

# **SMOKE-FREE ENVIRONMENTS (CONTROLS AND ENFORCEMENT) AMENDMENT BILL**

Supplement to Departmental Report

**Further Issues and additional Information sought by the Health  
Committee**

**Prepared by the Ministry of Health  
For presentation 23 March 2011**

## Creating an offence for the purchase of a tobacco or herbal smoking product by a person under 18

The Committee has asked for advice relating to creating an offence for a person under 18 to purchase tobacco.

### Background

It is currently an offence to sell, or supply in a public place, tobacco or herbal smoking products to a person under 18. It is not an offence for a person under 18 to purchase a tobacco or herbal smoking product.

There are a number of provisions in the Smoke-free Environments Act 1990 that create offences related to the act of smoking, for example, smoking -

- in workplaces;
- in schools and early childhood centres;
- in passenger service vehicles;
- in certain travel premises;
- on licensed premises;
- in restaurants;
- in casinos; and
- in certain gaming machine venues.

However, **none** of these make the **smoker** liable for the commission of the offence. In each case it is the person who allows or enables the illegal smoking to take place who commits the offence. For example, in the case of a licensed premise the offence is for a licensee “not taking all reasonably practicable steps to ensure that no person smokes at any time in a part of the premises that is not an open area”.

Some jurisdictions do make smokers liable for these types of offences. However, many, such as Victoria in Australia stop short of making it an offence for a minor to purchase tobacco.

To include a provision in the Bill to make it an offence for under-18s who purchase a tobacco or herbal smoking product, while there are no provisions in the legislation to target adult smokers who offend the smoking prohibitions, would potentially also raise issues of discrimination under the New Zealand Bill of Rights Act.

In contrast, the Sale of Liquor Act 1989 does make it an offence for a minor to purchase alcohol. This is the relevant section:

#### *Section 162 Purchasing of liquor by minors*

- (1) Every person commits an offence and is liable to a fine not exceeding \$2,000 who, being under the age of 18 years, purchases any liquor on or from any licensed premises.  
(2) [Repealed]  
(3) [Repealed]  
(4) [Repealed]

(5) Subsection (1) does not apply to a person who purchases liquor on or from licensed premises at the request of a member of the police acting in the course of his or her duties.

Section 162 (5) of that Act allows for Police to undertake alcohol controlled purchase operations with young people with no risk that the young person could be liable for prosecution.

### **Compliance / Enforcement**

In regard to smoke-free legislation, ensuring retailer compliance is much easier to achieve than controlling underage purchasers. Unlike the situation with the purchase of alcohol, where minors could be on licensed premises for a lengthy period of time, a tobacco sale takes place in a matter of seconds and the purchaser normally leaves the premises immediately. These circumstances would make the enforcement of any change difficult to undertake.

Compliance/enforcement efforts directed towards children and young people have the potential to divert Smoke-free Officer resources away from the retailers themselves.

The Ministry of Health currently does not prosecute people under 17 if they are caught selling tobacco products to minors in a controlled purchase operation. Many stores employ young people and there is not minimum selling age for tobacco. A reason for this is that the young person could not be prosecuted in the District Court (Under-17s appear in the Youth Court). This could effectively mean that only 17-year-olds would be liable for prosecution under any amendment.

### **Comment**

The tobacco industry has long advocated making it an offence for a minor to purchase tobacco. The industry has been accused, by tobacco control advocates, of using this as a strategy to deflect attention and responsibility from itself. There have also been arguments raised that the existence of an offence for under-age smoking could potentially protect the industry from possible future law suits related to the harm suffered by smokers who became addicted while still under-age.

The arguments for creating this offence tend to rest on the notion of individual responsibility. However, most children and young people who smoke, like most adults who smoke, are addicted and need help to quit. Nicotine addiction is extremely strong and it can take very few cigarettes before someone is addicted to smoking. This is particularly a concern for children and young people who take up smoking before they are fully aware of the health consequences and can exercise an informed choice.

In general, tobacco policy relies on incentives (through tobacco excise tax) and health education (eg, graphic pictorial health messages on tobacco products and media campaigns) to trigger attempts to quit smoking, backed up by better support for smokers to quit, such as smoking cessation services and subsidised nicotine

replacement therapies. The general intent is not to vilify or victimise smokers, but rather to encourage healthy behaviour change.

Smoking prevalence is much higher among Māori and Pacific ethnic groups and also in lower socio-economic groups compared to the rest of the population. Age of smoking initiation also varies by population sub-group. In 2008, the average age of initiation for Māori smokers in the 15-19 age group was 11.6 years old, compared to 14.2 years for the 15-19 year old smokers in the population as a whole. One implication of this is that many more young Māori will already be addicted by the time they could even be considered for prosecution under the proposal.

The Ministry does not support the creation of an offence for the purchase of a tobacco product by a person under 18.

### **Recommendation**

No change to the Bill.

## **Retail tobacco displays: timelines for entry into force of prohibition**

Apart from the explicit decision to allow small retailers 24 months to comply, the policy was silent as to when the display prohibition should come into force. This was consistent with the intent to allow flexibility over lead-in times and compliant solutions in order to reduce unnecessary compliance costs as the scheme is introduced.

### **Issue for decision**

The Bill as drafted would implement the policy as follows:

1. The provisions relating to the prohibition of retail displays would come into force 6 months after the Bill is passed – this would set a default position of visible retail displays being prohibited.
2. However, these provisions also included the ability to make temporary transitional regulations for up to 24 months for particular classes of retail business (with the regulations able to specify what intermediate steps different classes of business must take towards compliance).

This can be described as an “exempt out” approach. It was considered a preferable way to draft the policy into legislation as it minimised the matters able to be dealt with by subsequent regulation.

After considering the submissions on the Bill and the workability of the scheme, the Departmental Report suggested an alternative “phase in” approach whereby the provisions would continue to come into force after 6 months, but that for the first 24 months only those classes of business brought into the scheme (eg. for whom regulations had been passed) would be required to comply.

This recommendation resulted from the consideration and trade-off of a number of issues, including particularly:

- the desirability of not extending the initial coming into force beyond 6 months (so that if regulations could be made for certain classes, then there would be no delay in bringing them into compliance)
- the difficulty in dealing with all the various categories of retailer who may have good grounds for requiring some flexibility, as the regulations would all have to be in place within 6 months to exempt them from the scheme
- the additional difficulty in getting other regulations required to fully implement the new regime (eg regulations for price notices, age restriction signs, health warnings etc.) developed and promulgated within 6 months.

In considering the Departmental Report, the Health Committee expressed concern that the new “phase in” proposal, while solving some of the regulation-making difficulties with the Bill as drafted and responding to concerns raised by retail interests, risked softening the intent of the Bill and allowing too long for the overall prohibition to come into force.

The Committee indicated a preference to:

- return to an “exempt out” approach, with temporary transitional regulations available to delay or modify compliance for specified classes of retailers where necessary (eg. to give effect to the government’s policy to allow 24 months for small retailers to comply)
- allow for a longer initial lead in time (ie the time allowed from passage of the Bill until the retail display provisions come into force) so that in the default case, retailers not being exempted would have sufficient time to adapt, and in the case of transitional exemptions, there would be time to develop the regulations for the classes of retailer being granted a longer lead-in time by regulation.
- the total lead in time be limited to 24 months from the date of passage of the Bill (and not 6 months plus 24 months, ie. 30 months as in the Bill as drafted)

The Committee asked for officials’ advice on the above approach, and suggested a combination of 9 months plus 15 months, ie an initial lead in time of 9 months until the retail display provisions come into force, and a further transitional period of 15 months being available for those classes of retailer potentially being exempted under temporary transitional regulations (such as small retailers in line with the government’s policy).

However the Committee indicated other combinations of initial lead in time plus temporary exemption time would be possible, eg, 12 months plus 12 months.

### **Comment**

The Ministry concurs with the Health Committee’s consideration to date and the preference it has expressed, ie. an “exempt out” regime to deal with classes of business requiring longer lead in times, but with a maximum total lead-in time of 24 months until all tobacco displays are prohibited.

We consider the key issue for decision is the breakdown within the total 24 month lead in period between:

1. the amount of initial lead-in time from passage of the Bill until the retail display provisions come into force for anyone not exempted out
2. the amount of additional lead-in time allowed for classes of business that obtain temporary transitional exemptions through regulation.

By the end of the initial lead-in time (ie. 1 above) regulations would need to be approved and fully in place for:

- specifying which classes of retailer would be exempt for an additional 15 months, and what transitional arrangements would apply for these retailers (eg partial or temporary covers for existing retail displays) - essential
- specifying the product lists, price notices, health messages and R18 warnings that would be needed for those classes of retailer not being granted an exemption – highly desirable
- clarifying what are acceptable modes of compliance for the amount of visibility “reasonably necessary” to make a sale or take delivery of tobacco products - desirable

In our view the realistic options are:

- Option A: 9 months plus 15 months (ie the Health Committee's initial preference)
- Option B: 12 months plus 12 months

Assuming the Bill is passed by 1 June 2011, the relevant time frames would then be:

- Option A: Retail display provisions come into force and necessary regulations in place by 9 months later, ie. by 1 March 2012
- Option B: Retail display provisions come into force and necessary regulations in place by 12 months later, ie. by 1 June 2012

Under both options, all retailers would be in full compliance with the full prohibition on visible retail displays by 24 months after passage of the Bill (eg. 1 June 2013).

The relative advantages of option B over option A are:

1. Allows more time for engagement with enforcement officers and retailers to determine workable and generally acceptable approaches to the regulatory issues (ie which classes get longer exemptions, what signs and notices are required, which solutions give certainty over acceptable visibility during sale, restocking etc.)
2. Allows more time to work through necessary regulation preparation processes, regulatory impact statement(s), Cabinet approval etc.
3. In particular, allows time to manage the Christmas holiday period and any possible delays associated with the general election, eg. government formation period
4. Allows more time for those retailers who will be moving to full compliance at the outset to make the necessary arrangements, including potentially costly changes to their shop-fittings. (This increases the opportunities for combining the adjustment with other changes or refurbishments they may be otherwise making.)
5. Minimises any distortionary effect between classes of retailers, since exempted retailers only gain an extra 12 months (as compare to 15 months under option A)

We also note that previous introduction of Smoke-free legislative amendments and regulations (such as prohibiting smoking in the workplace, and requiring pictorial health messages on tobacco packages) has established 12 months as a standard lead-in period. This has been shown to provide sufficient time for affected parties to adapt and also for the necessary administrative and regulatory arrangements to be put fully into place.

### **Recommendation**

On balance, the Ministry recommends option B, ie: 12 months initial lead in and 12 months additional maximum transitional exemption period.

### **Background – Cabinet policy paper and decisions**

The Cabinet paper sets out the policy of providing appropriate flexibility over options for compliance and adequate lead-in times for different types of business. This was

proposed as a combination of legislative amendment followed by the development of guidelines and regulations working in consultation with smoke-free enforcement officers and retail interests. The objective is to enable a smooth transition and reduce unnecessary compliance costs.

The key paragraphs in the Cabinet paper were:

25. The central and most significant proposal in this package is to prohibit the visual display of tobacco products for sale. This would be implemented by a combination of amendments to the Smoke-free Environments Act and subsequent regulations in order to help minimise compliance costs. Further detail is given in paragraphs 45-53 below. It is therefore proposed to also amend the current regulation-making powers under the Smoke-free Environments Act to ensure resulting regulations can give appropriate flexibility to provide options for different types of business to comply, and also allow for adequate lead-in times for compliance in each case.

...and ...

52. In order to deal responsibly with the compliance cost issue and the impacts on small business it is proposed to move in two steps: firstly to introduce amended legislation to clearly establish the new policies on removing retail displays and related matters, and then secondly to develop detailed regulations and guidelines in consultation with retail interests. These regulations and guidelines would lead to flexible solutions to comply with the law and reasonable transition criteria and timeframes to minimise the downside impact on business, particularly small businesses which may be vulnerable to shifting income streams. It is proposed to work these up with active input from retailers and smoke-free enforcement officers to ensure effective and workable solutions that achieve the policy goal but minimise as far as possible the regulatory impacts and compliance costs, relative to the size of the businesses affected.

53. The process would also provide an opportunity to further educate retailers and explore business opportunities from being 'part of the solution', eg. selling nicotine replacement patches, lozenges and gum to help smokers quit. This would enable people to choose between an expensive product that harms them, and an inexpensive product that helps them quit, and could provide retailers with a new line of business to replace tobacco.

Cabinet subsequently agreed [CAB Min(10) 38-5A refers] .....

2. **agreed** to a package of new and improved controls on the retailing of tobacco products, comprising:
  - 2.1 prohibiting the display of tobacco products for sale;
  - 2.2 tightening controls on the display of trading names that include terms signifying the availability or price of tobacco for sale;

- 2.3 taking a consistent approach to the regulation of related matters such as the retail display of smoking accessories, display and signage requirements for automatic vending machines, requirements for health warnings and “Smoking Kills” signs, and display of tobacco product price lists;
- 2.4 providing that any contract or other form of agreement which offers a sponsorship, gift, rebate, prize or reward in exchange for the promotion or sale of tobacco products is void to the extent to which it is inconsistent with the Smoke-free Environments Act 1990;
- 2.5 providing smoke-free enforcement officers with powers to issue infringement notices for offences involving the sale of tobacco products to people under 18 years of age;
3. **agreed** the package described in paragraph 2 above would best be implemented by a combination of amending the Smoke-free Environments Act 1990, including regulation-making powers as necessary, and developing further regulations under the amended Act;
4. **note** the combination of amended legislation and developing further regulations allows for flexibility over options and timeframes for compliance in order to avoid unnecessary compliance costs and impacts on small retail businesses;
5. **agreed** that small retailers shall be given 24 months to comply with the prohibition on the display of tobacco products;
6. **directed** the Ministry of Health to:
  - 6.1 work with retailers and smoke-free enforcement officers on effective options to minimise compliance costs and impacts on small retail businesses;
  - 6.2 report back to SOC with proposals for further regulations under the Smoke-free Environments Act 1990 by 30 June 2011;

## Remote Sales

### Issue

The Ministry of Health's Departmental Report recommended that the Bill be extended to specifically also apply to tobacco 'remote sales' situations (including the Internet). The latest RT version of the Bill (PCO 14886 v4.3) makes this change. However the Ministry has some concerns as to the wording, and possible unintended consequences, of these new provisions.

### Background

The Ministry when recommending this amendment was particularly focussed on Internet sales, because some supermarkets, duty-free stores and a small number of other retailers are selling tobacco products through this method. The Ministry is not aware of any other forms of remote sales occurring in New Zealand.

The Ministry currently considers an Internet site selling tobacco products would only be allowed if the site complied with the normal requirements of the smoke-free legislation, for example, requirements for health warning and no-sale-to-under-18s signage. However, it was thought appropriate that this situation be clarified in the legislation.

The Bill as currently drafted provides the following definition for a remote sale -

“**remote sale** of a tobacco product or herbal smoking product means a sale (whether by retail or wholesale) of the product pursuant to a contract that—

“(a) has been entered into (using the Internet, by telephone or mail order, or in any other way) between—

“(i) a seller whose business is or includes offering the product for sale (whether by retail or wholesale);

and

“(ii) a person (whether the purchaser or a person acting on the purchaser's behalf) who is at a distance from the seller's place of business; and

“(b) contains a term providing for the product to be delivered to the purchaser by or on behalf of the seller”.

The provisions of the Bill that relate to remote sales (e.g, the new section 23(3)) make it clear that these sales can only be made on “request”.

However, it is the Ministry's view that the definition of “remote sales”, which also extends to mail order catalogues, unnecessarily widens the exemptions to the advertising provisions. These catalogues are printed for customers generally and also include items other than tobacco products. Currently, the Ministry would deem a mail order catalogue that notified the availability of tobacco, even if the catalogue is provided on request, a tobacco product advertisement. This would also apply to any email that promoted or notified the availability of tobacco through an Internet site.

There are a fast growing number of New Zealand based Internet sites that require people to register in order to receive direct communications (usually in the form of an email) about various deals and to make purchases from the site, these include, 1-day.co.nz, grabone.co.nz,. treatme.co.nz. The Ministry could envisage a situation whereby a retailer might argue that because a person has proactively registered with a site this may be deemed to be a “request” by the person to receive this information.

### **Comment**

While the latest version of the Bill explicitly recognises the ability of sellers to make remote sales, it may provide potential loopholes that could be exploited to actually increase the advertising or visibility of tobacco or herbal smoking products. It may unintentionally allow for more flexibility in how tobacco is marketed and sold in New Zealand.

The Ministry believes that it would be more beneficial to either make the provisions more specific to Internet sales (without any reference to mail order catalogues or telephone sales), or, alternatively, remove the remote sales provisions from the Bill completely and continue with the status quo.

### **Recommendation**

1. Make the provisions that currently relate to remote sales more specific to Internet based sales; **or**
2. Remove all the remote sales provisions from the Bill.

## **Trading names and specialist tobacconists**

The Departmental Report presented to the Health Committee on 16 March raised the issue of the (small) number of existing businesses that genuinely trade as specialist tobacconists and have trading names that include terms such as “tobacconist”.

The Bill requires all such businesses to cease displaying words like “tobacconist” on the exterior of their businesses. This provision would come into effect at the same time as other provisions relating to retail displays (ie. 6 months after Royal Assent in the Bill as drafted, or 12 months after Royal Assent if the Committee agrees to the Ministry’s current recommendation).

The Departmental Report raised the possibility that some “allowance could possibly be made in genuine circumstances relating to existing businesses”, but did not make a clear recommendation to change the Bill to provide for this. The issue was not discussed in detail at the meeting on 16 March. This note is intended to clarify the issue, and present a clearer option to change the Bill should the Committee wish to.

### **Comment**

The policy intent behind the trading names advertising provision is to generally prevent tobacco retailers displaying names on the outside of their buildings that effectively promote tobacco products. The concern was that this would become a much more widely used marketing technique after the display prohibition comes into force. Smoke-free enforcement officers had already begun to notice an increase in the number of retailers using this technique. Often these are dairies or other general convenience stores, and not businesses specialising solely in the sale of tobacco products. The main intent of this provision in the Bill is to prevent existing businesses from starting to use this technique, and to reverse the situation where businesses had recently begun to exploit the technique.

The Committee heard from two submitters in particular who operate what might be termed “specialist” tobacco retailers, i.e, they are not general retailers who happen to sell tobacco. Such businesses are relatively few in number, perhaps 20 nationwide.

As a matter of policy, it would be desirable if the Bill does lead to reduced tobacco sales over time. This implies that some businesses reduce sales or cease selling tobacco altogether, consistent with the Government’s goal of an essentially smoke-free New Zealand by 2025. However, the immediate commercial impact of the law change on the small number of genuine specialist tobacconist businesses could be particularly severe, given they would also be subject to the new in-store display prohibition and the tightening of other controls.

Under the Bill as drafted they could continue to trade (under a different name that does not identify tobacco) provided they do not display tobacco products. As the Committee heard from some submitters, this would leave them as essentially unidentified shops. It is hard to anticipate how exactly they would respond. But this could have unintended consequences, for example a prominent reference to products sold inside being a matter of adult choice intended for people over 18 could potentially make the premises more alluring to curious minors.

The current Act (section 23(1)(c)) only allows such retail names to be displayed in accordance with regulations. The relevant regulation<sup>1</sup> currently allows retailers to display a trade name denoting tobacco products on the exterior of their premises in up to two places without any restriction (eg. size). If the name is displayed more than twice, each occurrence must be accompanied by a warning message immediately beneath the name in lettering at least half as big.

It would be possible to retain this regulatory regime (which could be tightened) to provide an exemption for those existing businesses that specialise in tobacco products and would otherwise have no obvious means of describing the nature of their business in their name.

### **Recommendation**

If the Committee wishes to address the particular effect of the trading name advertising ban on existing specialist tobacconist businesses, this could be achieved by inserting or retaining a provision along the lines of the current section 23(1)(c) for those specialist tobacconists only. This would allow for them to continue displaying a trading name which includes a term specifying tobacco products, subject to regulation.

This would need clear criteria to prevent abuse, such as:

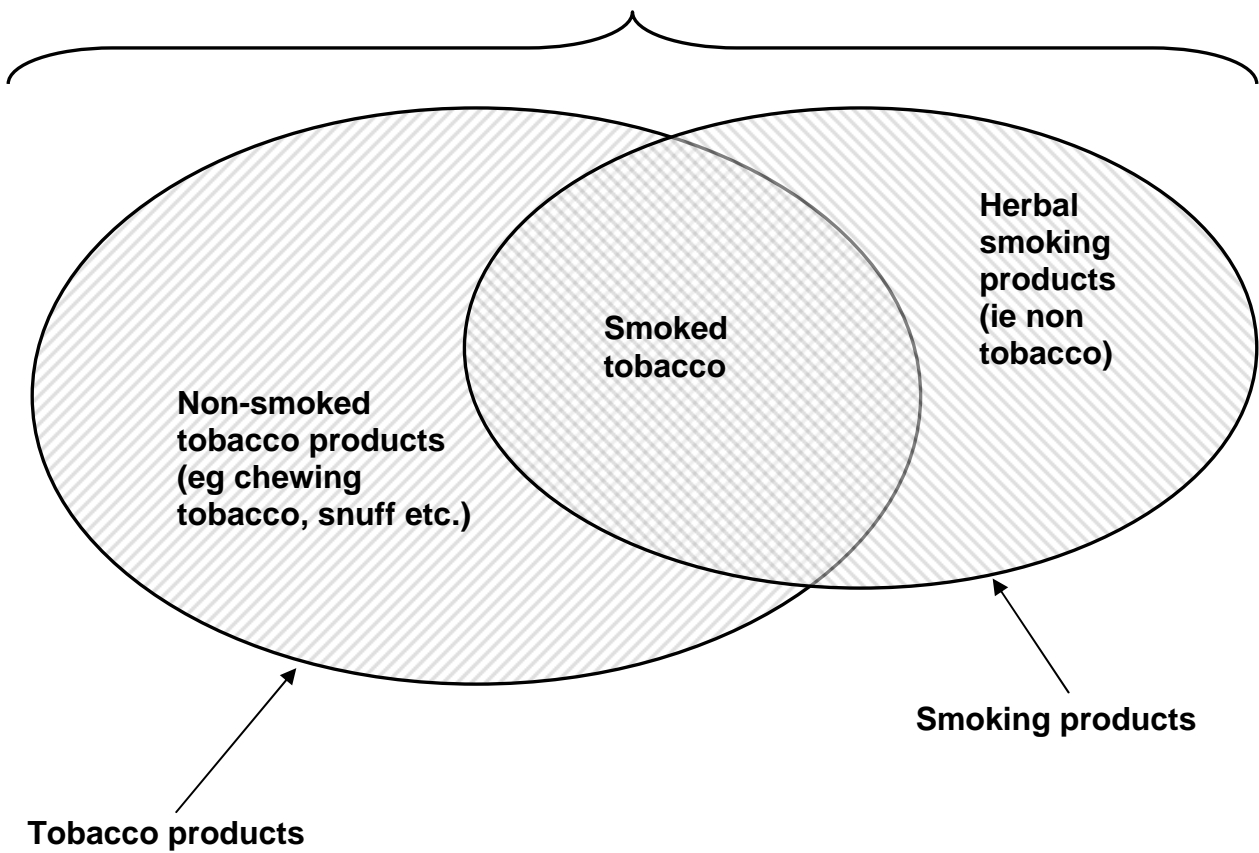
- the business must have been in existence in its current premises and in its current corporate structure as at 9 December 2010 (ie. the date the Bill was introduced)
- the business must be a standalone business and the existing business premises must be separated from any other retail premises by a wall, and must not open directly into any other retail premises
- the business must earn at least 80 per cent of its turnover (gross revenue) from the sale of tobacco products, and must demonstrate annually that it continues to meet this threshold
- the business must not identify itself as also selling any products other than tobacco (If it wishes to do so, it should change its name to remove any reference to tobacco.)
- the business must not sell any products or services intended for children or adolescents, or sell any general grocery items such as bread, milk, snack foods, other confectionary, newspapers, magazines, or electronic media (such as CDs or DVDs)
- the name must not be displayed more than twice, must not be more prominent than is reasonably necessary to identify the business, and must do no more than is reasonably necessary to identify the fact that trade in tobacco products is the purpose of the business
- the display of the name must also comply with any regulations.

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<sup>1</sup> Smoke-free Environments Regulations 2007, Part 3 regulation 30

**Diagram explaining the relationship between the definitions of tobacco products, smoking products and herbal smoking products**

**Tobacco products and herbal smoking products**



## **General Information requests from the Committee**

### **Reducing the nicotine content in tobacco**

Historically, tobacco products have been exempt from standards governing contents and design that are typically applied to other consumer products, including foods and pharmaceuticals. All tobacco products have contents and emissions that could be regulated, including nicotine levels.

Smokers continue to smoke and find it hard to quit because of the addictiveness of nicotine in tobacco and the effectiveness of tobacco smoke in delivering this nicotine to the brain. In principle, addictiveness could be controlled by regulating the amount of nicotine in cigarettes, as well as the additives that are used to enhance the absorption of nicotine.

Potential disadvantages of this approach are that smokers could compensate for the reduced nicotine by smoking more or inhaling more deeply to increase the delivery of nicotine, thus potentially increasing the risk of harm. The problem with the nicotine-removal idea is that tobacco users would continue to seek nicotine up to the level that provides a satisfactory dose.

Conversely, substantially raising the levels of nicotine in tobacco products could slightly lower the daily intake of the harmful toxins. However, whether this would be sufficient to significantly reduce exposure to the toxic and cancer causing emissions from tobacco is unknown<sup>2</sup>. Raising nicotine levels may also addict new smokers more quickly.

### **Electronic Cigarette (e- cigarette)**

The purpose of this section is to provide you with information on an emerging product in the area of tobacco control - the e cigarette. A submitter produced one of these products during the hearings.

New and emerging electronic nicotine delivery systems (ENDS) potentially have some role in smoking cessation and reducing the harms caused by smoking. However not enough is known of them to make this assessment.

### **Background**

The e-cigarette, invented by a Chinese company (Ruyan), is a 'nicotine inhaler' that is marketed as a substitute for standard tobacco-containing smoked cigarettes. Non-nicotine versions have been available for some time but as nicotine is the substance smokers are addicted to, the non-nicotine versions are unlikely to be particularly popular.

The e-cigarette consists of a tubular device similar in appearance to a cigarette. A cartridge containing nicotine, propylene glycol and flavouring is placed in the device

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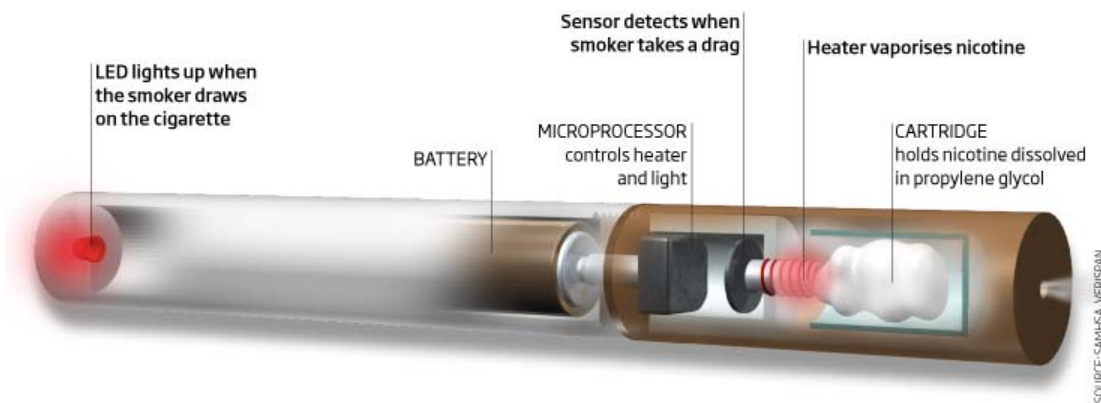
<sup>2</sup> World Health Organization. 2007. *The Scientific Basis of Tobacco product regulation : Report of a WHO Study Group (WHO technical report series; no. 945)*

and heated, allowing for the inhalation of nicotine vapour (see figure 1). According to the product patent, lip pressure sensed by the mouthpiece primes an electric circuit. The user draws in diluting air, which after a momentary delay switches off the electric pump and heater after each puff. Nicotine is then vaporised ultrasonically at high temperature (atomised) in a fine aerosol (0.2- 3 µm diameter) of non-toxic propylene glycol, which condenses in room air into a visible puff of mist.

### Figure 1: Electronic Cigarette

#### Smoke without fire

Suck on an e-cigarette and it produces a cloud of nicotine-carrying vapour with none of the toxic by-products of burning tobacco



Source: New Scientist *Electronic Cigarettes: A safe substitute?* 11 Feb 2009

In New Zealand the nicotine-containing cartridges used in the e cigarette are classed as medicines as they are designed to be included in a medical device that delivers nicotine for inhalation by a human being. Until such time as the manufacturer or distributor of the product submits an application, the product is an unapproved medicine and its distribution would be an offence under Section 20 of the Medicines Act.

Nicotine when found in its natural form (for example tobacco) does not fall under the Medicines legislation.

The delivery device, without the nicotine cartridge, could be sold on its own as long as no therapeutic claims are made. Likewise a cartridge that does not contain nicotine, or any other substance that falls under the Medicines Act, could potentially be sold.

As a pharmacy-only medicine, an individual could import the product for their own use. However, any attempt to sell it commercially could be an offence under the Medicines Act. The Ministry of Health has recently become aware of nicotine containing cartridges being imported and sold in New Zealand. An investigation into this is underway. A manufacturer could apply to MEDSAFE to register the product as a medicine in New Zealand. The product would have to be considered under the same regulatory framework as all medicines available in New Zealand.

As the e-cigarette delivers only nicotine in a mist of propylene glycol, without the other 4,000 or so other chemicals in tobacco smoke, it is far safer than smoking. Compared to a puff on a cigarette the e-cigarette delivers less than half the amount

of nicotine. This leaves the question whether smokers can get enough nicotine to satisfy their addiction.

### **Does this device help people stop smoking?**

There are no published data to show that the e-cigarette helps people quit smoking. Given that this device provides nicotine to the user then, like other nicotine replacement therapies (NRT), it is likely to offer some relief of tobacco withdrawal symptoms that people experience when they quit.

Data from one small New Zealand study<sup>3</sup> shows that the e-cigarette does relieve cravings as well as the nicotine inhaler (a NRT product available in pharmacies), although it delivered only a small amount of nicotine.

It remains to be seen if the e-cigarette helps people stop smoking long-term. The World Health Organization made it clear in a statement published in 2008 that they did not consider the electronic cigarette to be a legitimate therapy for smokers trying to quit.

### **Is the e-cigarette safe?**

The risks to smokers of pure nicotine, delivered in doses seen with the e-cigarette and NRT products, are extremely low. Animal studies suggest that the use of long-term (20 hours a day, five days a week during a two-year period) inhaled nicotine is safe.

Dr Murray Laugesen (who appeared before the Committee) has undertaken a number of safety tests<sup>4,5</sup> and concluded that the toxicants found in tobacco smoke are not present in the e-cigarette.

Propylene glycol is the other major component of the e-cigarette. It is used in pharmaceuticals, as a solvent and preservative. It is used also in personal lubricants. It is used in semi-moist pet food. In the food industry it is used as a solvent, humectant (*helps hold water*) and preservative. Its mist is used in theatrical stage productions.

In animal studies propylene glycol does not appear to pose a significant hazard via inhalation of the vapour. The compound appears to be safe when used as a food preservative or in cosmetics. It has also been used on children as an aerosol germicide in the United States in the 1940's without adverse effects. However, the effects of inhaled propylene glycol on the lungs are unknown.

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<sup>3</sup> Bullen C, Glover M, Laugesen M, Lin R, McRobbie H, Thornley S. Effect of an E-cigarette on cravings and withdrawal, acceptability and nicotine delivery: randomised cross-over trial. *Society for Research on Nicotine and Tobacco (SRNT)*. Dublin, 2009.

<sup>4</sup> Laugesen M. Ruyan nicotine electronic inhaler/e-cigarette: Bench-top tests. *Society for Research on nicotine and Tobacco*. Dublin, Ireland, 2009.

<sup>5</sup> Laugesen M, Thornley S, McRobbie H, Bullen C. How safe is an e-cigarette? *Society for Research on Nicotine and Tobacco*. Portland Oregon, 2008.

The current safety data would therefore suggest that the e-cigarette poses few risks to people, and is safer than continuing to smoke. However, this should be confirmed with data from long-term outcome studies.

### **Would the e-cigarette be attractive to young people?**

The e-cigarette could be attractive to young people. A concerning aspect is that the nicotine cartridges come in flavours, for example, chocolate and cappuccino. There has also been some concern expressed in the tobacco control sector about e-cigarettes potentially being a gateway into smoking tobacco (though the Ministry of Health has not sighted any evidence backing these claims).

### **Would e-cigarettes maintain nicotine addiction rather than quitting?**

Evidence suggests the more environments there are where smokers cannot smoke the more likely they are to make a quit attempt and maintain their quit status. There is an argument the e-cigarette, rather than being a mode to reduce tobacco smoking, could be used a nicotine maintenance device for times when smokers cannot smoke (eg. socially, in the workplace, etc).

### **Would e-cigarettes counteract the intent of de-normalising tobacco use?**

An important part of de-normalising smoking is reducing the places people see smoking. The more people see the behaviour the more they get the impression that it is something that is normal, even when only 20% of the population are actually smoking.

Having the ability to use these “look a like” products in indoor environments may well making smoking seem more normal to young people in particular.

### **Comment**

To be of value from a public health perspective, devices of this type should aid smokers attempting to quit their nicotine addiction. The next best outcome would be for existing smokers to switch only to using e-cigarettes or other safer alternative product, for example, SNUS (a small tea bag like oral tobacco product which has been processed to reduce the level of nitrosamines (cancer causing agents found in tobacco)).

Unwanted outcomes could include young people using these products and becoming nicotine dependent and existing smokers using them to maintain their addiction in environments where they cannot smoke rather than quitting entirely.

The Ministry of Health believes there are research questions still to be answered around the e-cigarette before the Ministry would support its introduction and/or promotion in New Zealand. Trials to assess long term cessation outcome and safety are needed.

## **Cochrane Collaboration Review Summaries on Smoking Cessation Medication**

### **Nicotine Replacement Therapy (NRT)**

NRT aims to reduce withdrawal symptoms associated with stopping smoking by replacing the nicotine from cigarettes. NRT is available as skin patches that deliver nicotine slowly, and chewing gum, nasal spray, inhalers, and lozenges/tablets, all of which deliver nicotine to the brain more quickly than from skin patches, but less rapidly than from smoking cigarettes. This review includes 132 trials of NRT, with over 40,000 people in the main analysis. It found evidence that all forms of NRT made it more likely that a person's attempt to quit smoking would succeed. The chances of stopping smoking were increased by 50 to 70%.

Most of the studies were performed in people smoking more than 15 cigarettes a day. What limited evidence there is suggests no overall difference in effectiveness of different forms of NRT nor a benefit for using patches beyond 8 weeks. NRT works with or without additional counseling, and does not need to be prescribed by a doctor. Heavier smokers may need higher doses of NRT. People who use NRT during a quit attempt are likely to further increase their chance of success by using a combination of the nicotine patch and a faster acting form. Preliminary data suggests that starting to use NRT shortly before the planned quit date may increase the chance of success. Adverse effects from using NRT are related to the type of product, and include skin irritation from patches and irritation to the inside of the mouth from gum and tablets.

There is no evidence that NRT increases the risk of heart attacks.

### **Champix (varenicline)**

When people stop smoking they experience cravings to smoke and unpleasant mood changes. Nicotine receptor partial agonists such as varenicline aim to reduce withdrawal symptoms and smoking satisfaction. We found 11 randomized controlled trials of varenicline compared with placebo. Three of these trials also included a direct comparison with bupropion. One other trial tested varenicline against placebo, as maintenance therapy for those who had recently quit with varenicline. Two further trials compared varenicline with nicotine patches. One trial gave varenicline to all participants, but varied the delivery of behavioural support. This trial is not included in the analyses, but contributes to the data on safety and tolerability. From these data, varenicline at standard dose increased the chances of quitting more than two-fold compared with placebo. Low-dose varenicline roughly doubled the chances of quitting, and reduced the number and severity of side effects. The number of people stopping smoking with varenicline was higher than with bupropion.

The two trials with nicotine patches did not show a clear benefit of varenicline over the patches. The main side effect of varenicline was nausea, but this was mostly at mild or moderate levels and usually subsided over time. After the licensing phase, there were concerns that varenicline may be linked with depressed mood, agitation or suicidal thinking and behaviour in some smokers. Surveillance studies

and further analyses of the trial data have not so far found strong support for this association.

## **Bupropion (Zyban)**

Multiple trials of bupropion (Zyban) for smoking cessation show that it increases the number of successful quit attempts. The side effects of bupropion include insomnia, dry mouth and nausea and rarely (1:1000) seizures and perhaps psychiatric problems, but the last is unclear. The tricyclic antidepressant nortriptyline increases quit rates. The side effects of this medication include dry mouth, constipation, nausea, and sedation, and it can be dangerous in overdose. The efficacy of bupropion and nortriptyline appears to be similar to that for nicotine replacement and not restricted to people with a history of depression or depressive symptoms during smoking abstinence. Selective serotonin reuptake inhibitor antidepressants (for example, fluoxetine) have not been shown to help smoking cessation.

## **Mortality and morbidity from smoking cannabis**

There are two reviews that have sought to summarise these issues. The first is, Copeland, Jan, 2006, *Evidence-based answers to cannabis questions: a review of the literature*, Canberra, Australian National Council on Drugs. The second is Room, R; Fischer, B; Hall, W et al. 2008, *Cannabis Policy: moving beyond stalemate*. Oxford: Beckley Foundation.

For proven and possible short-term adverse health effects, Copeland concluded that, unlike other drugs of abuse such as heroin or cocaine, there have been no documented cases of death from cannabis overdose. However in 8 of 5539 deaths cannabis use disorder was nominated as an underlying cause of death. Proven and possible long-term adverse health effects resulting from heavy use over the long term were also examined in respect of cardiovascular disease, cancer, respiratory illness and impaired immune and reproductive function. It was suggested that cannabis smoking may be a rare trigger of a heart attack, especially in the presence of other risk factors such as obesity and cigarette smoking. There was a lack of well controlled studies on the link between cannabis use and cancer.

The effect of cannabis on the airway has received more attention because of the similarity with tobacco. These tend to show cannabis as a cause of respiratory inflammation and minor diseases in lung function. There was no conclusive evidence suggesting an effect on cannabis on the immune system or on the reproductive function - although there are enough indications to take a precautionary approach during pregnancy by not consuming cannabis.

The most comprehensive summary of cannabis mortality and morbidity is in the Beckley Foundation report which is also more recent. This report would suggest that in terms of acute toxicity (ie poisoning or overdose), worldwide there are two reported deaths associated with cannabis poisoning but it is not clear that THC was responsible for the deaths. There have been reports of myocardial infarction following cannabis use but it is thought that these occurred in people with pre-existing heart conditions. There is also the risk of death from accidents, such as car crashes.

The health effects of long-term use are not well understood and research is inconclusive or contradictory and often confounded by tobacco and alcohol use.

However, chronic use has been associated with chronic bronchitis and impaired immune systems. No evidence has been found of increased rates of emphysema in cannabis smokers.

Some studies have found an increased risk of developing oral squamous cell carcinoma but other studies have failed to find an association between cannabis use and oral cancer. There is more evidence of an association between cannabis use and lung cancer but the studies have been criticised as being small and poorly controlled for tobacco use.

In New Zealand, there were 2,185 hospital admissions in 2009 related to cannabis use (2,007 of these were secondary diagnoses) - 94% of these were for mental health issues. There were no recorded admissions for respiratory problems.

A recent New Zealand study by the Cannabis and Respiratory Disease Research Group<sup>6</sup> found a link between cannabis use and lung cancer, suggesting that smoking a joint of cannabis per day has a similar risk to smoking a pack of cigarettes a day.

This was a case-control study of 79 cases of lung cancer in adults 55 years of age or less, conducted in eight district health boards in New Zealand. A control group of 324 people was randomly selected from the electoral roll, with frequency matching by age group and district health board. The risk of lung cancer increased 8% for each joint-year of cannabis smoking, after adjustment for confounding variables including cigarette smoking, and 7% for each pack-year of cigarette smoking, after adjustment for confounding variables including cannabis smoking. The study therefore concluded that long term cannabis use increases the risk of lung cancer in young adults.

While cannabis smoking (defined as lifetime use of  $\geq 20$  joints) was not associated with a significantly increased risk of lung cancer, the highest third of users ( $>10.5$  joint-years of exposure) had a significantly increased risk, after adjustment for age, sex, ethnicity, pack-years of cigarette smoking and a family history of lung cancer. The authors therefore estimated that that about 5% of lung cancer in those aged 55 years and under in New Zealand may be attributable to cannabis smoking.

Another study<sup>7</sup> by the same authors found that cannabis use did not increase the risk of head and neck cancer; however, because of the limited power and duration of use studied, a small or longer-term effect could not be excluded.

Whilst on the face of it, on a per cigarette basis cannabis smoking may be more harmful than smoking tobacco, there seems to be very little research on this although there is a study which looks at the genotoxicity which highlights some

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<sup>6</sup> Sarah Aldington,1 Matire Harwood,1 Brian Cox,2 Mark Weatherall,3 Lutz Beckert,1 Anna Hansell,4 Alison Pritchard,1 Geoffrey Robinson,1 and Richard Beasley1,5, On behalf of the Cannabis and Respiratory Disease Research Group. 2008. *Cannabis Use And Risk Of Lung Cancer: A Case-Control Study*. Eur Respir J. 2008 February; 31(2): 280–286.

<sup>7</sup> Sarah Aldington, Matire Harwood, Brian Cox, Mark Weatherall, Lutz Beckert, Anna Hansell, Alison Pritchard, Geoffrey Robinson, and Richard Beasley, On behalf of the Cannabis and Respiratory Disease Research Group. 2008 *Cannabis use and cancer of the head and neck: Case-control study*, Otolaryngol Head Neck Surg March 1, 2008 vol. 138 no. 3 374-380.

differences (Maertens, R; White, P; Rickert, W et al. 2009. The Genotoxicity of Mainstream and Sidestream Marijuana and Tobacco Smoke Condensates. In *Chem. Res. Toxicol* 22: 1406-1414). Some people are known to seek to mitigate the potential harms from smoking cannabis by consuming it through a vapouriser or water pipe.

## Smoking prevalence Iceland and Ireland

### Iceland

The Committee asked for additional information after one submitter claimed that *“After the Iceland smoking ban youth smoking aged 15-19 years has increased!! Against the falling general trends of mature markets and more specifically Iceland. It went from 14.4 percent to 17%. 6 years later it remained higher before the ban at 15.2 percent”*. Patrick Basham makes similar points in a paper attached to Philip Morris’s submission.

The Icelandic data for smoking prevalence among 15-19 year olds fluctuates considerably from year to year, probably because of a small sample size of the survey. In 2000, the year before the display ban, which came into force in August 2001, the 15-19 smoking prevalence figure for Iceland was relatively low at 14.4 percent. It was between 17-18 percent in the two years on either side of the 14.4 percent. Given the volatility, the trend is much more important in interpreting the data than a comparison of particular years. The general trend is downwards. The full data are set out below. The contribution the removal of tobacco product displays in 2001 contributed to this is difficult to assess. As noted elsewhere, a display ban is expected to reduce smoking uptake, particularly among young people, in the long-term rather than to produce a sudden drop in smoking prevalence.

#### Iceland – Smoking prevalence – 15-19 years and 15-89 years

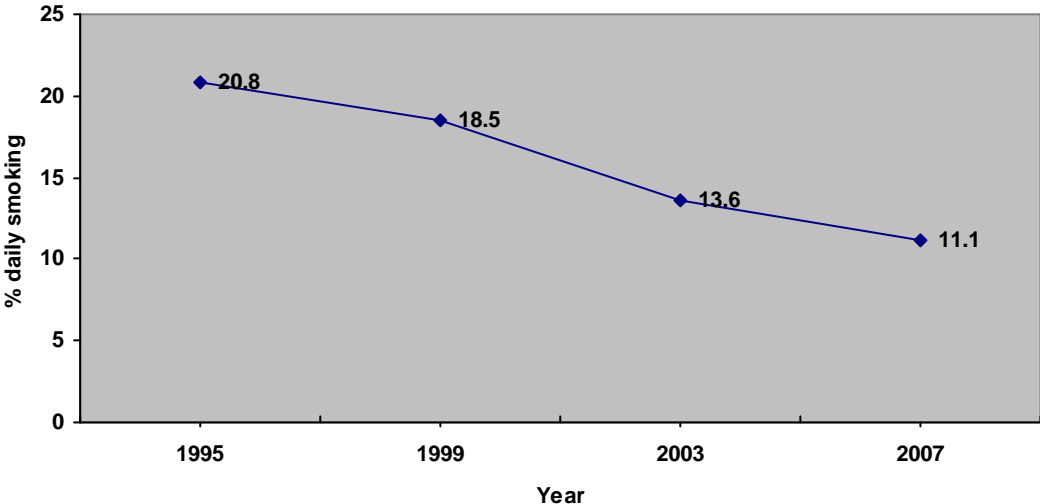
Year	Daily smoking prevalence (15-19) %
1995	18.3
1996	16.4
1997	19.2
1998	17.4
1999	17.2
2000	14.4
2001	17.5
2002	17.9
2003	16.9
2004	12.4
2005	15.7
2006	12.2
2007	15.2
2008	13.7
2009	12.7
2010	7.2

Year	Daily smoking prevalence (15-89) %
1995	26.5
1996	27.4
1997	26.8
1998	24.6
1999	25.0
2000	22.4
2001	22.9
2002	21.9
2003	21.9
2004	19.8
2005	19.2
2006	18.8
2007	19.0
2008	17.6
2009	15.4
2010	14.2

Source: Statistics Iceland *Smoking habits of 15-89 year olds in Iceland*.

Data from the European School Survey Project on Alcohol and Other Drugs (below) shows a similar downward trend.

Changes in daily smoking among 15-year old Icelandic students  
(Ban implemented 2001)



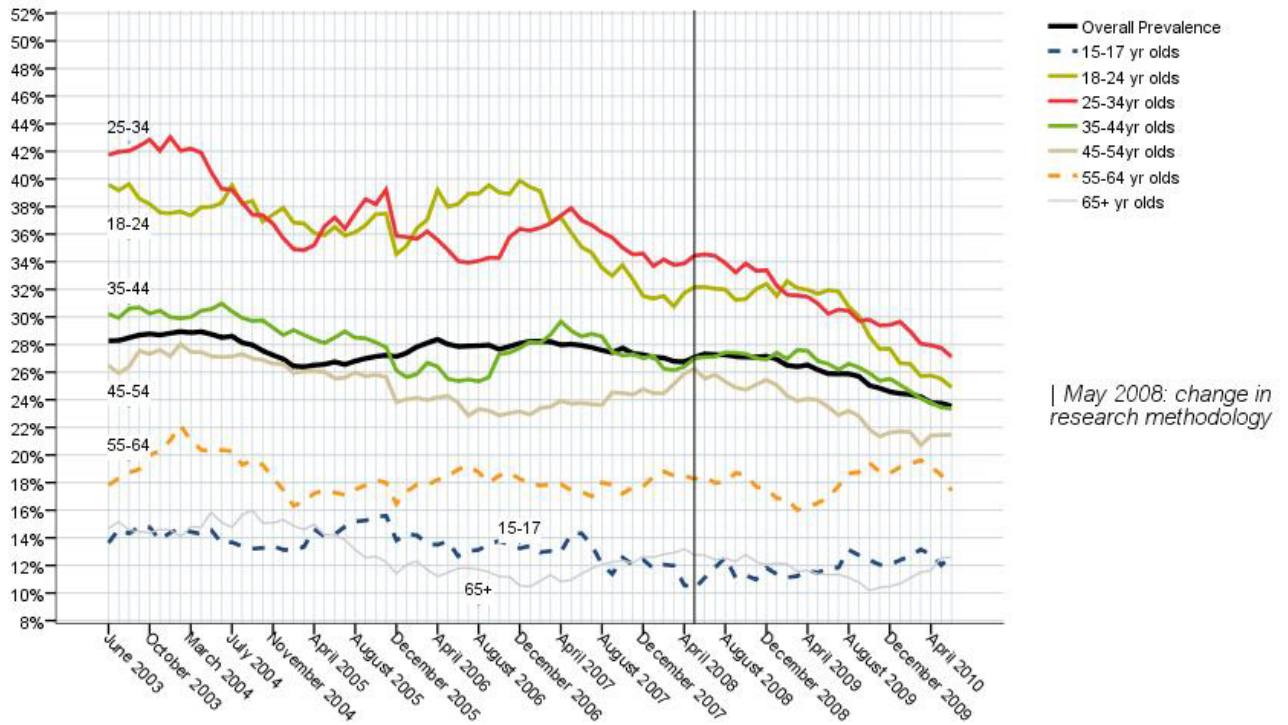
**Ireland**

Tobacco displays were only placed out of sight in Ireland from July 2009. It is clear from the graph below that general smoking prevalence has declined in Ireland in recent while smoking prevalence for 15-17 year olds is volatile. Any claim that smoking prevalence had increased in Ireland, either generally or among 15-19 year olds since the display ban came into force would require trend data for more than one year.

## Cigarette Smoking Prevalence by Age Group

Fig 2.2

12 month moving average trend ending June 2010



Source: website, Office of Tobacco Control, Ireland - <http://www.otc.ie/fig.asp?image=2010Charts/Fig2.2.jpg>

### Research Evidence: Impact of tobacco displays

The Committee asked for information on the research evidence relating to placing tobacco products out of sight in retail outlets and about the experience of other jurisdictions.

The Committee received and heard a considerable amount of evidence concerning the impact the proposed change might be expected to have on smoking prevalence and tobacco consumption. Several submitters objected that there was insufficient evidence to proceed because research cannot prove that the removal of tobacco displays from retail outlets will result in a reduction in smoking prevalence. There is an insistence that it is necessary to prove a causal relationship between removing tobacco displays and a decline in smoking prevalence before a policy change can be justified (eg, BAT and the paper by Jonathan Klick attached to its submission). This view is accompanied by criticism of the quality of the research which indicates that removing tobacco displays will help to address the tobacco problem and on the experience of overseas jurisdictions which have removed displays – for example, papers by Klick, Patrick Basham (Canada's ruinous tobacco display ban: economic and public health lessons IEA Discussion Paper No.29) and Jorge Padilla (*The effectiveness of display bans: the case of Iceland: A report for Philip Morris International*) - the last mentioned reports both attached to PMI's submission). In addition there are suggestions of an increase in illicit trade in tobacco as a result of a ban on retail displays.

The Ministry's view is that it is not necessary to prove an immediate cause and effect relationship between removing tobacco displays and a drop in smoking prevalence. To demand this level of evidence is to require something that is almost impossible to achieve. In most cases jurisdictions that have put tobacco out of sight have done so recently and the removal of tobacco displays is invariably not the only initiative these jurisdictions have taken to reduce smoking prevalence and tobacco consumption. Smoking prevalence rates have almost invariably declined in these jurisdictions but it is difficult to isolate the contribution display bans have made to this.

Moreover, the display ban is primarily aimed at reducing the long-term uptake of smoking among young people. It is unlikely to have a rapid impact on the smoking behaviour of addicted smokers, though there is evidence that it will assist those trying to quit and help to prevent relapse among those who have quit smoking. The Ministry's expectation, therefore, is that no sudden drop in smoking prevalence is to be expected. Rather, existing smokers will, by and large, continue to purchase their usual brands from their usual sources. However, the removal of prominent tobacco displays will help to make tobacco seem less 'normal'. As a result of the removal of tobacco displays, and with support from other components of the Government's tobacco control strategy, smoking prevalence will continue to fall as younger cohorts move through.

Recent research that specifically attempting to determine the impact of the ban on retail tobacco displays in Ireland after the ban had been in place for one year supports this contention. One paper (Evaluation of the removal of point-of-sale tobacco displays in Ireland - Ann McNeill, Sarah Lewis, Casey Quinn, Maurice Mulcahy, Luke Clancy, Gerard Hastings, Richard Edwards – *Tobacco Control* 2010) found that compliance with the law was very high and that recall of displays dropped significantly among adults and teenagers after the legislation came into force.

A related paper (Economic evaluation of the removal of tobacco promotional displays in Ireland Casey Quinn, Sarah Lewis, Richard Edwards, Ann McNeill – *Tobacco Control* 2010) observed no change in sales data in any retail category over and above seasonal patterns and an underlying downward trend over time. The paper concluded that the removal of point of sale displays is aimed at reducing the effects of tobacco advertising on children and is therefore likely to have an impact on sales over a much more protracted time period. This should enable retailers to adapt over time, perhaps using such regulations as an opportunity to play a role in promoting healthier products in the local community.

There is abundant research evidence about the effectiveness of tobacco advertising, of which tobacco displays are a part, in promoting tobacco use. The Smoke-free Environments Act 1990 (the Act) prohibited most forms of tobacco advertising, but exempted the display of products that were for sale inside retailers' premises. One response to this change has been a greater emphasis on in-store tobacco displays usually displayed prominently behind the counter, sometimes with large blocks or patterns of the same brand displayed to attract attention

The 2003 amendment to the Act partially addressed the problem by limiting the number of packs that could be displayed (to no more than two packs of each brand

variant and 100 packs of cigarettes and 40 of cartons). Presumably so that blocks of the same brand could continue to be displayed, there was an increase the number of brand variants - the same brand became available in different pack sizes or with minor variations. In New Zealand the number of brand variants available for sale increased from 134 in 1999, to 152 in 2002, to 184 in 2006, and to 213 in 2009. This emphasis on tobacco displays this suggests that they are seen as an effective means of promoting tobacco.

This view was supported by several who made submissions. Professor Janet Hoek, Department of Marketing, University of Otago, referred to the robust evidence base for removing tobacco displays, pointing, for example to research showing that the risk of experimentation increases as exposure to displays increases, and that displays impede and complicate quit attempts. In regard to there being no reliable evidence display removal will reduce smoking prevalence, she noted that marketers know visibility is key to sales success, that there is no logical reason why the removal of displays would not reduce smoking prevalence. She further noted that the causal evidence of a link between removing displays and smoking prevalence sought by some submitters cannot be provided until the intervention has been implemented and monitored over time.

The literature is well summarised by Drs Janine Paynter, ASH, NZ, and Richard Edwards, University of Otago, Wellington, who in 2009 published an article in the international journal *Nicotine & Tobacco Research* (Paynter, J, and Edwards, R,: The impact of tobacco promotion at the point of sale: A systematic review, *Nicotine and Tobacco Research*, 2009 11 (1) 25-35) which reviewed the evidence that point of sale tobacco promotion influences key smoking-related behaviours and beliefs, increases susceptibility to smoking in youth, undermines smokers' quit attempts, and promotes relapse among ex-smokers. They considered twelve frequently cited peer reviewed studies, ten of which were focused on children.

The results from experimental studies were consistent with the cross-sectional and longitudinal studies in children, showing significant association between smoking initiation and tobacco at point of sale. Although acknowledging the limitations of the evidence, for example in meeting the criteria for causality, the authors conclude that given the addictiveness of tobacco, the severity of the health hazards posed by smoking, the evidence that tobacco promotion encourages children to start smoking, and the consistency of the evidence that point of sale promotion influences children's smoking, ample justification exists for banning point of sale advertising and displays of smoked tobacco products.

A list of research papers is available if required.

### **Illicit Trade and the closure of retail outlets**

Some submitters suggested that placing tobacco products out of sight would encourage illicit trade in tobacco and cause closures of retail outlets.

The Ministry looked closely at the illicit trade issue last year when the issue of raising the tobacco excise was considered. Illicit trade was raised as a potential problem and appropriate steps were taken to monitor the situation. It may be too early to

draw conclusions, but nothing has been brought to the Ministry's attention to date to suggest the tobacco excise increases on 28 April 2010 and 1 January 2011 have caused any change in illicit trade to date. Compared with the potential impact of the tobacco excise increase the risk of an increase in illicit trade resulting from the removal of tobacco displays seems minor.

The information regarding the closure of tobacco retail outlets is mainly based on Canada's experience, but the illicit trade problem in Canada results from particular circumstances there which do not apply in New Zealand. The main cause in the decline in retail outlets is generally attributed to contraband tobacco (which is a particular problem in parts of Canada) rising sales taxes and higher credit card fees. Retail displays don't always rate a mention.