusion of a prohibited ingredient, such as ‘caffeine’, ‘menthol’ and ‘vitamin’.

It would include a provision to allow additional descriptors to be prohibited in the future as a means to help future-proof the legislation. It would also prohibit packaging that could cause a person to believe that it contains a prohibited additive.

Table 6: Examples of international brand and variant name regulations

Prohibitions to packaging and labelling, or promotions, which:	UK	Ireland	Canada
Create an erroneous impression about its characteristics, health effects, risks or emissions	✓	✓	✓
Suggests a product is less harmful than others, or aims to reduce the effect of some harmful components of smoke	✓	✓	✓
Suggests a product has vitalising, energizing, healing, rejuvenating, natural or organic properties	✓	✓	×
Suggests a product has other health or lifestyle benefits	✓	✓	×
Refer to taste, smell or any flavourings or other additives, or the absence of any such thing	✓	✓	×*
Resembles a food or a cosmetic product	✓	✓	×
Suggests a product has improved biodegradability or other environmental advantages	✓	✓	×
Evoke a colour in the brand name	×	×	✓
Evoke a characteristic of a filter in the brand name	×	×	✓

*Cannot imply there is a prohibited additive

Measure 9: Require Health Promotion Inserts to encourage and empower people who smoke to quit

Modelled on international best practice and in line with the WHO FCTC, this measure would require manufacturers to enclose a HPI into the retail packaging of cigarettes and loose processed tobacco. It would involve a change to the TPP Act to require HPIs to be added to specified packages. The TPP Act provides a definition for an 'insert' and for 'retail packaging' but does not currently require HPIs.

HPIs are a means to deliver quitting support and encouragement to all Australian people who smoke, every time they open a new tobacco pack. Appearing as a small card inside the pack, HPIs would include messages highlighting the benefits of quitting and promote effective cessation resources and strategies. HPIs are accessible and acceptable to people who smoke, but as yet are an untapped channel for communicating with Australian people who smoke.[250 251] This is consistent with the latest behavioural change theories.[252] Research that shows that the effectiveness of fear appeals increases when they are accompanied by efficacy messages.[253 254]

As part of comprehensive tobacco control measures, HPIs are designed to complement new and updated health warnings on the outside of packs. HPIs are consistent with the *Guidelines for Implementation of Article 11*, which encourage the use of 'positive and supportive information' and state that the effectiveness of health warnings that generate negative emotions can be enhanced when combined with information designed to increase motivation and confidence in the ability to quit.[255]

Content of individual HPIs would seek to address one of three critical knowledge domains:

- highlight the benefits of quitting (building response efficacy)
- promote effective services, tools, and resources available to support cessation (building self-efficacy)
- provide behavioural recommendations to help people who smoke to build skills and confidence in overcoming cravings, triggers, and other difficult situations when they make a quit attempt (building self-efficacy).

Where images are used in HPIs, steps will be taken to help ensure they represent and resonate with the diverse smoking population. Messages would be designed to be accessible to a lower literacy audience and, where possible, would adhere to government guidelines that recommend using a reading age of Year 7 ensure that materials are easy to understand.[256]

HPIs would be rotated on an annual basis to maximise visibility and minimise wear-out effects, in line with *Guidelines for Implementation of Article 11* of the WHO FCTC. The rotation schedule would align with the proposed rotation of new and updated health warnings to maximise effectiveness.

Canada has had pictorial HPIs since 2012. Canada's inserts have been found to increase quit attempts, even after controlling for traditional predictors of cessation.[257] An evaluation found that those who read the inserts a few times were 1.57 times more likely to make a quit attempt than those who never read the inserts.[258] Further, it found that the inserts were read by a sizeable number of people who smoke, with 26-31 per cent of Canadian people who smoke surveyed having read the inserts at least once in the prior month at each survey wave.[259]

Box 4. The effectiveness of health warnings and the added benefit of HPIs

Health warnings are a set of pictorial and written health warnings describing the harmful effects of tobacco use, displayed on each packet and package of tobacco products. In line with Article 11 of the Framework Convention on Tobacco Control, they provide a strong and confronting message to people who smoke about the harmful health effects of smoking and also convey the 'quit' message. Australia introduced the current suite of GHWs in 2012 under the *Competition and Consumer (Tobacco) Information Standard 2011*.

An evaluation of Australian GHWs conducted in 2018 concluded there is strong evidence of GHWs effectiveness in meeting their objectives, however the current suite of images have worn out. The evaluation recommended that GHWs are updated to increase their impact. GHWs are mature and well-developed tobacco control policy, with implementation occurring across 134 jurisdictions. When implemented in conjunction with plain packaging, WHO endorses GHWs as a 'best buy' for preventing tobacco related NCDs.

Health Promotion Inserts (HPIs) are small information cards included in tobacco product packets, which include cessation tips and highlight the benefits of quitting.

Canada has had pictorial inserts since 2012, with HPIs appearing in variety of tobacco product packets. Canada's inserts have been found to increase quit attempts, with those who read the inserts a few times in the prior month 1.57 times more likely to make a quit attempt at the subsequent wave than those who never read the inserts.

The HPIs can provide response efficacy and self-efficacy messages, consistent with health communication recommendations that suggest that fear-arousing messages (such as GHWs) should be followed by behavioural recommendation to help escape the source of fear. The greatest opportunity for behavioural change occurs when strong fear appeals combine with high response efficacy (a belief that quitting averts health risks) and self-efficacy messages (belief that one is capable of quitting).

Figure 9: Three draft Health Promotion Inserts developed for Australian people who smoke (illustrative example only)

Measure 10: Require mandatory disclosure of tobacco industry sales volumes and pricing (10A); and require mandatory disclosure of tobacco industry advertising, promotion and sponsorship activities and expenditure (10B)

Reporting and information disclosure requirements for reporting entities will give effect to Australia's obligations under the FCTC Articles 5(3), 12(c), 13(4)(d) and 20.

In line with the WHO FCTC, measure 10A would require manufacturers and importers of tobacco products to disclose tobacco product sales and pricing data to the Australian Government. This would include (for each tobacco product) the total number of units imported, sold or supplied and/or destroyed; the total mass imported, sold or supplied and/or destroyed; and the total dollar value of sales revenue including excise duty. Importers and manufacturers would be required to submit these reports to the Australian Government on an annual basis.

This measure will improve access to data to support ongoing policy development, implementation, and evaluation. It will also facilitate ongoing compliance and enforcement activities. The Australian Government currently has limited access to data on sales volumes and pricing for specific brands and products. The reporting requirement will ensure there is information available that relates to the size of the market, including information about how much of each kind of tobacco product is imported, the total amount sold or supplied as well as information about such things as sales revenue.

In line with the WHO FCTC, measure 10B would require manufacturers and importers of tobacco products to disclose any activities and expenditure on tobacco industry advertising, promotion, and sponsorship to the Australian Government on an annual basis. This information is necessary to have comprehensive advertising prohibitions, and will support policy development, implementation, and evaluation, and will enhance transparency in relation to tobacco industry political contributions, electoral expenditure and influence activities. Such transparency will provide valuable data for government policy development and evaluation of tobacco control measures. Collected data will help identify emerging trends on new and novel tobacco advertising, promotion and sponsorship activities, which undermine the existing tobacco control framework. Publication of these reports will also support consumers to understand where marketing and promotional expenditure is directed.

For both 10A and 10B, aggregated and de-identified information provided by manufacturers/importers may be published on the Department's website for key categories. Any data published would be published in accordance with the Australian Privacy Principles and would provide benefit to other public health stakeholders in tobacco control. Legitimate researchers undertaking research assessed to be in the public interest may apply to the Department for access to more detailed data. Publication of

information concerning tobacco industry advertising, promotion and sponsorship will also raise awareness of the strategies and tactics used by the tobacco industry to promote its products and tobacco use and interfere with public health policies.

The implementation of this measure is supported by Articles 13.4(d) and 20(2) of the WHO FCTC to which Australia is a party.

Notably:

Article 13.4(d) states:

> Each party shall… require… the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion, and sponsorship not yet prohibited.

Article 20(2) states that Parties:

> shall establish … programmes for national, regional and global surveillance of the magnitude, patterns, determinants and consequences of tobacco consumption and exposure to tobacco smoke. To this end, the Parties should integrate tobacco surveillance programs into national, regional, and global health surveillance programmes so that data are comparable and can be analysed at the regional and international levels, as appropriate.

Internationally aspects of this measure have been implemented in a number of jurisdictions, such as Canada, USA, NZ, and EU.

Measure 11: Protect tobacco control policy from commercial and other vested interests

Australia's implementation of measures to protect tobacco control policy from commercial and other vested interests to date has been informed by Article 5.3 of the WHO FCTC and other relevant FCTC implementation guidelines and Conference of the Parties (COP) decisions relevant to the protection of tobacco control policy from all commercial and other vested interests.

There is a well-established body of evidence that demonstrates that the tobacco industry has operated for decades with the intention of subverting the role of governments in developing and implementing public health policies to combat the tobacco epidemic,[260] [261] for example through direct and indirect political lobbying and campaign contributions.[262] Tobacco industry's use of lobbying activities, public relations campaigns, litigation, political donations, funding research and the use of front groups have led to the successful opposition of tobacco regulation and influenced perceptions about the lack of demand to ban smoking.[263] The WHO further describes that industry interference and manipulation of the media has been used 'to discredit scientific research and influence governments in order to propagate the sale and distribution of its deadly product'.[264]

In November 2019, Australia took the preliminary step of developing and publishing the Guidance for Public Officials on Interacting with the Tobacco Industry (Guide). This Guide outlines the obligations placed on public agencies and officials by the WHO FCTC and provides a best-practice framework for the implementation of Australia's commitment under Article 5.3 to protect public health policy from the commercial and other vested interests of the tobacco and e-cigarette industry.[265]

The Guide provides an important source of information for public officials but has not been fully effective in deterring the tobacco industry's influence over tobacco policy and regulatory settings.[266] Therefore, additional regulatory measures are needed to limit the influence of the tobacco industry over public health policies to reduce tobacco use.

Measure 11 provides for the creation of targeted regulatory interventions to further protect public health polices from the influence of the tobacco industry. This measure will contribute to the further implementation of the recommendations in the WHO Guidelines for Implementation of Article 5.3, with the primary goal of increasing awareness among the public, government and non-government

organisations about Article 5.3 and industry interference in tobacco control policy. By further clarifying compliance expectations, Measure 11 seeks to achieve tobacco control policies which are effective in reducing tobacco use. For further information on the design and implementation of strategies to support Measure 11, see discussion below on the implementation and evaluation of the proposed measures.

Measure 12: Require dissuasive measures on tobacco products

Dissuasive measures on tobacco products are those that have an on-product health warning such as 'Causes stroke' and/or which are unattractively coloured.

As part of comprehensive tobacco control measures, requiring cigarettes to have dissuasive features would complement and extend new and updated health warnings on the exterior packaging. Tobacco plain packaging measures have reduced the appeal of smoking by removing imagery that people who smoke use to affiliate themselves with the brand they smoke. Like their packaging, cigarettes themselves can be a powerful communication tool. Cigarettes with on-product warnings and that are unattractively coloured can impact perceptions of product harm, quality, taste, and desirability.[267] [268]

Compared to a standard cigarette, cigarettes with on-product warnings better communicate the risks and harms of smoking during the moment of consumption in a manner that cannot easily be avoided. For example, when out socially and someone is passed a cigarette from a friend, they may not see the health warning on the cigarette packet but will see the warning on the single cigarette stick. As noted by author, Crawford Moodie, when commenting on proposed Canadian cigarette warnings, 'Avoidant behaviour would be more difficult with warnings on each cigarette, as [people who smoke] typically see a cigarette when taking it from a pack, when lighting it, and when it is in the ashtray'.[269]

Experimental research indicates that cigarettes with on-product warnings and/or that are unattractively coloured are perceived as significantly less appealing, more harmful, and less likely to encourage trial, compared to a standard cigarette.[270] [271] Further, dissuasive cigarettes remind people who smoke of the risks of smoking, and can evoke conflicting feelings as people who smoke struggle to reconcile unappealing cues with the experience and identity sought.[272] [273]

This measure is expected to increase consumer knowledge of health harms of smoking and reduce the appeal of tobacco products. It is expected to reduce smoking uptake among youth and increase success in quitting among people who smoke, by weakening positive feelings about tobacco products. The measure could act as a deterrent for initiation among youth and young adults, who are especially sensitive to social appearance.[274] Over time, it will contribute to reducing smoking prevalence.

Dissuasive measures on tobacco products help to increase negative health perceptions about smoking and contribute to lowering smoking prevalence by discouraging uptake and encouraging cessation.[275] See Figure 10 for examples of dissuasive cigarette designs.

Figure 10: Examples for dissuasive measures on tobacco products tested in Australia[276] [277]

Having on-product warnings help to ensure that health messaging reaches people who may have limited visibility of the GHWs, for example because they have been offered a cigarette from someone and have not handled or viewed its packaging.

Australian market testing has identified that on-product warnings and unattractively coloured products may make smoking less enjoyable. Market research has identified on-product warning messages that are impactful for Australian smokers, with placement on the stick found to be particularly effective. Further market testing is needed to identify a colour/s that is dissuasive to most Australians.

Consistent with the approach to GHWs and HPIs, and in keeping with findings from Australian market testing, rotation requirements would apply to maximise visibility and minimise wear-out effects.

This measure would modify current requirements in the TPP Act to require messages to be printed on cigarettes, and/or to modify the colour of a product. Currently the TPP regulation 3.1.2 allows cigarettes to only be marked with an alphanumeric code which is not related to the brand or variant name.

During the stakeholder workshops there was support for dissuasive measures on tobacco products being pursued as part of the thematic review.[278]

This measure is supported by a number of WHO FCTC Articles. Notably, the Guidelines for Article 11 of the WHO FCTC[xii] encourage parties (in Clause 11) to consider requiring health warnings on individual cigarette sticks.[xiii]

Canada has implemented regulations for the requirement of health warnings on cigarettes, little cigars (with tipping paper), and filtered cigarette tubes.[279, 280] The Canadian dissuasive health warning designs involve two sets of 6 bilingual warning images, with black text on a white background, with the sets changed after 24 months. The warning will appear on the tipping paper (paper that wraps over the filter) portion of the cigarette. However, in the case of a cigarette that does not have tipping paper, the health warning must be displayed on a display area that consists of the surface of the paper that covers the rolled tobacco. Every manufacturer must, to the extent possible, use each health warning set out in each applicable rotation of health warnings in respect of an equal number of each size of each brand name of cigarettes, little cigars and tubes that they package in a year. The new regulations came into force on 1 August 2023 and will be implemented through a phased approach that will see on-product health warnings on tobacco products in retail settings within 12-24 months.

[xii] WHO Framework Convention on Tobacco Control, 'WHO Framework Convention on Tobacco Control' (World Health Organization), 2003). Available at: WHO.

[xiii] WHO Framework Convention on Tobacco Control, 'Draft Guidelines For Implementation Of Article 11 Of The WHO Framework Convention On Tobacco Control "Packaging And Labelling Of Tobacco Products"', (Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control, World Health Organization, 2008). Available at: FCTC-COP3-7.

What is the likely net benefit of each option?

This section outlines the benefits and cost for each of the three options proposed in this IA.

A Regulatory Burden Measurement Framework has been applied to each option outlined in the IA. The Regulatory Burden Measurement Framework follows the guidelines provided by the Office of Impact Analysis.[281] The regulatory burden measurements are calculated on a ten-year basis. As per the guidelines of the Office of Impact Analysis, costs are presented on an average per year basis, with one-tenth of the initial start-up costs added to the expected ongoing annual regulatory burden costs to provide the annual average cost that is expected for the first ten years of the proposed regulation. A range of assumptions have been used as model inputs. Many of the key assumptions are the same between the measures, with a few variations. Whilst 2022 ABS data shows that around 2 million Australians are smoking daily, a placeholder allowance has been included in the regulatory burden measurements for 1 million affected smokers. The rationale for reducing this figure is that not all smokers will necessarily be impacted by the proposed reforms with some choosing to quit. The uncertainty around this has been counterbalanced by providing a generous estimate for average time impact costs. [282] This input has been placed in the regulatory burden inputs which can be found in the Appendices from Table 10 onwards. Some other consistent assumptions are that work-related labour costs are valued at $79.63 per hour, and non-work-related time costs are valued at $36 per hour[283] Training is assumed to take 30 minutes per staff member with 30 minutes of trainer time for every hour of training received; and that there are eight staff per retail outlet. The number of tobacco retailers has been estimated at 35,000 drawing on ABS statistics relating to the cumulative number of retail trade businesses in operation in Australia in 2022 and [284] New South Wales.[285] This input has been placed in the regulatory burden inputs which can be found in the Appendices from Table 10 onwards.

The key inputs that are based on the assumptions vary between the measures as noted below.

The regulatory burden estimates depend on publicly available data and external (third party) perspectives on how proposed regulations will impact on industry participants. Each provision is currently modelled independently of other provisions. The cumulative regulatory burden of multiple provisions in Option 3 is assumed to be additive, except for potential stockholding consequences where the joint roll out of provisions is expected to mitigate the potential for stock losses. The next stage of the process will be a critical assessment of the proposed measurement approach. The next requirement will be to 'ground truth' the model inputs, update wage and price assumptions, verify population figures, provide more accurate figures on the scale of operations, and assess the scale of adjustments to regulation, as required.

Detailed tables of the Regulatory Burden Measurement Framework can be seen in the Appendices.

Evidence has shown that the implementation of preventive tobacco control measures leads to fewer Australians dying prematurely due to smoking, and an overall reduction in healthcare and productivity costs. In addition to the likely benefits prevention and cessation of smoking will have for the health, wellbeing and quality of life for individuals, in the long term reduced prevalence of smoking can be expected to reduce the burden of costly tobacco-attributable illness, and reduce health, social and economic inequalities for smokers, their families and the wider Australian community. This is particularly the case for populations who experience higher rates of smoking. It is anticipated that the measures will contribute to prevent hundreds of thousands of premature deaths, increase workers' economic productivity and reduce the burden on carers. The reduction of tobacco-related illness would also likely reduce pressure on time-constrained health professionals and the health care system.

If considered in the context that tobacco use is a leading cause of preventable death and disease and is a key health risk factor for Australians, the benefits of this suite of reforms are expected to have far-reaching health, wellbeing, social and economic impacts for Australia.

Option 1A: maintain status quo and allow the Regulations to sunset

Aspects of the regulatory framework for plain packaging and advertising prohibitions would cease to operate. These restrictions have contributed to a reduction on smoking rates. Allowing the regulations to sunset would have few, limited benefits and significant costs and undermine Australia's efforts in tobacco control.

Benefits

There would be very minor benefits for tobacco retailers in reduced compliance costs. Tobacco manufacturers and importers would no longer have to comply with advertising restrictions, including plain packaging and at the point of sale. Sellers of tobacco products may receive direct benefits of increased sales of tobacco products due to the removal of advertising restrictions.

Costs

Allowing the Regulations to sunset would mean that aspects of the plain packaging requirements and retail advertising prohibitions would be removed. Removing the Regulations would have significant costs because regulating advertising and promotion reduces smoking uptake and prevalence. Comprehensive advertising bans have been shown to reduce smoking uptake by an average of 6 per cent and smoking prevalence by an average of 4 per cent.[286] Without the Regulations, the reduced social, economic, and health impacts that have arisen from Australia having strong controls on tobacco advertising would be lost. Without the Regulations, the benefits of the regulatory framework would be lost, and the removal could be expected to result in:

- a relative increase in the appeal of tobacco products to consumers compared to current state
- reduced effectiveness of health warnings on the retail packaging of tobacco products compared to current state
- increased ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products compared to current state.

Removing the Regulations would also mean that Australia would no longer be giving effect to obligations Australia has as a Party to the WHO FCTC.

An analysis of the social cost of this option has been conducted. According to the Australian Bureau of Statistics' *Insights into Australian Smokers, 2021-22* report, there were 1.978 million Australian smokers who smoked on a daily basis in 2021-22, representing 10.1 per cent of the adult population.[287] The National Drug Research Institute's central estimate was that tobacco use in Australia imposed a social cost of $136.9 billion in 2015-16.[288] This implied an average social cost of $57,048 for each of the 2.4 million Australian adults that were estimated to smoke daily in 2015-16. Accounting for inflation this would mean that the National Drug Research Institute estimates would suggest a social cost per smoker averaged $64,659 per smoker in 2020-21, and a total social cost of $127.9 billion. The implication is that a 1 per cent increase in the number of smokers (i.e., a net addition of 19,780 daily smokers) could be expected to impose an annual social cost in the vicinity of $1.3 billion. A 4 per cent increase in the number of smokers, a suggested scale of the impact of comprehensive advertising bans in research, would have an annual social cost in the vicinity of $5.1 billion.

A selection of the summary of tangible and intangible costs of tobacco use in Australia are outlined in Table 7 below.

Table 7: Summary of a selection of costs of tobacco use in Australia (with ranges) 2015/2016[289]

Summary of costs (with ranges*) in 2015/16			
Domain	**Central estimate ($)**	**Low bound ($)**	**High bound ($)**
Tangible costs			
Tangible costs of premature mortality	4,045,343,309	4,045,343,309	4,045,343,309
Avoided healthcare costs	-2,275,922,187	-2,275,922,187	-
Healthcare	6,787,191,713	4,926,406,396	8,143,292,217
Other workplace costs	4,985,357,708	4,003,870,310	6,039,946,435
Other tangible costs	5,701,263,430	5,648,714,854	5,727,941,138
Total tangible costs	**19,243,233,973**	**16,348,412,682**	**23,956,523,099**
Intangible costs			
Intangible costs of premature mortality	92,108,544,749	49,058,706,233	272,906,689,958
Intangible costs of smoking attributable ill-health	25,562,393,635	2,937,793,265	102,880,616,235
Total Intangible costs	**117,670,938,384**	**61,996,499,498**	**375,787,306,193**
TOTAL COSTS	**136,914,172,357**	**68,344,912,180**	**399,743,829,292**
*High and low values were not calculated for all domains; may not sum due to rounding			

Source of table: S Whetton et al, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (National Drug Research Institute, Curtin University, 2019). Available at: T273.pdf (curtin.edu.au).

Option 1B: Retain the tobacco control regulatory framework in its current form

The current regulatory framework is effective in achieving its aim of reducing tobacco-related harm. However, this regulatory framework could be strengthened to address limitations and inefficiencies and further reduce smoking prevalence.

Benefits

Retaining the current regulatory framework in its current form would ensure that the current advertising prohibitions continue to be an important part of Australia's tobacco control activities. Other benefits to retaining the current regulatory framework are that it would continue contributing to public health outcomes. Consumers, regulators, and industry would also face no additional regulatory burden.

Consultation for the Review in 2019 found that the majority of stakeholders considered the TAP Act to remain relevant and fit-for-purpose and that it has supported a reduction in smoking in Australia.[290] The Post-Implementation Review of the Tobacco Plain Packaging legislation found that the plain packaging measure (plain packaging and enlarged health warnings) is achieving its aims and that 'tobacco plain packaging is having a positive impact on its specific mechanisms as envisaged in the TPP Act'.[291] While the full effect of the tobacco plain packaging measure is expected to continue to be realised over time, expert analysis over the period 1 December 2012 to 30 September 2015 showed that smoking prevalence was 0.55 percentage points lower during this period than it would have been without the 2012 packaging changes.[292]

The Post-Implementation Review concluded that tobacco plain packaging was improving public health and was expected to have substantial public health outcomes into the future. Plain packaging was also found to increase the effectiveness of the health warnings.[293]

A growing body of Australian research is also demonstrating the positive effects of the plain packaging measure on the intended mechanisms by which the policy is intended to act.[294] This includes research that indicates that the measure reduces the appeal of tobacco products, increases the effectiveness of health warnings, and reduces the ability of tobacco products to mislead consumers.

Since the introduction of plain packaging measures, there has been a decrease in smoking prevalence amongst young people in Australia including a reduction of exposure of young people to tobacco promotion and a reduction in perception of smoking prevalence.[295] There has also been a decrease in smoking amongst disadvantaged Australians and an increase in people who have never smoked.[296]

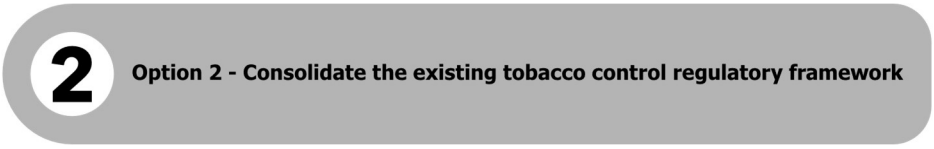
Other benefits to retaining the current regulatory framework are that it would continue contributing to public health outcomes. Consumers, regulators, and industry would also face no additional regulatory burden. However, evidence suggests that legislative reforms will have significantly greater impact than retaining the current regulatory framework in its current form.

Costs

As outlined earlier, despite significant progress in reducing smoking prevalence, tobacco use continues to cause significant health, social and economic costs. Without further tobacco control measures, these costs will continue, and the Australian Government is unlikely to meet its target to reduce the daily smoking rate to below 10 per cent by 2025.

At the current 10.8 per cent smoking prevalence and adjusting National Drug Research Institute social cost of smoking estimates for 2015-16 into current prices, it is estimated that Option 1B would have a benchmark annual cost of $157 billion.[297] These costs would have increased since 2015/16, noting the Consumer Price Index indicates that the general price level in Australia in 2022 was 17.5 per cent above that prevailing in 2015-16. Tangible costs in this estimate include 'the reduction in economic output due to premature mortality, hospital separation costs, other medical and social care costs including the cost of informal care provided by family and friends, costs arising from workplace absenteeism and presenteeism, and spending on tobacco by people dependent on smoking.[298] Intangible costs include the value of life lost, pain and suffering from premature suffering and early loss of life attributable to smoking.

There would be some minor administrative costs to government to remake the existing TAP and TPP Regulations, but no additional regulatory burden created for industry.



Option 2: Consolidate the existing tobacco control regulatory framework

Option 2 seeks to modernise and streamline the regulatory framework for tobacco control by consolidating the legislation and addressing current limitations and inefficiencies.

Benefits

This option will improve the efficiency of the regulatory framework and its ability to achieve current objectives. It will also improve the scope of advertising prohibitions by including new and emerging products, such as e-cigarettes and other novel products.

Key impacts of this option include:

- improved public health outcomes
- greater clarity
- reduce uptake, increase cessation, and improve health knowledge among people who smoke
- improved enforcement and compliance powers and tools
- signalling of an ongoing commitment to the WHO FCTC.

The key beneficiaries are individuals who either cease using tobacco products or are dissuaded from using them in the first place. The ongoing commitment to tobacco control signalled by this option would consolidate and potentially increase the number of beneficiaries. In addition, family and associates would be less exposed to SHS and fire risks and would benefit in other ways from the extended lives of people who smoke and those with the potential to smoke.

Updating and improving health warnings would build on the success of the existing framework in reducing the smoking rate. The measures would promote greater awareness to people who smoke of the health risks associated with tobacco use and exposures and would increase the effectiveness of health warnings by increasing their noticeability. Restricting advertising would similarly build on existing measures, but would ensure that incidental advertisements would also be covered by the prohibition on advertising.

To the extent that the options improve the efficiency of tobacco control and enhance Australia's international reputation, there are also likely to be some benefits for the entire Australian population.

The measures will also support more efficient and effective compliance and enforcement activities that support the implementation of the measures. The refinements to the TAP Act include a move to a civil penalty regime – making enforcement and deterrence easier with a range of options available, such as fines and injunctions. The amendments will introduce powers and functions for authorised persons to investigate alleged contraventions of the TAP Act. The amendments will also enable the Department to seek injunctions or enforceable undertakings for alleged contraventions of the TPP Act. Authorised Officers will be able to seek monitoring warrants for the purpose of confirming compliance with the requirements of the TPP Act and TAP Act respectively.

Cost

In addition to costs relating to preparing the consolidated legislation, there will be implementation costs for government agencies. These implementation costs will be mitigated by potential efficiency gains for government agencies responsible for tobacco control implementation.

Tobacco companies and retailers might need to devote some time and resources to investigate the implications of the option, including costs initially to re-engineer their packaging processes to accommodate the changes in labelling. However, this should have little, if any, additional ongoing impact on regulatory burdens. The consolidation of legislation will have no material impact on commercial activities for tobacco retailers. The other proposals (sponsorship, publicity, and packaging) are in essence, clarification and reinforcement of existing regulations. These factors are interpreted as being implemented by government to enforce compliance with requirements and are therefore outside the scope of the requirement for a Regulatory Burden Measurement Framework.[299]

There is a possibility that tobacco companies may reduce their sponsorship and publicity activities thereby lowering the costs of their operations. However, as this is hypothetical these actions have not been included in the calculations.

For e-cigarette manufacturers and retailers, there would be some costs to investigate and comply with the restrictions on advertising. The TAP Act and TPP Act do not currently apply to e-cigarettes, so this would be a one-off cost in addition to time and resources for e-cigarette manufacturers and retailers, to ensure their advertising and promotion activities comply with the restrictions. There may be some costs related to the removal of already purchased branding and advertising that would no longer be permitted. Once implemented, the ongoing costs to e-cigarette companies and retailers would be limited as they are for tobacco companies. There may similarly be some eventual operational cost savings for e-cigarette companies and retailers if they reduce their advertising, sponsorship, and publicity activities.

Table 8: Summary of impact for Option 2

Key	Benefits	Costs

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
Measure 1 Consolidate legislation: TPP Act and Regulations; TAP Act and Regulation; 2005 Court Enforceable Undertakings; Fire Risk Regulations; Oral Tobacco Ban; and Information Standard	Reduced duplication of compliance and enforcement functions. Alignment of policy and enforcement within government through a single regulatory framework	Greater clarity on tobacco control legislation and regulations. Will not require any additional expenditure on tobacco process equipment.	Greater clarity on tobacco control legislation and regulations. Will impose no stock losses.	Greater clarity on tobacco control legislation and regulations	Greater clarity on tobacco control legislation and regulations	Greater clarity on tobacco control legislation and regulations	Greater clarity on tobacco control legislation and regulations	Greater clarity on tobacco control legislation and regulations
	Cost of drafting new legislation and regulations; parliamentary processes to refine and enact new legislation	Minor costs associated with obtaining assurance that consolidation does not involve substantive changes including legal or marketing services.	Negligible for each individual retailer but accounts for 90% of estimated regulatory burden because of the number of retailers					
Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): $3.667m **Total regulatory burden estimate for individuals:** $0 **Total substantive compliance costs (average annual):** $3.667m								
Measure 2 Update and improve health warnings	Reduced smoking and externalities; increased use of cessation services	Alignment of messages with packaging could simplify quality assurance processes			Reduced negative externalities	Improved information about harms for tobacco use	Improved information about harms for tobacco use	Improved information about harms for tobacco use Improved diversity of images and representation
	Cost of establishing new regulatory framework; monitoring and enforcement costs; increased cost of cessation services	Set up costs in the first year include cost of planning and modifying manufacturing processes; system design, training, professional services, re-engineering and potential cost of unsold stock following transition period. Ongoing costs include training, professional services and operation costs	Potential cost of unsold stock following transition period. Cost of training and quality control.	Potential cost of unsold stock following transition period, Cost of training and quality control.				

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $3.064 **Total regulatory burden estimate for individuals:** $0 **Total substantive compliance cost (average annual):** $3.064m								
Measure 3 Further restrict advertising provisions	Greater control of tobacco advertising activity	Lower costs associated with promotion activities			Reduced public visibility of the tobacco industry and novel and emerging products	Reduced scope for positive imaging associated with tobacco use and novel and emerging products	Reduced exposure to advertising	Reduced exposure to advertising
	Cost of establishing new regulatory framework; monitoring and enforcement costs	A faster retrenchment of market; costs of downsizing promotion activities.						Information will continue to be accessed if not policed effectively by regulators
Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Negligible (adjustment costs offset by cost savings) **Total substantive compliance costs** (average annual): Negligible								
Measure 4 Improve coverage, enforcement, and compliance for tobacco control	Improve confidence that tobacco control regulations are being enforced				Improve confidence that tobacco control regulations are being enforced			
	Costs of shifting enforcement responsibilities between departments; training costs for new enforcement officers;							
Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Negligible **Total substantive compliance costs** (average annual): Negligible								

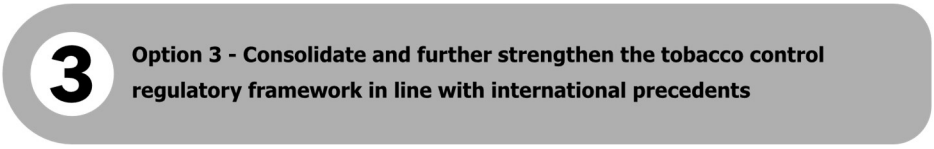
Regulatory burden measurement framework

It is estimated that Option 2 would cost $3.7 million (business cost). Regulatory burdens for Option 2 are expected to only accrue to the tobacco industry, with limited impact on retailers and individual people who smoke. The main drivers for the first-year costs to business are the design of new systems to comply, training for staff, and stock losses.

Further detail on the likely regulatory burden of Option 2 is provided in Appendix 1.

Savings to offset Regulatory Burden Measurement (RBM)

Due to the high cost imposed by tobacco use, it would require just 12 people to permanently quit smoking each year to justify the regulatory burden of $3.7 million of Option 2. This is equivalent to 0.00047 per cent of people who smoke and represents 1 in 210,705 people who smoke.



Option 3: Consolidate and further strengthen the tobacco control regulatory framework in line with international precedents

Option 3 seeks to strengthen the regulatory framework for tobacco control in line with international precedents, and to modernise and streamline the relevant regulatory framework as outlined in Option 2.

Option 3 includes the four measures set out in Option 2, as well as the following policy measures (measure 5 – 12):

- Measure 5: Standardise tobacco product size – cigarette pack, carton and stick size, RYO tobacco pouch size and filtered cigar and cigarillo pack size.
- Measure 6: Reduce tobacco product attractiveness and palatability by restricting the use of additives.
- Measure 7: Reduce tobacco product attractiveness by regulating product design features that create novelty value.
- Measure 8: Prohibit the use of brand and variant names that falsely imply reduced harm.
- Measure 9: Require Health Promotion Inserts to encourage and empower people who smoke to quit.
- Measure 10A: Require mandatory disclosure of sales and expenditure data.
- Measure 10B: Require mandatory disclosure of advertising and promotion expenditure data.
- Measure 11: Protect tobacco control policy from commercial and other vested interests.
- Measure 12: Require dissuasive measures on tobacco products.

Benefits

Option 3 is expected to have the most significant public health benefits. Of the three options, this option will provide the greatest contribution to assisting the government to reduce smoking prevalence.

The various components of Option 3 are designed to work in a complementary and synergistic manner to reduce prevalence by:

- limiting the exposure of the public to messages and images that may persuade consumers to smoke
- reducing product differentiation thereby reducing appeal to different market segments, reducing use and uptake, particularly among youth
- reducing the attractiveness and appeal of tobacco products, particularly to youth
- removing small pouches of RYO tobacco from low price points that appeal to youth in particular
- reducing the shift from experimentation to regular use of tobacco products
- reducing the ability of tobacco products and the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking
- building self-efficacy and response efficacy to create greater behavioural change and encourage cessation

- improving transparency and access to data to support Australia's ongoing tobacco control measures.

The wider range of provisions within Option 3 increases the potential for positive reinforcement between provisions. For example, an aim of HPIs is to reinforce the GHW messages by providing information that will support people who smoke with attempts to quit smoking. Likewise, Option 3 includes provisions to reduce the attractiveness of smoking by not just limiting device design aspects but also through limiting product branding and promotion activities. More comprehensive data disclosure requirements will enhance the ability to monitor not only the overall performance of provisions but also analyse their impact on vulnerable cohorts such as the less affluent.

Each provision is expected to have a higher impact on reducing smoking prevalence when working with the other recommended provisions than if introduced in isolation. This approach has also been shown to be effective through the comprehensive range of measures implemented by Australian governments to date, which have provided a synergistic effect in reducing smoking prevalence and been instrumental in ensuring its long-term decline.

It has been argued that the 'hardening hypothesis', which proposes that tobacco control measures have more readily influenced people who smoke who found it relatively easy to quit smoking, has created a 'hardening' effect with remaining people who smoke being increasingly resistant to tobacco control measures. Factors associated with 'hardening' may include motivation to quit, nicotine dependence, quit outcomes or a combination of these factors. However, reviews have shown that the weight of evidence available does not support the 'hardening hypothesis'.[300] Rather, evidence suggests that people who smoke have instead become more motivated to quit and less dependent on smoking, and a multifaceted approach to tobacco control has proven to positively impact 'hardening' indicators by increasing motivation to quit and reducing opportunities for tobacco use.[301]

Key beneficiaries from these policy measures include:

- people who have never smoked who are discouraged from taking up smoking
- family and associates who are less exposed to SHS and fire risks, and benefit in other ways from the extended lives of people who smoke and those with potential to smoke

As Option 3 is intended to reduce the prevalence of tobacco use and have significant public health benefits across the Australian population, it is expected that a range of diverse groups with higher smoking rates or who are at a higher risk of harm from smoking will benefit.

It is anticipated that the reforms outlined in Option 3 will have a greater impact in helping to bridge the divide and improve the health of certain groups experiencing disadvantage within the Australian population. For example, people who lived in areas of most disadvantage are more than three times as likely to be current daily smokers than those in areas of least disadvantage.[302]

Further, as smoking has been reported as the largest contributory factor in the difference in life expectancy between those with mental health conditions and those without, it is anticipated that these reforms will improve the health outcomes for those with mental health conditions.[303] There is also evidence that pregnant women who quit improve their health, and that of their foetuses and newborns and it is anticipated that the suite of reforms outlined in Option 3 will have a positive health impact on pregnant women and their children.[304] Finally, as the suite of reforms in Option 3 is expected to reduce prevalence and uptake among youth and young adults, this is likely to impact positively on health consequences and reduce the development of chronic disease across the full life course.

It is noted that 12 per cent of the total preventable health burden for First Nations people arises from tobacco use, and the use of e-cigarettes is growing. Whilst the components of Option 3 are population-level measures, they will also have an important impact on reducing smoking rates among First Nations people and contributing to the target within the NTS of reducing rates among First Nations peoples (aged 15 or over) to 27 per cent or less by 2030.

First Nations peoples are at a higher risk of harm from tobacco use and have a high prevalence of tobacco use.[305] In recognition of this, the policy approach for health warnings, health promotion inserts and dissuasive measures on tobacco products will include market testing to ensure resonance and impact with First Nations peoples, as well as other population groups. Quantitative surveys and qualitative focus groups are undertaken to inform the development and improvement of messages and graphic images to better understand the impact on those who smoke all types of tobacco products. First Nation perspectives are gathered within this research as a key population group, along with other high-risk populations (such as those who are culturally and linguistically diverse) to ensure that messaging is effective and culturally safe.

Continued targeted investments are necessary to support culturally safe and locally relevant approaches to reduce smoking prevalence among First Nations people and meet national targets. Early interventions to discourage and prevent use of e-cigarettes and to support cessation are also critical. In the 2023-24 Budget the Government announced $141.2 million to expand the Tackling Indigenous Smoking program to prevent the uptake and reduce the prevalence of smoking and vaping. Option 3 will complement and work in tandem with First Nation specific tobacco control measures like the Tackling Indigenous Smoking program, targeted communication campaigns, and dedicated clinical support services provided via Aboriginal Medical Services and states and territory led programs.

Option 3 gathers data that would support the development and implementation of broader tobacco control efforts. The measures would result in additional information being disclosed to regulators on tobacco product ingredients, advertising, promotion, and sales data. Requiring the disclosure of this information to regulators would align with the obligations under the WHO FCTC by strengthening efforts to prevent tobacco industry interference in public health policies by ensuring that information provided by industry is transparent and accurate (Article 5.3); to inform the development of public awareness of the strategies and activities of the tobacco industry and its products, such as those relating to advertising, promotion and sponsorship (Article 12 and the Guidelines for Implementation of Article 12 of the WHO FCTC); and to support the development and implementation of relevant policies, activities and regulations, and monitoring of market trends (Article 10 and the Partial Guidelines on the Implementation of Articles 9 and 10).

The measures outlined in this IA are expected to have a complementary and synergistic effect on reducing smoking prevalence. They are designed to work in harmony to reduce tobacco product attractiveness and appeal, minimise misperceptions of harm, and encourage and motivate people who smoke to quit. It is noted that some measures will require the tobacco industry to amend their products in order to comply. However, given the evidence base requiring the current health warnings and messaging to be updated and improved, it is proposed that all measures outlined in this IA be implemented at the same time. This will reduce costs to business and increase the efficiency of implementation. All the proposed policy measures have been introduced internationally and align with Australia's obligations under the WHO FCTC. It is proposed that measures proposed in this IA will work together to achieve the overall public health outcomes of reducing uptake among people who do not smoke and increasing cessation among those currently smoking.

Costs

Option 3 would have costs primarily for the tobacco industry. These costs are discussed in more detail in the RBM section below.

There is some potential that the measures would increase prices, but this is not expected to be significant because the majority of the retail price component is made up of tobacco excise and GST. Tobacco excise and GST are existing measures which are outside the remit of this legislative review. It should be noted, however, that the Department is supportive of price-based incentives for people who smoke to quit as research shows taxation is one of the most effective and efficient ways to curb tobacco consumption.[306]

The only measure that would be expected to have a direct impact on price point is the standardisation of pack size for RYO tobacco. A large segment of the RYO products offered in the Australian market are smaller pack sizes which are intended to keep the upfront cost more affordable for people who smoke, including lower socio-economic groups and youth. Increasing the minimum pack size to 30 grams will increase the upfront cost to people who smoke, however, is not expected to increase the cost of RYO tobacco per gram, assuming no change to consumption habits.

There is potential that the measures would result in product withdrawals. While this may restrict individual consumers' choice in products, the withdrawal of tobacco product offerings and a narrower choice of products are a positive outcome from a public health perspective. The changes to product familiarity are likely to disrupt the regular cycle for people who smoke who are brand loyal and will likely cause consideration as to whether the consumer wants to seek a new product or attempt to quit.

Changes to any regulatory framework can create risks of unintended consequences. For example, it could be hypothesised that changes to tobacco products would result in increased illicit trade in tobacco or affect e-cigarette usage patterns. However, the risk of this is expected to be low. The introduction of tobacco plain packaging significantly changed the market of tobacco products, with a number of brand and variants not being continued in the Australian market post implementation. Further, the Australian Government's proposed regulatory interventions into the e-cigarette market is likely to further minimise the risk of an increase in demand for e-cigarettes among youth.[307]

The Post Implementation Review for tobacco plain packaging found that the TPP Act had no effect on the tobacco black market in Australia.[308] The Review referred to a number of peer-reviewed studies which assessed the potential changes in the Australian illicit tobacco market since the implementation of the tobacco plain packaging measure.[309] These studies found no change in reported use of unbranded illicit tobacco, no evidence of increased use of contraband cigarettes, low levels of use of cigarettes likely to be contraband, and no increase in purchases of tobacco from illegal trade.[310]

As a result, the measures are not expected to result in increases in illicit trade. Further, complementary regulatory measures, such as on existing e-cigarette advertising regulations, will also minimise the risk of a material uptake of e-cigarettes following any tobacco control regulatory change.

Implementation costs for government agencies will be mitigated by potential efficiency gains for those government agencies responsible for tobacco control implementation. The additional compliance requirements are not expected to be onerous, and the main additional cost would be for laboratory testing of tobacco products to ensure tobacco products are compliant with Measure 6 that would reduce tobacco product attractiveness and palatability by restricting the use of additives. The Australian Government would pay for this testing of products.

The Australian Government may also consider cost recovery options. The Regulations may prescribe fees that may be charged in relation to activities carried out by the Australian Government in the performance of functions or the exercise of powers under the proposed legislation.

Regulatory burden measurement framework

It is estimated that Option 3 imposes a regulatory cost on businesses of $21.77 million per year. This cost is calculated based over a ten-year period, whereby the required number of smoking cessations are relatively trivial (for example $21.77 million per year would be justified with 73 permanent quits per year, which is 0.0028 per cent of the 2.6 million people who smoke daily in Australia). It is noted, however, that the 73 quit count applies to those who completely cease smoking and never relapse. Given the difficulty of breaking nicotine addiction, it is likely that many more, potentially several hundred, will need to attempt to quit for 73 to be completely successful.

Regulatory burdens for Option 3 are likely to be most concentrated on the tobacco industry but will also impact retailers and individual tobacco users. However, the sheer number of tobacco users means that even small per user regulatory burden impacts add up to a larger aggregate impact estimate than the more concentrated impacts on industry. For example, the estimate for the regulatory burden for Option 3 has an average annual burden of $21.77 million, but of this burden $12.6 million relates to burdens faced by existing tobacco users. The per user impact assumptions are not large (on average around $100 per user or $10 on a per year basis), but with an assumed impact on one million tobacco users, the national burden scales up into the millions of dollars.

The nature of the expected burden on individual users relates to inconveniences associated with adapting to the new regulatory environment including learning about and adapting consumer patterns to the proposed regulatory changes. Individual tobacco users are likely to be particularly inconvenienced adapting to changes in brand names, product design, and the removal of palatability additives or devices. These four measures are also likely to be the ones that are likely to impose a burden for retailers, as retailers need to understand the implications of these measures and they will often be the point of contact for tobacco users learning about the changes.

For the tobacco industry, the primary burden will relate to managing often complex transition processes as they will likely require:

- advice from external professionals
- re-designing of systems
- re-engineering of manufacturing processes, sometimes requiring the purchase of new equipment[xiv]
- training of affected staff
- planning stock management through transitions (a twelve-month roll-out will limit but not eliminate stock losses).

Individual measures will also have ongoing cost impacts for the tobacco industry:

- mandatory disclosure requirements, advertising/promotion restrictions, and palatability regulations are likely to add to their ongoing administration burden
- the change-over of GHWs and HPIs are likely to impose ongoing operation costs including quality control impacts.

There are also areas where there is a potential for reductions in ongoing operation costs for the tobacco industry, for example:

- ongoing quality control systems are likely to be streamlined by regulations that standardise product design, limit the type of palatability agents that can be added to tobacco, and the proposed measures relating to GHWs are likely to allow simpler synchronisation between ten warnings and the standard of ten packs of cigarettes per carton
- standardising product designs should simplify manufacturing processes and hence lower production costs
- simpler, less diverse, product lines should also simplify management and marketing processes, and thus also lower ongoing training cost requirements.

Savings to offset RBM

Due to the high cost imposed by tobacco use, it would require just 73 people to permanently quit smoking each year to cover the $21.77 million estimate for the regulatory burden of Option 3. At 0.0028 per cent of the Australian smoking population, this means that the social benefits of lower

[xiv] The manufacture of tobacco products no longer takes place in Australia, however OIA guidelines recommend that it is appropriate to measure the burden of Australian regulations on manufacturing costs, irrespective of the country in which manufacturing takes place.

smoking rates are likely to offset the $21.77 million regulatory burden estimate if the policies encourage 1 out of every 37,420 people who smoke to quit smoking.

The $21.77 million regulatory burden estimate is an estimate, but even if the total annual cost for Option 3 was $100m (almost five-times larger than the $21.77 million regulatory burden estimate), this expense would still be justified as long as at least 337 people who smoke successfully and permanently quit smoking each year. 337 people who smoke represent 0.013 per cent of the Australian smoking population. In other words, spending $100 million per year on tobacco control policies would be justified if they were expected to be instrumental in helping 1 out of every 7,727 people who smoke to quit smoking each year. Further detail on the likely regulatory burden of Option 3 is provided in Appendix 2 and the proposed impact on stakeholders in Table 9. The individual regulatory impact of each policy measure is provided in Appendices 3-8.

The table below outlines a high-level overview of the proposed impacts on stakeholders arising from Measures 5 – 12, which are the additional measures unique to Option 3.

Table 9: Summary of impact for additional Option 3 measures

Key	Benefits	Costs

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
 **Measure 5** **Standardise tobacco product size – cigarette pack, carton and stick size, RYO tobacco pouch size and little cigar and cigarillo pack size**	Reduced smoking uptake and negative externalities	Reduced manufacturing complexities and costs	Less frequent need to update product information for retailers		Reduced negative externalities	Reduced smoking uptake	Reduced smoking uptake; enhanced ability to read price signals; potential increase in cessation	Unclear impact, with cost rather than size more likely to drive behaviour change.
	Cost of establishing new regulatory framework; minimal monitoring and enforcement costs	Cost of planning and modifying manufacturing processes including package redesign and re-engineering implications; training costs; may turn to price competition; potential cost of unsold stock following transition period; reduced ability to exploit and extract value from different segments of the tobacco market and would likely require professional services.	May turn to price competition; potential cost of unsold stock following transition period	May turn to price competition; potential cost of unsold stock following transition period	Training costs.		Reduced choice	
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $-24.870m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $1.8m **Total substantive compliance costs** (average annual): $-23.0**7m**							

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
 **Measure 6** **Reduce tobacco product attractiveness and palatability by restricting the use of additives**	Reduced smoking uptake and negative externalities; improved data accuracy from reporting to improve policy-making	Simplify manufacturing processes and lower costs of production			Reduced negative externalities	Reduced smoking uptake	Reduced smoking uptake; increase in quit attempts and successful cessation	Anything to make tobacco less attractive is beneficial, with the removal of menthol likely to provide a long-term impact.
	Cost of establishing new regulatory framework, including laboratory testing, monitoring, and enforcement	Cost of altering ingredient and reporting; reduced ability to target consumers and increase market share; potentially costly transition period with stock, planning and re-engineering implications, training costs, external professional services.	Cost of any unsold stock following transition; costs of understanding and explaining changes to consumers; customer dissatisfaction with new products	Cost of any unsold stock following transition			Reduced choice	
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $14.429 **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $3.6 **Total substantive compliance costs** (average annual): $18.029							
 **Measure 7** **Reduce tobacco product attractiveness by regulating product design features that create novelty value**	Reduced smoking uptake and negative externalities; improved data from reporting to improve policy-making	Simplify manufacturing processes and costs in the long term. Minimal stock losses due to a 12-month roll out period. Decrease ongoing quality control costs.			Reduced negative externalities	Reduced smoking uptake	Reduced smoking uptake; increase in quit attempts and successful cessation	Anything to make tobacco less attractive is beneficial, with the removal of menthol likely to provide a long-term impact.
	Cost of establishing new regulatory framework; limited monitoring and enforcement costs other than additional training	Costs of transition planning, modifying manufacturing processes, reporting; reduced ability to increase market share; dealing with unsold stock following transition period; manufacturing / advertising cost reduction due to simplified product range	Some transition costs from simplified product range; potential cost of unsold stock following transition period	Potential cost of unsold stock following transition period			Reduced product choice and a loss of access to product information	
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $-3.815m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $3.6m **Total substantive compliance costs** (average annual): -$0.215m							

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
 **Measure 8** **Prohibit the use of brand and variant names that falsely imply reduced harm**	Reduced smoking uptake				Reduced negative externalities	Reduced smoking uptake	Reduced smoking uptake; potential for reduction in prices if price competition occurs	Appropriate use of terms to deter smoking
	Cost of establishing new regulatory framework; potentially additional training	Costs of modifying products; package redesign implications, dealing with unsold stock; may turn to price competition; reduced product and brand differentiation; cost in providing information to retailers about product name changes. Minimal stock losses. Professional services.	Potential cost of unsold stock following transition period; learning new product names and costs and explaining that to consumers	Potential cost of unsold stock following transition period			Limited impact on current smoker rates who already know the products; reduced access to information about product differences; reduced choice. Some learning costs for those who smoke.	
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $14.549 **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $3.6m **Total substantive compliance costs** (average annual): $18.149							
 **Measure 9** **Require Health Promotion Inserts to encourage and empower people who smoke to quit**	Reduced smoking and externalities; increased use of cessation services				Reduced negative externalities		Increased cessation attempts, and successful cessation, especially by women, those intending to or having recently attempted to quit	Useful in promoting cessation, but would be strengthened through use of visuals – noting there are lots of language groups
	Cost of establishing new regulatory framework (designing HPIs) and updating HPIs; monitoring and enforcement costs; increased cost of cessation services	Cost of planning and modifying manufacturing processes including planning and packaging process; cost for producing inserts; minimal stock losses, printing costs.	Potential cost of unsold stock following transition period	Potential cost of unsold stock following transition period	Increased environmental waste		Producers may pass increased cost to consumers	Unintended consequences may include waste and creating incentives to collect HPIs i.e. a new category of 'collectables'

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $5.104m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $0 **Total substantive compliance costs** (average annual): $5.104m							
 **Measure 10A** **Require mandatory disclosure of sales and expenditure data**	More accurate data to inform decision-making on measure to reduce smoking prevalence. Greater transparency will reduce monitoring costs	Does not require the purchase of any additional equipment.			Benefit from informed policy decisions and improved taxpayer spending		Potential access to more information	Reporting data would demonstrate whether tobacco control measures are working
	Cost of establishing new regulatory framework; monitoring and enforcement costs may increase due to improved data	Increased costs relating to reporting requirements and would require industry to disclose data, training costs, professional service costs.	Training costs.	Increased costs relating to data collection, depending on extent of current data collection, training costs.				Industry data may mislead communities if appropriate qualifications and analysis does not accompany data
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $0.020m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $0 **Total substantive compliance costs** (average annual): $0.020m							
 **Measure 10B** **Require mandatory disclosure of advertising and promotion expenditure data**	More accurate data to inform decision-making on measure to reduce smoking prevalence. Greater transparency will reduce monitoring costs	Does not require the purchase of additional equipment.			Benefit from informed policy decisions and improved taxpayer spending		Potential access to more information	Reporting data would demonstrate whether tobacco control measures are working
	Cost of establishing new regulatory framework; monitoring and enforcement costs may increase due to improved data	Increased costs relating to reporting requirements and would require industry to disclose data. Professional services.		Increased costs relating to data collection, depending on extent of current data collection				Industry data may mislead communities if appropriate qualifications and analysis does not accompany data

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total new substantive compliance costs (average annual): $0.019m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $0 **Total substantive compliance costs** (average annual): $0.019m *Note: costs for this measure are reflected in the total compliance costs that have been separately identified for measures 3, 4, 6 and 10.*							
 **Measure 11** **Protect tobacco control policy from commercial and other vested interests.**	Increased compliance with Article 5.3 of the WHO FCTC, reduced industry influence on tobacco control policy development and implementation, increased accountability, and transparency of industry activities							
	Cost of establishing new regulations							
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $0.00							
 **Measure 12**	No significant training requirements.						Reduced smoking uptake; increase in quit attempts and successful cessation	

Measure	Government	Manufacturers and importers	Retailers	Wholesalers	General public	Youth	People who smoke	First Nations Peoples
Require dissuasive measures on tobacco products.	Cost of establishing new regulatory framework (designing dissuasive product regulations); ongoing monitoring and enforcement, planning and packaging process re-engineering implications, potential expenditure on packaging equipment, minimal stock losses, professional services.	Cost of re-engineering products to ensure compliance with dissuasive product regulations					Reduced choice	
	Total regulatory burden estimates for business (including manufacturers, retailers, wholesalers): Total substantive compliance costs (average annual): $2.074m **Total regulatory burden estimates for individuals:** Total substantive compliance costs (average annual): $0 **Total substantive compliance costs** (average annual): $2.074m							

Who did you consult and how did you incorporate their feedback?

Purpose and objectives of consultation

The Exposure Draft contained tobacco control measures provided for by Options 2 and 3 of this IA. The purpose and objectives of the consultation were to ensure the tobacco control measures set out by the Exposure Draft were fit-for-purpose and contributes to achieve the Australian Government's objectives with respect to tobacco control.

Public consultation of the Exposure Draft was delivered through the Department's Consultation Hub, where members of the public were invited to make written submissions. To support the accessibility of the consultation process, a consultation paper accompanied the Exposure Draft to provide an overview of the proposed reforms and rationale of the drivers behind the proposed reforms, along with survey questions. The Consultation Hub was open for submissions from 31 May to 14 July 2023. Targeted consultation was also undertaken with the tobacco industry, public health stakeholders, and First Nations' representatives.

The consultation process was undertaken in accordance with Australia's obligations under Article 5.3 of the FCTC. Article 5.3 of the FCTC obliges Australia to take steps to protect its tobacco control policy setting and implementation from interference from the tobacco industry and its interests. This also extends to the e-cigarette industry. Consistent with Australia's obligations under Article 5.3 of the FCTC, consultation with tobacco and e-cigarette industry, individuals and organisations whose interests may be aligned with the tobacco industry will be limited to what is necessary to enact effective tobacco control measures and will be undertaken in a transparent and accountable manner. Therefore, the Department engaged an external consultancy to conduct consultation with tobacco industry representatives on implementation and timing matters which may arise from the regulatory obligations proposed in the Exposure Draft. The external consultancy also facilitated the targeted consultation sessions with public health stakeholders and First Nations' representatives. These consultations were guided by the requirements of article 5.3 of the WHO FCTC and key consultation questions as set out in the Department's consultation paper.

This consultation process on the Exposure Draft followed two earlier, broader public consultation processes that were undertaken to inform the Review. Relevant reports outlining these earlier consultations can be found at https://consultations.health.gov.au/population-health-and-sport-division/review-of-tobacco-control-legislation/.

Figure 11: Summary of key consultation activities

The first phase of the earlier consultation process in 2019 sought views and suggestions on the current legislation via open public online responses and the second phase of consultation sought to collaboratively explore options for regulatory improvements via targeted stakeholder workshops. Specifically, from January–March 2019, the Department conducted a public submission process on its

online Consultation Hub seeking stakeholder feedback on the existing legislation to inform the development of options for regulatory improvement. This included options for modernising, streamlining, and simplifying the TPP Act and TAP Act. It also provided opportunity for feedback to be received on other aspects of tobacco control that the government could consider. A total of 75 submissions were received from individuals and consumers, academics, public health organisations, state and territory health departments, Commonwealth agencies, tobacco manufacturers, importers, wholesalers, packagers, and retailers.

From May-July 2019, a series of stakeholder workshops were held with stakeholders, comprising representation across Commonwealth, state and territory governments, public health organisations, experts, and academics. The tobacco and e-cigarette industry were not included in these workshops, consistent with obligations under Article 5.3 of the WHO FCTC, which states:

"in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law".[311]

Outcomes of the 2019 consultation provided a number of suggestions for government consideration, such as increasing penalties for offences, prohibiting brand and variant names with words that imply lower harm or natural/organic ingredients and prohibiting filter capsules.[312] The Department considered feedback from this consultation to inform development of the evidence-based measures outlined in Option 3 and included in the Exposure Draft, as discussed below.

Outcomes of 2023 consultation on the Exposure Draft

The public consultation on the Exposure Draft received 148 written submissions (including survey responses), including from public health experts, private industry and individuals. Contributions from the tobacco industry, public health stakeholders, and First Nations representatives were received through 8 targeted consultation sessions. Feedback received during the public consultation process informed this IA and the finalisation of the consolidated legislation for Parliament.

The following section sets out key views of stakeholders and how the preferred option has been modified to take account of stakeholder views, or why dissenting views have not been adopted. Consistent with Article 5.3, tobacco and e-cigarette industry feedback on implementation has been considered separately from non-industry feedback on the Exposure Draft. Industry includes tobacco or e-cigarette businesses, including manufacturers, distributors, importers and retailers of tobacco products. It also includes peak bodies representing tobacco or e-cigarette-related businesses. Non--industry encompasses a broad range of stakeholders, including public health experts, academics, advocacy organisations, government agencies, individuals and First Nations peoples.

It is noted that due to Article 5.3 of WHO FCTC, this IA only considers industry views as they relate to implementation considerations. Industry views relating to the policy intent of a measure have not been considered.

Summary of key feedback from consultation

Overall themes

Stakeholder views on the Exposure Draft were diverse with some key areas of agreement and disagreement. This section briefly summarises the outcomes of the stakeholder consultations. The summary highlights the dominant themes emerging from the various stakeholders.

A key area of agreement related to the implementation of the Exposure Draft. Stakeholders from different sectors, including industry and non-industry stakeholders, considered the effectiveness of the Exposure Draft towards achieving its stated objectives will be dependent on effective compliance and enforcement by the Australian Government.

First Nations' peoples in the consultation session also advocated for strengthening some of the measures, such as using visual images to communicate health promotion messages. Industry representatives also strongly advocated for Government to tackle the illicit trade in tobacco more actively, arguing that imposing further requirements as outlined in the Exposure Draft, without

additional enforcement activity, further erodes the tobacco industry, including retailers', ability to compete with illicit providers.

A key area of disagreement between industry and non-industry stakeholders was timing. Industry stakeholders considered they needed more time to implement the measures, such as removing the proposed prohibited ingredients from its products, making adjustments to tobacco packaging, providing for the addition of inserts to product packages, and establishing reporting regimes. In contrast, public health stakeholders and First Nations' peoples considered the proposed tobacco control measures builds on the success of Australia's tobacco control measures and should go further.

Key themes

Design of legislation

Non-industry stakeholders noted that the proposed consolidation of the existing tobacco control laws considered under the Review would promote clarity and efficiency in the administration of the national tobacco control framework. However, non-industry stakeholders noted that the Exposure Draft could be strengthened to address environmental impacts of tobacco products and meet future challenges of the tobacco market e.g. expanding definitions to capture other emerging or novel products and future products and clarify specific terms such as 'lobbying'. Further, some non-industry stakeholders suggested the proposed legislation be amended to prevent unintentional override of tobacco control measures in the states and territories. For example, one non-industry peak body said, 'Many of the more practical legislative powers in our national tobacco control matrix are at state/territory level, and nothing in the new Commonwealth scheme should in any way detract from those legislative systems'.

Industry stakeholders noted the Exposure Draft does not address illegal tobacco products or black-market e-cigarettes-. That increased compliance costs and responsibilities will be borne by businesses and not by the illicit market. Industry stakeholders noted the implementation of the proposed measures may shift demand and supply to the illicit market and recommended strong, effective, and coordinated enforcement of domestic tobacco control frameworks across Australia to minimise any risk of growing the illicit market. Industry stakeholders recommended amending the definition of 'e-cigarette' so that it excludes devices that do not contain nicotine. Industry stakeholders also recommended compliance education programs, particularly for retailers, to facilitate compliance. One industry stakeholder commented that 'the proposed reforms to tobacco control will not materially reduce smoking prevalence.'

Commencement timeframe

Non-industry stakeholders suggested the commencement provisions and transition timeframes were appropriate and implementation should not be delayed. Non-industry stakeholders recommended the inclusion of personal liability provisions to promote accountability, and further deter non-compliance. It was also noted that the proposed reforms should be accompanied with education and cessation support for people who smoke. A First Nations' representative suggested, 'Cessation support is critical to the reform's ongoing success. The reforms themselves are not enough'.

Industry stakeholders stated that the proposed commencement provisions and transition timeframes were unworkable because of the volume of changes required to be delivered and met by the proposed legislation. Stakeholders noted the proposed reforms would also require material industry investment to deliver requirements. Therefore, industry stakeholders recommended extending implementation timeframes, including for retailers, manufacturers, and importers and for Government to deliver education programs for industry and consumers, to promote understanding of new requirements. One industry peak body commented, 'provisions should be provided for retailers to allow for the sell-through of stock naturally, provided there is a hard manufacturer and importer deadline for compliance with the new regime.'

Advertising and sponsorship

Non-industry stakeholders noted the proposed advertising and sponsorship measures appropriately extend to cover e-cigarettes. However, they recommended further restrictions regarding online sales, political donations and lobbying by the tobacco industry. For example, a non-industry peak body

reflected on political donations, 'Exemptions to bans on tobacco and e-cigarette sponsorship for politicians, political parties, members of Parliament and electoral candidates creates a significant conflict of interest which stands to undermine tobacco control efforts to date, and which could ultimately affect the health and wellbeing of Aboriginal and Torres Strait Islander peoples, and indeed all Australians'.

Non-industry stakeholders recommended:

- strengthening the proposed legislation through further restricting social media advertising bans
- future-proof to ensure new advertising and promotional platforms are captured
- greater restrictions on tobacco and e-cigarette industry engagement with politicians.

Industry stakeholders noted that proposed advertising restrictions may stop business to business communication (in-turn affecting the availability of information on products sold between businesses). Industry stakeholders recommended that the legislation allow product information to be shared between retailers and suppliers and allowing business to business marketing, including incentives such as rebates and rewards. On industry stakeholder noted 'bans on retailer incentives simply entices the stocking of unregulated illicit product.'

Health promotion inserts and graphic health warnings

Non-industry stakeholders reflected the proposed health promotion inserts and updated and improved graphic health warnings are likely to have positive impacts on cessation rates where messages are evidence-based and rotated as a series of multiple warnings/inserts. Broad support was given for the requirement that images and inserts be prescribed by regulations on recommendation of the Commonwealth Chief Medical Officer. Non-industry stakeholders, however, did recommend health promotion inserts and graphic health warnings capture a diverse range of health and other risks, in the case of HPIs contain cessation advice, are not stigmatizing, and recommended visual images and health promotion messages to be culturally safe by partnering with Aboriginal community-controlled sectors in their development. It was also recommended that consideration of the potential environmental impacts of including health promotion inserts in tobacco products is considered.

Industry stakeholders suggested that there is likely to be significant cost and time to acquire and adjust machinery and production processes in order to meet the requirements for 'equal as possible' distribution of HPI and GHWs within a carton. Industry stakeholders also noted there will likely require a need for manual processes to insert HPI into RYO pouches and unknown feasibility, costs and time to automate this process. Industry stakeholders also suggested considerations be given to quality and safety matters arising from the inclusion of HPIs within a RYO pouch where it will sit against tobacco (e.g., moisture effects on HPIs with potential distortion of image and text). Industry stakeholders also raised the impost on retailers and potential increased wastage for distributors due to sell-through requirements to comply with the proposed HPI and GHW rotations. In summary, industry stakeholders recommended:

- reconsideration of the requirement to achieve 'equal as possible' of HPIs and GHWs within a carton, and instead allow for 'equal as possible' distribution across a larger unit of product
- removal of the requirement for HPIs in RYO, or if they are required, alternative placement of the HPI (inside the flap rather than the pouch)
- adjustments to the design and materials required for HPIs, including materials being recyclable, not recycled.

Brand and variant names

Non-industry stakeholders noted the proposed measures to prohibit brand and variant names will restrict tobacco industry using them as a promotional tool to incentivise smoking. However, they recommended the prohibition on numerical numbers for brand variants be extended to include variant numbers spelt out in letters and other terms which evoke pleasant associations. Further, public health stakeholders recommended that brand and variant names must only be present on cigarette packet and carton packaging, rather than adhesive labels.

Industry stakeholders noted the brand and variant requirements are likely to reduce consumer choice, therefore shifting demand to the illicit market and be confusing for customers and retail staff on how to identify preferred brand and variant. They noted this could lead to potential health and safety risks for tobacco retailers and that this may create burdensome stock control, potentially requiring the running of two (old and new) sets of inventory. One Industry stakeholder noted 'proposed changes to brand variants will diminish consumer trust in legitimate products and fuel the black market.' Industry stakeholders recommended effective compliance education programs for retailers and consumers, to promote understanding of requirements and to minimise the risk of confusion at sale points.

Product standardization and ingredients

Non-industry stakeholders noted the packaging and product requirements would contribute to the reduction of sales to youth through the banning of flavours that appeal to young people. However, may not adequately capture all circumstances upon which flavour is used (e.g., to mask or reduce unpleasant flavours or used in tobacco product accessories). Non-industry stakeholders also noted that filters can also be used to make tobacco products attractive. One non-industry stakeholder noting, 'filters are also an added component that increases the attractiveness and palatability of tobacco products.'

Non-industry stakeholders recommended:

- expanding the prohibited list and reduce the permitted list,
- including cooling agents/menthol alternatives to prohibited ingredients and
- to ensure that tobacco product accessories (such as filter tips, cards, capsules etc.) are not able to contain ingredients that are prohibited by the regulations.
- reducing any ability for tobacco product accessories being used to alter the intensity of the tobacco product with which they are used (e.g. by reducing the harshness and strength of taste of the product, without necessarily altering the flavour).

Non-industry stakeholders further recommended strengthening the plain packaging requirements of tobacco products by requiring all inner surfaces, sides of lining and foil to be Pantone 448C. In addition, it was also recommended that all retail packaging and cartons be made out of recycled cardboard, and that all elements of printing and packaging must not prevent it from being recycled.

Industry stakeholders noted the impact of the restrictions on ingredients is likely to lower product quality by prohibiting naturally occurring ingredients, or ingredients required to preserve the product (e.g., casing ingredients). One industry stakeholder noting, 'the ban on flavours and menthol volume will force consumers to the illicit market immediately'. Industry stakeholders recommended:

- the exception to ingredients required for the purposes of achieving product compliance should be consistently applied across the regulatory framework
- the use of additives necessary for the manufacture of tobacco products should be permitted, for example sugar to replace endogenous sugars that is broken down or lost during the curing process
- that there should be a differentiation between casing and topping ingredients, and that only topping ingredients should be banned.

Further, industry stakeholders noted the product standardisation requirements are likely to impact on manufacturing complexity and cost. For example, at one of the targeted consultation sessions, industry representatives noted the proposed RYO standard pouch (30 grams) was likely to increase implementation costs since retailers generally stocked 25-gram RYO pouches. Meaning retailers would need to remove the 25-gram RYO pouches from sale after the proposed sell through period, to replace with the new standard size. Industry recommended the following implementation changes:

- adjustments to packaging tolerances to reduce implementation costs.
- increase of standard cigarette pack sizes to 25 sticks instead of 20 sticks because the 25 stick pack is uncommon globally, which would make it more difficult for illicit tobacco operators to facilitate their importation into Australia and will support law enforcement agencies in identifying illicit tobacco products in Australia

- standardise RYO tobacco pouches to be a more common 25-gram size instead of the proposed 30 grams to reduce implementation costs (and reduce the amount of unsold product that would need to be removed from sale)

Permanent bans

Non-industry stakeholders recommended amendments to strengthen the legislation to include nicotine pouches and to allow (future) permanent bans of 'all novel people harming products'. One non-industry peak body also noted consideration should be given to export exception. They noted, 'The exportation of regulated tobacco items is importing harm to other nations. There is also a risk of these products being then transferred back into Australia without safeguard.'

Further, non-industry stakeholders suggested provisions in the legislation be included to allow for Ministerial orders to impose permanent bans on tobacco products or classes of tobacco products, accessories, or products that resemble tobacco products and to ensure that novel tobacco products can be banned. Non-industry stakeholders also recommended consideration be given to whether the permanent ban on novelty cigarettes and novelty cigarette lighters (Consumer Protection Notices 15 and 18 of 2011) should be brought within Chapter 4 of the Bill. It was further noted that exemptions relating to shisha should be removed.

Industry stakeholders suggested the permanent ban should be removed and noted the use of smoke-free products such as snus and oral nicotine pouches can expand the range of options to quit smoking.

Compliance and enforcement

Non-industry stakeholders noted the legislation should be further strengthened in respect to the penalties being amended to be in alignment with corporate and financial sector penalties at the Federal level and setting penalties for specified provisions as the greater of the penalty units specified. That corrective advertising where offending conduct has occurred be required and the ability of a Court to disqualify a person from managing corporations for a period the court thinks appropriate where the person has contravened or been involved in a contravention. One non-industry stakeholder said, 'the clear delineation between the enforcement of, and penalties for, the Tobacco Industry and others in selling non-compliant and illicit products, and not the targeting of individual end-point consumers, will help to minimise the risk of contributing to the over-policing of population groups, such as Aboriginal and Torres Strait Islander peoples.'

Industry stakeholders noted the possession offence provisions should allow an exception for the possession of non-compliant product by tobacco product importers, distributors and their agents, where not for sale or supply, so as to allow these businesses to cycle out non-compliant product or to import and prepare stock for supply.

Reporting

Non-industry stakeholders reflected that the proposed reporting measures would enable the Australian Government to monitor trends in the tobacco market, including use of tobacco and assess the impact of tobacco control measures. However, non-industry stakeholders suggested:

- expanding the scope of reporting entities, including extending to wholesalers/distributors
- increasing the amount of information required to be reported by reporting entities, including greater detail on ingredients and products sold, country of origin for tobacco, and environmental, social and governance
- consideration be given to allow for a broader range of permissible purposes for an authorised officer to exercise monitoring powers.

One non-industry peak body also recommended the collection of demographic data relating to the sale and supply of tobacco and e-cigarette products, and that this data, as well as any other data relating to marketing and research which relate to First Nations peoples, be shared with First Nations communities, organisations, and researchers. The peak body noted, 'Indigenous data sovereignty is the focus of Priority Reform 4 of the National Agreement on Closing the Gap and highlights the importance of ensuring that Aboriginal and Torres Strait Islander data is accessible by the people and communities

whom the data represent. Access to data allows communities to make informed decisions and set priorities and directions for community actions to improve quality of life and health outcomes.'

Industry stakeholders suggested the implementation of the reporting requirements may have anti-competitive outcomes and violate intellectual property laws because of the potential release of commercially sensitive information. It was also noted that there may be misalignment of reporting period with annual reporting cycle for businesses, creating additional compliance costs. Stakeholders further noted that there may possibly be an inability to provide ingredient information when importers are importing products on the part of other companies, or using certain flavourings sourced externally, the ingredients of which are not known to the company. One industry stakeholder recommended further consultation with industry on the proposed reporting requirements, 'to clarify the potential impacts and avoid adding unnecessary reporting obligations on legal businesses.' Industry stakeholders recommended:

- consideration be given to the need to protect commercially sensitive information
- delaying the commencement of the reporting requirements by a number of years
- allowing reporting entities to report according to their financial year.
- additional consultation on the design of the reporting requirements
- the legislation reflect situations where industry does not hold ingredient information

The Exposure Draft was updated and finalised on consideration of the feedback received from the public consultation. For example, First Nations representatives were supportive of the proposed measures and noted during targeted consultation sessions that compliance and enforcement of the proposed measures were critical to its success in achieving its stated outcomes for First Nations people. The Department will act to support its compliance and enforcement approach to meet community expectations, by establishing a compliance and enforcement work program focused on the new tobacco control measures. Implementation is considered later in this IA.

In relation to Measure 10, tobacco industry stakeholders noted that there would be challenges associated with complying with the requirements proposed in the Exposure Draft as the reforms will cause disruption to operations (and therefore reporting) as industry transitions to the new regulatory requirements. Therefore, amendments to the legislation were incorporated to commence the reporting requirements annually from 1 July 2025 rather than 1 July 2024. Amendments to the types of reporting required under Measure 10 were also undertaken following feedback that reporting on research and development would unduly burden reporting entities.

Other changes made to the Bill following consideration of the public consultation feedback included:

- Amending the definition of 'e-cigarette' to ensure that vaping devices which resemble toys, foods, drinks, cartoon characters, animals, musical instruments etc. are captured by the advertising and sponsorship prohibition;
- Amending the definition of 'prohibited term' to ensure that brand and variant names cannot include terms such as 'cool', 'extra', or 'fresh' which imply a positive quality; and
- Updating advertising prohibition exceptions for journalism, to prevent advertorials where the person that publishes the material receives a benefit of any kind for publishing the material, from a manufacturer, importer, distributor or retailer of tobacco products.

Where feedback received during the Exposure Draft consultation process was not incorporated in the final legislation, this decision was based on consideration of the Government's policy intent, evidence presented in submissions, and the likely contribution of changes to the public health objectives of the policy. For example, consideration of the feedback from stakeholders on standardized cigarette pack size balanced potential compliance and implementation benefits (which indicate that a pack size of 25 sticks would make illicit tobacco packs easier to identify), against the weight of the evidence supporting the policy intent, and international precedent. This informed the decision to retain the proposed 20 stick pack size. Likewise, in finalising the legislation feedback from both public health and industry stakeholders regarding the proposed prohibited ingredients was considered. The prohibited ingredients prescribed in the final regulations will be based on the available evidence, policy objectives as set out in the Bill, and international regulatory precedent, and feedback from consultations.

What is the best option from those that you have considered?

Following consultation, Option 3 remains the recommended option, expected to provide the greatest contribution to a reduction in smoking rates compared to Options 1A, Options 1B and 2.

Option 1A would serve to reverse Australia's efforts in relation to tobacco control. The reduced social, economic, and health impacts that have arisen from Australia having strong controls on tobacco advertising would be lost, and this option would come with significant social, health and economic costs.

Option 1B would have the least impact on the continued social, economic, and health costs of smoking compared to Options 2 and 3. While Option 1B would not have direct regulatory burden costs, the broader costs of not taking action to reduce the smoking rate would generate far greater social, economic, and health costs compared to Options 2 and 3.

Option 2 which includes the consolidation of the existing tobacco control regulatory framework would improve the regulatory framework, especially for health warnings and advertising, and support improved compliance and enforcement activities. Updating and improving health warnings would build on the success of the existing framework in reducing the smoking rate. The measures would promote greater awareness to people who smoke of the health risks associated with tobacco use and exposures, and would improve the effectiveness of health warnings by increasing their noticeability. Restricting advertising would similarly build on existing measures but would ensure that incidental advertisements would also be covered by the prohibition on advertising. Other measures to consolidate the regulatory framework would support clarity for businesses involved in the tobacco industry to comply and improve the efficiency of the administration of the framework.

Option 2 would create some costs to tobacco companies and retailers to comply with the changes to the legislation. However, the regulatory burden for Option 2 is expected to only accrue to the tobacco industry, with limited impact on retailers and individuals who smoke, and would cost around $3.7 million per year. Due to the high cost imposed by tobacco use, it would require just 12 people to permanently quit smoking each year to justify the regulatory burden of $3.7 million of Option 2. While it is not possible to estimate the specific number of individuals that would benefit from these measures, they would build on the ongoing effectiveness of the existing regulatory framework in reducing the smoking rate. However, Option 2 is unlikely to result in a significant reduction in the smoking rate.

Option 3 includes consolidating and further strengthening the tobacco control regulatory framework in line with international precedents and includes all the benefits of Option 2. Additionally, Option 3 provides for further measures that evidence suggests will be effective in reducing the smoking rate. In particular, the measures would reduce tobacco product attractiveness and palatability through a range of measures and support people who smoke to quit by the use of HPIs. The various components of Option 3 are designed to work in a complementary and synergistic manner to reduce the prevalence of smoking. Option 3, which seeks to strengthen the regulatory framework for tobacco control in line with international precedents, and modernise and streamline the relevant regulatory frameworks, is therefore expected to have the most significant public health benefits.

Of the options canvassed in this IA, Option 3 will contribute the greatest to assisting the government to reduce the smoking rate in Australia. Further, the benefits of Option 3 in reducing the number of people who smoke in Australia is well within the estimated social and financial benefits that will flow from its implementation. Option 3 is expected to have the highest impact on reducing smoking prevalence. If considered in the context that tobacco use is a leading cause of preventable death and disease and is a key health risk factor for Australians, the benefits of this suite of reforms are expected to have far-reaching health, wellbeing, social and economic impacts for Australia. The estimate for the regulatory burden for Option 3 has an average annual burden of $21.77 million, but of this burden $12.6 million relates to burdens faced by existing tobacco users, with the remainder of the burden falling on tobacco retailers, manufacturers, importers, and wholesalers. A significant reason for Option 3 being the best option of those considered is that due to the high cost imposed by tobacco use, it would require only 73 people to permanently quit smoking each year to cover the $21.77 million estimate for the

regulatory burden of Option 3. As $21.77 million is an estimate only, even if the total annual cost of this option was $100 million, this expense would still be justified as long as at least 337 people who smoke successfully and permanently quit smoking each year. In other words, this means that spending $100 million per year on tobacco control policies would be justified if they were expected to be instrumental in helping 1 out of every 7,727 people who smoke to quit smoking each year. This assessment indicates a significant return on the investment required to bring about the reforms outlined in Option 3, with far-reaching health, social and economic impacts for the Australian community.

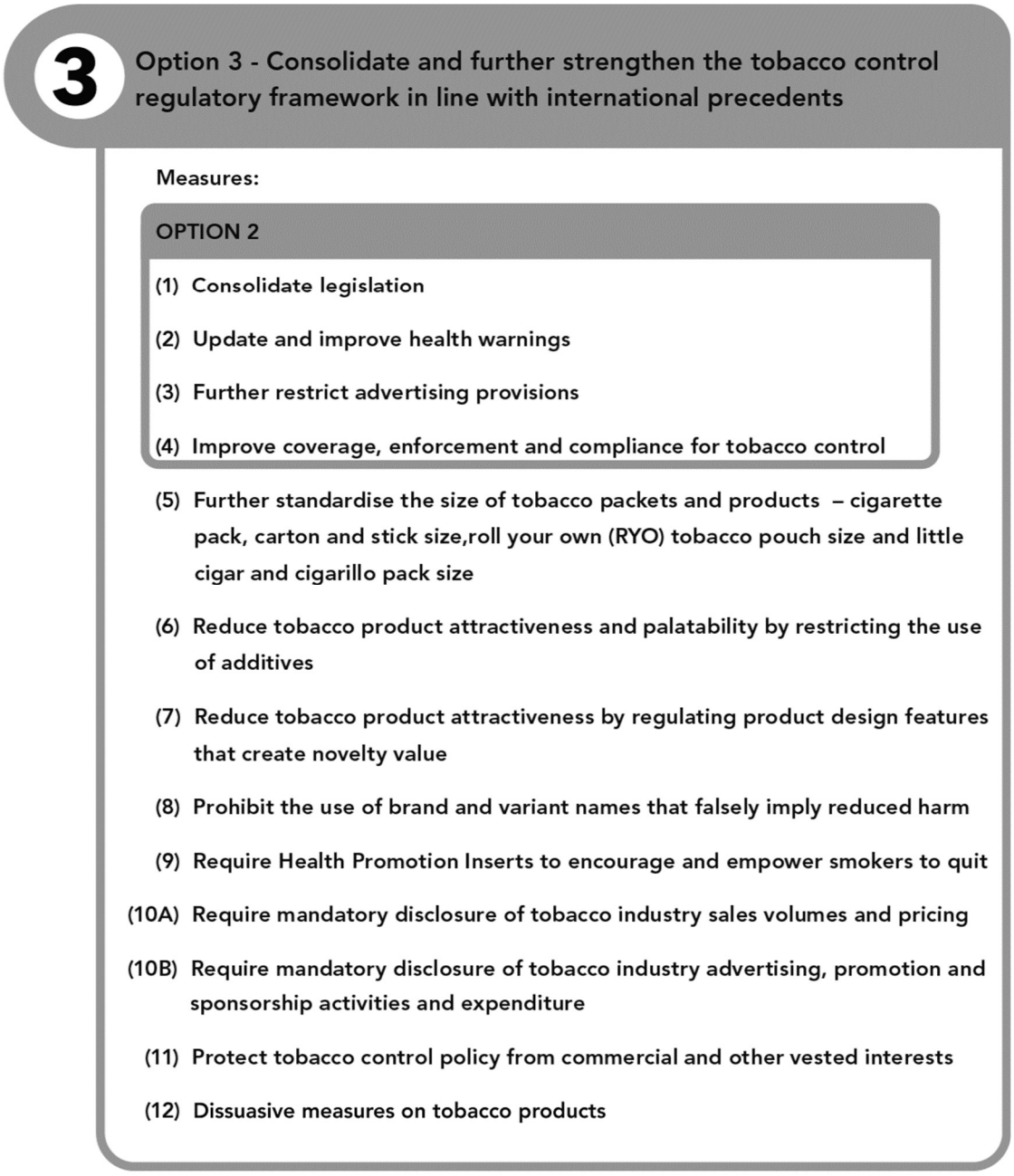
The population cohorts who benefit from these policy measures are broad and include people who smoke, people who do not smoke, people who have quit smoking and sub-groups of the population with higher smoking rates. This Option will serve to provide better health and wellbeing outcomes to a range of Australian communities including First Nations people, people from socioeconomically disadvantaged communities, people living with mental health conditions, people with chronic health conditions, pregnant women and children.

The average annual estimate has not materially changed following the consultation. Prior to consultation, the average annual burden was estimated at $20.65 million. However, based on very limited and confidential information provided relating to health promotion inserts, average annual burden has increased by $1.12 million. It is also noted even if the total annual cost for Option 3 was $100m (almost five-times larger than the $21.77 million regulatory burden estimate), this expense would still be justified as long as at least 337 people who smoke successfully and permanently quit smoking each year.

Option 3 also addresses the key themes that have arisen from the 2019 and 2023 consultation processes including further restricting advertising provisions, consolidating legislation, adapting the regulatory framework to support the regulation of novel and emerging products and improving tobacco control by centralising the administration, monitoring, and enforcement of legislative interventions with one agency.

How will you implement and evaluate your chosen option?

Figure 1212: Recommended option



Implementation

The implementation of Option 3 will require extensive government reform and modest investment. It will require a coordinated effort across multiple sectors and will take time to roll out in its entirety.

Legislative amendment is the key implementation mechanism of Option 3. It will require legislation to be consolidated and for measures to be added or enhanced in relation to health warnings, advertising, enforcement and compliance, standardisation of tobacco products and their contents, tobacco product design features, brand and variant names, HPIs, reporting, commercial interference, and dissuasive tobacco products requirements.

The proposed legislation has been developed with Australia's obligations under Article 5.3 of the WHO FCTC as a central consideration. As a first step, implementation of measures outlined in this IA will address Australia's obligations by requiring transparent and accurate reporting from the tobacco industry and replacing voluntary agreements with the tobacco industry with regulation (Measure 10), increasing awareness of the addictive and harmful nature of tobacco products (especially Measures 2 and 6), and denormalising corporate social responsibility through bans on tobacco and e-cigarette sponsorship (Measure 3).

To continue to increase awareness about Article 5.3 and the risks associated with tobacco industry interference in public health policy, in July 2023 the Minister for Health and Aged Care, the Hon Mark Butler MP wrote to all federal Senators and Members of Parliament to remind them of Australia's obligations under Article 5.3, and to share a copy of the Guidance for Public Officials on Interacting with the Tobacco Industry. Any future regulations to formalise these obligations as outlined in Measure 11 will be informed by whole-of-government and public consultation.

However, to achieve success, tobacco control must be comprehensive and multi-faceted. The success of Option 3 will be influenced by programs delivered at all levels of Government in Australia, through public health organisations such as Cancer Councils, and through clinical guidelines, support programs and communication campaigns. Implementation of Option 3 will complement and work in tandem with other Australian Government tobacco control measures including reforms to the regulation of e-cigarettes/vapes, the Tackling Indigenous Smoking program, targeted communication campaigns and support for cessation. The proposed measures outlined in this IA will complement the existing tobacco control measures and the Australian Government will continue to consider future measures consistent with the NTS to reduce smoking prevalence amongst First Nations people.

There are a range of implementation risks associated with implementation of new measures. The ability of the tobacco industry to meet implementation timeframes, including rotation and printing requirements for the graphic health warnings, health promotion inserts and measures regulating the design and appearance of tobacco products is a key consideration. The risk of implementation delays has been addressed through consultation with industry stakeholders within the scope of Article 5.3 of the WHO FCTC and will continue to be managed through provision of clear advice on the regulatory amendments to ensure early awareness of changes and required timeframes.

Potential stock losses for suppliers and retailers of tobacco products following the implementation of new requirements under Measure 2, Measures 5 through 9, and Measure 12 are mitigated by a phased sell-through period in which industry will have 12 months to sell, export or repackage their products that would not comply with the new legislation.

In addition to the 12-month transition afforded for wholesalers and manufacturers/importers, there is an additional 3-months provided for retailers to sell-through products that would not comply with the new legislative requirements. The stock losses associated for each Option 2 and Option 3 are investigated respectfully under Appendix 1 and Appendix 2.

Stock that does not comply with the new legislative requirements will be monitored as a part of regular routine inspection programs conducted by Authorised Officers. Old stock that is detected after the sell through period will be treated as being non-compliant with the tobacco product requirements of the new legislation. Those instances of non-compliance will be considered in accordance with the Department's Tobacco Control Enforcement Policy to ensure that enforcement and any potential penalties are proportional to the nature of the contravention. Suppliers and retailers will be supported to understand their new obligations through education and awareness materials.

Transition

Legislative amendment would be followed by a phase-in period of 12 months for manufacturers, importers and distributors, while retailers would receive an additional 3 month sell through period. Manufacturers and retailers would require time to meet updated regulatory requirements, and a phase-in period would allow time for existing products to be removed from the market and for

compliant products to enter the market. Government would also require time to support measures such as the production of new and updated health warnings and HPIs and establish systems to manage reporting data.

For tobacco manufacturers, the phase-in period would have a number of implications, including planning and package re-design. Although the costs of amending products to meet the Australian market requirements would take place overseas, the costs may ultimately be borne by Australian consumers. Tobacco companies will likely need to undertake extra training for staff to understand and meet the requirements, as well as developing processes to prepare reports. For any non-compliant stock not sold during the phase-in period, tobacco manufacturers will have direct costs per packet either to repackage or write-off. The changes would be likely to require tobacco companies to seek internal and external professional services (for example legal or marketing services).

Tobacco wholesalers will have to either repackage or write-off stock for any product not sold at the conclusion of the phase-in period and would have to update systems and processes to align with the new compliant products imported into Australia (for example, updating product names in their systems).

Tobacco retailers will have to return any stock that is not sold during the phase in period and may have some additional costs related to replacing old stock with new compliant products. Tobacco retailers can be expected to spend time explaining the changes to consumers of tobacco products seeking new products given the restriction on naming, additives, and pack sizes.

Tobacco manufacturers, importers and wholesalers will be provided with a 12 month sell through period from the commencement of the Act to enable sufficient time to clear the market of old products that will no longer comply with legislation and introduce products which the new tobacco product requirements.

In addition to the 12-month transition period for manufacturers, importers and wholesalers will be transitioning new product into the supply chain, tobacco retailers will be provided an additional three months to sell through, write off or return remaining stock.

Individuals who use tobacco products will have to learn about the changes, which is assumed to take around 30 minutes on average for each smoker. In particular, users will have to adjust to the new restrictions on brand and variant names, removal of design features they may prefer, and change their purchasing habits to align with the standardised pack sizes for cigarettes and RYO tobacco. The implementation of Option 3 will require extensive government reform and investment. It will require a coordinated effort across multiple sectors and will take time to roll out in its entirety.

Education

The Department will publish guidance materials of the new legislative requirements that clearly identify the changes which have been made, and their implications for various stakeholder groups. A resource page will be developed on the Department's website to support industry and consumers to ensure they are informed of the changes and to support compliance with the reforms. The webpage will provide guidance material and fact sheets educating stakeholders and the public of the requirements of the legislation, how they are enforced, and a webform to enable people to submit enquiries. The Department will develop guidance materials to be distributed to retailers at 3 stages of the transition period, outlining the changes and expectations to be met in order to comply with the new legislation.

Reporting

Reporting entities will be required to submit annual reports each financial year for tobacco product ingredients and marketing and promotional expenditure, and quarterly reports for tobacco product volumes. The reporting scheme will commence on 1 July 2025, requiring the 2024-25 financial year retrospective baseline reporting for each of these reports. The collection of baseline data will enable more comprehensive evaluation of the effect of the new policy measures and will facilitate compliance and enforcement activities and support future policy development.

Laboratory testing

A laboratory testing regime will be implemented to monitor for the presence of prohibited additives as part of enforcement for Measure 6: Reduce tobacco product attractiveness and palatability by restricting the use of additives. The laboratory testing regime will work synergistically with tobacco product ingredient reporting. The scope of the testing regime will include all tobacco products that are prohibited from including the prohibited additives listed in Table 5.

Monitoring

Implementation will be supported by enforcement and monitoring activities that ensure compliance with new regulatory provisions.

Evaluation

Option 3 will be evaluated in line with the Commonwealth Evaluation Policy. This policy provides for a principles-based evaluation approach that is fit-for-purpose, useful, robust, ethical, culturally appropriate, credible, and transparent where appropriate.

The evaluation matrix developed for Option 3 will be targeted and adaptable to the specific aims and outcomes of the relevant measures and will incorporate both existing and to-be-developed datasets and information sources, comparisons with comparable international initiatives, and will likely link into the measures implemented for vaping and e-cigarettes due to the clear links between the two reforms, stakeholders and health outcomes.

Information from evaluation will be used by the Department to guide future policy development and implementation. Findings will also be useful to international jurisdictions that may be considering similar tobacco control interventions by strengthening the international evidence-base.

Process evaluation

Process evaluation is important to monitor the extent to which requirements as outlined in legislation (and regulations) are being met by the tobacco industry and other parties. Process evaluation will seek to identify if there are any factors that may impact the ability to achieve intended outcomes, and if any changes are required to improve or ensure compliance with legislative requirements.

A key component will be ongoing evaluation of the Department's compliance and enforcement activities. This will include activity to expand the existing compliance regime, for example by including laboratory testing of tobacco product samples (Measure 6) and in respect of industry reporting requirements (Measure 6, 10A and 10B).

The tobacco industry will be engaged as needed, in a manner consistent with Australia's obligations under Article 5.3 of the WHO FCTC.

Outcome evaluation

Option 3 will contribute to a suite of tobacco control measures in Australia, such as campaigns and excise increases, that aim to reduce smoking prevalence. Outcome evaluation of Option 3 will seek to understand impact on smoking prevalence, as well as impact on medium-term objectives (the intended mechanisms to reduce prevalence).

It is important to note that the effects of Option 3 on smoking prevalence and tobacco consumption are likely to grow over time. This is because changes in initiation, cessation and relapse affect only a subset of current and future smokers, and as such their effects are slower to appear in population measures of smoking prevalence.[313] As impact on smoking prevalence will be realised over time, impact on medium term objectives will also be evaluated.

The long-term objectives of Option 3 are to reduce prevalence by:

- reducing uptake among non-tobacco users, with a particular focus on youth and young adults
- increasing cessation among current users of tobacco products.

The medium-term objectives of Option 3 are to:

- limit the exposure of the public to messages and images that may lead to tobacco use
- reduce the appeal and attractiveness of tobacco products to consumers
- reduce the ability of tobacco products and the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking
- increase the effectiveness of health warnings on the retail packaging of tobacco products
- increase the knowledge of health harms caused by tobacco use among people who smoke
- increase cessation knowledge and activity among people who smoke
- increase knowledge relating to the benefits of quitting among people who smoke.

In addition, Option 3 aims to improve access to data on tobacco sales and advertising information to help inform future policy to reduce smoking prevalence.

The impact on population measures of prevalence could be considered at approximately three years post implementation to ensure that outcomes can be appropriately measured, captured and compared. This is in line with the analysis conducted in the post-implementation review of plain packaging. Evaluation will consider data from national health surveys (e.g. National Health Survey, National Drug Strategy Household Survey, Australian Secondary Student's Alcohol and Drug Survey) and annual reports of sales data from the tobacco industry (Measure 10A). It may also consider other available data sources, such as data from Customs and the Australian Bureau of Statistics, state and territory governments, smoking cessation services, or surveys conducted by or for public health experts.

This data will be used to assess success by tracking progress towards the Australian Government targets outlined in the NTS and NPHS 2021-2030:

- daily smoking prevalence of less than 10 per cent by 2025 and 5 per cent or less for adults (≥18 years) by 2030
- reduce the daily smoking rate among First Nations peoples (≥15 years) to 27 per cent or less by 2030.

Additional options to be investigated

Impact on medium term objectives is likely to be considered two to three years post implementation. Where possible, the evaluation will be designed to enable assessment of attention and engagement of people who smoke on each new policy measure, so that the unique effects of each can be determined. Research may be commissioned to enable assessment of changes to factors such as appeal and attractiveness, the ability for products and packaging to mislead consumers about harms, health knowledge, cessation knowledge and the benefits of quitting. Methods may include online surveys and/or cohort studies.

Separate impact evaluations are recommended for updated and improved health warnings (Measure 3), HPIs (Measure 9) and Dissuasive measures on tobacco products (Measure 12). This will allow assessment of changes in knowledge and cessation activity among a broad sample of people that smoke, and people who have recently quit. It will also allow an assessment of impact on youth and young adults. Findings will help inform the development of future suites of GHWs, HPIs and messages for Dissuasive measures on tobacco products. Evaluations may be commissioned, and methods may include online surveys and/or cohort studies. Further data could also be used to track the impact of these measures on cessation activity, including calls to and engagement with Quitline services, website traffic and insights and mobile application downloads.

State and territory governments, public health organisations and experts, smoking cessation services, and the research community are likely to have valuable roles in contributing to the Government's impact evaluation through the contribution of aligned data and research. Reports outlining the findings from impact evaluation will be published where possible.

Appendices

Appendix 1: Regulatory Burden Measurement Framework for Option 2

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information on the measures provided by Option 2.

Key assumptions include that the proposal:

- will have no impacts for community organisations or individuals
- has planning implications for tobacco companies as they investigate any implications from the proposed changes
- will not result in production or re-engineering consequences
- will result in some training costs as staff in tobacco companies are briefed on the legislation and regulatory changes, but there are no training requirements for retail
- training costs in firms are assumed to have a 50 per cent premium to account for trainers' time (this assumption presumes that staff will be able to receive training in groups, but there will also be time involved in preparing training sessions)
- will not require any additional expenditure on tobacco processing equipment
- will impose no delay costs on regulated firms
- will impose no stock losses
- is likely to require tobacco companies to seek internal or external professional services (for example legal or marketing services), which is valued here at executive rates
- will have no ongoing quality control, reporting, or distribution cost implications.

The estimates use labour costs data from the *Regulatory Burden Measurement Framework*.[314] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply.

Key inputs include:

- number of tobacco companies impacted (split between large and medium sized), retailers and individual (people who smoke)
- the average wage rate (as per the Regulatory Burden Measurement Framework)
- the number of hours that each company will need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff will require, split between set-up and ongoing requirements (which are assumed here to be negative, representing a decline in training requirements compared with what would be expected under the status quo)
- equipment purchases or modification costs (currently assumed as zero)
- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation comes into effect (number of cigarette packet equivalents, assumed to be zero)
- the cost per packet to the tobacco industry either to repackage or write-off stock losses

- the time to redesign and implement engineering requirements (re-configuring machinery to new requirements, assumed to be zero)
- the change in executive and administrative hours devoted to quality control due to simplified product range (assumed to be zero).[xv]

Tables 10 and 11 below provide the regulatory burden estimates based on assumptions for Option 2 which includes the following measures:

- consolidate existing legislation
- update and improve health warnings on tobacco products
- expand advertising prohibitions
- improve coverage, enforcement, and compliance for tobacco control.

Table 10: Regulatory burden inputs: Consolidate the existing tobacco control regulatory framework

Cost model Inputs				
	Major	**Small-medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1,600	780	1	0
Training *(hours to be valued at administrator rate)*				
4 First year	300	55	2	0
4 Ongoing	50	10	0.4	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	360	78	0	0
6 Ongoing (incl communications)	10	5	0	0
Stock losses				
7 Packets	5,000	500	50	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	480	224		
9 Implementation	384	224		
Quality Control				
10 Executive hours	-52	-52	0	
10 Administrative	-260	-260	0	

[xv] Formulas relating to set up costs: System design = Affected firms * Planning hours * Executive hourly wage; Training in firms = Affected firms * Training Hours * Administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = Affected individuals * Training hours * Administrative hourly wage; Professional services = Affected firms * Professional hours * Executive hourly wage. Re-engineering costs relate only to Graphic Health Warnings, the remaining set up costs are assumed to be zero. These include: equipment cost, re-engineering, stock losses, training, professional services, quality control, operation costs, design, preparation. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

Table 11: Regulatory burden estimates based on assumptions: Consolidate the existing tobacco control regulatory framework

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	7.093			7.093
Training	8.488		0.000	8.488
New equipment purchases	0.000			0.000
Professional Services	0.295			0.295
Re-engineering	0.596			0.596
Stock losses	3.533			3.533
Total compliance set up costs	*20.006*	0.000	0.000	*20.006*
Ongoing Costs (Annual)				
Training	1.694			1.694
Quality control	-0.186			-0.186
Professional Services	0.010			0.010
Operating Costs	0.149			0.149
Government subsidies				
Total Ongoing compliance costs	*1.666*	0.000	0.000	*1.666*
Total Substantive Compliance Costs (Average Annual)	**3.667**	**0.000**	**0.000**	**3.667**

Tables 12 and 13 below provide a greater level of detail in relation to Option 2, Measure 2 which seeks to update and improve health warnings on tobacco products as follows:

Table 12: Regulatory burden inputs: Update and improve Health Warnings on tobacco products

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected Firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1200	700	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	200	50	2	0
4 Ongoing	50	10	0.4	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	240	70	0	0
6 Ongoing (incl communications)	10	5	0	0
Stock losses				
7 Packets	5,000	500	50	0
8 Price per packet	2	2	2	0
Re-engineering				
9 Design	480	224		
9 Implementation	384	224		
Quality control				
10 Executive Hours	-52	-52	0	
10 Administrative	-260	-260	0	

Table 13: Regulatory burden estimates based on assumptions: Update and improve Health Warnings on tobacco products

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	1.194			1.194
Training	8.451		0.000	8.451
New equipment purchases	0.000			0.000
Professional services	0.205			0.205
Re-engineering	0.596			0.596
Stock losses	3.533			3.533
Total compliance set up costs	*13.980*	0.000	0.000	*13.980*
Ongoing costs (annual)				
Training	1.694		0.000	1.694
Quality control	-0.186			-0.186
Professional services	0.010			0.010
Operation costs	0.149			0.149
Government subsidies				
Total ongoing compliance costs	*1.666*	0.000	0.000	*1.666*
Total substantive compliance costs (average annual)	**3.064**	**0.000**	**0.000**	**3.064**

Appendix 2: Regulatory Burden Measurement Framework for Option 3

This section investigates the combined impact of implementing all nine measures simultaneously as well as modernising and streamlining the legislation (including all 9 measures and Option 2).

In the calculations it is presumed that all nine measures (measure 11 is assumed at zero cost), as well as the modernisation and streamlining of legislation takes place at the same time with implementation completed within one year.

The default position is to assume that the regulatory burden costs are additive, except for stock losses. Calculations are based on the option where stock losses are expected to be highest and then a further 10 per cent of the stock losses is added, which is expected from the sum of the nine measures combined. This formula is an attempt to avoid double counting stock that will be equally impacted by multiple initiatives, with the relatively arbitrary 10 per cent factor accounting for initiative-specific stock losses. As is stated for each of the individual measures, a 12-month roll-out period is expected to reduce the risks of large stock losses. A larger allowance for stock losses would be required should there be a lack of co-ordination in the announcement and implementation of the nine measures.

It is presumed that there will be no direct impacts of this proposed regulation on non-tobacco industry businesses (including transport businesses and retailers), or community groups. Given their larger numbers, regulatory burden estimates are particularly sensitive to assumptions about factors affecting retailers and individuals who smoke.

Table 14: Regulatory burden inputs: Consolidate and further strengthen the tobacco control regulatory framework in line with international precedents

Cost model Inputs				
	Major	**Medium**	**Retailers**	**Individuals**
1 Affected Firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	16,860	4,940	5	0
Training *(hours to be valued at administrator rate)*				
4 First year	3,960	685	34	4
4 Ongoing	110	25	0.4	0
5 Equipment purchases ($m)	5	2	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	1,890	488	8	0
6 Ongoing (incl communications)	120	55	0	0
Stock losses				
7 Packets	80,500	8,050	85	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	13,480	2,304		
9 Implementation	30,384	8,224		
Quality Control				
10 Executive hours	-156	-104	-4	
10 Administrative	-780	-520	0	
Reporting				
Design	120	60	0	0
Preparation (Admin)	60	20	0	0
Preparation (Executive)	6	4	0	0

Table 15: Regulatory burden estimates based on assumptions: Consolidate and further strengthen the tobacco control regulatory framework in line with international precedents

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	42.314			42.314
Training	143.804		126.00	269.804
New equipment purchases	20.25			20.25
Professional Services	46.180			46.180
Re-engineering	19.985			19.985
Stock losses	6.481			6.481
Total compliance set up costs	*279.014*	0.000	*126.00*	*405.014*
Ongoing Costs (Annual)				
Training	1.721		0.000	1.721
Quality control	-22.768			-22.768
Testing	0.003			0.003
Professional Services	0.112			0.112
Operating Costs	2205			2.205
Government subsidies				0.000
Total Ongoing compliance costs	*-18.728*	0.000	*0.000*	*-18.728*
Total Substantive Compliance Costs (Average Annual)	**9.174**	**0.000**	**12.600**	**21.774**

Administrative Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.115			0.115
New equipment purchases				
Application and notification costs				
Total administrative set up costs	*0.115*	*0.000*	*0.000*	*0.115*
Ongoing Costs (Annual)				
Record keeping	0.025			0.025
Testing				
Communications				
Total Administrative Ongoing costs	0.025	0.000	0.000	0.025
Total Administrative Costs	**0.037**	**0.000**	**0.000**	**0.037**

Average annual regulatory costs (from business as usual)				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Administrative	0.037	0.000	0.000	0.037
Compliance	9.174	0.000	12.600	21.774
Delay	0.000	0.000	0.000	0.000
Total, by sector	**9.210**	**0.000**	**12.600**	**21.810**

Appendix 3: Regulatory Burden Measurement Framework for Measure 5 (Option 3) – Standardise tobacco product size – cigarette pack, carton and stick size, RYO tobacco pouch size and little cigar and cigarillo pack size

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

Some of the key assumptions include that the proposal:

- would have no impacts for community organisations
- would have mainly planning, package redesign and re-engineering implications for tobacco companies during the implementation phase (although the re-engineering costs will take place overseas, the costs may ultimately be borne by Australian consumers and so are included here)
- would add to training costs through the implementation phase, but product simplification would probably reduce future training requirements
- would assume training costs in firms at a 50 per cent premium to account for trainers' time through the implementation phase, but product standardisation would probably reduce future training requirements
- would not require the purchase of any additional equipment
- would impose some learning costs on people who smoke who would need to adapt to product changes
- would require individuals who smoke to learn about the changes, which is included as 'training' costs for individuals (it is assumed here that this learning has a one-off impact of taking up 30 minutes of time on average for each smoker)
- would impose no delay costs on regulated firms
- would likely require tobacco companies to seek internal and external professional services (for example legal or marketing services)
- would impose minimal stock losses (but not zero) due to a twelve-month roll-out period
- would reduce ongoing quality control costs due to the simplification of the product range imposed by the proposed regulation
- would pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour costs data from the *Regulatory Burden Measurement Framework*.[315] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium sized), retailers and individual (people who smoke)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations

- the number of hours of extra training per company that staff would require, split between set up and ongoing requirements (which are assumed here to be negative, representing a decline in training requirements)
- the time spent by the average individual to learn and understand the implications of the proposed changes (treated as a training cost for individuals)
- equipment purchases (currently assumed as zero)
- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation comes into effect (number of cigarette packet equivalents)
- the cost per packet to the tobacco industry either to repackage or write-off stock losses
- the time to redesign and implement engineering requirements (re-configuring machinery to new requirements)
- reductions in executive and administrative hours devoted to quality control as a result of the simplification of the product range imposed by the proposed regulation.[316]

Table 16: Regulatory burden inputs: Standardise tobacco product size

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected Firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1,000	500	2	0
Training *(hours to be valued at administrator rate)*				
4,5 First year	1,000	150	8	0.5
4 Ongoing	-50	-20	-2	0
5 Equipment purchases ($m)	0	0	0	0
Professional services *(hours to be valued at executive rate)*				
7 First year	200	50	2	0
7 Ongoing (incl communications)	10	5	0	0
Stock losses				
8 Packets	50,000	5,000	50	
9 Price per packet	2	2	2	
Re-engineering				
10 Design	2,080	520		
10 Implementation	8,000	2,000		
Quality Control				
11 Executive hours	-104	-52	-4	
11 Administrative	-2,080	-520	0	

Table 17: Regulatory burden estimates based on assumptions: Standardise tobacco product size

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	12.104			12.104
Training	33.857		18.000	51.857
New equipment purchases	0.000			0.000
Professional services	11.315			11.315
Re-engineering	4.128			4.128
Stock losses	3.830			3.830
Total compliance set up costs	*65.234*	*0.000*	*18.000*	*83.234*
Ongoing costs (annual)				
Training	-8.386		0.000	-8.386
Quality control	-23.017			-23.017
Testing				0.000
Professional services	0.010			0.010
Operating costs	0.000			0.000
Government subsidies				0.000
Total ongoing compliance costs	-31.394	0.000	0.000	-31.394
Total substantive compliance costs (average annual)	**-24.870**	**0.000**	**1.800**	**-23.070**

Appendix 4: Regulatory Burden Estimate Measurement Framework for Measure 6 (Option 3) - Reduce tobacco product attractiveness and palatability by restricting the use of additives

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

For this measure, some of the key assumptions include that the proposal:

- would have no impacts for community organisations
- has planning and re-engineering implications for tobacco companies during the implementation phase (although the re-engineering costs will take place overseas, the costs may ultimately be borne by Australian consumers and so are included here)
- would add to training costs during the implementation phase, but product simplification would likely reduce future training requirements
- would assume training costs in firms at a 50 per cent premium to account for trainers' time through the implementation phase but product standardisation would probably reduce further training requirements
- would require individuals who smoke to learn about the changes, which is included as 'training' costs for individuals (it is assumed here that this learning has a one-off impact of taking up 30 minutes of time on average for each smoker)
- would not require additional expenditure on tobacco processing equipment
- would impose no delay costs on regulated firms
- would impose minimal stock losses due to a 12-month roll-out period
- would be likely to require tobacco companies to seek external professional services (for example legal or marketing services)
- would decrease ongoing quality control costs due to simplified product range
- would impose additional reporting requirements on tobacco companies
- would pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework.*[317] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium sized), retailers and individual (people who smoke)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements (which are assumed to be negative)
- equipment purchase or modification costs (assumed as zero)

- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation comes into effect
- the cost per packet to the tobacco industry either to repackage or write-off stock losses
- the time to redesign and implement engineering requirements
- the change in executive and administrative hours devoted to quality control due to simplified product range
- the reduction in the number of packets that no longer have prohibited additives to tobacco
- the cost of additives per package
- the amount of (executive) hours required to design new annual reports on additives
- the number of executive hours required to prepare annual reports.[318]

Table 18: Regulatory burden inputs: Reducing tobacco product attractiveness and palatability by restricting the use of additives

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected Firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	10,400	2,080	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	1,000	150	8	1
4 Ongoing	0	0	2	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	500	150	2	0
6 Ongoing (incl communications)	50	20	0	0
Stock losses				
7 Packets	50,000	5,000	50	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	6,240	260		
9 Implementation	3,000	1,000		
Quality control				
10 Executive hours	-104	-52	0	
10 Administrative	-520	-260	0	
Production cost saving				
11 Decrease in packets with additives	-100,000	-20,000		
12 Price of additives per packet ($)	0.05	0.05		
Reporting				
13 Design	60	30	0	0
14 Preparation (admin)	30	10	0	0
14 Preparation (executive)	3	2	0	0

Table 19: Regulatory burden estimates based on assumptions: Reducing tobacco product attractiveness and palatability by restricting the use of additives

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	8.447			8.447
Training	33.857		36.000	69.857
New equipment purchases	0.000			0.000
Professional services	11.578			11.578
Re-engineering	5.552			5.552
Stock losses	3.830			3.830
Total compliance set up costs	*63.264*	*0.000*	*36.000*	*99.264*
Ongoing costs (annual)				
Training	8.361		0.000	8.361
Quality control	-0.286			-0.286
Testing				0.000
Professional services	0.045			0.045
Operating costs	-0.018			-0.018
Government subsidies				0.000
Total ongoing compliance costs	8.103	0.000	0.000	8.103
Total substantive compliance costs (average annual)	**14.429**	**0.000**	**3.600**	**18.029**

Administrative Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs				
System design	0.057			0.057
New equipment purchases				0.000
Application and notification costs				0.000
Total administrative setup costs	*0.057*	*0.000*	*0.000*	*0.057*
Ongoing costs				
Record keeping	0.013			0.013
Testing				0.000
Communications				0.000
Total administrative ongoing costs	0.013	0.000	0.000	0.013
Total administrative costs	**0.018**	**0.000**	**0.000**	**0.018**

Average Annual Regulatory Costs (from business as usual)				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Administrative	0.018	0.000	0.000	0.018
Compliance	14.429	0.000	3.600	18.029
Delay	0.000	0.000	0.000	0.000
Total, by sector	**14.448**	**0.000**	**3.600**	**18.048**

Appendix 5: Regulatory Burden Measurement Framework for Measure 7 (Option 3) - Reduce tobacco product attractiveness by regulating product design features that create novelty value

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

It is assumed that the proposal:

- would have no impact on community organisations
- would have planning and packaging process re-engineering implications for tobacco companies during the implementation phase (although the re-engineering costs will take place overseas, the costs may ultimately be borne by Australian consumers and so are included here)
- would have modest training requirements
- would require individuals who smoke to learn about the changes, which is included as 'training' costs for individuals (it is assumed here that this learning has a one-off impact of taking up 30 minutes of time on average for each smoker)
- would not require any additional expenditure on packaging equipment (although there would be a risk of premature obsolescence, as manufacturing takes place overseas it is assumed that alternative markets would predicate this happening)
- would impose no delay costs on regulated firms
- would impose minimal stock losses (due to a 12-month roll-out period)
- would be likely to require tobacco companies to seek internal and external professional services (for example legal or marketing services)
- would impose an additional reporting requirement on tobacco companies
- would decrease ongoing quality control costs due to a simplified product range and additional reporting requirements
- would pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework*.[319] The estimates also implicitly assume that the extra ongoing compliance cost of this measure is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.
Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium sized), retailers and individual (people who smoke)
- the average wage rate
- the number of hours that each company will need to place into planning for the introduction of the new regulations; the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements (which are assumed here to be negative)
- equipment purchase or modification costs (currently assumed as zero)
- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by companies and retailers when the new regulation comes into effect

- the cost per packet to the tobacco industry to repackage or write-off stock losses
- time to redesign and implement engineering requirements
- the change in executive and administrative hours devoted to quality control due to simplified product range
- the reduction in the number of cigarette sticks needing capsules inserted
- the cost of producing and inserting the capsules
- hours required to design new annual reports on product design features and hours to write those reports.[320]

Table 20: Regulatory burden inputs: Regulating product design features that create novelty value

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	200	50	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	200	50	8	1
4 Ongoing	-50	-10	-2	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	200	50	2	0
6 Ongoing (incl communications)	10	5	0	0
Stock losses				
7 Packets	50,000	5,000	50	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	520	260		
9 Implementation	3,000	1,000		
Quality Control				
10 Executive hours	-104	-52	0	
10 Administrative	-520	-260	0	
Capsule cost saving				
11 Capsule Inserts (number)	-100,000	-20,000		
12 Price per capsule ($)	0.50	0.60		
Reporting				
13 Design	60	30	0	0
14 Preparation (admin)	30	10	0	0
14 Preparation (executive)	3	2	0	0

Table 21: Regulatory burden estimates based on assumptions: Regulating product design features that create novelty value

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.167			0.167
Training	33.534		36.000	69.534
New equipment purchases	0.000			0.000
Professional services	11.315			11.315
Re-engineering	1.452			1.452
Stock losses	3.830			3.830
Total compliance set up costs	*50.299*	*0.000*	*36.000*	*86.299*
Ongoing costs (annual)				
Training	-8.383		0.000	-8.383
Quality control	-0.286			-0.286
Testing				0.000
Professional services	0.010			0.010
Operating costs	-0.186			-0.186
Government subsidies				0.000
Total ongoing compliance costs	-8.845	0.000	0.000	-8.845
Total substantive compliance costs (average annual)	**-3.815**	**0.000**	**3.600**	**-0.215**

Administrative Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs				
System design	0.057			0.057
New equipment purchases				0.000
Application and notification costs				0.000
Total administrative setup costs	*0.057*	*0.000*	*0.000*	*0.057*
Ongoing costs				
Record keeping	0.013			0.013
Testing				0.000
Communications				0.000
Total administrative ongoing costs	0.013	0.000	0.000	0.013
Total administrative costs	**0.018**	**0.000**	**0.000**	**0.018**

Average Annual Regulatory Costs (from business as usual)				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Administrative	0.018	0.000	0.000	0.018
Compliance	-3.815	0.000	3.600	-0.215
Delay	0.000	0.000	0.000	0.000
Total, by sector	**-3.796**	**0.000**	**3.600**	**-0.196**

Appendix 6: Regulatory Burden Measurement Framework for Measure 8 (Option 3) Prohibit the use of brand and variant names that falsely imply reduced harm

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

Some of the key assumptions include that the proposal:

- would have no impact for community organisations
- would have mainly package redesign implications for tobacco companies, with training implications for both internal staff and retailers
- would not require purchase of additional equipment
- would impose some learning costs on people who smoke who would need to match new brand names with existing smoking practices
- would impose no delay costs on regulated firms
- would impose minimal stock losses due to a twelve-month roll-out period
- would require executive time to undertake planning (assumed here to be valued at three times the average hourly wage for large tobacco companies and double the average hourly wage for smaller tobacco companies)
- would require training of administrative staff and retailers as part of the set-up, with smaller ongoing training requirements
- would assume training costs in firms at a 50 per cent premium to account for trainers' time (this assumption presumes staff would receive group training)
- would be likely to require tobacco companies to seek internal or external professional services (for example legal or marketing services) which is valued here at executive rates
- would pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework.*[321] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium sized), retailers and individual (people who smoke)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements
- the time spent by the average individual to learn and understand the implications of the proposed changes
- equipment purchases (currently assumed as zero)

- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation would come into effect (number of cigarette packet equivalents)
- the cost per packet to the tobacco industry either to repackage or write-off stock losses.[322]

Table 22: Regulatory burden inputs: Limiting brand and variant names

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1,600	500	2	0
Training *(hours to be valued at administrator rate)*				
4,5 First year	1,000	150	8	1
4 Ongoing	50	20	2	0
6 Equipment purchases ($m)	0	0	0	0
Professional services *(hours to be valued at executive rate)*				
7 First year	200	50	2	0
7 Ongoing (incl communications)	10	5	0	0
Stock losses				
8 Packets	50,000	5,000	50	
9 Price per packet	2	2	2	

Table 23: Regulatory burden estimates based on assumptions: Limiting brand and variant names

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	12.534			12.534
Training	33.857		36.000	69.857
New equipment purchases	0.000			0.000
Professional services	11.315			11.315
Re-engineering	0.000			0.000
Stock losses	3.830			3.830
Total compliance set up costs	*61.536*	*0.000*	*36.000*	*97.536*
Ongoing Costs (Annual)				
Training	8.386		0.000	8.386
Quality control	0.000			0.000
Testing	0.000			0.000
Professional services	0.010			0.010
Operating costs				0.000
Government subsidies				0.000
Total ongoing compliance costs	8.396	0.000	0.000	8.396
Total substantive compliance costs (average annual)	**14.549**	**0.000**	**3.6**	**18.149**

Appendix 7: Regulatory Burden Measurement Framework for Measure 9 (Option 3) - Require Health Promotion Inserts to encourage and empower people who smoke to quit

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers provided limited, but some information on cost set ups.

Some of the key assumptions include that the proposal:

- would have no impacts on community organisations
- would have planning and packaging process re-engineering implications for tobacco companies during the implementation phase (although the re-engineering costs will take place overseas, the costs may ultimately be borne by Australian consumers and so are included here)
- would not have significant training requirements
- would potentially require expenditure on packaging equipment (or modification of equipment) to automate insert process
- would impose no delay costs on regulated firms
- would impose minimal stock losses due to a 12-month roll-out period
- would be likely to require tobacco companies to seek external professional services (for example legal or marketing services), which is valued at executive rates
- would increase ongoing quality control costs to ensure that inserts are placed correctly
- would impose printing costs on tobacco companies to print inserts
- would pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework.*[323] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium sized), retailers and individual (people who smoke)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements (which are assumed to be negative, representing a decline in training requirements compared with what would be expected under the status quo)
- equipment purchase or modification costs (currently assumed as $1 million for large tobacco companies and $500,000 for small-to-medium sized companies)
- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation would come into effect
- the cost per packet to the tobacco industry either to repackage or write-off stock losses

- the time to redesign and implement engineering requirements (re-configuring machinery to new requirements)
- increases in executive and administrative hours devoted to quality control to ensure inserts would be packaged correctly
- the number of inserts that each company would need to print each year
- the cost of printing and packaging each insert.[324]

Table 24: Regulatory burden inputs: Health Promotion Inserts

Cost Model Inputs				
	Major	**Small-to-Medium sized Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1000	500	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	200	50	0	0
4 Ongoing	50	10	0	0
5 Equipment purchases ($m)	3.5	1.8	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	200	50	0	0
6 Ongoing (incl communications)	10	5	0	0
Stock losses				
7 Packets	50,000	5,000	50	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	2,080	520		
9 Implementation	8,000	2,000		
Quality control				
10 Executive hours	104	52	0	
10 Administrative	2080	520	0	
Printing				
11 Inserts (number)	1,000,000	200,000		
12 Price per insert ($)	0.50	0.60		

Table 25: Regulatory burden estimates: Health Promotion Inserts

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.956			0.956
Training	0.090			0.090
New equipment purchases	15.75			15.75
Professional Services	0.167			0.167
Re-engineering	4.128			4.128
Stock losses	3.830			3.830
Total compliance set up costs	*24.92*	*0.0*	*0.0*	*24.92*
Ongoing costs (annual)				
Training	0.022			0.022
Quality control	0.720			0.720
Professional services	0.010			0.010
Operating costs	1.860			1.860
Government subsidies				0.000
Total ongoing compliance costs	2.612	0.000	0.000	2.612
Total substantive compliance costs (average annual)	**5.104**	**0.000**	**0.000**	**5.104**

Appendix 8: Regulatory Burden Measurement Framework for Measure 10A (Option 3) - Require mandatory disclosure of sales and expenditure data.

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

For this measure, some of the key assumptions include that the proposal would:

- impact only on tobacco companies and would have no direct impact on retailers, community organisations or individuals
- would not require the purchase of any additional equipment
- impose additional administrative requirements on tobacco companies, but as these administrative requirements would be the main purpose of the proposed regulations, the costs are counted here as substantive compliance costs
- impose no delay costs on regulated firms
- require executive time to undertake planning (assumed here to be valued at three times the average hourly wage for large tobacco companies and double the average hourly wage for smaller tobacco companies)
- require training of administrative staff as part of the set-up, with smaller ongoing training requirements
- assume training costs in firms to have a 50 per cent premium to account for trainers' time (assuming staff can train in groups)
- likely require tobacco companies to seek external professional services (for example legal or marketing services) which is valued here at executive rates
- include within data collation costs all costs associated with ongoing compliance with the proposed regulations
- pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework*.[325] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium enterprises)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements
- equipment purchases (currently assumed as zero)
- the number of hours of professional services required per company, split between set-up and ongoing
- the number of data releases per year required to comply with the mandatory disclosure regulations

- the number of hours (administrative and executive) required for each company to prepare the disclosure information and authorise their release.[326]

Table 26: Regulatory burden inputs: Mandatory disclosure of sales and expenditure

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	20	10	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	20	10	0	0
4 Ongoing	5	2.5	0	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	10	3	0	0
6 Ongoing (incl communications)	5	2.5	0	0
7 No of data releases per year	1	1	0	0
Data collation				
8 Administrative hours	20	7	0	0
8 Executive hours	2	1.5	0	0

Table 27: Regulatory burden estimates based on assumptions: Mandatory disclosure of sales and expenditure

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.019			0.019
Training	0.011		0.0	0.011
New equipment purchases	0.000			0.000
Professional services	0.009			0.009
Total compliance set up costs	*0.038*	*0.0*	*0.0*	*0.038*
Ongoing costs (annual)				
Training	0.003			0.003
Testing/Authorisation	0.002			0.002
Professional services	0.005			0.005
Operation costs	0.006			0.006
Government subsidies				0.000
Total ongoing compliance costs	0.016	0.0	0.0	0.016
Total substantive compliance costs (average annual)	**0.020**	**0.0**	**0.0**	**0.020**

Appendix 9: Regulatory Burden Measurement Framework for Measure 10B (Option 3) - Require mandatory disclosure of advertising and promotion expenditure data

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

For this measure, some of the key assumptions include that the proposal would:

- impact only on tobacco companies and would have no direct impact on retailers, community organisations or individuals
- would not require the purchase of any additional equipment
- impose additional administrative requirements on tobacco companies, but as these administrative requirements would be the main purpose of the proposed regulations, the costs are counted here as substantive compliance costs
- impose no delay costs on regulated firms
- require executive time to undertake planning (assumed here to be valued at three times the average hourly wage for large tobacco companies and double the average hourly wage for smaller tobacco companies)
- require training of administrative staff as part of the set-up, with smaller ongoing training requirements
- assume training costs in firms to have a 50 per cent premium to account for trainers' time (assuming staff can train in groups)
- likely require tobacco companies to seek external professional services (for example legal or marketing services) which is valued here at executive rates
- include within data collation costs all costs associated with ongoing compliance with the proposed regulations
- pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

Estimates use labour cost data from the *Regulatory Burden Measurement Framework*.[327] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium enterprises)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements
- equipment purchases (currently assumed as zero)
- the number of hours of professional services required per company, split between set-up and ongoing
- the number of data releases per year required to comply with the mandatory disclosure regulations

- the number of hours (administrative and executive) required for each company to prepare the disclosure information and authorise their release.[328]

Table 28: Regulatory burden inputs: Mandatory disclosure of promotion expenditure

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	40	20	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	40	20	0	0
4 Ongoing	5	2.5	0	0
5 Equipment purchases ($m)	0.0	0.0	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	20	7	0	0
6 Ongoing (incl communications)	5	2.5	0	0
7 No of data releases per year	1	1	0	0
Data collation				
8 Administrative hours	10	3	0	0
8 Executive hours	1	0.5	0	0

Table 29: Regulatory burden estimates based on assumptions: Mandatory disclosure of promotion expenditure

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.038			0.038
Training	0.022		0.0	0.022
New equipment purchases	0.000			0.000
Professional services	0.018			0.018
Total compliance set up costs	*0.077*	*0.0*	*0.0*	*0.077*
Ongoing costs (annual)				
Training	0.003			0.003
Testing/Authorisation	0.001			0.001
Professional services	0.005			0.005
Operation costs	0.003			0.003
Government subsidies				0.000
Total ongoing compliance costs	0.012	0.0	0.0	0.012
Total substantive compliance costs (average annual)	**0.019**	**0.0**	**0.0**	**0.019**

Appendix 10: Regulatory Burden Measurement Framework for Measure 12 (Option 3) - Require dissuasive measures on tobacco products

Estimates are presented below to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on publicly available data and a number of explicit assumptions (detailed below). Consultation with the tobacco industry and retailers did not provide material information to change these regulatory burden estimates.

For this measure, some of the key assumptions include that the proposal would:

- have no impacts on community organisations
- have planning and packaging process re-engineering implications for tobacco companies during the implementation phase (although the re-engineering costs will take place overseas, the costs may ultimately be borne by Australian consumers and so are included here)
- not have significant training requirements
- potentially require expenditure on packaging equipment (or modification of equipment) to automate insert process
- impose no delay costs on regulated firms
- impose minimal stock losses due to a 12-month roll-out period
- be likely to require tobacco companies to seek external professional services (for example legal or marketing services), which is valued at executive rates
- pass on any impacts on distribution companies as cost increases borne by the tobacco industry.

The estimates use labour cost data from the *Regulatory Burden Measurement Framework*.[329] The estimates also implicitly assume that the extra ongoing compliance cost of this proposal is relatively low, with minimal extra time required to comply and that just one data release is required from tobacco companies each year.

Key inputs for this measure include:

- the number of tobacco companies impacted (split between large and small-medium enterprises)
- the average wage rate
- the number of hours that each company would need to place into planning for the introduction of the new regulations
- the number of hours of extra training per company that staff would require, split between set-up and ongoing requirements (which are assumed to be negative, representing a decline in training requirements compared with what would be expected under the status quo)
- equipment purchase or modification costs (currently assumed as $1 million for large tobacco companies and $500,000 for small-to-medium sized companies)
- the number of hours of professional services required per company, split between set-up and ongoing
- the remaining stock held by tobacco companies and retailers when the new regulation would come into effect
- the cost per packet to the tobacco industry either to repackage or write-off stock losses
- the time to redesign and implement engineering requirements (re-configuring machinery to new requirements).[330]

Table 30: Regulatory burden inputs: Dissuasive measures on tobacco products

Cost Model Inputs				
	Major	**Small-Medium Enterprises**	**Retailers**	**Individuals**
1 Affected firms	3	3	35,000	1,000,000
2 Executive hourly wage	238.89	159.26	159.26	
2 Administrative hourly wage	79.63	79.63	79.63	36.00
Planning *(executive hours)*				
3 First year	1,000	500	0	0
Training *(hours to be valued at administrator rate)*				
4 First year	200	50	0	0
4 Ongoing	50	10	0	0
5 Equipment purchases ($m)	1.0	0.5	0.0	0.0
Professional services *(hours to be valued at executive rate)*				
6 First year	200	50	0	0
6 Ongoing (incl communications)	10	5	0	0
Stock losses				
7 Packets	50,000	5,000	50	
8 Price per packet	2	2	2	
Re-engineering				
9 Design	2,080	520		
9 Implementation	8,000	2,000		
Quality control				
10 Executive hours	104	52	0	
10 Administrative	520	260	0	
Printing				
11 Units	1,000,000	200,000		
12 Price per cigarette paper ($)	0.01	0.02		

Table 31: Regulatory burden estimates based on assumptions: Dissuasive measures on tobacco products

Substantive Compliance Costs				
Change in costs ($million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Set up costs (first year)				
System design	0.956			0.956
Training	0.090			0.090
New equipment purchases	4.500			4.500
Professional Services	0.167			0.167
Re-engineering	4.128			4.128
Stock losses	3.830			3.830
Total compliance set up costs	*13.670*	*0.0*	*0.0*	*13.670*
Ongoing costs (annual)				
Training	0.022			0.022
Quality control	0.286			0.286
Professional services	0.010			0.010
Operating costs	0.390			0.390
Government subsidies				0.000
Total ongoing compliance costs	0.707	0.000	0.000	0.707
Total substantive compliance costs (average annual)	**2.074**	**0.000**	**0.000**	**2.074**

References

[2] United Nations, 'Chapter IX, Health, WHO Framework Convention on Tobacco Control' (Web Page, United Nations Treaty Collection, 21 May 2003) UNTC.

[3] R West, 'Tobacco Smoking: Health Impact, Prevalence, Correlates and Interventions' (2017) *Psychology and Health* 32(8): 1018-1036. Available at: PMC (nih.gov) ; M Assunta, 'Global Tobacco Industry Interference Index' (Global Centre for Good Governance in Tobacco Control, 2021). Available at: globaltobaccoindex.org.

[4] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (Drug Statistics series no. 32 2020) 8. Available at: National Drug Strategy Household Survey 2019 (aihw.gov.au).

[5] Department of Health and Aged Care, 'National Prevention Health Strategy 2021-2030' (2021). Available at: National Preventive Health Strategy 2021–2030 | Australian Government Department of Health and Aged Care.

[6] World Health Organization, '*WHO Framework Convention on Tobacco Control*' (2003). Available at: https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=5EDE341A29ADE9F8E052C79F67A90C97?sequence=1.

[7] The Hon Greg Hunt (Minister for Health), 'National Press Club address – Long Term National Health Plan transcript' (2019). Available from: https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/national-press-club-address-long-term-national-health-plan.

[8] *Legislation Act 2003* (Cth).

[9] Department of Health, '*Review of Tobacco Control Legislation – Update'* (2020). Available from: Consultation Hub.

[10] Department of Health, 'National Drug Strategy 2017-2026' (2017). Available at: https://www.health.gov.au/sites/default/files/national-drug-strategy-2017-2026_1.pdf.

[11] Australian Institute of Health and Welfare, 'Australian Burden of Disease Study: Impact and Causes of Illness and Death in Australia 2015' (2019). Available at: Australian Institute of Health and Welfare (aihw.gov.au).

[12] Ibid.

[13] National Drug Research Institute, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (Curtin University, May 2019). Available at: T273.pdf (curtin.edu.au).

[14] Australian Bureau of Statistics (5 December 2022), *Insights into Australian smokers 2021-2022,* ABS website. Available at: https://www.abs.gov.au/articles/insights-australian-smokers-2021-22

[15] Australian Institute of Health and Welfare, 'Australian Burden of Disease Study 2018: Interactive data on risk factor burden' (November 2021). Available at: Australian Burden of Disease Study 2018: Interactive data on risk factor burden, Tobacco use - Australian Institute of Health and Welfare (aihw.gov.au).

[16] Q Luo et al, 'Projections of smoking-related cancer mortality in Australia to 2044', (2022) *J Epidemiol Community Health,* 792-799.

[17] D Levy, F Chaloupka and J Gitchell, 'The effects of tobacco control policies on smoking rates: a tobacco control scorecard', *Journal of Public Health Management & Practice* (2004) 10(4):338–53. Available at: The effects of tobacco control policies on smoking rates: a tobacco control scorecard - PubMed (nih.gov).

[18] M Scollo et al, 'Tobacco product developments in the market in the four years following plain packaging', *Tobacco Control* (2018) 27:580-584.

[19] *Court Enforceable undertakings with tobacco companies (Philip Morris, British American Tobacco Australia and Imperial Tobacco Limited) issued in 2005* (2005 Undertakings); *Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008* (*Fire Risk Regulations*); *Trade Practices Act 1974 – Consumer Protection Notice No. 10 of 1991 – Permanent Ban on Goods* (Oral Tobacco Ban); *Competition and Consumer (Tobacco) Information Standard 2011 (Information Standard).*

[20] The consultation document is available at: https://consultations.health.gov.au/population-health-and-sport-division/review-of-tobacco-control-legislation/supporting_documents.

[21] E Banks et al, 'Tobacco Smoking and All-Cause Mortality in a Large Australian Cohort Study: Findings From a Mature Epidemic with Current Low Smoking Prevalence' (2015) *BMC Medicine,* 13:38.

[22] Centers for Disease Control and Prevention, '*Smoking and Tobacco Use* Fast Facts and Fact Sheets' Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (May 2023). Available at: Fast Facts and Fact Sheets | Smoking and Tobacco Use | CDC.

[23] Ibid.

[24] US Department of Health and Human Services, '*The Health Consequences of Involuntary Exposure to Tobacco Smoke: a Report of the Surgeon General* (2006) Office of the Surgeon General. Available at: The Health Consequences of Involuntary Exposure to Tobacco Smoke - NCBI Bookshelf (nih.gov).

[25] Ibid.

[26] Australian Institute of Health and Welfare, '*Australian Burden of Disease Study: Impact and Causes of Illness and Death in Australia 2011'*, Australian Institute of Health and Welfare (May 2016). Available at: Australian Burden of Disease Study: impact and causes of illness and death in Australia 2011, Highlights - Australian Institute of Health and Welfare (aihw.gov.au).

[27] K Thurber et al, 'Tobacco Smoking and Mortality Among Aboriginal and Torres Strait Islander Adults In Australia' (2021) *International Journal of Epidemiology* 50(3): 942-954. Available at: Tobacco smoking and mortality among Aboriginal and Torres Strait Islander adults in Australia - PMC (nih.gov).

[28] Australian Bureau of Statistics, 'National Health Survey: First Results, 2017-18' (Australian Bureau of Statistics, February 2019). Available at: https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/latest-release.

[29] Australian Bureau of Statistics, 'National Aboriginal and Torres Strait Islander Health Survey' (Australian Bureau of Statistics, December 2019). Available at: National Aboriginal and Torres Strait Islander Health Survey, 2018-19 financial year | Australian Bureau of Statistics (abs.gov.au).

[30] Ibid.

[31] Australia Indigenous HealthInfoNet, 'Summary of tobacco use among Aboriginal and Torres Strait Islander peoples' (2020). Available at: Summary of tobacco use among Aboriginal and Torres Strait Islander peoples. (nla.gov.au).

[32] S Whetton et al, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (National Drug Research Institute, Curtin University, May 2019) 40-45. Available at: T273.pdf (curtin.edu.au).

[33] Ibid 57.

[34] Australian Institute of Health and Welfare, 'Tobacco' 2020. Available at: https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/tobacco.

[35] B Nyakutsikwa, J Britton, and T Langley, 'The effect of tobacco and alcohol consumption on poverty in the United Kingdom'(2021) *Addiction* 116(1):150–8. Available at: The effect of tobacco and alcohol consumption on poverty in the United Kingdom - PubMed (nih.gov).

[36] Australian Institute of Health and Welfare, 'Alcohol, tobacco & other drugs in Australia' (2023) . Available at: Alcohol, tobacco & other drugs in Australia, People with mental health conditions - Australian Institute of Health and Welfare (aihw.gov.au).

[37] Chesney E, Robson D, Patel R, Shetty H, Richardson S, et al. The impact of cigarette smoking on life expectancy in schizophrenia, schizoaffective disorder and bipolar affective disorder: An electronic case register cohort study. Schizophr Res, 2021; 238:29–35. Available from: https://www.ncbi.nlm.nih.gov/pubmed/34563995

[38] Productivity Commission, 'Mental Health Productivity Commission Inquiry Report' (2020) Report no. 95, Australian Government. Available at: Volume 1 - Inquiry report - Mental Health (pc.gov.au).

[39] National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. 'E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General' (2016, Centers for Disease Control and Prevention US). Available at: https://www.ncbi.nlm.nih.gov/books/NBK538688/.

[40] G Taylor et al, 'Smoking cessation for improving mental health' (2021) Cochrane Database of Systematic Reviews 3(3) CD013522. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8121093/.

[41] Jenkins S, Greenhalgh EM and Scollo MM. '9.A.6 Lesbian, gay, bisexual, trans, queer and intersex (LGBTQI+) people.' In Greenhalgh EM, Scollo MM and Winstanley MH (eds). Tobacco in Australia: facts and issues. Melbourne: Cancer Council Victoria; 2022. Available at: https://www.tobaccoinaustralia. org.au/chapter-9-disadvantage/in-depth/9a6_ lesbian-gay-bisexual-trans-queer-and-intersexLGBTQI-people

[42] S Whetton et al, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (National Drug Research Institute, Curtin University, May 2019). Available at: https://ndri.curtin.edu.au/NDRI/media/documents/publications/T273.pdf.

[43] S Troelstra et al, 'Smoking and sickness absence: a systematic review and meta-analysis' (2020) *Scandinavian Journal of Work, Environment & Health* 46(1):5-18. Available at: https://www.sjweh.fi/show_abstract.php?abstract_id=3848&fullText=1.

[44] N Guerin and V White, 'Australian Secondary School Students' Use of Tobacco, Alcohol, Over the Counter Drugs, and Illicit Substances: Second Edition' (Cancer Council Victoria, 2020). Available at: ASSAD 2017 Statistics & Trends: Second Edition (health.gov.au).

[45] Australian Institute of Health and Welfare, '*National Drug Strategy Household Survey 2019*' (Australian Institute of Health and Welfare, July 2020). Available at: AIHW.

[46] US Department of Health and Human Services, 'Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General' (US Department of Health and Human Services, 2012). Available at: CDC.

[47] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-cigarette Use Among Youth and Young Adults: A Report of the Surgeon General' (US Department of Health and Human Services, 2016). Available at: E-Cigarette Use Among Youth and Young Adults - NCBI Bookshelf (nih.gov).

[48] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General' (US Department of Health and Human Services, 2012). Available at: Preventing Tobacco Use Among Youth and Young Adults - NCBI Bookshelf (nih.gov).

[49] Ibid.

[50] Campaign for Tobacco Free Kids, 'The Path to Tobacco Addiction Starts at very young ages' (Tobacco Free Kids 2023). Available at: https://www.tobaccofreekids.org/assets/factsheets/0127.pdf.

[51]Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 'Smoking Cessation: A Report of the Surgeon General' (US Department of Health and Human Services 2020). Available at: https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/2020-cessation-sgr-factsheet-key-findings/index.html.

[52] Ibid 8.

[53] Ibid 9.

[54] Ibid.

[55] Australian Institute of Health and Welfare, '*National Drug Strategy Household Survey 2016: Detailed Findings*' (Australian Government, September 2017). Available at: AIHW.

[56] Dono et al, 'A population-level analysis of changes in Australian smokers' preferences for smoking cessation support over two decades – from 1998 to 2017' (2022) *The Lancet* 19 (February),

[57] Australian Institute of Health and Welfare, '*National Drug Strategy Household Survey 2016: Detailed Findings'* (Australian Government, September 2017). Available at: AIHW.

[58] Ibid.

[59] R Borland et al, 'How much unsuccessful quitting activity is going on among adult smokers? Data from the International Tobacco Control Four Country cohort survey'(2012) *Addiction* 107(3):673-82. Available at: PMC (nih.gov).

[60] E Greenhalgh, S Stillman and E Ford, '7.14 - Cessation assistance: Telephone- and Internet-based interventions' in E Greenhalgh, M Scollo, and M Winstanley (eds), *Tobacco in Australia: Facts and issues* (Cancer Council Victoria 2023). Available at: 7.14 Cessation assistance: telephone- and internet-based interventions - Tobacco in Australia; E van Wijk, L Landais and J Harting, 'Understanding the multitude of barriers that prevent smokers in lower socioeconomic groups from accessing smoking cessation support: a literature review'(2019) *Preventive Medicine* 123:143-51; E Roddy et al, 'Barriers and Motivators to Gaining Access to Smoking Cessation Services Amongst Deprived Smokers - a Qualitative Study' (2006) *BMC Health Services Research* 6(1):147. Available at: BMC Health Services Research; D Hammond et al, 'Do smokers know how to quit? Knowledge and perceived effectiveness of cessation assistance as predictors of cessation behaviour', *Addiction* (2004) 99(8):1042-8.

[61] E Greenhalgh et al, '7.2 - Quitting Activity' in E Greenhalgh, M Scollo, and M Winstanley (eds), *Tobacco in Australia: Facts and issues* (Cancer Council Victoria 2020). Available at: 7.2 Quitting Activity.

[62] M Wakefield, J Freeman and J Boulter, 'Changes associated with the National Tobacco Campaign: pre and post campaign surveys compared' in K Hassard *Australia's National Tobacco Campaign: evaluation report Vol. 1*. (Commonwealth Department of Health and aged Care, 1999); Australian Institute of Health and Welfare. 'National Drug Strategy Household Survey 2016: Detailed Findings' (Australian Government September 2017). Available at: Australian Institute of Health and Welfare (aihw.gov.au); M Wakefield, J Freeman and G Inglis, '5.0 - Changes associated with the National Tobacco Campaign; results of the third and fourth follow-up surveys 1997-2000' in K Hassard (ed), Australia's National Tobacco Campaign; evaluation report Vol. 3. Available at: Trove (nla.gov.au); N Tan, M Wakefield and J Freeman, '2.0 - Changes associated with the National Tobacco Campaign: results of the second follow-up survey' in K Hassard (ed), *Australia's National Tobacco Campaign; evaluation report Vol. 2*. (Commonwealth Department of Health and aged Care, 2000) 21-75. Available at: Trove (nla.gov.au).

[63] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (Australian Government 2020). Available at: National Drug Strategy Household Survey 2019 (aihw.gov.au).

[64] M Scollo and M Bayly, '10.6 Retail Value and Volume of the Australian Tobacco Market' in M Scollo and M Winstanley (eds), *Tobacco in Australia: Facts and issues*. (Cancer Council Victoria 2021). Available at: 10.6 Retail value and volume of the Australian tobacco market - Tobacco in Australia.

[65] Ibid.

[66] M Scollo and M Bayly, '1 0.3 The manufacturing and wholesaling industry in Australia - major international companies' in M Scollo and M Winstanley (eds), Tobacco in Australia: Facts and issues. (Cancer Council Victoria 2019). Available at: https://www.tobaccoinaustralia.org.au/chapter-10-tobacco-industry/10-3-the-manufacturing-and-wholesaling-industry-in-australia.

[67] World Health Organization, 'WHO Framework Convention on Tobacco Control' (WHO 2003). Available from: https://www.who.int/fctc/cop/about/en/.

[68] Ibid.

[69] World Health Organization, 'Tobacco Industry Interference with Tobacco Control' (World Health Organization, 2008). Available at: Tobacco industry interference with tobacco control (who.int).

[70] Department of Health, 'Guidance for Public Officials on Interacting with the Tobacco Industry' (Australian Government 2019). Available at: https://www.who.int/fctc/cop/about/en/.

[71] Ibid.

[72] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (Australian Government 2020). Available at: National Drug Strategy Household Survey 2019 (aihw.gov.au).

[73] E Banks, K Beckwith, and G Joshy, '*Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context'* (2020) Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health. Available At: ANU AGENDA.

[74] Department of Health and Aged Care, 'Notice of final decision to amend the current Poisons Standard – nicotine' (2020) Australian Government. Available at: Therapeutic Goods Administration (TGA).

[75] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-Cigarette Use Among Youth and Young Adults; A Report of the Surgeon General' (2016) US Department of Health and Human Services. Available at: E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General—Executive Summary.

[76] E Banks, K Beckwith and G Joshy, 'Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context' (2020) Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health. Available at: ANU AGENDA.

[77] National Health and Medical Research Council, 'CEO Statement: Electronic Cigarettes' (2020) Australian Government. Available at: Electronic cigarettes | NHMRC.

[78] E Banks et al, 'Electronic cigarettes and health outcomes: systematic review of global evidence' (2022) Australian National University, National Centre for Epidemiology and Population Health. Available at: Electronic cigarettes and health outcomes: systematic review of evidence (anu.edu.au).

[79] H Dai and J Hao, 'Flavored Electronic Cigarette Use and Smoking Among Youth' (2016) *Paediatrics* 138 (6). Available at: Flavored Electronic Cigarette Use and Smoking Among Youth | Pediatrics | American Academy of Pediatrics (aap.org).

[80] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General' (2016) US Department of Health and Human Services. Available at: E-Cigarette Use Among Youth and Young Adults - NCBI Bookshelf (nih.gov).

[81] S Glantz and D Bareham, 'E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications'(2018) *Annual Review of Public Health* 39: 215-35. Available at: E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications | Annual Review of Public Health (annualreviews.org).

[82] E Banks, K Beckwith and G Joshy, 'Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context' (2020) Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health. Available at: Open Research: Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context (anu.edu.au).

[83] D Eaton, L Kwan and K Stratton (eds), 'Public Health Consequences of E-cigarettes' (2018) Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems National Academies of Sciences, Engineering, and Medicine. Available at: AGLC4-2021-v1.pdf (mulr.com.au).

[84] D Mantey et al, 'E-cigarette marketing exposure is associated with e-cigarette use among US youth' (2016) *Journal of Adolescent Health* 58(6): 686-690. Available at: E-Cigarette Marketing Exposure Is Associated With E-Cigarette Use Among US Youth - ScienceDirect.

[85] A Hoffman et al, 'Flavour Preferences in Youth Versus Adults: a Review' (2016) *Tobacco Control* 25(2): 32-39. Available at: Tobacco Control (bmj.com).

[86] Jongenelis, M.I. E-cigarette product preferences of Australian adolescent and adult users: a 2022 study. *BMC Public Health* **23**, 220 (2023). https://doi.org/10.1186/s12889-023-15142-8 .

[87] E Greenhalgh and M Scollo, '18.2 Advertising and promotion of e-cigarettes'. In E Greenhalgh, M Scollo and M Winstanley (eds) Tobacco in Australia: Facts and Issues (Cancer Council Victoria, 2020). Available at:18.2 Advertising and promotion of e-cigarettes - Tobacco in Australia.

[88] Department of Health and Aged Care, 'What we're doing about smoking and tobacco' (Australian Government, 2023). Available at: What we're doing about smoking and tobacco | Australian Government Department of Health and Aged Care.

[89] Department of Health, 'National Preventative Health Strategy 2021-2030' (Australian Government, 2021). Available at: National Preventive Health Strategy 2021-2030.

[90] Y Hu et al, 'The Impact of Tobacco Control Policies on Smoking Among Socioeconomic Groups in Nine European Countries, 1990-2007'(2017) *Nicotine and Tobacco Research* 19(12): 1441-1449. Available at: Oxford Academic.

[91] Graph adapted from: Department of Health and Aged Care, 'Smoking Prevalence Rates' (Australian Government, 2018). Available at: Department of Health | Smoking prevalence rates; additional data provided from Australian Bureau of Statistics, 'National Health Survey: First Results' (ABS, 2017-18) and Smoker Status (2021-22). Available at: Australian Bureau of Statistics.

[92] S Dunlop et al, 'Australia's plain tobacco packs: anticipated and actual responses among adolescents and young adults 2010-2013' (2016) *Tobacco Control* 26(6):617-626. Available at: Tobacco Control| BMJ.

[93] J Young et al, 'Association Between Tobacco Plain Packaging and Quitline Calls: a Population-based, Interrupted Time-series Analysis' (2014) *The Medical Journal of Australia* 200(1): 29-32. Available at: Medical Journal of Australia - Wiley Online Library.

[94] J Huang, F Chaloupka and G Fong, 'Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis' *Tobacco Control* 23(1): 7-12. Available at: | Tobacco Control (bmj.com).

[95] WHO Framework Convention on Tobacco Control, 'Guidelines for implementation Article 11' (World Health Organization, 2013) 3. Available at: Guidelines for implementation of Article 11 (who.int).

[96] N Brewer et al, 'Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial'(2016) *JAMA Internal Medicine American Medical Association* 176(7):905-912.Available at: researchgate.net.

[97] Minister for Health. (2022). Reporting requirements under section 34a of the Tobacco Advertising Prohibition Act 1992, Accessed from: Commonwealth of Australia Tobacco Advertising Prohibition Act 1992 – Reporting requirements under section 34a of the Tobacco Advertising Prohibition Act 1992 (health.gov.au)

[98] Moola S, Tyagi J, Miller M, et al. The effects of e-cigarette advertising, promotion, and sponsorship on people's attitudes, beliefs and perceptions, intentions, and behaviours: a mixed methods systematic review. Sydney: The George Institute for Global Health, 2021.

[99] Sharma A, McCausland K, Jancey J. Adolescent's health perceptions of e-cigarettes: a systematic review. American Journal of Preventive Medicine 2021; 60(5):716-725.

[100] Baenziger ON, Ford L, Yazidjoglou A, et al. E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis. BMJ Open 2021; 11(3):e045603

[101] Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (Australian Government, 2023). Available at: National Tobacco Strategy | Australian Government Department of Health and Aged Care.

[102] Ibid.

[103] Australian Bureau of Statistics, 'Smoking 2020-2021' (Australian Government, 2022). Available at: Smoking, 2020-21 financial year | Australian Bureau of Statistics (abs.gov.au).

[104] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019'(Australian Government, 2020). Available at: AIHW.

[105] Australian Bureau of Statistics, 'Smoking 2020-2021' (Australian Government, 2022). Available at: abs.gov.au.
[106] S Whetton et al, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (National Drug Research Institute, Curtin University, 2019). Available: T273.pdf (curtin.edu.au).
[107] N Guerin and V White, 'Australian Secondary Students, Use of Tobacco, Alcohol, Over-the-counter Drugs, and Illicit Substances' (Cancer Council Victoria, 2nd ed, 2020). Available at: ASSAD 2017 | Department of Health and Aged Care.
[108] Ibid.
[109] Ibid.
[110] S Carroll et al, 'Climatic and community sociodemographic factors associated with remote Indigenous Australian smoking rates: an ecological study of health audit data' (2019) *BMJ Open* 9(7). Available at: BMJ Open.
[111] Raglan Maddox et al, 'Deadly news: the downward trend continues in Aboriginal and Torres Strait Islander smoking 2004–2019' (2020) *Australian and New Zealand Journal of Public Health* 44(6): 449-450. Available at: https://doi.org/10.1111/1753-6405.13049.
[112] Australian Bureau of Statistics, 'National Aboriginal and Torres Strait Islander Health Survey 2018-19' (Australian Government 2019). Available at: abs.gov.au.
[113] Australian Bureau of Statistics, 'Aboriginal and Torres Strait Islander peoples: smoking trends, Australia, 1994 to 2014–15' (Australian Government, 2017). Available at: abs.gov.au.
Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (Australian Government, 2023). Available at: National Tobacco Strategy | Australian Government Department of Health and Aged Care.
[115] Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (Australian Government, 2023). Available at: National Tobacco Strategy | Australian Government Department of Health and Aged Care.
[116] Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (Australian Government, 2023). Available at: National Tobacco Strategy | Australian Government Department of Health and Aged Care.
[117] Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (Australian Government, 2023). Available at: National Tobacco Strategy | Australian Government Department of Health and Aged Care.
[118] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General'(US Department of Health and Human Services, 2012). Available at: Preventing Tobacco Use Among Youth and Young Adults - NCBI Bookshelf (nih.gov).
[119] D Levy, F Chaloupka and J Gitchell, 'The effects of Tobacco Control Policies on Smoking Rates: a Tobacco Control Scorecard' (2004) *Journal of Public Health Management and Practice* 10(4):338–53. Available at: Journal of Public Health Management and Practice.
[120] H Saffer and F Chaloupka, 'The effect of tobacco advertising bans on tobacco consumption'(2000) *Journal of Health Economics* 19(6):1117–1137.
[121] W Quentin et al, 'Advertising Bans as a Means of Tobacco Control Policy: a Systematic Literature Review of Time-series Analyses'(2007) *International Journal of Public Health* 52(5):295-307.
[122] J Gotts et al, 'What are the respiratory effects of e-cigarettes?' (2019) *BMJ* 366: 15275. Available at: What are the respiratory effects of e-cigarettes? (bmj.com).
[123] S Byrne et al, 'E-cigarettes, Smoking and Health, 'A literature review update' (CSIRO 2018). Available at: E-cigarettes, smoking and health - CSIRO.
[124] C Kennedy et al, 'The cardiovascular effects of electronic cigarettes: a Systematic Review of Experimental Studies' (2019) *Preventative Medicine* 127: 105770. Available at: ScienceDirect.
[125] E Banks, K Beckwith and G Joshy, 'Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context' Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health; 2020.
[126] Therapeutic Goods Administration, 'Notice of final decision to amend the current Poisons Standard - nicotine' (Australian Government, 2020). Available at: Poisons Standard - nicotine.
[127] M Bayly et al, 'E-cigarette use and purchasing behaviour among Victorian adults: Findings from the 2018-19 and 2022 Victorian Smoking and Health Surveys' (Cancer Council Victoria, 2022). Available from: cancervic.org.au.
[128] Ibid.
[129] Gotts et al, 'What are the respiratory effects of e-cigarettes?' (2019) *BMJ* 336:l5275. Available at: https://www.bmj.com/content/366/bmj.l5275; Kennedy et al, 'The cardiovascular effects of electronic cigarettes: A systematic review of experimental studies' (2019) *Preventive Medicine* 137. Available at: https://www.sciencedirect.com/science/article/pii/S0091743519302464; Fetterman et al, 'Alterations in Vascular Function Associated With the Use of Combustible and Electronic Cigarettes' (2020) *Journal of the American Heart Association* 9(9). Available at: https://www.ahajournals.org/doi/full/10.1161/JAHA.119.014570.
[130] Bozier et al, 'The Evolving Landscape of Electronic Cigarettes: A Systematic Review of Recent Evidence' (2020) *CHEST* 157(5):1362-1390. Available at: The Evolving Landscape of e-Cigarettes: A Systematic Review of Recent Evidence - PubMed (nih.gov).
[131] Department of Health, 'Post-Implementation Review of Tobacco Plain Packaging' (Australian Government, 2016). Available at: The Office of Impact Analysis.
[132] Cancer Council Victoria, 'Plain Packaging. The Facts. Timeline, International Developments and Major News Stories' (Cancer Council Victoria). Available at: Cancer Council Victoria.
[133] Canadian Cancer Society. 'Cigarette Package Health Warnings: International Status Report' (Canadian Cancer Society, 7th Ed, 2021). Available at: ccs-international-warnings-report-2021.pdf (cancer.ca).

[134] M Omare et al, 'A Review of Tobacco Abuse and its Epidemiological Consequences' (2022) *Journal of Public Health* 30(6): 1485-1500. Available at: A review of tobacco abuse and its epidemiological consequences - PMC (nih.gov).

[135] World Health Organization, 'Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)' (World Health Organization, 2013). Available at: (who.int).

[136] C Ratneswaran et al, 'Desensitisation to Cigarette Package Graphic Health Warnings: a Cohort Comparison Between London and Singapore'(2016) *BMJ Open* 6(10):e012693. Available at: ccs-international-warnings-report-2021.

[137] H Parada et al, 'Trajectories of responses to pictorial cigarette pack warnings' (2018) *Nicotine and Tobacco Research* 20(7):876-881. Available at: PMC (nih.gov).

[138] C Ratneswaran et al, 'Desensitisation to cigarette package graphic health warnings: a cohort comparison between London and Singapore'(2016) *BMJ Open* 6(10):e012693. Available at: BMJ Open.

[139] H Parada et al, 'Trajectories of Responses to Pictorial Cigarette Pack Warnings'(2018) *Nicotine Tobacco Research* 20(7):876-881. Available at: Oxford Academic.

[140] D Anshari et al, 'Which type of tobacco product warning imagery is more effective and sustainable over time? A longitudinal assessment of smokers in Canada, Australia and Mexico', *BMJ Open* (2018) 8(7):e021983, e021983.full.pdf (bmj.com).

[141] G Stothart et al, 'Neural correlates of cigarette health warning avoidance among smokers', *Drug and Alcohol Dependence* (2016) 161: 155–162. Available at: Neural correlates of cigarette health warning avoidance among smokers - ScienceDirect.

[142] J Fridriksson et al, 'Smokers' Neurological Responses to Novel and Repeated Health Warning Labels (HWLs) From Cigarette Packages', *Front Psychiatry* (2018) 9:319. Available at: Frontiers.

[143] K Swayampakala et al, 'Over-Time Impacts of Pictorial Health Warning Labels and their Differences across Smoker Subgroups: Results from Adult Smokers in Canada and Australia' (2017) Nicotine Tob Res, 20(7):888–896.

[144] Essence Communications, 'Evaluation of effectiveness of graphic health warnings on tobacco product packaging: An Evaluation Report' (2018) report to the Australian Government Department of Health. Available at: Evaluation of effectiveness of graphic health warnings on tobacco product packaging.

[145] K Witte and M Allen, 'A meta-analysis of fear appeals: implications for effective public health campaigns', *Health Education and Behavior*, 2000, 27(5):591–615.

[146] E Greenhalgh et al, '7.6.3 Unassisted Versus Assisted' in E Greenhalgh, M Scollo and M Winstanley (eds), Tobacco in Australia: Facts and issues. (Cancer Council Victoria, 2022). Available at: https://www.tobaccoinaustralia.org.au; Y Castro, M Cano, M Businelle, V Correa-Fernández, W Heppner, CA Mazas and DW Wetter, 'A cross-lagged path analysis of five intrapersonal determinants of smoking cessation' (2014) *Drug and Alcohol Dependence*, 137:98-105. Available at: ScienceDirect. H Lee, D Catley and K Harris, 'Improving understanding of the quitting process: psychological predictors of quit attempts versus smoking cessation maintenance among college students' (2014) *Substance Use & Misuse*, 49(10):1332-9. Available at: tandfonline.com; A Richardson et al, 'Primary and Dual Users of Little Cigars/Cigarillos and Large Cigars: Demographic and Tobacco Use Profiles' (2013) *Nicotine and Tobacco Research*, 15, 1729–36; S Li et al, 'Mediation of smoking abstinence self-efficacy on the association of nicotine dependence with smoking cessation'(2014) *European Journal of Public Health*, 25(2):200-4. Available at: European Journal of Public Health | Oxford Academic; E Smit et al, 'Predictors of successful and unsuccessful quit attempts among smokers motivated to quit', *Addictive Behaviors* (2014), 39(9):1318-24. ScienceDirect; N Herd, R Borland and A Hyland, 'Predictors of smoking relapse by duration of abstinence: findings from the International Tobacco Control (ITC) Four Country Survey' *Addiction* (2009) 104(12):2088-99. Available at: ScienceDirect; R Borland and J Balmford, 'Perspectives on relapse prevention: an exploratory study', *Psychology and Health* (2005) 20(5):661-71. Available at: tandfonline.com. S Wang, R Borland and A Whelan, 'Determinants of intention to quit: confirmation and extension of western theories in male Chinese smokers', *Psychology and Health* (2005) 20(1):35-51. Available at: tandfonline.com.

[147] E Greenhalgh, S Stillman and C Ford,' 7.14 Cessation assistance: telephone- and internet-based interventions' in E Greenhalgh, M Scollo, and Winstanley (eds) Tobacco in Australia: Facts and Issues (Cancer Council Victoria: March 2020). Available at: Tobacco in Australia. E van Wijk, L Landais and J Harting, 'Understanding the multitude of barriers that prevent smokers in lower socioeconomic groups from accessing smoking cessation support: a literature review', (2019) *Preventive Medicine*, 123:143-51. Available at: ScienceDirect; E Roddy et al, 'Barriers and motivators to gaining access to smoking cessation services amongst deprived smokers – a qualitative study' (2016) *BMC Health Services Research*, 6(1):147. Available at: | BMC Health Services Research |; J Hartmann-Boyce et al, 'Behavioural interventions for smoking cessation: an overview and network meta-analysis' (2021) Cochrane Database of Systemic Reviews 1: CD013229. Available at: Cochrane Library.

[148] M Scollo et al, 'Tobacco product developments in the market in the Australian market in the four years following plain packaging' *Tobacco Control* (2018) 27:580-584.

[149] Ibid.

[150] J Thrasher et al, 'Cigarette Brands with Flavour Capsules in the Filter: Trends in Use and Brand Perceptions Among Smokers in the USA, Mexico and Australia, 2012-2014 (2016) *Tobacco Control*, 25, 275–83; C Moodie, et al, 'Use of Cigarettes With Flavor-Changing Capsules Among Smokers in the United Kingdom: An Online Survey' (2016) *Nicotine and Tobacco Research* 21(11): 1547–55. Available at: Oxford Academic.

[151] J Hoek et al, 'Effects of Brand Variants on Smokers' Choice Behaviours and Risk Perceptions' (2016) *Tobacco Control* 25(2): 160–5. Available at: PubMed (nih.gov).

[152] M Scollo et al, 'Tobacco product developments in the Australian market in the 4 years following plain packaging', *Tobacco Control* (2018) 27:580-584. Available at: PubMed (nih.gov).

[153] A Blackwell et al, 'Should cigarette pack sizes be capped?'(2019) *Addiction*, 115(5): 802-809. Available at: onlinelibrary.wiley.

[154] A Persoskie et al, 'How Tobacco Companies Have Used Package Quantity for Consumer Targeting' (2018) *Tobacco Control* (2019) 28, 365–73.Available at: Tobacco Control (bmj.com).

[155] Ibid.

[156] M Bayly, M Scollo and M Wakefield, 'Who Uses Rollies? Trends in Product Offerings, Price and Use of Roll-Your-Own Tobacco in Australia'(2018) *Tobacco Control*, 28: 317–24.

[157] N Guerin and V White, 'ASSAD 2017 Statistics & Trends: Australian Secondary Students' Use of Tobacco, Alcohol, Over-the-counter Drugs, and Illicit Substances'(2nd ed Cancer Council Victoria, 2020) 18. Available at: ASSAD 2017 Statistics & Trends: Second Edition (health.gov.au).

[158] G Kong et al, 'Systematic Review of Cigars, Cigarillos, and Little Cigars Among Adolescents: Setting Research Agenda to Inform Tobacco Control Policy'(2019) *Addictive Behaviors*, 96, 192–7.Available at: ScienceDirect.

[159] A Nyman et al, 'Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use'(2016) *Tobacco Regulatory Science* 2(3): 239–51. Available at: PMC (nih.gov).

[160] E Antognoli et al, 'Cigarettes, Little Cigars, and Cigarillos: Initiation, Motivation, and Decision-Making'(2018) *Nicotine and Tobacco Research* 20, S5–S11. Available at: Cigarettes, Little Cigars, and Cigarillos: Initiation, Motivation, and Decision-Making - PMC (nih.gov).

[161] V White and T Williams, 'Australian secondary school students' use of tobacco, alcohol, and over-the-counter and illicit substances in 2014' (Centre for Behavioural Research in Cancer Council Victoria, 2016). Available at: Secondary school students' use of tobacco, alcohol and other drugs in 2014 report (health.gov.au).

[162] R Borland and S Savvas, 'Effects of Stick Design Features on Perceptions of Characteristics of Cigarettes' (2013) *Tobacco Control* 22: 331–7.

[163] C Moodie et al, 'Are All Cigarettes Just the Same? Female's Perceptions of Slim, Coloured, Aromatized and Capsule Cigarettes'(2015) *Health Education Research* 30(1): 1–12. Available at: Oxford Academic (oup.com).

[164] A Ford et al, 'Adolescent Perceptions of Cigarette Appearance' (2014) *European Journal of Public Health* 24(3): 464–8. Available at: European Journal of Public Health | Oxford Academic (oup.com).

[165] *Tobacco Plain Packaging Regulations 2011* (Cth) Division 2.1.

[166] World Health Organization, 'Raising taxes on tobacco' (World Health Organization, 2023) Available from: https://www.who.int/activities/raising-taxes-on-tobacco#:~:text=Evidence%20shows%20that%20significantly%20increasing,Framework%20Convention%20on%20Tobacco%20Control.

[167] M Bayly, M Scollo and M Wakefield 'Who uses rollies? Trends in product offerings, price and use of roll-your-own tobacco in Australia'(2019) *Tobacco Control,* 28:317-324.

[168] N Guerin, and V White, *'ASSAD 2017 Statistics & Trends: Australian Secondary Students' Use of Tobacco, Alcohol, Over-the-counter Drugs, and Illicit Substances'* (Cancer Council Victoria,2018). Available from: ASSAD 2017.

[169] Australian Institute of Health and Welfare, 'National Drug Strategy Household Survey 2019' (Australian Government, 2020). Available at: National Drug Strategy Household Survey 2019, Summary - Australian Institute of Health and Welfare (aihw.gov.au).

[170] N Guerin, and V White, *'ASSAD 2017 Statistics & Trends: Australian Secondary Students' Use of Tobacco, Alcohol, Over-the-counter Drugs, and Illicit Substances'* (Cancer Council Victoria,2018). Available from: ASSAD 2017.

[171] World Health Organization, 'Report on the Scientific Basis of Tobacco Product Regulation – TRS 1015' (World Health Organization, October 2019). Available at: WHO.

[172] Purcell Consulting, 'The Effects of Cigarette Additives on the Palatability of Cigarettes' (Purcell Consulting, March 2013). Available at: Palatability-Purcell.pdf (smokefreetasmania.com).

[173] World Health Organization, '*Report on the Scientific Basis of Tobacco Product Regulation – TRS 1015*' (World Health Organization, October 2019). Available at: WHO.

[174] Purcell Consulting, '*The Effects of Cigarette Additives on the Palatability of Cigarettes*' (Purcell Consulting, March 2013). Available at: Palatability-Purcell.pdf (smokefreetasmania.com).

[175] Department of Health and Aged Care, 'Australian Cigarette ingredient *information'* (Australian Government, 2018). Available at: Australian Government Department of Health and Aged Care.

[176] World Health Organization, 'Fact Sheet on Ingredients in Tobacco Products' (World Health Organization, 2014). Available at: Fact sheet on ingredients in tobacco products (who.int).

[177] World Health Organization, 'Partial guidelines for implementation of Articles 9 and 10' (World Health Organization, 2014). Available at Partial guidelines for implementation of Articles 9 and 10 (who.int).

[178] World Health Organization, '*Report on the Scientific Basis of Tobacco Product Regulation – TRS 1015*' (World Health Organization, October 2019). Available at: WHO.

[179] Purcell Consulting, '*The Effects of Cigarette Additives on the Palatability of Cigarettes*' (Purcell Consulting, March 2013). Available at: Palatability-Purcell.pdf (smokefreetasmania.com).

[180] World Health Organization, *WHO Study Group on Tobacco Product Regulation: Report on the Scientific Basis of Tobacco Product Regulation: Sixth Report of a WHO Study Group*, World Health Organization, 2017, accessed 13 November 2020.

[181] R Talhout et al, 'Cigarette Design Features: Effects on Emission Levels, User Perception, and Behavior'(2018) *Tobacco Regulatory Science*, 4(1): 592–604.Available at: PMC (nih.gov).

[182] World Health Organization, '*Partial guidelines for implementation of Articles 9 and 10'* (World Health Organization, 2014). Available at Partial guidelines for implementation of Articles 9 and 10 (who.int).

[183] J Thrasher et al, 'Cigarette Brands with Flavour Capsules in the Filter: Trends in Use and Brand Perceptions Among Smokers in the USA, Mexico and Australia, 2012-2014'(2016) *Tobacco Control* 25: 275–83; C Moodie, et al, 'Use of Cigarettes With Flavor-Changing Capsules Among Smokers in the United Kingdom: An Online Survey' (2019) *Nicotine and Tobacco Research* 21(11): 1547–55. Available at: PMC (nih.gov).

[184] O Wackowski et al, 'In Their Own Words: Young Adults' Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives'(2018) *Nicotine and Tobacco Research* 20(9): 1076–84; J Edmond, et al 'Flavour Capsule Cigarette Use Among US Adult Cigarette Smokers'(2018) *Tobacco Control* 27: 650–5.

[185] J Thrasher et al, 'Cigarette Brands with Flavour Capsules in the Filter: Trends in Use and Brand Perceptions Among Smokers in the USA, Mexico and Australia, 2012-2014'(2016) *Tobacco Control* 25: 275–83; C Moodie, et al, 'Use of Cigarettes With Flavor-Changing Capsules Among Smokers in the United Kingdom: An Online Survey' (2019) *Nicotine and Tobacco Research* 21(11): 1547–55. Available at: PMC (nih.gov).

[186] S Rossel, 'Focus on the Filter' (Tobacco Reporter, 2016). Available at: Focus on the filter - Tobacco Reporter.

[187] M Wakefield et al, 'Australian smokers' experiences and perceptions of recessed and firm filter cigarettes'*(2020) Tobacco Control* 30(6):660-667.

[188] Ibid.

[189] C Czoli and D Hammond, 'Cigarette packaging: Youth perceptions of "natural" cigarettes, filter references, and contraband tobacco', *Journal of Adolescent Health* (2014) 54(1):33-39.

[190] R O'Connor et al, 'Filter Presence and Tipping Paper Color Influence Consumer Perceptions of Cigarettes'(2015) *BMC Public Health*, 15: 1-7. Available at: BMC Public Health.

[191] Ibid.

[192] Ibid.

[193] SJ Greenland, 'The Australian experience following plain packaging: the impact on tobacco branding' (2016) *Addiction*, 111(12): 2248–58. Available at: Wiley Online Library.

[194] J Hoek and P Gendall, 'Policy options for extending standardized tobacco packaging'(2017) *Bulletin of the World Health Organization* 95(10): 726-728. Available at: Bulletin of the World Health Organization (nih.gov).

[195] R Borland and S Savvas, 'The effects of variant descriptors on the potential effectiveness of plain packaging' (2014) *Tobacco Control* 23(1): 58–63.

[196] J Hoek et al, 'Effects of brand variants on smokers' choice behaviours and risk perceptions'(2016) *Tobacco Control*, 25(2): 160-5.

[197] Ibid.

[198] T Dewhirst, 'Into the black: Marlboro brand architecture, packaging and marketing communication of relative harm'(2018) *Tobacco Control* 27(2): 240-2. Available at: Tobacco Control (bmj.com).

[199] R Borland and S Savvas, 'The effects of variant descriptors on the potential effectiveness of plain packaging' (2014) *Tobacco Control* 23(1): 58-63.

[200] E Leas et al, 'Which cigarettes do Americans think are safer? A population-based analysis with wave 1 of the PATH study' (2017) *Tobacco Control* 26(e1): e59-e60.

[201] H Yong et al, 'US smokers' beliefs, experiences and perceptions of different cigarette variants before and after the FSPTCA ban on misleading descriptors such as "light," "mild," or "low"'(2018) *Nicotine & Tobacco Research* 18(11): 2115-23. Available at: Oxford Academic .

[202] R Borland and S Savvas, 'The effects of variant descriptors on the potential effectiveness of plain packaging' (2014) *Tobacco Control* 23(1): 58-63.

[203] J Hoek et al, 'Effects of brand variants on smokers' choice behaviours and risk perceptions'(2016) *Tobacco Control* 25(2):160-5.

[204] J Liberman, '16.2 Litigation brought by Australian consumer and regulatory groups against the tobacco industry' In M Scollo and M Winstanley (eds) *Tobacco in Australia: Facts and issues* (Cancer Council Victoria, 2018). Available at: Tobacco in Australia

[205] The ACCC has court-enforceable undertakings with the three largest tobacco manufacturers in Australia - Philip Morris (Australia) Limited, British American Tobacco Australia Limited and Imperial Tobacco Australia Limited - to no longer use terms such as 'mild' or 'light'.

[206] M Bayly, B Freeman and M Scollo, '10.8.2.1 Packaging that conveys varying levels of harm' in M Scollo and M Winstanley (eds) Tobacco in Australia: Facts and Issues (Cancer Council Victoria, 2017). Available at: Tobacco in Australia.

[207] I Gubchik and V Rumynski, 'Brands', Cigarety (web page) Brands (cigarety.by)

[208] B King and R Borland, 'What was 'light' and 'mild' is now 'smooth' and 'fine': new labelling of Australian cigarettes' (2005) *Tobacco Control*, 14(3):214-5 Available at: http://dx.doi.org/10.1136/tc.2005.011692.

[209] A Sanders-Jackson, A Tan and K Yie, 'Effects of health-oriented descriptors on combustible cigarette and electronic cigarette packaging: an experiment among adult smokers in the United States' (2018) *Tobacco Control*, 27(5): 534-541.

[210] R O'Connor et al, 'Perceptions of "Natural" and "Additive-free" cigarettes and intentions to purchase' (2016) *Health Education and Behavior* 44(2):222-226.

[211] J Pearson et al, 'Widespread belief that organic and additive-free tobacco products are less harmful than regular tobacco products: results from the 2017 US Health Information National Trends Survey', *Nicotine and Tobacco Research* (2019) 21(7): 970-973.

[212] A Sanders-Jackson, A Tan and K Yie, 'Effects of health-oriented descriptors on combustible cigarette and electronic cigarette packaging: an experiment among adult smokers in the United States', *Tobacco* Control (2018) 27(5): 534-541.

[213] R O'Connor et al, 'Perceptions of "Natural" and "Additive-free" cigarettes and intentions to purchase', *Health Education and Behavior* (2016) 44(2): 222-226.

[214] G Skaczkowski et al, 'Influence of premium versus value brand names on the smoking experience in a plain packaging environment: an experimental study', *BMJ Open* (2017) 7(1): e014099. Available at: BMJ Open.

[215] WHO Framework for Convention on Tobacco Control, 'Guidelines for Implementation of Article 5.3' (World Health Organization, 2013). Available at: WHO.

[216] A Gallagher and A Gilmore, 'Euromonitor International now accepts tobacco industry funding: a win for PMI at the expense of research on the tobacco industry' (*Tobacco Control Blog*, 2019). Available at: Blog - Tobacco Control (bmj.com)

[217] PMI Impact, 'Selected Projects: Second Funding Round' Philip Morris International (web page) PMI Impact - Selected Projects: Second Funding Round (archive.org).

[218] D Levy, F Chaloupka and J Gitchell, 'The effects of tobacco control policies on smoking rates: a tobacco control scorecard' (2004) *Journal of Public Health Management & Practice* 10(4): 338–353. Available at: Journal of Public Health Management and Practice (lww.com).

[219] Ibid.

[220] B Freeman, '11.11 Internet promotion' in M Scollo and M Winstanley (eds) Tobacco in Australia: Facts and Issues (Cancer Council Victoria, 2019). Available at: Tobacco in Australia.

[221] Ibid.

[222] Section 9 of the *Tobacco Advertising Prohibition Act 1992* (Cth) defines the meaning of tobacco advertisement to include any writing, still or moving picture, sign, symbol or other visual image, or any audible message or any combination of two or more of those things, that gives publicity to, or otherwise promoted or is intended to promote smoking, the purchase or use of a tobacco product or a range of tobacco products, the whole or part of a trade mark or design in respect of goods that are or include tobacco products, the whole or part of the name of a person who is a manufacturer of tobacco products and whose name appears on or on the packaging of some or all of these products or any other words or designs or combination of words and design that are closely associated with a tobacco product or a range of tobacco products. Exceptions include political discourse, words used on products, packaging, business documents and on the premises of manufacturers, non-tobacco products having the same name as a tobacco product, certain advertisements for non-tobacco products and anti-smoking advertisements.

[223] World Health Organization, 'WHO Framework Convention on Tobacco Control (World Health Organization, 2003). Available at: WHO FCTC.

[224] Australian Bureau of Statistics, 'Smoking - 2020-2021 financial year' (Australian Government, 2022). Available at: Australian Bureau of Statistics (abs.gov.au).

[225] Tait R, Whetton S and S Alsop, 'Identifying the social costs of tobacco use in Australia in 2015/16'. (National Drug Research Institute, Curtin University, 2019). Available at: T273.pdf (curtin.edu.au).

[226] Australian Institute of Health and Welfare, 'Australian Burden of Disease Study 2018: Interactive data on risk factor burden' (Australian Government, 2021). Available at: Australian Institute of Health and Welfare (aihw.gov.au).

[227] Department of Health, 'Draft National Preventive Health Strategy 2021 – 2030' (Australian Government, 2021). Available at: Draft NPHS March 2021.pdf (health.gov.au)

[228] Ibid.

[229] M Wakefield, J Freeman and J Boulter, 'Changes associated with the National Tobacco Campaign: pre and post campaign surveys compared' in: K Hassard (ed) 'Australia's National Tobacco Campaign: evaluation report Vol. 1' (Department of Health, 1999) Ch 2. Available at: Trove (nla.gov.au).

[230] N Tan, M Wakefield and J Freeman, 'Changes associated with the National Tobacco Campaign: results of the second follow-up survey' in: K Hassard (ed) 'Australia's National Tobacco Campaign; evaluation report Vol. 2'. (Department of Health and Aged Care, 2000) Ch 2. Available at: Trove (nla.gov.au).

[231] Ibid.

[232] World Health Organization, 'Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control' (World Health Organization, 2013). Available at: who.int; World Health Assembly, 'Transparency in Tobacco Control Process' (World Health Organization, 2001) WHA54.18. Available at: (who.int).

[233] World Health Organization, 'Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control' (World Health Organization, 2013) 5: Principle 1: '*There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests*'. Available at: who.int.

[234] A Landman, P Ling and S Glant 'Tobacco Industry Youth Smoking Prevention Programs: Protecting the Industry and Hurting Tobacco Control' (2002) *American Journal of Public Health* 92(6): 917–930; M Wakefield et al, 'Effect of televised, tobacco company-funded smoking prevention advertising on youth smoking-related beliefs, intentions, and behavior' (2006) *American Journal of Public Health* 96(12): 2154-2160; M Wakefield, et al. Youth Responses to Anti-Smoking Advertisements from Tobacco-Control Agencies, Tobacco Companies, and Pharmaceutical Companies' (2005) *Journal of Applied Social Psychology* 35(9): 1894–1910.

[235] Department of Health and Aged Care, 'Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia' (Australian Government, 2019). Available at: Australian Government Department of Health and Aged Care.

[236] Ipsos-Eureka and Department of Health and Ageing. 'Public health value of disclose cigarette ingredients and emissions data' (Australian Government, 2009). Available at: Wayback Machine (archive.org).

[237] Ibid.

[238] S Greenland, 'The Australian experience following plain packaging: the impact on tobacco branding' (2016) *Addiction* 111(12): 2248-2258. Available at: Wiley Online Library.

[239] Mp consulting and Department of Health, 'Tobacco Control Legislation Review: Analysis and Summary of Public Consultation Submissions' (Australian Government, 2019). Available at: (health.gov.au)

[240] National Center for Chronic Disease Prevention and Health Promotion Office on Smoking and Health (US), 'Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General' (US Department of Health and Human Services, 2012). Available at: (nih.gov).

[241] National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, 'E-Cigarette Use Among Youth and Young Adults; A Report of the Surgeon General' (US Department of Health and Human Services, 2016). Available at: (nih.gov).

[242] O Baenziger et al, 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis'(2021) *BMJ Open* 11(3): e045603. Available at: BMJ Open.

[243] Ibid.

[244] National Health and Medical Research Council. 'CEO Statement: Electronic Cigarettes'(National Health and Medical Research Council, 2022). Available at: Electronic cigarettes | NHMRC.

[245] Australian Tax Office, 'Illicit tobacco' (Australian Government, 2023). Available at: (ato.gov.au).

[246] Cancer Council Australia, 'Tobacco control - Policy priorities 1.5 Regulate the design, contents, labelling and disclosure requirements for tobacco products' in 'National Cancer Control Policy' (Cancer Council Australia, 2023). Available at: National Cancer Control Policy.

[247] Ibid.

[248] World Health Organization, 'Report on the scientific basis of tobacco product regulation: WHO Technical Report Series, no. 1015' (World Health Organization, 2019). Available at: *(TobReg)*.

[249] World Health Organization, 'Banning Menthol in Tobacco Products' (World Health Organization, 2016) 11: 56. Available at: (who.int).

[250] E Brennan et al, 'Public support for introducing cigarette pack inserts in Australia' (2021) *Tobacco Control* 30(1): 117-118.

[251] C Moodie, 'Adult smokers' perceptions of cigarette pack inserts promoting cessation: a focus group study' (2018) *Tobacco Control* 27(1): 72-77. Available at: (bmj.com).

[252] K Witte, 'Putting the fear back into fear appeals: the extended parallel process model' *Communication Monographs* (1992) 59(4): 329-49. Available at: doi.org/10.1080/03637759209376276; K Witte and M Allen, 'A meta-analysis of fear appeals: implications for effective health campaigns' (2000) *Health Education & Behavior* 27(5): 591-615. Available at: (sagepub.com); A Bandura, 'Self-efficacy: towards a unifying theory of behavioral change' (1978) *Advances in Behaviour Research and Therapy* 1(4): 139-161; M Fishbein and I Ajzen, '*Predicting and changing behavior: The Reasoned Action Approach'* (Psychology Press, 1st ed, 2009).

[253] K Witte and M Allen, 'A meta-analysis of fear appeals: Implications for Effective Health Campaigns' (2000) *Health Education & Behavior*, 27(5): 591-615.

[254] M Tannenbaum et al, 'Appealing to fear: a meta analysis of fear appeal effectiveness and theories' (2015) *Psychological Bulletin* 141(6): 1178-1204. Available at: (nih.gov).

[255] World Health Organization, 'Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)' (World Health Organization, 2013). Available at: (who.int).

[256] Australian Government, 'Style Manual, Accessible and Inclusive Content, Literacy and Access' (Web Page – Australian Government Style Manual) Literacy and access | Style Manual.

[257] J Thrasher et al, 'The Use of Cigarette Package Inserts to Supplement Pictorial Health warnings: An Evaluation of the Canadian Policy', *Nicotine Tobacco Research,* 2014, 17(7): 870-875. Available at: Oxford Academic.

[258] Ibid.

[259] Ibid.

[260] H Weishaar et al, 'Global health governance and the commercial sector: a documentary analysis of tobacco company strategies to influence the WHO framework convention on tobacco control' (2012) *PLoS Medicine* 9(6): e1001249. Available at: PLOS Medicine.

[261] World Health Organisation, 'Tobacco Industry Interference with Tobacco Control' (World Health Organisation, 2008). Available at: (who.int)

[262] Ibid.

[263] K Bryan-Jones and S Chapman, 'Political dynamics promoting the incremental regulation of second-hand smoke: a case study of New South Wales, Australia' (2006) *BMC Public Health* 6(1): 192. Available at: PMC (nih.gov).

[264] World Health Organisation, 'Tobacco Industry Interference with Tobacco Control' (World Health Organisation, 2008). Available at: (who.int).

[265] Ibid.

[258] K Bryan-Jones and S Chapman, 'Political dynamics promoting the incremental regulation of second-hand smoke: a case study of New South Wales, Australia' (2006) *BMC Public Health* 6(1): 192. Available at: (nih.gov); C Watts et al,' How tobacco companies use the revolving door between government and industry to influence policymaking: an Australian case study' (2023) *Public Health Research and Practice* online early publication. Available at: PHRP.

[267] K Gallopel-Morvan et al, 'Consumer Perceptions of Cigarette Design in France: A Comparison of Regular, Slim, Pink and Plain Cigarettes' (2019) *Nicotine & Tobacco Research* 21(7): 911-917. Available at: (nih.gov).

[268] C Moodie et al, 'The Response of Young Adult Smokers and Non-smokers in the United Kingdom to Dissuasive Cigarettes: An Online Survey' (2019) *Nicotine Tobacco Research* 21(2): 227-233. Available at: (nih.gov).

[269] C Moodie, 'Warnings on every cigarette: extending health messaging to the consumption experience' (2018) *Canadian Medical Association Journal* 190(43): E1271-E1272. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30373739.
[270] I Lund and J Scheffels, 'Adolescent perceptions of dissuasive sticks: a web survey among 16–20 year olds in Norway' (2018) *BMC Public Health* 18: 974. Available at: BMC Public Health | Full Text (biomedcentral.com).
[271] J Hoek et al, 'Dissuasive cigarette sticks: the next step in standardised ('plain') packaging?' (2015) *Tobacco Control* 25(6): 699-705.
[272] J Hoek and C Robertson, 'How do young adult female smokers interpret dissuasive cigarette sticks? A qualitative analysis' (2015) *Journal of Social Marketing* 5(1): 21-39.
[273] J Hoek et al, 'Dissuasive cigarette sticks: the next step in standardised ('plain') packaging?' (2015) *Tobacco Control* 25(6): 699-705.
[274] Ibid.
[275] K Gallopel-Morvan, O Droulers and G Pantin-Sohier, 'Dissuasive cigarettes: which cues are the most effective at deterring young people from smoking?' (2019) *Public Health* 174: 22-30.
[276] I Lund and J Scheffels, 'Adolescent perceptions of dissuasive sticks: a web survey among 16–20 year olds in Norway' (2018) *BMC Public Health* 18: 974. Available at: BMC Public Health | Full Text (biomedcentral.com).
[277] J Hoek et al, 'Dissuasive cigarette sticks: the next step in standardised ('plain') packaging?' (2015) Tobacco Control 25(6): 699-705.
[278] Mp Consulting and Department of Health, 'Tobacco Control Legislation Review: Analysis and Summary of Public Consultation Submissions' (Australian Government, 2019). Available at: (health.gov.au).
[279] R Cunningham, 'Canada publishes proposed regulations to require a health warning directly on every cigarette', Blog | Tobacco Control (Blog, 18 July 2022) Blog - Tobacco Control (bmj.com).
[280] Health Canada, 'Government of Canada proposes to print health warnings on individual cigarettes', Health Canada News (News Release, 10 June 2022), Canada.ca.
[281] Office of Impact Analysis, 'Regulatory Burden Measurement Framework' (Australian Government, 2022). Available at: (pmc.gov.au).
[282] Australian Bureau of Statistics (5 December 2022), *Insights into Australian smokers 2021-2022,* ABS website. Available at: https://www.abs.gov.au/articles/insights-australian-smokers-2021-22
[283] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework' (Australian Government, 2020). Available at: (pmc.gov.au).
[284] Marsh L, Doscher C & Robertson L (2013) Characteristics of Tobacco Retailers in New Zealand. *Health & Place* 23, 165-170.
[285] Watts C, Addressing the over-supply of tobacco: How tobacco retail reform is essential to drive smoking rates down further. Cancer Council NSW. 12 March 2019
[286] D Levy, F Chaloupka and J Gitchell, 'The effects of tobacco control policies on smoking rates: a tobacco control scorecard'(2004) *Journal of Public Health Management & Practice* 10(4): 338-353. Available at: Journal of Public Health Management and Practice (lww.com).
[287] Australian Bureau of Statistics (5 December 2022), *Insights into Australian smokers 2021-2022,* ABS website. Available at: https://www.abs.gov.au/articles/insights-australian-smokers-2021-22
[288] National Drug Research Institute, 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16' (Perth, Western Australia, Australia: Curtin University, 2019), Available at: http://ndri.curtin.edu.au/NDRI/media/documents/publications/T273.pdf.
[289] Ibid.
[290] Mp Consulting and Department of Health, 'Tobacco Control Legislation Review: Analysis and Summary of Public Consultation Submissions' (Australian Government, 2019). Available at: Citizen Space.
[291] Office of Impact Analysis, 'Post-Implementation Review of Tobacco Plain Packaging' (Australian Government, 2016). Available at: (pmc.gov.au).
[292] Ibid.
[293] Ibid.
[294] E Greenhalgh and M Scollo, '11A.9 Real-word research on the effects of plain packaging', in E Greenhagh, M Scollo and M Winstanley (eds) Tobacco in Australia: Facts and Issues (2022). Available at: Tobacco in Australia.
[295] M Zacher et al, 'Personal tobacco pack display before and after the introduction of plain packaging with larger pictorial health warnings in Australia: An observational study of outdoor cafe strips' (2014) *Addiction* 109(4): 653-662. Available at: 10.1111/add.12466.
[296] E Greenhalgh and M Scollo, '11A.9 Real-world research on the effects of plain packaging', in E Greenhagh, M Scollo and M Winstanley (eds) Tobacco in Australia: Facts and Issues (2022). Available at: Tobacco in Australia.
[297] S Whetton et al, '*Identifying the Social Costs of Tobacco Use to Australia in 2015/16'* (National Drug Research Institute, Curtain University, 2019). Available at: T273.pdf (curtin.edu.au).
[298] Ibid.
[299] Office of Impact Analysis, 'Regulatory Burden Measurement Framework' (Australian Government, 2022). Available at: (pmc.gov.au).
[300] E Banks, K Beckwith and G Joshy, 'Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context'. (Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health, 2020). Available from: ANU AGENDA.

[301] M Harris Met al, 'Review of evidence regarding attributes and behaviours of smokers as smoking prevalence falls, including evidence statement to the 'hardening hypothesis' (Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health; 2020). Available at: medRxiv.

[302] Australian Bureau of Statistics, Insights into Australian smokers 2021-22. Available at https://www.abs.gov.au/articles/insights-australian-smokers-2021-22

[303] Chesney, E, Robson, D, Patel, R, Shetty, H, Richardson, S, Chang, C, McGuire,P, McNeill, A 'The impact of cigarette smoking on life expectancy in schizophrenia, schizoaffective disorder and bipolar affective disorder: An electronic case register cohort study' (2021) Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8653908/

[304] Diamanti, A, Papadakis, S, Schoretsaniti, S, Rovina, N, Vivilaki, V, Gratziou, C, Katsaounou, P 'Smoking cessation in pregnancy: An update for maternity care practitioners'(2019) . Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6770622/

[305] Department of Health and Aged Care, National Tobacco Strategy 2023-2030. Available at https://www.health.gov.au/resources/publications/national-tobacco-strategy-2023-2030.

[306] F Chaloupka, K Straif and M Leon, 'Effectiveness of tax and price policies in tobacco control' (2011) *Tobacco Control* 20(3): 235-238.

[307] Therapeutic Goods Administration, 'Consultation: Proposed reforms to the regulation of nicotine vaping products' (Australian Government, 2022). Available at: Therapeutic Goods Administration.

[308] Office of Impact Analysis, 'Post-Implementation Review Tobacco Plain Packaging 2016' (Australian Government, 2016) Pt 1: 5. Available at: https://oia.pmc.gov.au/sites/default/files/posts/2016/02/Tobacco-Plain-Packaging-PIR.pdf

[309] Siggins Miller and Department of Health 'Regulatory Burden Measurement & Analysis of Cost and Benefits' (Siggins Millar, 2016) Government Costs: 35-39. Available at: Tobacco Plain Packaging PIR – Appendix C (pmc.gov.au); M. Scollo et al, 'Use of Illicit Tobacco Following Introduction of Standardised Packaging of Tobacco Products in Australia: Results from a National Cross-sectional Survey' (2015) *Tobacco Control* 24(2): ii76-ii81; M. Scollo et al, 'Changes in Use of Types of Tobacco Products by Pack Sizes and Price Segments, Prices Paid and Consumption following the Introduction of Plain Packaging in Australia' (2015) *Tobacco Control* 24(2): ii66-ii75; M. Scollo et al, 'Early Evidence about the Predicted Unintended Consequences of Standardised Packaging of Tobacco Products in Australia: A Cross-sectional Study of the Place of Purchase, Regular Brands and Use of Illicit Tobacco' (2014) *BMJ Open* 4(8). Available at: BMJ Open.

[310] The peer-reviewed studies are also consistent with the AIHW NDSHS data that indicates that the reported use of illicit tobacco in Australia declined from 6.1% in 2007 to 3.6% in 2013. M. Scollo, M. Zacher, K. Coomber and M. Wakefield, 'Use of Illicit Tobacco Following Introduction of Standardised Packaging of Tobacco Products in Australia: Results from a National Cross-sectional Survey' (2015) *Tobacco Control* 24(2): ii76-ii81. Available at: PMC (nih.gov); M. Scollo et al, 'Early Evidence about the Predicted Unintended Consequences of Standardised Packaging of Tobacco Products in Australia: A Cross-sectional Study of the Place of Purchase, Regular Brands and Use of Illicit Tobacco' (2014) *BMJ Open* 4(8): 3. Available at: BMJ Open.

[311] Guidelines for implementation of Article 11, WHO FCTC. Available at https://fctc.who.int/who-fctc/overview/treaty-instruments/packaging-and-labelling-of-tobacco-products

[312] Department of Health and Aged Care, Tobacco Control Legislation Review: Analysis and Summary of Public Consultation Submissions. (May 2019) Available at https://consultations.health.gov.au/population-health-and-sport-division/review-of-tobacco-control-legislation

[313] Chipty T, Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia, 2016

[314] Office of Impact Analysis, 'Regulatory Burden Measurement Framework', (Australian Government, 2022). Available at: Regulatory Burden Measurement Framework (pmc.gov.au)

[315] Ibid.

[316] Formulas: *Set up costs:* System design = affected firms * planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage, professional services = affected firms * professionals hours * executive hourly wage; re-engineering = affected firms * (design hours * executive hourly wage + implementation hours * administrative hourly wage); stock losses = affected firms * count of redundant packets * price per packet; equipment cost = assumed to be zero.

Ongoing costs: Training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); professional services = affected firms * professional hours * executive hourly wage; quality control = affected firms * quality control hours (reduction) * hourly wage. The average annual total compliance cost = set up costs/10+ average annual ongoing costs.

[317] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

[318] Formulas: *Set up costs:* System design = Affected firms * Planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage; equipment cost = assumed to be zero; professional services = affected firms * professional hours * executive hourly wage; re-engineering = affected firms * (design hours * executive hourly wage + implementation hours * operation hourly wage); stock losses = affected firms * count of redundant packets * price per packet.

Ongoing costs: training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); professional services = affected firms * professional hours * executive hourly wage; quality control = affected firms * quality control hours (reduction) * hourly wage; operation costs = affected firms * reduced number of packets without additives * cost of additives per pack; *Report costs:* Design = affected firms * design hours * executive hourly wage;

preparation = affected firms * hours * wage. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

[319] Office of Best Practice Regulation, Regulatory Burden Measurement Framework, Office of Best Practice Regulation, March 2020, https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf

[320] Formulas: *Set up costs:* System design = Affected firms * Planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage; equipment cost = assumed to be zero; professional services = affected firms * professional hours * executive hourly wage; re-engineering = affected firms * (design hours * executive hourly wage + implementation hours * administrative hourly wage); stock losses = affected firms * count of redundant packets * price per packet.
Ongoing costs: training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); professional services = affected firms * professional hours * executive hourly wage; quality control = affected firms * quality control hours (reduction) * hourly wage; operation costs = affected firms * reduced number of capsule inserts * cost per filter with inserts; *Report costs:* Design = affected firms * design hours * executive hourly wage; preparation = affected firms * hours * wage. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

[321] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

[322] Formulas: *Set up costs:* System design = Affected firms * Planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage; equipment cost = assumed to be zero; professional services = affected firms * professional hours * executive hourly wage; stock losses = affected firms * count of redundant packets * price per packet. *Ongoing costs:* training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); professional services = affected firms * professional hours * executive hourly wage. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

[323] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

[324] Formulas: *Set up costs:* System design = Affected firms * Planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage; equipment cost = assumed to be zero; professional services = affected firms * professional hours * executive hourly wage; Re-engineering = Affected firms * (design hours * Executive hourly wage + implementation hours * Administrative hourly wage); Stock losses = Affected firms * Count of redundant packets * Price per packet.
Ongoing costs: training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); professional services = affected firms * professional hours * executive hourly wage. Quality control = Affected firms * Quality control hours (reduction) * hourly wage; operation costs = affected firms * number of inserts to be printed * printing and packaging cost per insert. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

[325] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

[326] Formulas: *Set up costs:* System design = Affected firms * Planning hours * executive hourly wage; Training in firms = affected firms * training hours * administrative hourly wage * 1.5 (to incorporate time of trainers); individual training = affected individuals * training hours * administrative hourly wage; equipment cost = assumed to be zero; professional services = affected firms * professional hours * executive hourly wage.
Ongoing costs: training = affected firms * training hours (reduction) * administrative hourly wage * 1.5 (trainers' time); testing/authorisation = affected firms * No. of data releases per year * Executive data release hours * Executive hourly wage; professional services = affected firms * professional hours * Executive hourly wage; operation costs = affected firms * No of data releases per year * Administrative data release hours * Administrative hourly wage. The average annual total compliance costs = set up costs/10 + average annual ongoing costs.

[327] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

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[329] Office of Best Practice Regulation, 'Regulatory Burden Measurement Framework', (Australian Government, 2020). Available at: https://oia.pmc.gov.au/sites/default/files/2022-06/regulatory-burden-measurement-framework-mar20-2.pdf.

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affected firms * professional hours * executive hourly wage; Re-engineering = Affected firms * (design hours * Executive hourly wage + implementation hours * Administrative hourly wage); Stock losses = Affected firms * Count of redundant packets * Price per packet.

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