



Health

Draft Public Health (Tobacco) Regulation 2016
Regulatory Impact Statement

REGULATORY IMPACT STATEMENT

TITLE OF REGULATORY PROPOSAL:

**Draft Public Health (Tobacco) Regulation
2016**

PROPONENT:

NSW Ministry of Health

RESPONSIBLE MINISTER:

Minister for Health

RELEVANT ACT:

Public Health (Tobacco) Act 2008

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1. Purpose of this regulatory impact statement

This regulatory impact statement serves two purposes associated with the draft Public Health (Tobacco) Regulation 2016 (Draft Regulation):

- 1) to meet the requirements of the Subordinate Legislation Act 1989 in terms of a regulatory impact statement (RIS); and
- 2) to serve as a Better Regulation Statement in accordance with the requirements of the Government's Guide to Better Regulation.

The Subordinate Legislation Act intends to ensure that regulations benefit the community and are reviewed periodically. To demonstrate that, the proponent agency must prepare and publish a RIS that articulates the objectives of the proposed regulation and considers a range of options to achieve those objectives. A RIS must also consider the economic and social costs of the proposed regulation with only that option which produces the greatest net benefit to the community being chosen.

The Guide to Better Regulation identifies seven principles that characterise good Regulation. The principles are:

- 1) the need for government action should be established,
- 2) the objective of government action should be clear,
- 3) the impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options,
- 4) Government action should be effective and proportional,
- 5) consultation with business and the community should inform regulatory development
- 6) the simplification, repeal, reform or consolidation of existing regulation should be considered, and
- 7) regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness.

To demonstrate adherence to these principles when proposing a new regulation, the proponent agency must prepare a better regulation statement (BRS). A BRS must identify and justify compliance costs and show the action taken to minimise these costs. This RIS also serves as a BRS.

2. Consultation and Submissions on the RIS and Draft Regulation

The RIS and Draft Regulation will be provided to stakeholders and released for a period of 4 weeks for public consultation. The Ministry is keen to hear submissions on issues raised in this RIS as well as any other matter contained in the Draft Regulation.

Submissions on the proposed RIS and Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au.

Submissions must be received by **27 May 2016**.

Individuals and organisations should be aware that generally submissions made in respect of the RIS and Draft Regulation may be made publically available under the Government Information (Public Access) Act 2009. The Ministry of Health may also circulate submissions for further comment to other interested parties or to publish parts of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated.

3. Approach taken in this Regulatory Impact Statement

The RIS considers the objectives of the Public Health (Tobacco) Act 2008 and the Draft Regulation and the costs and benefits of the Draft Regulation. The RIS also considers a number of alternatives to the Draft Regulation.

4. Draft Public Health (Tobacco) Regulation 2016

The Draft Regulation has provisions in relation to:

- The advertising on tobacco and e-cigarette packaging
- The display of retail prices of tobacco products and e-cigarettes
- The display of health warnings and other notices
- Penalty infringement notice offences

To a large extent the Draft Regulation recreates the provisions of the existing Public Health (Tobacco) Regulation 2009 subject to a number of minor changes:

- Transitional arrangements that were included in the 2009 Regulation have been removed as they are no longer needed
- A number of the provisions have been specifically amended to apply to e-cigarettes
- A number of new penalty infringement notices offences have been included in the Draft Regulation.

5. Objectives of the Public Health (Tobacco) Act 2008

The objectives of the Public Health (Tobacco) Act are set out in s3 of the Act which provides:

- (1) The object of this Act is to reduce the incidence of smoking and other consumption of tobacco products and non-tobacco smoking products, particularly by young people, in recognition of the fact that the consumption of those products adversely impacts on the health of the people of New South Wales and places a substantial burden on the State's health and financial resources.*
- (2) This Act aims to achieve that object by:*
 - (a) regulating the packaging, advertising and display of tobacco products, non-tobacco smoking products and e-cigarettes, and*
 - (b) prohibiting the supply of tobacco products, non-tobacco smoking products, e-cigarettes and e-cigarette accessories to children, and*
 - (c) reducing the exposure of children to environmental tobacco smoke.*

The Act recognises the overwhelming evidence that demonstrates that tobacco consumption is one of the major risk factors for cancer, stroke and heart disease in our community as well as contributing to a range of other serious medical conditions including emphysema, bronchial diseases and vascular disease. These conditions affect not only the individual suffering from the disease but also their families, carers and friends; their employers and the employers of those who are required to care for them; and the broader community through the supply of health and welfare services.

It is noted that these objectives have changed since the commencement of the Act, due to the emerging sale and use of e-cigarettes. The World Health Organisation and National Health and Medical Research Council have recommended banning the sale of e-cigarettes and accessories to minors and limiting advertising and promotion of e-cigarettes in a way that appeals to youth. Amendments were made to the Act in 2015 to extend a number of the existing provisions, and the objectives clause, to e-cigarettes¹.

The objective of government policy is therefore to reduce the number of people in the community who use tobacco products by:

- reducing the visibility of tobacco products and e-cigarettes in the retail environment and thereby reversing the perception that tobacco products are an everyday consumer good like milk, bread or newspapers;
- further restricting the promotion and marketing of tobacco products and e-cigarettes, particularly to children and young people; and
- restricting the exposure of children to environmental tobacco smoke

5.2 The need for government action and the impact of tobacco use

5.2.1 The cost of tobacco smoking

Tobacco smoking is a leading cause of chronic disease and premature death in New South Wales. It is a major risk factor for cardiovascular disease, a range of cancers, chronic obstructive pulmonary disease, coronary heart disease and a variety of other diseases and conditions.²

In Australia, up to two-thirds of deaths in current smokers can be attributed to smoking.³ Since 2003 the rate of death attributable to smoking has been declining in NSW.² In 2013, a total of 5,460 deaths were attributed to smoking in NSW (3,441 males and 2,019 females).²

In 2013-14, a total of 46,335 hospitalisations were attributed to smoking in NSW, which was approximately 1.6% of all hospitalisations.² The rate of hospitalisations attributable to smoking decreased in males by almost 23% but remained stable in females in NSW between 2001-02 and 2013-14.²

¹ Public Health (Tobacco) Amendment (E-cigarettes) Act 2015

² Centre for Epidemiology and Evidence. HealthStats NSW. Sydney: NSW Ministry of Health. Available at: www.healthstats.nsw.gov.au

³ Banks E, Joshy G, Weber MF, Liu B, Grenfell R, et al. Tobacco smoking and all-cause mortality in a large Australian cohort study: findings from a mature epidemic with current low smoking prevalence. *BMC Medicine*, 2015; 13(1):38. Available from: <http://www.biomedcentral.com/1741-7015/13/38>

Tobacco smoking was responsible for 7.8% of the total burden of disease in Australia in 2003, with lung cancer, chronic obstructive pulmonary disease, and ischemic heart disease accounting for more than three-quarters of this burden.⁴ The total social costs of tobacco use in Australia were estimated to be \$31.5 billion.⁵

In 2006/7, the social costs of tobacco use in NSW were estimated to be \$8.4 billion annually, with tangible costs, such as hospital costs, estimated at \$2.9 billion or 35% and intangible costs, such as pain and suffering, estimated at \$5.5 billion or 65%.⁶

5.2.2 Smoking by children and young people

The teenage years are the most common time for taking up smoking, with 80 per cent of current smokers saying they began before the age of 20 years. Early uptake is associated with heavier smoking and greater difficulty in quitting.⁷

Nicotine dependence is established rapidly even among adolescents⁸ and preventing young people from commencing smoking will reduce smoking-related deaths and illness and the associated costs in the long term.

In 2014, 6.7% of secondary school students aged 12-17 years were current tobacco smokers compared to 27.3% in 1984.² A decline has been observed in current tobacco smoking in both male students (23.9% to 7.9%) and female students (30.9% to 7.1%).from 1984 to 2011²

The proportion of students who had ever smoked has declined from 67.9% in 1984 to 21.1% in 2011.² The percentage of school students who smoked in the past 7 days prior to the survey also fell from 22.4% in 1984 to 6.4% in 2011.²

5.3 The objectives and overview of the proposed Public Health (Tobacco) Regulation 2016

The Draft Regulation is intended to support the objectives and operation of the Act. An overview of the Draft Regulation is set out below.

⁴ Begg S, Vos T, Barker B. et al. The burden of disease and injury in Australia, 2003.

PHE 82. Canberra: AIHW, 2007. Available at www.aihw.gov.au/publications/index.cfm/title/10317

⁵ Collins DJ, Lapsley HM. *The cost of tobacco, alcohol and illicit drug abuse to Australian society in 2004-05*. National Drug Strategy Monograph Series no. 64. Canberra: Department of Health and Ageing, 2008. Available at

www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishind.nsf/Content/mono64fschedul

⁶ Collins DJ, Lapsley HM. *The Social Costs of Smoking in NSW in 2006/07 and the Social Benefits of Public Policy Measures to Reduce Smoking Prevalence*. Sydney: NSW Department of Health, 2010. Available at www.health.nsw.gov.au/tobacco/Publications/social-cost-of-smoking.pdf.

⁷ U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

⁸ Fiore MC, Baily WC, Cohen SJ, et al. *Treating tobacco use and dependence. Clinical Practice Guideline*. Rockville MD: US

Part 2 of the Draft Regulation is aimed at limiting the scope of tobacco and e-cigarette advertising in such a way that would appeal to children and young people and ensure that appropriate health warnings are on tobacco products that contain an advertisement. Accordingly, clause 8 prohibits tobacco and e-cigarette products being packaged in a package that contains any statement alluding to sporting, sexual or business success, depicts holograms, people or cartoons or other scenes that have appeal to children and young people. Clause 9 requires any tobacco product that does have an advertisement to also contain a health warning.

Part 2 also sets out what is not considered to be an e-cigarette advertisement. Clause 7 provides that a trademark or brand name on an e-cigarette package does not constitute an e-cigarette advertisement. Under the Act, following changes made in 2015⁹, e-cigarettes advertising is generally subject to the same strict restrictions as apply to tobacco advertising. However, it was recognised that there are differences between e-cigarettes and tobacco advertising. Accordingly, the Act allows regulations to be made exempting certain matters from the definition of e-cigarettes. As e-cigarettes are not subject to the Commonwealth plain packaging laws, clause 7 excludes trademarks and brand names from the definition of e-cigarette advertising.

Part 2 also sets out the prescribed quantities of “illegal tobacco” (being tobacco without a health warning or tobacco not in its original packaging) that is deemed to be for sale for the purposes of sections 6(4) and 7(4) of the Act. Under sections 6(4) and 7(4), if quantities of illegal tobacco over the prescribed amount are found on tobacco retailer premises, there is a deemed breach of sections 6 and 7 of the Act and an inspector can confiscate the tobacco product. The prescribed quantities are set at:

- 100 grams for tobacco that is not in its original packaging in breach of section 6 of the Act, and
- 50 cigarettes or 50 grams of tobacco for tobacco that does not have a health warning in breach of section 7 of the Act.

Part 3 sets out provisions relating to advertising on premises and sets out the circumstances in which retail prices of tobacco and e-cigarette products may be displayed in retail premises. The Government recognises that consumers expect to be able to obtain information as to whether a retailer sells specific products and the prices of those products. Therefore Part 3 of the Draft Regulation prescribes certain types of tobacco and e-cigarette advertising that is permitted at point of sale by allowing retailers to display a price ticket or single price board to give notice to customers about price.

Part 4 sets out the requirements on retailers to display health warnings and other notices. Under Part 4 tobacco retailers are required to display, at the point of sale:

- a health warning regarding the dangers of tobacco products as set out in Schedule 1
- a notice regarding the fact that tobacco sales to minors are prohibited, as set out in Schedule 1

⁹ Amendments were made in the Public Health (Tobacco) Amendment (E-cigarettes) Act 2015

Part 4 also sets out the notices, set out in Schedule 1 of the Draft Regulation, that must be displayed on a tobacco or e-cigarette vending machine. In addition, Part 4 allows retailers to display a sign that states “tobacco sold at this cash register only” where the retail premises have more than one point of sale.

Part 5 sets out the manner in which notice of tobacco retailing must be given. Under the Act, a person must notify the Health Secretary prior to engaging in tobacco retailing¹⁰. Part 5 of the Draft Regulation requires that such notice be given via the www.onegov.nsw.gov.au website which provides for an ease of notification. Part 5 and Schedule 2 also provides for the offences in the Act and Regulation that are penalty infringement notice offences, that is offences for which a penalty infringement notice can be issued in lieu of a prosecution.

6. Alternatives to the Draft Regulation

A number of alternatives to the Draft Regulation have been considered, these are:

1. No regulation.
2. Making the regulation with no provisions relating to tobacco advertising and signage requirements at the point of sale.

6.2 Option 1 - No regulation

Under this option, there would be no regulations made under the Act. This would mean:

- The regulations would not prescribe a quantity of “illegal tobacco” for the purposes of sections 6(4) and 7(4) of the Act. This would frustrate the intention of Parliament as the deeming provisions in these sections would have no effect.
- There would be no restrictions on tobacco or e-cigarette packages including images that appeal to children and young people eg cartoon characters and holograms.
- There would be no signage requirements for retailers with more than one point of sale for retailers to indicate which cash register is to be used for tobacco sales.
- There would no requirements on retailers to display a health warning and notice about sales to minors at the point of sale.
- The requirement in section 14 for a prescribed notice to be displayed on the front of any tobacco vending machine would be ineffective and there would be no requirement for retailers to display other public health messages, including the Quitline telephone number, at point of sale.
- There would be no restrictions on the display of retail prices for tobacco and other smoking products at point of sale such that those prices could be displayed in a manner that encourages greater consumption of tobacco products or their purchase and consumption by young people.
- The notification system for tobacco retailers, required by section 39 of the Act, would arguably be ineffective as notice must be given in accordance with the regulations.
- There would be no penalty infringement notice offences which would mean that all breaches of the Act would need to be pursued by way of a formal prosecution.

¹⁰ Section 39 of the Public Health (Tobacco) Act

6.2.1 Evaluation of Option 1

Option 1 would render certain sections of the Act effectively nugatory (such as sections 6(4), 7(4) and 39) as there would be no regulations to give effect to these provisions. The lack of effective signage requirements would mean that the smokers are not reminded of the dangers of smoking and how to get help if they want to quit. There would also be no regulations relating to advertising of tobacco or e-cigarette products. The evaluation of such an approach is considered in Option 2 below and is not supported.

This approach would not support the operation and objectives of the Act and is not supported. Lack of regulation in this area would introduce a lack of parity with other Australian jurisdictions and would not be consistent with NSW's commitment to reduce exposure to tobacco, smoking rates, the uptake of smoking and the burden of smoking related illness.¹¹

6.3 Option 2 - Making the regulation with no provisions relating to advertising and signage requirements

Under this option, a regulation could be made that does not have specific provisions relating to advertising or signage requirements. This would mean:

- There would be no restrictions on tobacco or e-cigarette packages including images that appeal to children and young people eg cartoon characters and holograms, and
- There would no requirements on the requirements to display health warnings and sales to minors at the point of sale.

6.3.1 Evaluation of Option 2

Under option 2, in respect of tobacco and e-cigarette packaging, it could be argued that these restrictions are not necessary due to Commonwealth plain packaging laws and therefore this option should be supported¹². However, the Commonwealth laws only apply to tobacco products and do not apply to e-cigarettes. Further, NSW Health inspectors generally inspect tobacco retailers for a range of purposes. Where, as part of an inspection it is determined that there are breaches of the packaging requirements, there is a public benefit in having NSW law that can be enforced by NSW Health officers.

In respect of point of sale signage requirements, if there were no requirements for retailers to display health warnings and signs relating to sales to minors, then smokers (and potential smokers) would not be reminded of the dangers of smoking, and the prohibition against selling tobacco products to minors, at the point of sale. While some retailers may choose to display such signage, without a legislative requirement, uptake is expected to be small.

This approach is not considered the more appropriate way to support the operation and objectives of the Act and is not supported.

¹¹ *NSW Tobacco Strategy 2012-2017*, available at www.health.nsw.gov.au/tobacco/Publications/nsw-tobacco-strategy-2012.pdf.

¹² Tobacco Plain Packaging Act 2011 (Cth)

7. Costs and benefits of the Draft Regulation

7.1 Costs

The costs associated with the proposed regulation fall into 4 broad categories:

- i) Costs associated with restrictions on advertising (including restrictions on product displays and price displays),
- ii) Costs associated with displaying prescribed signs,
- iii) Costs associated with tobacco retailers notifying the Health Secretary of their existence, and
- iv) Other costs.

7.1.1 Costs associated with restrictions on advertising

The Draft Regulation includes a range of restrictions on the advertising of tobacco and e-cigarette products. These restrictions include:

- Restrictions on the wording and images that may be used on tobacco and e-cigarette packages (clause 8). This ensures that images that may be appealing to children (such as cartoon characters) may not be displayed on packets, and other words and images that may appeal to young people, such as those that allude to sexual or sporting success, may not be used on tobacco or e-cigarette packets or cartons,
- Providing that advertising on or within (ie not on the outside of the package) tobacco packages must contain the health warning set out in Schedule 1,
- Preventing the display of advertisements in registered clubs to the extent that the premises of a registered club is not a public place (clause 12), and
- Restrictions on the display of prices of tobacco or e-cigarette products (clause 13).

These restrictions impose costs on tobacco manufacturers and wholesalers by restricting their ability to promote their brands including by means of price competition and promotion and their ability to launch new product lines. However, it is noted that, in respect of tobacco products, these restrictions already apply to a large degree as a result of Commonwealth plain packaging laws and that therefore additional costs are not being imposed as a result of the Draft Regulation.

The Draft Regulation imposes costs on retailers by similarly preventing them from more aggressively promoting tobacco products via promoting aggressive price competition. It does this by restricting the display of retail prices (clause 13). These costs are largely unchanged in comparison to the existing Regulation.

It is not possible to quantify the extent to which these restrictions actually reduce the sale of tobacco products. However it is clear that since restrictions were introduced in the Public Health (Tobacco) Regulation 1999 rates of smoking in the community have dropped significantly. In 2004, 24.7% of males and 20.6% of females smoked while in 2014 the equivalent figures are 18.9% and 12.3%. In 2002, 14.6% of secondary students smoked while in 2014 the figure is 6.7%. It is not possible to calculate what proportion of these decreases are due to the matters dealt with in the regulation as they have been implemented as part of a comprehensive approach to tobacco control which includes: social marketing and education campaigns to prevent uptake of smoking, cessation support and regulation,

compliance monitoring and enforcement strategies at the State and Federal levels in relation to the manufacture, advertising and retail of tobacco products, smoke-free environments, tobacco plain packaging and tax excise.

7.1.2 Costs associated with displaying prescribed signage

The costs associated with displaying prescribed signage are expected to be minimal and largely unchanged from the existing Regulation.

All prescribed signs are available from the NSW Ministry of Health at no charge simply by contacting Population Resources on 1300 655 957 or via email popresources@doh.health.nsw.gov.au.

There will of course be a small cost to retailers in the time taken to initially put the signs up and replace any that become damaged. There will also be some opportunity cost associated with the inability to utilise any such space for other advertising. However, this is expected to be minimal as the sizes set by Draft Regulation are not unduly burdensome (being an area of no less than 2000 cm² for health warning notices under clause 14 and at least 15 cm high and 21 cm wide for the sale to minor sign under clause 15) and the time taken to put up the signs is expected to be minimal.

The mandatory display of signage at the point of sale is likely to impose a cost on business through lost sales and by discouraging purchases, for example the health warning notice must state **Smoking Kills Call the Quitline 137 848**. The signage regarding sales to minors is likely to have the dual effect of discouraging some young people from attempting to purchase tobacco products and secondly of constantly reminding retailers of the criminal nature of the offence and the very substantial penalties associated with it and thus assisting in deterring retailers from selling to minors. Any “costs” involved in lost potential sales to minors are not properly costs to consider as it is illegal to sell tobacco products and e-cigarettes to minors. It is noted that there has been a significant drop in the proportion of secondary school students that are recent smokers, from 14.6% in 2002 to 6.7% in 2014. However, again the reduction in smoking rates is likely to be as a result of the implementation of a comprehensive approach to tobacco control in NSW and at the Commonwealth level and is difficult to establish what role one part of the approach played in reducing smoking rates.

7.1.3 Costs associated with notifications and applications to the Health Secretary

Section 39 of the Public Health (Tobacco) Act provides that a person may not engage in tobacco retailing unless he or she has first notified the Health Secretary in the manner prescribed by the Regulations that he or she intends to engage in tobacco retailing. In the absence of the Regulation prescribing the manner of notification there would be in practice be no requirement to notify.

Clause 19 of the Draft Regulation provides that notification is to be done via the internet at the www.onegov.nsw.gov.au website. There is no fee associated with a notification and the only cost associated is likely to be the time taken to complete the notification. This is estimated to be less than 15 minutes for the average user and for users with minimal computer skills it is estimated to take less than 30 minutes. The requirement to notify has

been in existence since 2009 and so any costs will only occur in respect of new business or alterations to existing notifications, estimated to be 1000 per year.

7.1.4 Other costs

There is a range of other costs associated with the Draft Regulation. These costs include enforcement costs incurred by Public Health Units of Local Health Districts who undertake investigatory and enforcement activity, with legal and prosecutorial assistance provided by the NSW Ministry of Health's Legal Branch. The Ministry provides additional funding to augment tobacco control activities carried out by the Public Health Units.

7.2 Benefits of the Draft Regulation

There are benefits from the Draft Regulation relating to strong public health policy.

The Draft Regulation places restrictions on the advertising of tobacco products and e-cigarettes, restrictions on the sale of such products to minors and requires tobacco retailers to display appropriate signage relating to the health impacts on smoking.

As noted earlier, tobacco smoking is a major cause of preventable death and results in large costs to the community through early death and costs to the health system. The Draft Regulation is one part of a comprehensive strategy and regulatory approach to reducing smoking rates and costs to the community. NSW Health and its partners also invest in tobacco control through the regulation of smoke-free environments via the *Smoke-free Environment Act*, mass media prevention campaigns as well as a range of population-wide and targeted smoking cessation support programs. These interventions complement the Federal Government's advertising, taxation, pricing and plain packaging policies. All components of this comprehensive strategy, including the Draft Regulation, assist in reducing the smoking rate which will in turn benefit the community through decreases of death and illness and reduced health costs that are borne by all members of the community.

8. Summary

The analysis in the RIS shows that the Draft Regulation will impose the greatest benefit to public health and the community while imposing minimal costs on businesses. These costs are largely unchanged from the existing Regulation and are outweighed via the benefits to the community that arise from controlling and regulation tobacco and e-cigarette products for the benefit of public health. The Draft Regulation is considered to be the best method to achieve the Government's objectives.

Appendix A – Organisations to be consulted

AMA (NSW Branch)
Asthma Foundation
Australian Association of Convenience Stores
Australian Hotels Association
Australian Retailers Association
Australian Vape Vendors Council
BP
Caltex
Cancer Council NSW
Cancer Institute NSW
Citizen Vape
Clubs NSW
Coles
CTC Tobacconists
Eros Adults Only Association
EVO Vaporizer
Franchise Council of Australia
Freechoice Tobacconists
General Council of Small Business Australia
Heart Foundation – NSW Division
IGA Supermarkets
Liquor Gaming and Racing NSW
Liquor Hospitality Miscellaneous Union
Liquor Merchants Association
Local Health Districts
Master Grocers Australia
Medical Services Committee
Motor Traders' Association of NSW
National Association of Retail Grocers Association
Mister E-cigs
New Nicotine Alliance
Newsagent Association of NSW
NSW Office of Small Business
Nicoventures
NSW Police
Non-smokers Movement in Australia
Nuance Group
Restaurant and Caterers Association
Royal Australasian College of Physicians
Service Stations Association
Small Business NSW
SmokeMart
Steam - e-cigs
VapeRis
Vapestix Australia
Vape Industries

Vending Machines Association
Statutory Health Corporations
WhySmoke
Woolworths