PHILIP MORRIS
LIMITED

PHILIP MORRIS LIMITED'S SUBMISSION TO THE NATIONAL PREVENTATIVE HEALTH TASKFORCE CONSULTATION:

AUSTRALIA: THE HEALTHIEST COUNTRY BY 2020

2 January 2009

Executive summary

Reducing the harm caused by tobacco use is an important part of achieving the National Preventative Health Taskforce's (NPHT) vision of Australia as the healthiest country in the world by 2020. But despite the Second Technical Report's title of *Making Smoking History*, the NPHT recognises that tobacco use will not be "history" in 2020. Today, over 3 million Australians use tobacco products; in the future, it is estimated that more than 2 million will, even if NPHT's proposed target of reducing smoking prevalence to 9% is achieved.

Governments and the public health community should pursue tobacco control measures that are based on the principle of reducing the harm caused by tobacco use. Australia has already seen smoking prevalence cut in half over the last twenty years. As a business, we believe smoking prevalence will continue to decline, as do many in the public health community.*

Even if smoking prevalence continues to decline, Philip Morris Limited can continue to operate successfully within a highly regulated environment by competing for a share of the existing market of adult consumers who use tobacco products.

While we support regulation of the industry, we have strong concerns about some of the recommendations contained in the Technical Report – such as plain packaging and point of sale display bans, which are unnecessary, unproven, and unlawful, and excessive taxation.

It is clear that some of the proposed measures proposed will significantly reduce our ability to compete for a share of the existing adult smoker market, violating competition principles whilst not contributing to public health. Such measures are not based on sound evidence, are neither effective nor appropriate, and, at bottom. are nothing more than efforts to de-legitimise the sale and use of tobacco products – in effect, implementing prohibition through regulation.

It is disappointing that the NPHT does not feel that the industry they seek to regulate can contribute to the development of that regulation. We strongly disagree with this view. Regulation of any industry is best achieved through a collaborative, consultative approach with all stakeholders. This results in regulation that is effective, enforceable, and with minimal unintended, negative consequences.

Consultation will be particularly important for developing tobacco product regulations, an area recognised by the NPHT as having a role to play in reducing harm for those adults who continue to smoke. It recommends "*introduc[ing] legislation that gives the government powers to ban, specify or mandate any particular tobacco product constituents, emissions, additives or other aspects of manufacture and design*."

We support the establishment of science-based standards for tobacco products to reduce harm and we recommend several specific regulatory steps to reach that objective.

The NPHT itself acknowledges that Australians will continue to smoke in 2020; in fact, its goal of 9% smoking prevalence assumes this. The question therefore, is

not *whether* there will be to a tobacco industry in 2020, but rather *what kind* of industry should be present. We look forward to working with the Australian Government and the public health community to answer that question.

Philip Morris Limited
Moorabbin, Victoria
2 January 2009

[*] For example, S Chapman, *Public Health Advocacy and Tobacco Control: Making Smoking History* (2007), p. 200.

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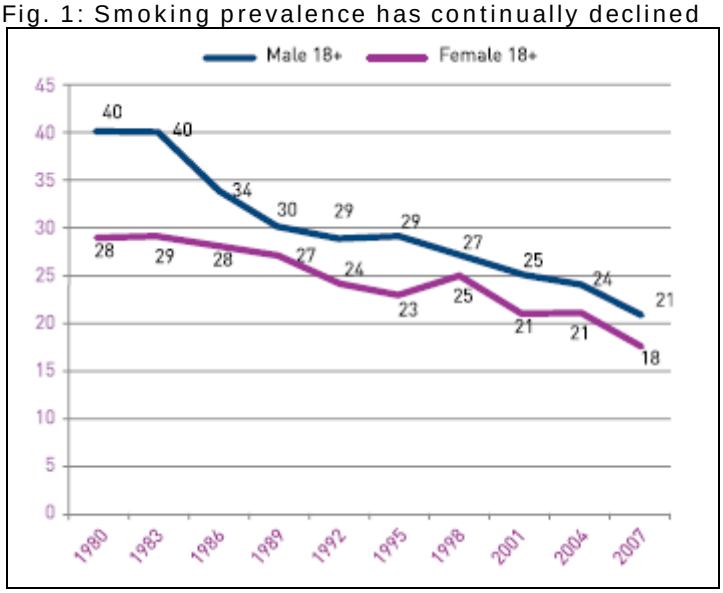
1 Introduction

The National Preventative Health Taskforce (NPHT) establishes a vision of Australia as the healthiest country in the world by 2020.[1] Philip Morris Limited (PML), the nation's second-largest tobacco company and an affiliate of Philip Morris International (PMI), the world's leading international tobacco company, is pleased to provide its views and evidence so that the Government can better consider the NPHT's proposed strategies and implement effective regulation.

The NPHT's stated objective is to reduce adult smoking prevalence in all communities to the same level as that in California: 9%.

Australia has one of the lowest smoking rates in the world. Smoking prevalence has been declining consistently for decades, as illustrated in *Figure 1*, taken from the Technical Report.

Fig. 1: Smoking prevalence has continually declined



Source: Technical Report at 6, Figure 5 (full citations contained therein)

The NHPT proposes a range of regulatory and non-regulatory measures to accelerate that decline: media campaigns to encourage people to quit smoking; a drastic increase in tobacco excise tax; mandating plain packaging of tobacco products; enlarging graphic health warnings; prohibiting retailers from displaying the tobacco products they sell; and regulating tobacco products.

[1] *Australia: the Healthiest Country By 2020* (the Discussion Paper) is accompanied by three technical reports, including Technical Report No. 2, *Tobacco Control in Australia: Making Smoking History* (the Technical Report). The Technical Report was prepared for the National Preventative Health Taskforce (NPHT) by the Tobacco Working Group (TWG).

HOW DID CALIFORNIA DO IT?

The Technical Report cites California as a model to emulate: "*In California … the prevalence of daily smoking is already less than 9%. It should be feasible for Australia to achieve a reduction in smoking similar to that achieved in California.*"[2]

So how did California do it?

Not through excise tax increases. The excise tax on cigarettes purchased in California is less than half that of Australia's current tax: equivalent to less than 10 Australian cents per cigarette. The excise tax *increase* proposed by the Technical Report is almost as great as total excise incidence in California.[3]

In fact, a majority of California voters rejected a similar excise tax increase proposal because it was excessive and unfair. California voters rejected a proposed tobacco excise increase of US$2.60 per pack. Voters expressed concerns that the proposed tax increase was too high and would disproportionately impact working families. A polling analyst summed it up: "*I think there's an element of fairness that's operating against it ... I think people recognize the disincentiveness (for smoking), but it's also about fairness. Is it too much? Is this too onerous a tax?*"[4]

Not through prohibitive pricing. The price equivalent of a packet of 30 mid-priced cigarettes is nearly 25% less than comparable cigarettes in Australia.[5]

Not by mandating plain packaging. California, like all US states, has federally-mandated text-only, side-of pack health warnings.

Not by display bans or "modernised" bans on advertising. California still allows adults who smoke to see and select from among the brands they prefer, and still allow manufacturers and retailers to communicate with them through a variety of restricted means.

The Technical Report notes that California "*led the way in the US with a well-funded media campaign commencing in 1988 and a strong push towards smoke-free environments.*"[6] Indeed, California dedicates a portion of all tobacco excise tax revenues to smoking prevention campaigns.

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[2] Technical Report, p. 3. California's current smoking prevalence, defined by the Technical Report as including daily as well as weekly smokers, is 14.3%. See Technical Report, p. 3, footnote 5 and source cited there.

[3] Annex 1 compares Australian tax and price levels with those in California, and provides exchange rate and other assumptions upon which these calculations are based.

[4] MK Hong et al., *Tobacco Control in California 2003-2007: Missed Opportunities*, Paper CA2007, Center for Tobacco Control Research and Education, University of California, San Francisco, 2007, pp. 81-98 (quoting Field Poll analyst Mark DiCamillo on p. 94).

[5] Pack of 20 *Basic* brand cigarettes, converted into Australian dollar equivalent of 30 cigarette pack. *Source*: telephone call on 15 December 2008 to *Vons Sunset Vista Supermarket*, 2511 Daly Street, Los Angeles, CA 90031, tel. (+1 323) 662-8107. See Annex 1 for methodology.

[6] Technical Report, p. 2.

1.1 PML supports the proposal to use education and media campaigns to reduce smoking prevalence

Education and media campaigns have been a central component of Australian tobacco control policy. States have committed "*unprecedented budgets*" to media campaigns encouraging smokers to quit and discouraging non-smokers from starting.[7] Australian governments have consistently stated that media campaigns are a "*successful approach*"[8] for reducing smoking prevalence[9] and preventing youth smoking.[10]

PML supports the use of education to reduce smoking prevalence, and believes the Government should consider allocating a portion of tobacco excise revenues to fund those initiatives.[11]

1.2 Regulation should be adopted following accepted "best practice regulation" principles

The Government has committed to adopting laws or fiscal measures only if they are necessary, proven effective, and are proportionate.[12] The Australian Government's *Best Practice Regulation Handbook* establishes key principles of best regulatory practice:

- "*Not acting to address 'problems' until a case for action has been clearly established*"
- Identifying *"a range of feasible policy options (including self-regulatory and co-regulatory approaches)*" and assessing "*their benefits and costs (including compliance costs)*"
- Adopting *"[o]nly the option that generates the greatest net benefit for the community, taking into account all the impacts*".[13]

When governments follow good governance principles, "*the community and business sector can have confidence that the decisions made by the Government in relation to regulation will contribute to improved living standards.*"[14] The converse is equally true: When the principles are not followed, business confidence is shaken and Australians are ill-served by the people elected to represent them.

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[7] S Chapman, Public Health Advocacy and Tobacco Control: Making Smoking History (2007), p. 200.

[8] New South Wales Government media release, *Graphic Anti-Smoking Ads Turning Teens Off Cigarettes*, 8 February 2008; South Australia Government media release, *Hard-hitting quit campaign to reach parents*, 2 January 2009.

[9] See, for example, Victorian Government media release, *Tobacco Reforms Help Reduce Number of Smokers*, 14 January 2008.

[10] See, for example, NSW Government media release, *Graphic Anti-Smoking Ads Turning Teens Off Cigarettes*, 8 February 2008.

[11] We do not support media campaigns designed to demonise tobacco companies or smokers.

[12] Australian Government, *Best Practice Regulation Handbook*, Canberra, 2007, pp. 2-3.

[13] Ibid., pp. 3-4.

[14] Government of Victoria, Department of Treasury and Finance, *Victorian Guide to Regulation*, Melbourne, 2007, p. i.

The Government should apply those principles as it considers regulatory options to reduce the harm caused by tobacco products.

1.2.1 Australia has passed the limit of the ability of regulations on tobacco advertising, marketing, sales and public smoking to advance health objectives

Tobacco regulations in Australia are among the most extensive in the world. For example:

- All tobacco advertising, and all use of tobacco trademarks other than on packages and products, has been prohibited since 1992.[15]

- Tobacco packages are mandated to carry health warnings that cover more of the principal pack facings than the manufacturer's trademark and brand logos– the largest warnings in the world, and well in excess of global treaty requirements.[16]

- Smoking is (or will be) prohibited in bars, restaurants and nightclubs– as well as other indoor workplaces – in every State and Territory. A number of jurisdictions have prohibited smoking in some *outdoor* areas.

- Retail display of tobacco products is restricted in size and location in every State and Territory. A number of them will prohibit displays altogether.[17]

- Tax represents the majority of the price of a pack of cigarettes, and tax rates increase twice each year in line with inflation. The approach has been recognised as a best practice by the World Health Organization.[18]

A tobacco control expert recently expressed the view that in such highly regulated countries, *there are limits in the ability of further regulations to advance public health objectives*.[19] He suggested that in such countries, some tobacco control advocates appeared to be "*lobbying for impractical [regulatory] goals based on an ideological view of appropriate interventions rather than a pragmatic public health orientation*", and expressed the concern that "*existing regulatory measures, such as blanket advertising bans, graphic package warnings, or industry de-normalization, have come to be seen as an end in themselves rather than as a means of achieving improved public health*."[20]

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[15] *Tobacco Advertising Prohibition Act 1992* (Cth). The Act's prohibitions are so extreme that it required specific amendments to the Act to allow tobacco companies to have business cards, be listed in the telephone book, and issue product recall notices (which obviously require publication of a tobacco product brand name). State and Territory laws prohibit advertising within points of sale. Proposals to expand that prohibition are discussed in Section 7.

[16] *Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2006* (Cth). Proposals to require larger warnings and eliminate all other pack information are discussed in Section 4.

[17] The proposal to require a national ban on retail display of tobacco products is discussed in Section 5.

[18] We discuss the proposal to drastically increase tobacco excise tax rates in Section 2.

[19] D Sweanor, "A Canadian's Perspective: Limits of Tobacco Regulation", *William Mitchell Law Review*, vol. 34, no. 4, 2008, pp. 1595-1604, 1595 (emphasis added).

[20] Ibid.

That seems to describe Australia's current regulatory environment and a number of the regulatory measures proposed by the NPHT. PML supports regulation to reduce the harm caused by tobacco products, but regulation should not be designed to prevent adults from buying and using tobacco products. Nor should it deprive consumers of receiving information about tobacco products or manufacturers and retailers of their ability to compete. And keeping regulation "*on the political agenda*,"[21] as the Technical Report puts it, should not be a goal in itself.

1.2.2 Tobacco products themselves are not regulated, and they should be

While marketing, packaging, sales and use are strictly regulated, tobacco products themselves are not regulated. One Australian expert remarked that "*it is bizarre that no regulations at all are applied to the product or its emissions*."[22] We support empowering the Government to establish science-based standards for tobacco products to reduce harm. In Section 6, we recommend several specific regulatory steps to reach that objective.

1.3 Meaningful consultation results in better policy

Australian good governance principles recognise that meaningful consultation is essential for good policy:

> "*[C]onsultation ensures that both the regulator and the regulated have a good understanding of the problem, alternative options to address it, potential administrative and compliance mechanisms, and associated benefits, costs and risks. Lack of consultation can lead to regulation that is inappropriate to the circumstances, costly to comply with and poorly adhered to.*"[23]

While the Discussion Paper says that "*business and industry both have important roles to play for obesity and alcohol*",[24] tobacco retailers, PML and every other organisation that makes money from tobacco products are collectively dismissed as "*road blocks to progress*" which will "*do everything in their power to discredit or dilute prevention programs*."[25]

A number of proposals in the Discussion Paper and Technical Report reflect that bias.

The Technical Report often presents one side of the facts and ignores conflicting evidence. For example, a TWG member-written study is characterised as "strong evidence" of the effectiveness of retail display bans, but the Report omits real-world evidence which shows that bans have had no concrete effect on smoking prevalence.

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[21] Technical Report, p. 11.

[22] NJ Gray, "The modern cigarette, an unregulated disaster", *Medical Journal of Australia*, vol. 187, no. 9, 5 November 2007, pp. 502-03.

[23] *Best Practice Regulation Handbook*, p. 4.

[24] Discussion Paper, p. 6.

[25] Discussion Paper, p. xi.

Other areas are glossed over without any analysis. For example, the Technical Report devotes a *single sentence* to assessing the costs of the regulatory changes it advocates: "*Many of the measures required over the next decade would be almost cost-free to government*." There is no estimation of costs to consumers or businesses. Similarly, the Technical Report recommends an immediate 29.5% increase in the tobacco excise tax, yet does not provide any estimate of the effect on revenues, smoking prevalence, or illicit trade.

Consultation is not a favour; it isn't advocacy; and it doesn't mean consulting only with those with whom the consulters agree. Broad, transparent consultation is the best way – indeed, the only way – to scrutinise policy proposals and make sure that good ideas are not left behind.

2 Australia's current excise tax system is a global best practice and should be maintained

Tobacco excise policy is an integral part of the Government's comprehensive tobacco control program. In Australia, fiscal measures, together with a range of other regulatory measures, have contributed to a significant, consistent decline in tobacco use.

WHAT'S PROPOSED?
An immediate 29.5% increase in tobacco excise tax, which would take the recommended retail price of a pack of 30 cigarettes from $13.50 to $15.98.* At an undefined point, the Technical Report suggests the Government use tax to guarantee retail prices at $20.00 a pack or higher.

PML'S VIEW: Australia's current system is a world best practice, proven effective at reducing demand, increasing revenues and minimising consequences that are contrary to public health goals. It should be maintained. Sudden and steep increases in excise tax with the objective of making cigarette prices prohibitive is likely to lead to consumer downtrading to cheaper cigarettes and illicit products, neither of which advances public health or revenue objectives.

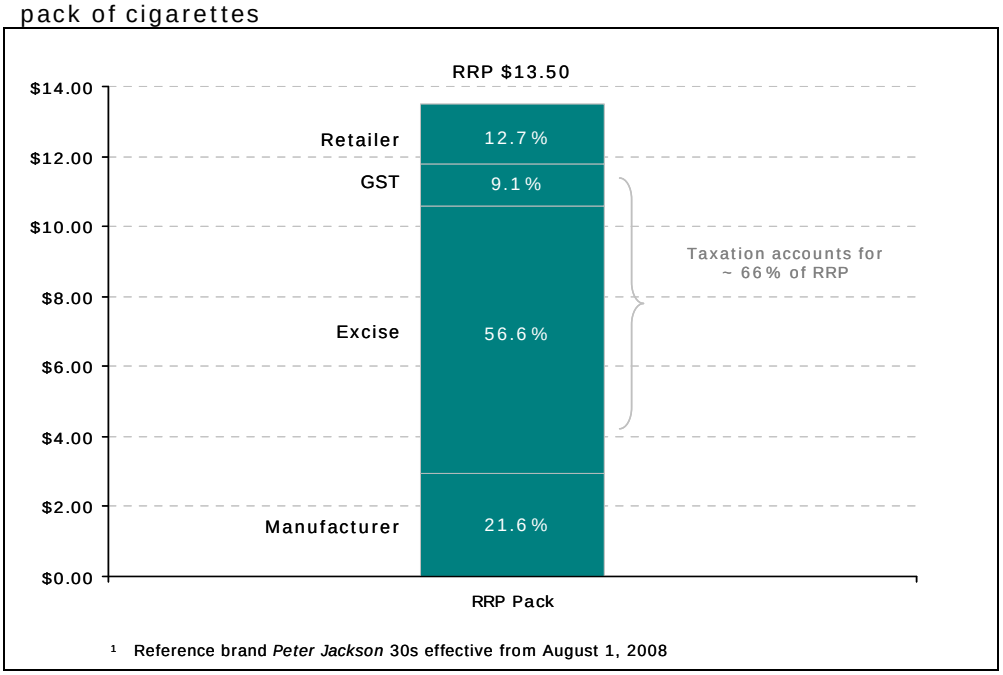
*assuming tax fully passed on and no other wholesale or retail price increases

2.1 Australia's current tax system has raised revenue and discouraged smoking

In November 1999, the Australian Government implemented a unit-specific taxation system for machine-made cigarettes. Today, every cigarette is subject to 25.450 cents excise tax – or $7.635 for a pack of 30 cigarettes.[26] The federal Government makes more money from cigarette sales than all members of the Australian tobacco industry combined, as illustrated in *Figure 2*.

[26] The current excise rate for cigarettes less than 0.8 grams is $0.25454 per cigarette. Excise on other tobacco products, such as loose tobacco for hand-rolling, is set at an equivalent rate. Imported cigarettes pay equivalent levels of import duties.

Fig. 2: Government share of the recommended retail price of a pack of cigarettes



Source: PML estimates, Australian Tax Office

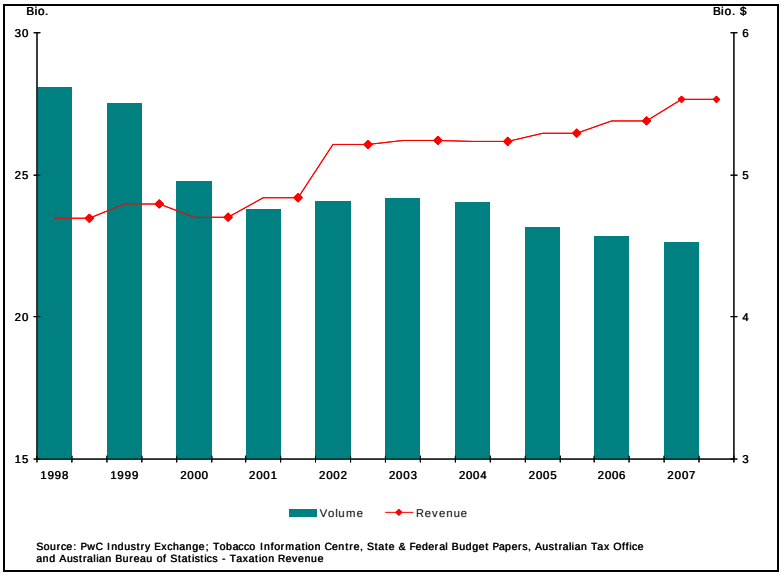
Since 1999, excise tax has increased twice each year in line with inflation. (If inflation is negative, excise does not decrease.) Because GST is owed on tobacco excise, inflation-based excise increases have gradually ratcheted up the real dollars a consumer spends on tax for tobacco products. In 2007-08, the federal government collected $5.53 billion in tobacco excise revenue; it projects that will increase to $5.55 billion in the current fiscal year.[27]

Under its current approach, Australia's cigarette excise tax level has increased by 35% since November 1999. *Figure 3* illustrates that, under that approach, tobacco excise revenue increased by 18% while industry sales volumes have declined by 18%.[28]

[27] Australian Government Budget 2008-09, Budget Paper No. 1, Statement 5 – Revenue – Revenue estimates by revenue head, Table 6: Australian Government general government revenue.

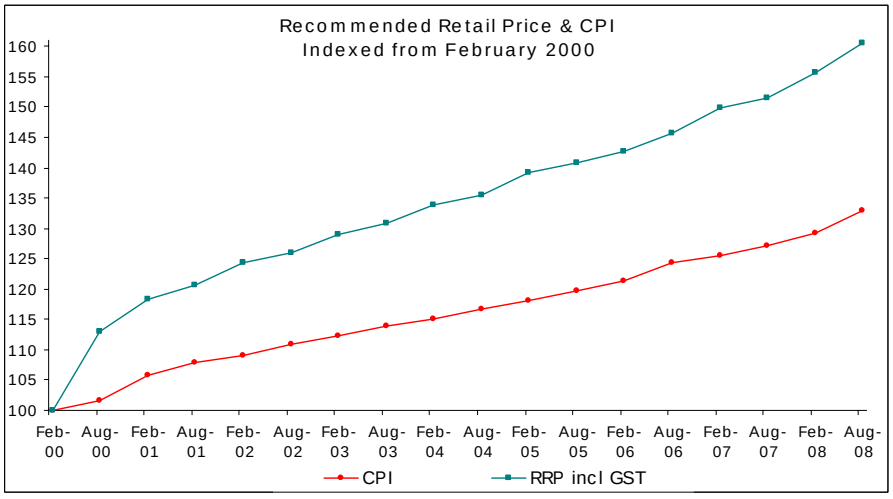
[28] The cigarette volume decline of 18% is from 1999 to 2007, while excise revenue and excise rate increases represent the period from 1999 to 2008. Full year cigarette volume figures for 2008 will not be available until January 2009.

Fig. 3: Excise revenue increases while industry sales volume declines



The Technical Report observes that "*cigarettes in Australia are less costly than they are in many other countries*."[29] Although that partly reflects different costs of living in those countries and a falling Australian dollar, the recommended retail price of *Peter Jackson* 30's has increased by 60% since 2000, significantly above the inflation rate.[30] *Figure 4* illustrates that point.

Fig. 4: The real recommended retail price of cigarettes has significantly increased



The Technical Report itself establishes that the real costliness of cigarettes to consumers (as measured by the minutes worked per week in order to pay for a packet of cigarettes) has tripled in Australia over the last twenty-five years, as illustrated by *Figure 5*.

[29] Technical Report, p. 13.

[30] Although excise tax and GST have played an important part in those increases, other factors (such as increasing production and input costs and competitive pricing decisions) also play a role.

Fig. 5: The real costliness of cigarettes has tripled since 1983

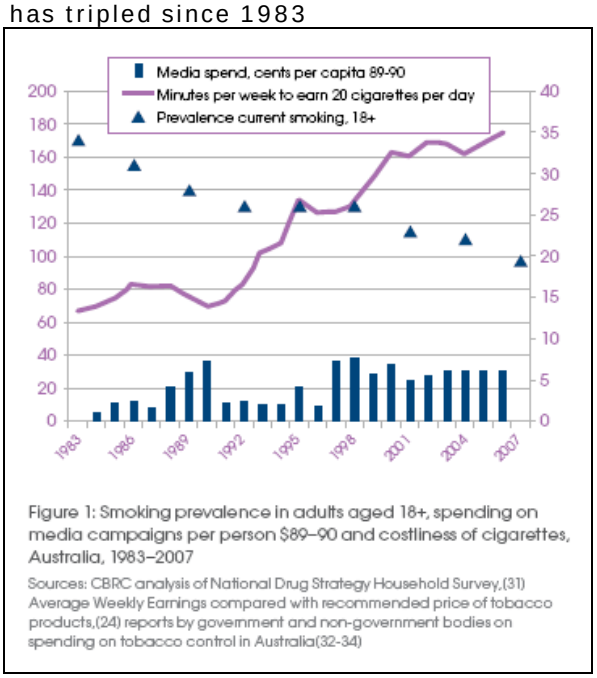


Figure 1: Smoking prevalence in adults aged 18+, spending on media campaigns per person $89–90 and costliness of cigarettes, Australia, 1983–2007

Sources: CBRC analysis of National Drug Strategy Household Survey,(31) Average Weekly Earnings compared with recommended price of tobacco products,(24) reports by government and non-government bodies on spending on tobacco control in Australia(32-34)

Source: Technical Report at 2

The WHO includes Australia's system as an "international best practice" on its tobacco control website, and uses a document written by the Technical Report's author to make its case.[31] There is no reason to change the current tax system and policy of tax increases in line with inflation.

2.2 The NPHT proposes immediately implementing a drastic tobacco excise tax increase

The Technical Report recommends "*increas[ing] excise and customs duty on tobacco to discourage smoking and to provide funding for prevention activities…*"[32] It proposes an immediate increase of 7.5 cents per cigarette, a 29.5% increase over the current excise tax. Assuming manufacturers and retailers do nothing more than pass on that excise tax increase, the recommended retail price of a pack of 30 *Peter Jackson* cigarettes would increase from $13.50 to $15.98, of which the government share would be $11.34.[33]

Later, "*once effective measures are in place*", the Technical Report recommends using excise increases to ensure a minimum price of $20 per packet and increasing tax in subsequent years by a minimum of 5% above the Consumer Price Index.[34] Exactly such a policy led to a significant illicit trade problem in the UK. Although the UK's policy has long since been reversed, its consequences are still felt today, and the UK has one of Europe's highest levels of illicit trade.

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[31] See WHO Tobacco Free Initiative, *Taxation: success stories and lessons learnt*, http://www.who.int/tobacco/training/success_stories/taxation/en/index.html, citing and linking to M Scollo and R Borland, "Taxation reform as a component of tobacco control policy in Australia".

[32] Technical Report, p. vii.

[33] By definition, such an excise increase would be inflationary, since tobacco products constitute 2.27% of the Australian Consumer Price Index.

[34] Technical Report, p. 15

2.3 A tobacco excise tax increase is not necessary to fund smoking prevention initiatives

The Technical Report suggests that the 29.5% increase in tobacco excise tax is needed "*to provide funding for prevention activities*."[35] We disagree. The sole measure for which the Technical Report estimates any cost is $40 million for media campaigns, which represents less than three-quarters of 1% of current tobacco excise revenue. Even if additional funds were needed, they could be obtained from current tobacco excise revenues. However, the Technical Report does not indicate current tobacco excise revenues, nor discuss their current allocation, nor provide any evidence of a revenue shortfall. The Technical Report and the Discussion Paper simply do not demonstrate a fiscal need for the proposed departure from Australia's current tax system – an essential element of a Best Practice case for regulation.

2.4 Increasing excise taxes in order to make cigarettes unaffordable to adult smokers is a form of prohibition and will lead to unintended consequences

We support excise taxes as an appropriate part of the government's fiscal strategy to address both public health and revenue objectives. However, we do not support excessive taxes that are intended to make cigarettes unaffordable to adult consumers. Doing so is a form of prohibition and, as described below, is likely to lead to unintended consequences.

2.5 Tax-driven price increases can lead consumers to switch to cheaper tobacco products, which undermines public health objectives.

Even tobacco excise tax increases that are more moderate than what is proposed by the NPHT can lead consumers to substitute to cheaper products instead of quitting. Any tax policy which encourages such a shift in demand does not advance legitimate public health policy objectives.

For example, from 1997 until 2000, the United Kingdom increased excise by inflation plus 5%.[36] Consumers responded by shifting to cheaper brands and cheaper tobacco products. In 2004, the United Kingdom's Chief Medical Officer explained:

> "*The duty-paid market in the UK has also seen a real change since 1997. As price has increased, a new market in ultra-low and low/economy-price cigarettes has expanded. The ultra-low price share of the cigarette market increased from 15% in 1997 to 35% in 2004; the low-price share rose from 15% to 22%. Rather than quitting in the face of price rises, smokers had an alternative route to maintain their addiction without paying more. They could also trade down to hand-rolling tobacco. This expansion in ultra-low/economy-price brands again dents the health impact made by price rises.*"[37]

[35] Technical Report, p. vii.

[36] United Kingdom Chancellor Budget Speeches, 17 March 1998, 9 March 1999 and 21 March 2000.

[37] United Kingdom Department of Health, Annual Report of the Chief Medical Officer 2004 on the State of Public Health: Tobacco and Borders - Death Made Cheaper, p. 18.

A similar phenomenon occurred in Singapore: Tax-driven price increases led to the proliferation of low-priced brands and lower-than-anticipated reductions in consumption.[38]

Canada, too, has seen the proliferation of low-priced brands as tax rates have risen. That country's most recent report to the FCTC Conference of Parties remarked that *"[a]lthough 'discount' brands are available (in some cases for as little as $7 per pack) in all provinces and territories, and their popularity is rapidly growing, the top selling products remain the premium brand products. However it is noteworthy that price discounted 'value brands' currently account for 44% of Canadian cigarette sales."*[39]

Australian consumers faced with a tax-driven price increase would have the option of switching to lower-priced brands as well: There is a 9.4% price gap between the recommended retail price of *Peter Jackson* 30's and the recommended retail price of an equivalent pack size in a leading low-cost brand, *Brandon*.[40] This amounts to a $1.28 price gap per pack. Many adult smokers have already changed to lower priced brands as a result of the high cost of tobacco products: The share of market held by low-priced brands has increased from 1.68% in 2004; to 4.57% in 2007; and 6.18% in 2008.[41]

There would be no public health benefit to an excise increase which leads adult smokers to choose cheaper brands. From a fiscal perspective, the impact on excise tax revenue would be neutral, with a potential decline in GST revenues.

2.6 Higher excise tax increases are likely to encourage illicit trade, which does not advance health objectives and harms society

The NPHT acknowledges that effective measures need to be in place before drastically increasing the price of cigarettes, but fundamentally fails to acknowledge that its proposed short-term 29.5% increase in excise is a dramatic one which can encourage the illicit trade in tobacco products.

2.6.1 The last time Australia increased excise tax as significantly as the Technical Report's "modest proposal", the trade in illicit tobacco products flourished with no real decline in prevalence

The Technical Report states that "*a sharp increase in the costliness of cigarettes between November 1999 and February 2001, following government reforms to excise duty, was followed by a sharp drop in consumption*."[42]

While *tax-paid* consumption decreased during that period, illicit trade increased. When the tobacco excise increase was implemented in 2001, "*smuggling [was] not believed to be a major issue"* and "*chop-chop*", tax-evading rolling tobacco, *"appears to be used mainly by the very poor*."[43] By 2002, the situation had

[38] See, for example, "Cheap puff invasion," (Singapore) *Straits Times*, 28 February 2005.

[39] WHO Framework Convention on Tobacco Control Party Report, Canada, p. 15.

[40] PriceWaterhouseCoopers Industry Exchange, August 2008.

[41] Ibid.

[42] Technical Report, p. 14.

[43] Scollo & Borland, p. 3.

dramatically changed: the Commissioner of Taxation noted the "*proliferation of chop-chop in Australian markets as a major risk to revenue*"[44]. An ATO-commissioned report at the time attributed between $99 million and $450 million in excise loss to the illicit sale of chop-chop[45].

2.6.2 Countries the Technical Report cites as "best practice" have struggled with illicit trade – and are holding tax levels down

Increases in excise tax levels beyond the inflation rate can result in lost revenue without corresponding declines in tobacco product consumption. That has already happened in the UK, Singapore, and Canada.

The UK

The United Kingdom increased excise taxes by 5% above inflation from 1997 through 2000 in order to reduce tobacco consumption and to increase revenues. While many adult smokers turned to lower priced tobacco products, some consumers also purchased non-United Kingdom duty paid products and revenue gains were not realised. When the United Kingdom reverted to increasing tobacco excise in line with inflation, the problem stabilised. The World Health Organisation's European Region Report described the situation:

> *"By 1999, the revenue lost through tobacco smuggling was estimated to be about 25% of all tobacco revenue. In March 2000, the [UK] Government announced a strategy to tackle the smuggling problem ... Taxes were increased by 5% above inflation in 2000 and in line with inflation in 2001 and 2002. Since then tobacco smuggling has been stabilised and its growth reversed for the first time in a decade; Government revenues rose again after late 2000.*"[46]

The UK has continued to annually increase tobacco excise tax in line with inflation in all Budgets since. This approach, coupled with specific measures to reduce illicit trade, is yielding results. In March 2006 UK Treasury reported that since the introduction of the *Tackling Tobacco Smuggling Strategy*, the size of the illicit cigarette trade was down by almost a quarter.[47] Nevertheless, the consequences of the UK's previous approach are still felt years later, as the UK remains one of the countries in Europe with the highest share of illicit trade.[48] One in six cigarettes smoked in the UK is illicit. This translates into approximately 9.5 billion cigarettes every year which evade detection at the country's borders.[49]

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[44] Australian Taxation Office, *Commissioner of Taxation Annual Report 2001-02*, p. 164.

[45] Ibid., p. 165.

[46] World Health Organization European Region, *Taxation of tobacco products in the WHO European Region: practices and challenges*, 2004, p. 16.

[47] [UK] HM Treasury, *New responses to new challenges: reinforcing the tackling tobacco smuggling strategy*, HM Revenue and Customs, March 2006, p. 11.

[48] The UK Department of Health recently acknowledged that "*the UK market is still characterised by high levels of illicit tobacco use*." [UK] Department of Health, *Public Consultation on the Future of Tobacco Control*, 31 May 2008, p. 21.

[49] *Project Star*, a KPMG study to quantify the levels of contraband and counterfeit cigarettes across the European Union conducted under the Agreement between the European Community and Philip Morris International, estimated total cigarette consumption in the UK for 2007 at 59.4 billion cigarettes. Although the UK is not a party to the Agreement the study includes the UK.

Singapore

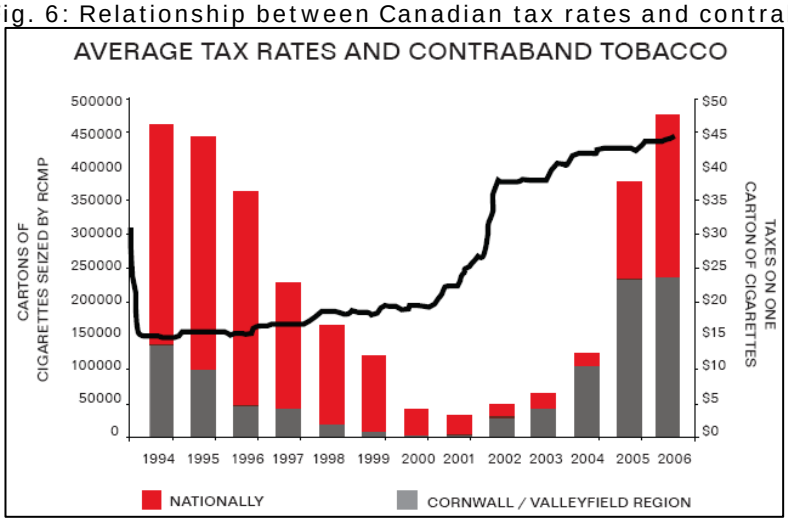
Excise tax increases also led to unintended consequences in Singapore. From 1999 to 2005, the Singapore government increased excise tax on cigarettes by over 190%. Despite those significant increases, excise revenue did not increase as the government anticipated, and actually declined between 2004 and 2005.[50] Singapore government budget papers show that the government anticipated S$942 million in tobacco excise revenue during 2005, the actual revenue collected fell short by S$230 million.[51] That was due, in part, to the fact that the increases generated greater demand for illicit tobacco.[52] The Singapore government decided *not* to increase tobacco excise tax in 2006. The Finance Minister, Lee Hsien Loong, explained the rationale in his 2006 Budget Speech:

> "*I seriously considered raising tobacco duties, but have reluctantly decided against it because we are already seeing revenues declining, not because people are smoking less but because smuggling has gone up.*"[53]

Canada

Canada, too, has seen tobacco taxes reach the levels where the price gap between illicit products and legal, tax-paid cigarettes is so large that any increases in excise taxes will be unlikely to reduce consumption nor increase revenues. The Royal Canadian Mounted Police (RCMP), the Canadian counterpart to the Australian Customs Service (ACS), have observed a close relationship between increased tax rates and increased levels of illicit trade, as illustrated in *Figure 6*.

Fig. 6: Relationship between Canadian tax rates and contraband



Source: Royal Canadian Mounted Police, 2008 Contraband Tobacco Enforcement Strategy, p. 8.

[50] Singapore Budget Highlights Financial Year 2006/2007, Appendix 7.1 "Total Estimated Receipts for FY2006 by Object Class", p. 33, and "Total Estimated Receipts for FY2007 by Object Class," Revenue and Expenditure Estimates, Summary Tables of Revenue and Expenditure Estimates, p. 1.

[51] Ibid.

[52] Singapore Immigration & Checkpoints Authority and Singapore Customs figures from 1999 to 2005. See, for example, Singapore Immigration & Checkpoints Authority, "Bad News For Contraband Smugglers," Press Release, 8 February 2006. Also see the series of Singapore Customs press releases on actions against the illicit tobacco trade at http://www.customs.gov.sg/topNav/new/Offence+Highlights.htm

[53] Singapore Budget Speech 2006, pp. 16-17.

The RCMP explained that tax levels were the *primary driving force* behind tobacco smuggling in Canada:

> "*Tax evasion has traditionally been the primary driving force behind tobacco smuggling operations. The difference in price between contraband and legal tobacco products allows for a significant profit to be made. Simply put, organized crime involvement in the contraband tobacco market is driven by greed*."[54]

The result, in their words, is a vast "underground economy":

> "*Illicit sales of contraband tobacco contribute to an underground economy worth hundreds of millions of dollars. Traditionally seen as a victimless crime, tobacco trafficking is now regarded as a significant source of income for all levels of organized crime, who reinvest the substantial profits to support other criminal activities. The linkages between the illicit tobacco market and organized crime have increased exponentially over the last six years. While tobacco is a legal substance that is consumed by approximately 5 million Canadians, a growing number are purchasing contraband tobacco without realizing the negative impact it is having on Canadian communities and Canada's economic integrity*."[55]

One Canadian tobacco control advocate concluded that excise tax has reached its limit as an effective mechanism for tobacco control in Canada:

> "*An example of this can be seen in relation to tax policy. Canada was able to dramatically increase the price of cigarettes, in part because the price had been so low. Tripling real prices has a tremendous dampening effect on consumption, but tripling prices again is nearly impossible. Among other issues facing Canada, there is now a significant contraband market … The presence of these alternative, untaxed sources of supply clearly limit the pursuit of policies that are aimed at making tobacco products less available to smokers through further tax increases*."[56]

2.6.3 Changing Australia's current fiscal approach risks fuelling illicit trade

The illicit tobacco trade remains a real threat in Australia. Australia's Commissioner of Taxation acknowledged that the "*legal market for domestically grown tobacco effectively ended in October 2006*"[57] but predicted that, "*the risk has now shifted from [illicit] tobacco leaking from licensed growers to illicit*

[54] Royal Canadian Mounted Police, *Contraband Tobacco Enforcement Strategy*, 2008, p. 18.

[55] Ibid., p. 1.

[56] Sweanor, pp. 1599-1600.

[57] Australian Taxation Office, Commissioner of Taxation Annual Report 2006-07, p. 92.

importation of tobacco and tobacco products."[58] Indeed, both domestically grown and illegally imported chop-chop is still prevalent.[59]

The ACS has noted a significant increase in both smuggled cigarettes and smuggled tobacco. For example, in December 2007 the ACS calculated a "*14-fold increase in the quantity of [smuggled] tobacco and double the quantity of [smuggled] cigarettes compared to 2006*"[60]. In its 2007-08 Annual Report, ACS said the increase "*reflects the world-wide rise in cases of large-scale organised cigarette and tobacco smuggling,*"[61] and explained that its growth reflects "*the large sums of money that can be made by avoiding paying the high level of duties levied on tobacco products entering Australia*."[62] Increasing tobacco excise beyond CPI risks worsening that situation.

None of that is to say that illicit trade is the inevitable result of excise tax increases. Clearly, tax is an incentive and therefore an important factor in regard to illicit trade in tobacco products. The World Bank has stated: "*Differences in price between countries or states will clearly increase the incentives to smuggle cigarettes. However, the determinants of smuggling appear to be more than price alone*."[63] If excise tax is used in order to increase the price of cigarettes, it is critical that the government implement appropriate policies to effectively counter illicit trade in tobacco products.[64]

Australia's current system optimises the government's revenue and health objectives while keeping illicit trade under control. Altering that balance could entail significant unintended consequences.

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[58] Ibid.

[59] See, e.g., K Poh, "Where there's smoke, there's chop-chop: Warning issued on illegal tobacco", *Altona* (VIC) *Star*, 27 May 2008 ("*Illegal home-grown tobacco, or 'chop-chop,' is being sold in Hobsons Bay for as little as $70 for half a kilogram*." Quoting a consumer, "*People buy it because it's a lot cheaper…For 50 cigarettes, you'd pay about $17 at Safeway. You could buy chop-chop for a third of the price*."); J Gregory, "No jail for illegal tobacco", *Brisbane Courier Mail*, 16 January 2008 (defendant was found with 400 kilograms of 'chop-chop' with an excise value of $121,000 when police raided home in Brisbane's southern suburbs).

[60] Australian Customs Service, Media Release, "Customs stems unprecedented flood of smuggled cigarettes and tobacco," 19 December 2007.

[61] Australian Customs Service, *Annual Report 2007-08*, p. 13.

[62] Ibid.

[63] World Bank, *Curbing the Epidemic: Governments and the Economics of Tobacco Control*, chapter 5, 1999.

[64] For example, the increase in excise revenue between 2001 and 2002 illustrated in Figure 4 was, in part, due to strategies implemented by ATO to eliminate chop-chop.

3 The government should adopt additional measures to combat illicit trade

Smuggled, counterfeit, and tax-evading tobacco products are bad for public health, consumers, our business, and society at large.[65] As the Technical Report states, "[*t]he availability of illicit tobacco products (products on which taxes have been avoided) undermines the effectiveness of taxation … in reducing affordability to prevent uptake and promote quitting, particularly among low-income groups … It is essential that we do not let illicit trade become a problem in Australia.*"[66]

> WHAT'S PROPOSED? Implementing unspecified "effective measures" to combat illicit trade; "actively participat[ing]" in FCTC protocol negotiations and banning duty-free sales of tobacco products.
>
> PML'S VIEW: Illicit trade threatens public health objectives, government revenues, and our business. We support strong, proven measures to combat illicit trade, and we outline six steps to take now. Banning duty free sales is not one of them.

As noted in the previous section, illicit tobacco trade is a problem. The proposals to abandon Australia's proven excise tax approach and mandate plain tobacco packaging would exacerbate the problem.

The Technical Report recommends that the government "*actively participate in the negotiation of an effective protocol to the FCTC*" and implement unspecified "*effective measures to prevent revenue evasion*" before implementing significantly increasing tobacco excise tax.[67] We agree, and recommend six key actions that have proven effective:

(1) establishing a coordinated national strategy to combat illicit trade;

(2) consistently enforcing laws against illicit trade, and amending those laws to ensure they provide a strong deterrent;

(3) establishing a comprehensive *positive* licensing system to define, control and protect the legitimate trade in tobacco products;

(4) considering requiring mechanisms for tracking and tracing tobacco products to ensure the integrity of the manufacturers' supply chain, and supporting international efforts to require that in other countries;

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[65] The Royal Canadian Mounted Police put it more pointedly: "*The public needs to be aware that profits from illegal tobacco products are also funding other criminal activities, such as drug and gun trafficking. Furthermore, some of these organized crime groups are known to use violence to ensure profit. Be aware that you are funding criminal activity if you are purchasing products that are not sold legitimately*." RCMP Contraband Tobacco Enforcement Strategy, p. 1.

[66] Technical Report, p. 13 (citations omitted).

[67] Technical Report, p. 15.

(5) requiring manufacturers to implement a system or systems for authenticating genuine products and identifying counterfeit tobacco products; and

(6) developing effective consumer communications programs to reduce demand for illicit tobacco products.

3.1 The government should establish a co-ordinated national strategy to coherently address illicit trade

A number of Federal and State agencies have a role to play in combating illicit trade – including, among others, the ACS, the Australian Taxation Office (ATO), Federal and State police, and Federal and State Departments of Health. There is currently no mechanism for developing co-ordinated, coherent strategies for identifying, prosecuting and preventing illicit tobacco trade, although the ATO / ACS Tobacco Industry Forum provides a useful means of sharing information and experience.[68]

3.2 The Government should enforce and amend laws to deter illicit trade

A national strategy should include a review of the penalties for selling illegal tobacco products, in order to ensure that they act as an effective deterrent to illicit traders. Smugglers are switching to smuggling tobacco because it is lucrative and poses low risk.[69] For example, Customs recently detected and prevented an illegal operator from selling nearly 10,000 kilograms of illicit imported tobacco. Although the excise revenue that should have been paid was over $2.9 million, the smuggler was fined only $66,000 – the maximum allowed by law.[70] Fines at those levels are unlikely to meaningfully deter large-scale organised criminal organisations involved in illicit tobacco trade. In contrast, the fines for cigarette smuggling in Singapore are a multiple of the amount of duty evaded, with a greater multiple for repeat offenders. Cigarette smugglers can be subject to jail time as well. Singapore Customs' latest annual report highlights a case in which a smuggler was fined was jailed 3 years and fined S$27million for evading S$1.8million of duty.[71]

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[68] The Tobacco Industry Forum is jointly led by ATO and Customs, and provides government and industry with a forum for consultation and discussion on issues of mutual concern. See: http://www.ato.gov.au/businesses/content.asp?doc=/content/00129620.htm&pc=001/003/043/004/011&mnu=&mfp=&st=&cy=1

[69] ACS Annual Report, p. 13.

[70] Australian Customs Service, Media release, *$66,000 penalty for convicted tobacco smuggler*, 22 October 2008.

[71] Singapore Customs, *2006-07 Annual Report*, p. 47. Section 128L (4) and (5) of the *Singapore Customs Act* provides:

> "*(4) Any person who is guilty of any specified offence involving goods consisting wholly or partly of relevant tobacco products shall, if such tobacco products exceed 2 kilogrammes in weight, be liable on conviction —*
>
> *(a) to a fine of —*
>
> *(i) not less than 15 times the amount of the customs duty, excise duty or tax the payment of which would have been evaded by the commission of the offence; and*
>
> *(ii) not more than 20 times the amount of the customs duty, excise duty or tax the payment of which would have been so evaded or $10,000, whichever is the greater amount; or*

3.3 The Government should adopt a comprehensive licensing system to define and oversee the supply chain

We support the Technical Report's recommendation that the Federal Government should establish a comprehensive national licensing system to address illicit trade.[72] The approach is supported by the Framework Convention on Tobacco Control, which provides that "*[e]ach Party shall endeavour to adopt and implement further measures including licensing, where appropriate, to control or regulate the production and distribution of tobacco products in order to prevent illicit trade*."[73]

Currently tobacco product manufacturers are licensed by the ATO; importers are licensed by the ACS; and wholesalers and retailers are licensed pursuant to various State and Territory laws. There is, to our knowledge, no mechanism for sharing information among those organisations in order to co-ordinate responses.

In our view, positive licensing can serve as the cornerstone of an anti-illicit trade strategy, and would be effective at ensuring that only legitimate and qualified businesses are engaged in the manufacture, importation, distribution, marketing and sale of tobacco products. Licenses could encompass many of the separate anti-contraband provisions of Australian law, such as manufacturer supply chain controls and oversight of the retail environment, while providing infrastructure for future measures.

A controlled network for legitimate products would improve the Government's ability to prevent the illegal trade in cigarettes and collect taxes applicable to tobacco products. Moreover, industry participants who are required to apply and pay for a licence are more likely to be aware of the consequences of dealing in illicit products and feel a commitment to follow the regulation. A national approach would provide additional uniformity and certainty for businesses.

We recognise that implementing a positive licensing system can raise logistical challenges. For example, there needs to be appropriate infrastructure in place to process license applications, and efficient, centralized mechanisms for manufacturers and wholesalers to verify that their customers are appropriately licensed. But States and Territories that have implemented positive licensing systems have found them to be a useful mechanism for informing license holders of legal requirements, monitoring compliance, and sanctioning non-compliance with a variety of laws.[74] We support the same approach with other members of the supply chain, including manufacturers and importers.[75]

(b) to imprisonment for a term not exceeding 3 years, – or to both.

[72] Technical Report, p. 28. The Report discusses licensing in the context of ensuring that retailers and manufacturers comply with laws; we suggest that complying with fiscal responsibilities should be included in any assessment of "fitness."

[73] Framework Convention on Tobacco Control, art. 15.7.

[74] Similarly, the Technical Report notes that "*Licensing of retailers was the most effective way of informing tobacco retailers and wholesalers of their legal obligations, and of ensuring that authorities had the information necessary to enforce tobacco control laws*." Technical Report, p. 27.

[75] Although we agree that license revocation can be an appropriate penalty for non-compliance, we do not support the notion of constricting the number of retailers as a means to reduce supply, as apparently suggested by the Technical Report (p. 27).

3.4 Tracking and tracing requirements can protect the integrity of the supply chain

The importance of an effective international tracking and tracing regime is recognised in the FCTC[76] and the Draft Illicit Trade Protocol.[77] Such a system can follow the movement of bulk quantities of genuine product through the supply chain such that, upon a seizure of contraband product, law-enforcement officials can readily determine where the seized product came from; where it was supposed to go; and who actually received it along the distribution chain.

Although implementing such requirements unilaterally would have limited value for Australia, it could be used as a means for Australia to support international efforts to require a similar approach in other countries, in the context of the FCTC protocol on illicit trade,

3.5 Authentication systems can be used by manufacturers, retailers, consumers and governments

A reliable and secure means of authenticating whether products are genuine or counterfeit can also help fight illicit trade. Tools which allow counterfeits to be rapidly identified can help enforcement officers; they can also provide a basis for consumers and the trade to reject counterfeits, thereby reducing the market and profits of counterfeiters.

PMI has developed a system which allows authentication in a simple and inexpensive manner, requiring no special equipment, readers or technical training. Importantly, it is a rapid response system – establishing whether a product is authentic or counterfeit for consumers, trade or law enforcement officials within one minute. PML would be willing to implement such a product authentication system in Australia. The value of the system is maximised only when consumers and the trade know about the existence of such a system, so that retailers and consumers can reject illicit products.

3.6 The Government should use communication initiatives to discourage consumers from purchasing illicit products

Stimulating consumer awareness of the consequences of buying illegal cigarettes can reduce demand for illicit tobacco products, and can be done in a way (both in content and in the media employed) that does not give publicity to or promote the use of tobacco products. The following themes have provided the focus for communication initiatives elsewhere:

- *Organised crime*. Counterfeiting and smuggling are organised criminal activities – this year PML's affiliate organised a campaign in Lithuania to highlight this fact.

- *Labour conditions.* Employees who work in counterfeiting factories are subjected to poor working conditions.

- *Product quality and compliance.* Fake products are often poor quality cigarettes that do comply with government regulatory requirements. The

[76] Framework Convention on Tobacco Control, art 15.2 (b).

[77] Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products. Chairperson's text for a protocol on illicit trade in tobacco products, FCTC/COP/INB-IT/2/3, 18 August 2008.

Department of Health has communicated that point to address chop-chop issues in the past.

- *Fair trade.* The illicit trade unfairly competes with legitimate retailers and costs jobs. Germany faces a similar problem and in response earlier this year PML's affiliate there organised a campaign highlighting the job losses caused by illicit trade.

3.7 Banning duty-free sales will not help control illicit trade

The Technical Report suggests that "*An effective policy to prevent the development of illicit trade … would abolish duty free sales*." It provides *no* evidence to support that assertion. (We note, for example, that most Australian duty-free sales occur within airports, which are among the most tightly controlled places in the world.)

We do not believe countries should abolish duty-free sales of tobacco products: Allowing international travellers to purchase duty free products is an established and expected practice, and is even recognised by international treaties. Duty-free cigarette sales, like all other sales of tobacco products, should be subject to meaningful and effective regulation.

For example, we would support a requirement that all duty-free product be clearly marked as such, and we agree with recommendations from leaders in the customs enforcement community who have called for the computerization of government systems controlling the movement of duty-suspended goods to help such authorities monitor and track shipments, thus reducing the opportunities for the diversion of duty-suspended product into domestic commerce. We also support strict, consistent enforcement of the maximum allowances of duty-free tobacco products that an individual can purchase.

4 PML supports warning requirements but opposes regulations which destroy trademarks

Australia currently requires the largest tobacco package health warnings in the world. Seven different text-and-picture warnings appear on packs at any given time; seven additional warnings are rotated in regular intervals. The warnings constitute the majority of the principal areas on the pack, and exceed the size required by the Framework Convention on Tobacco Control.

> WHAT'S PROPOSED? Taking the unprecedented step of requiring plain packaging for tobacco products; enlarging and refreshing health warning messages "*much more frequently*"; prohibiting descriptors.
>
> PML'S VIEW: We agree that all tobacco products should bear clear health warnings. Mandating plain packaging or dedicating the *entire* package to government warnings is extreme and disproportionate, unsupported by the evidence, and would constitute an expropriation for which compensation is due.

4.1 The plain packaging proposal should be rejected as unnecessary, unsupported by the evidence, and unlawful

The Technical Report recommends prohibiting brand imagery, colours, corporate logos, and trademarks on tobacco packages. Its proposed regulation would permit manufacturers only to print "*the brand name in a mandated size, font and place, in addition to required health warnings and other legally mandated product information such as toxic constituents, tax-paid seals or package contents*."[78]

We strongly oppose proposals to require plain packaging of tobacco products. The evidence does not support the opinion that plain packaging reduces smoking prevalence. It will likely encourage illicit trade and lower prices for legal products

[78] Technical Report, p. 20. It further recommends requiring that a "*standard cardboard texture would be mandatory, and the size and shape of the package and cellophane wrapper would also be prescribed…Plain packaging would also need to encompass pack interiors and the cigarette itself, given the potential for manufacturers to use colours, bandings and markings, and different length and gauges to make cigarettes more 'interesting' and appealing. Any use of perfuming, incorporation of audio chips or affixing of 'onserts' would also need to be banned*." Ibid.

The Technical Report recommends adopting those regulations under the Trade Practices Act 1974, although it does not explain how any of those requirements are within any of the heads of power in the Act.

The Technical Report also recommends amending Schedule 2 to the *Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004* to "*prescribe health warnings that cover at least 90% of the front and 100% of the back of the pack*" (Technical Report, p. 22), which would effect plain packaging without using those exact words. Whatever means is used, we oppose proposals to expropriate tobacco trademarks.

In addition, plain packaging will impose severe restrictions – tantamount to expropriation - on the use of long-held and extremely valuable intellectual property rights, will significantly restrict competition, and will breach the Government's obligations under international trade agreements.

The use of tobacco products has been declining for decades; they cannot be used in virtually any public place; they are sold in packs dominated by health warnings; they cannot be advertised; they are the subject of significant public health campaigns; and they are subject to higher taxes than any other consumer good. Eliminating one of the last remaining forms of product differentiation can only be reconciled with a strategy of preventing tobacco manufacturers from engaging in legitimate commerce.

4.1.1 The public health benefit of plain packaging is not supported by the evidence

In 1997 the Australian Federal Government considered and rejected a proposal to mandate plain packaging of cigarettes. It explained that "*To date, generic packaging of tobacco products has not been implemented anywhere in the world. As such, there is no international experience of the effect of generic packaging on consumer behaviour. In addition, there is limited primary research on the potential effect of generic packaging on the factors underlying or relevant to the uptake and cessation of tobacco consumption*." Those conclusions remain true today.[79]

Although the Technical Report asserts that "*there is good evidence that [mandating plain packaging] would have a profound effect on young image conscious teenagers*,"[80] there is no sound evidence that plain packaging is effective at or necessary for reducing smoking prevalence.

Studies cited in the Technical Report merely indicate that smokers prefer packets with imagery to those that do not.[81] None of the research establishes, however, that plain packaging would cause consumption or prevalence to decline.

On the contrary, governments have consistently concluded that the case for plain packaging is "*speculative*". For example, the UK Department of Health concedes that research into plain packaging "*is speculative, relying on asking people what they might do in a certain situation. The assumption is that changes in packaging will lead to changes in behaviour*."[82] The Technical Report's statement that "*[t]he UK Government has announced its intention to mandate plain packaging of tobacco products*"[83] is incorrect: the UK is *not* proposing to require plain packaging. The UK government consultation document cited in the Technical Report states that the "*specific proposals are not being considered at present*."[84] In fact, after its consultation was completed, the UK Department of Health concluded that there was *insufficient evidence to support plain packaging*

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[79] *Government Response to the Report of the Senate Community Affairs Reference Committee The Tobacco Industry and the Costs of Tobacco-Related Illness*, 1997, p. 30.

[80] Technical Report, p. vi.

[81] See sources cited in Technical Report, reference numbers 188 and 189.

[82] UK Department of Health. *Consultation on the future of tobacco control*. London: Department of Health UK, 2008, p. 39 (UK Consultation Paper) (emphasis added).

[83] Technical Report, p. 3

[84] UK Consultation Paper, p. 39, cited in Technical Report, reference number 42.

and concluded that "*more needs to be done to develop our understanding of how the packaging of tobacco products influences smoking by both adults and young people*." [85]

Studies have confirmed that pack design does not play a role in uptake of smoking or continued smoking. For example, one study concluded:

> *"Most kids receive their first cigarette from friends. There is no brand choice – the choice is simply to smoke or not to smoke. Therefore, in the uptake process brand and package are very minor components. This means that changing the package will not have any major effect on the decision(s) to smoke or not to smoke."*[86]

The Technical Report suggests that plain packaging improves recall of health warnings; the actual studies, however – including those the Technical Report relies upon – are not so clear cut. For example, although Health Canada found that recall of starker and shorter warnings (e.g., "*Smoking can kill you*") was enhanced on plain packages, recall of longer warnings (e.g., "*Tobacco smoke causes fatal lung disease in nonsmokers*") was diminished. Another Canadian study found that even though plain packaging made health warnings appear more serious, "*recall of the health warning does not appear from our research to be affected by plain packaging*."[87] And a 1992 New Zealand study, relied upon by the TWG, showed that plain packaging did not have any effect on the recall rates of health warning presented on tobacco products sold in New Zealand.[88]

Real world experience demonstrates that unbranded packaging does not deter tobacco consumption. In Canada, approximately 22% of the cigarette market is estimated to consist of illicit cigarettes, most of which are sold in clear plastic bags.[89] Similarly, the rise in chop-chop sales in Australia demonstrates that consumers are willing to smoke unbranded (and illegal) tobacco when other tobacco products become too expensive or less attractive. And many countries experience significant sales of individual unpackaged cigarettes where low income levels make pack purchases unaffordable for adult smokers.

Rather than deterring smoking, plain packaging will prevent manufacturers from competing (other than through pricing) and will encourage illicit trade. The rest of the smoking population is likely to continue to choose to purchase cigarettes in plain packaging. Nothing in the data presented by the Technical Report suggests otherwise.

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[85] UK Secretary of State for Health Alan Johnson, *Written Ministerial Statement: Tobacco Legislation*, 9 December 2008.

[86] Expert Panel Report for Health Canada, *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products*, National Survey of Teens: Knowledge, Attitudes, Beliefs and Smoking Behaviours, p. 184 (March 1995) (emphasis added).

[87] There was an exception for daily smokers for whom the health warning recall was higher when presented on plain pack, possibly due to novelty effect that was expected to be "temporary." Ibid.

[88] P Beede et al, "The Effect of Plain Packages on the Perception of Cigarette Health Warnings", *Public Health*, vol. 106, 1992, p. 317.

[89] RCMP Contraband Tobacco Enforcement Strategy, p. 4.

4.1.2 Requiring plain packaging severely limits legal product manufacturers' ability to compete

Trademarks and unique visual packaging elements are important competitive tools for product manufacturers and trademark owners. In emphasizing the importance of trademarks, the European Court of Justice stated that manufacturers "*must be able to attract and retain customers by the quality of their products or services, which is made possible only by distinctive signs allowing them to be identified*."[90]

Trademarks allow manufacturers to differentiate their products from competing products and position them on a quality spectrum as premium-, medium-, or low-priced brands. Plain packaging will make it much harder – if not altogether impossible – for manufacturers to differentiate their brands, particularly in an environment where other activities such as advertising and sponsorship are heavily curtailed.[91]

By reducing manufacturers' ability to differentiate their products, plain packaging will reduce their ability to maintain higher prices for premium- and medium-positioned brands. Consequently, manufacturers will be forced to reduce prices of those brands. Indeed, the UK Consultation Paper recognises that "*Plain packaging may force tobacco companies to compete on price alone, resulting in cigarettes becoming cheaper*."[92] We would go further: Plain packaging *will* reduce overall cigarette prices, because price will be the only way manufacturers will be able to compete for a share of the market.

4.1.3 Competition principles require the rejection of plain packaging proposals

The Competition Principles Agreement between the Commonwealth and each of the State and Territory Governments requires that regulations not restrict competition unless:

(a) the benefits of the restriction to the community as a whole outweigh the costs; and

(b) the objectives of the legislation can *only* be achieved by restricting competition.[93]

Even if it had established that plain packaging reduces smoking prevalence (and it has not done so), the NPHT fails to demonstrate (nor even suggest) that plain

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[90] C-349/95 Frits Loendersloot v. George Ballantine & Son. Ltd. And Others (11 November 1997).

[91] The ability to continue to use brand names will have little impact in light of the rule that names must be printed in uniform colour, typeface and size. Despite the name, the similarity of the packs will certainly lead to consumer confusion and ultimately complete commoditization of the market. Introducing new versions of existing brands will be extraordinarily difficult, if not impossible, as consumers will have no way of easily identifying new brand extensions other than reading the typeface on the pack (assuming there is point of sale display). In fact, distinguishing existing versions of the same brand will be difficult.

[92] UK Consultation Paper, p. 41.

[93] Clause 5 (emphasis added). The Competition Principles Agreement is one of three intergovernmental agreements that underpin the National Competition Policy. See National Competition Council, Compendium of National Competition Policy Agreements (2nd edn.), 1998, pp. 13–23.

packaging is the only available means to reduce smoking prevalence. To the contrary, evidence-based options are both available and, contrary to plain packaging, likely to advance public policy objectives. Rather than seeking the *least restrictive* (and proven) regulatory measures, the Technical Report has chosen *burdensome regulation* that appears designed to de-legitimise tobacco products, eliminate competition in the tobacco industry, and eliminate long-standing and valuable trademark rights.

Competition principles embodied in State, Territory and Commonwealth law and practice therefore require the government to reject the proposal to require plain packaging.

4.1.4 Plain packaging is likely to increase illicit tobacco trade

The opinion that plain packaging would reduce smoking prevalence is already belied by the persistence of chop-chop. Eliminating brands will further motivate consumers to switch to cheaper unbranded alternatives, and will worsen the existing problem of chop-chop by removing an incentive to purchase licit, higher-quality products (and removing a means of verifying that tobacco products are genuine and licit).

Mandating plain packaging will make it easier and less costly for counterfeiters to produce cigarette packages. Mandating plain packaging will also stimulate consumer demand for branded packaging. While the evidence does not suggest that consumers will quit because of generic packaging, the studies cited in the Technical Report *do* suggest that consumers branded packaging to plain packaging. That preference will provide an additional incentive for counterfeiters and smugglers of branded packs.

4.1.5 Mandating plain packaging would require the Government to compensate trademark owners for expropriating some of the world's most valuable brands

Section 51 (xxxi) of the Australian Constitution provides that the Federal Government shall provide "*just terms*" for any "*acquisition of property … for any purpose in respect of which the Parliament has power to make laws*." Protected property includes "*every species of valuable right and interest.*"[94]

Trademarks are protected, valuable property rights. As IP Australia states, "*A registered trade mark gives you the legal right to use, license or sell it within Australia for the goods and services for which it is registered*."[95] IP Australia recognises that using trademarks is "*an important means of maintaining goodwill with your clients and improving your bottom-line*."[96] Equally important, using a registered trademark gives the owner the right to exclude others from using it.[97]

A law which prevents effective use of or control over property rights constitutes an "acquisition" even if title to the property interest does not actually pass to the Government. Where property rights have been "*effectively sterilized*"[98], leaving

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[94] Minister of State for the Army v Dalzie (1944), 68 CLR 261, 290 (Starke J).

[95] http://www.ipaustralia.gov.au/trademarks/what_index.shtml

[96] http://www.ipaustralia.gov.au/trademarks/what_index.shtml

[97] Section 20(1) *Trade Marks Act 1995* (Cth).

[98] Newcrest Mining (WA) Ltd v Commonwealth [1997] HCA 38; (1997) 190 CLR 513, 635 (Gummow J), 148 (Kirby J).

nothing but "*an empty shell*"[99], the Court has accepted that the property owner has experienced sufficient deprivation of property rights for section 51(xxxi) to apply.[100]

Federal legislation mandating plain packaging would prevent trademark owners and their licensees from using and exercising control over their property rights – effectively a restrictive covenant against using the trademarks to the benefit of the Commonwealth – and would therefore constitute a Federal "acquisition" for purposes of section 51(xxxi).[101] A trademark that cannot be affixed to products and product packaging is worthless – particularly since Federal and State laws limit the use of tobacco trademarks to tobacco products and packaging.[102] A Federal law preventing trademark owners and licensees from using trademarks on tobacco packaging could also effectively permit *others* to "acquire" the trademarks, since non-use causes trademark registrations to lapse.[103]

It is "*unthinkable*" that citizens "*in a democratic society ... would regard with equanimity the expropriation of their or other private property without proper compensation*."[104] Even if the Government could demonstrate that plain packaging were a proportionate and lawful measure (which it is not), the Federal Government will be required to provide trademark owners just terms compensation for the value of the expropriated trademarks. In that context, the value of tobacco manufacturers' trademarks, brand logos and pack designs are enormous, including some of the most valuable commercial property in the world.

4.1.6 Eliminating trademarks would violate international treaty obligations

International treaties such as the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) and the Paris Convention for the Protection of Industrial Property require parties – including Australia – to follow minimum standards concerning the availability, scope and use of intellectual property rights.

Mandating plain packaging would violate those treaty obligations. Plain packaging not only unjustifiably encumbers the use of a trademark,[105] it also violates the principle that the nature of the goods to which a trademark is applied shall in no case form an obstacle to the registration of the trademark.[106] In short, plain packaging would install a dual-class system of trademarks – one class for tobacco

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[99] Smith v ANL Ltd [2000] HCA 58; (2000) 176 ALR 449, 472 (Kirby J).

[100] Newcrest Mining (WA) Ltd v Commonwealth [1997] HCA 38; (1997) 190 CLR 513 (proclamations which effectively extinguished the benefit of mining leases amount to an acquisition of property for the purposes of section 51(xxxi)).

[101] Because only the Commonwealth Government has the power to create trademarks, States and Territories cannot pass laws which would revoke, destroy or impair those rights. Section 51(xviii) *Commonwealth of Australia Constitution Act 1901*

[102] See *Tobacco Advertising Prohibition Act 1992* s15 (unlawful to publish a tobacco advertisement); s9(1)(c),(d) (advertisement includes trademark and design elements); s9(2) (packaging and tobacco products themselves do not constitute advertisement).

[103] Restricted to non-use by plain packaging legislation, distinctive visual elements would become subject to total loss. Under Australian law, existing trademarks would be subject to cancellation after five years of non-use. Section 92.(4)(b) *Trade Marks Act, 1995*.

[104] Smith v ANL Ltd [2000] HCA 58; (2000) 176 ALR 449, 486 (Callinan J)

[105] TRIPs, Article 20.

[106] TRIPs, art 15.4; Paris Convention for the Protection of Industrial Property, art 7.

products and one class for other goods. Such a dual-class trademarks system would put Australia out of step with the rest of the world and in breach of its obligations under both TRIPs and the Paris Convention.

While none of those international agreements absolutely prevents governments from encumbering or altering trademark rights, they do suggest that trademark encumbrances may only be implemented when shown to be *necessary*, *effective*, and in the *least restrictive manner*. No such showing has been made to justify banning the use of trademarks on cigarette packaging.

4.1.7 Expropriating trademarks for speculative policy benefits sends a bad message to Australia's trading partners and threatens Australian intellectual property abroad

Australia has a strong interest in rigorously defending trademark rights. The Department of Foreign Affairs and Trade explained that, "*As a trading nation with a strong research tradition and a need for access to new technologies, Australia has interests in the agreed international standards on the protection and exploitation of intellectual property rights*."[107]

Free Trade Agreements currently in force between Australia and other sovereign states recognise the value of protecting trademarks.[108] The Australian Government has underscored the importance of trading partners mutually recognise the value of protecting trademarks from expropriation or unwarranted government encumbrance or interference.[109]

Encumbering or extinguishing tobacco trademark use without strong, objective evidence of necessity, effectiveness and proportionality would send the wrong message to Australia's trading partners about the value the Australian Government places on intellectual property.

Requiring generic packaging is unsupportable: there is no good evidence that it would have any impact on smoking prevalence; it would unquestionably harm competition and damage manufacturers and consumers; and there is a real risk that mandating plain packaging would undermine public health objectives. Australia should continue to reject plain packaging proposals.

AUSTRALIA SHOULD CONTINUE TO REJECT
PLAIN PACKAGING PROPOSALS

"[*A]ny attempt to use [Commonwealth] powers to introduce further tobacco control legislation needs to be considered in the context of the increasingly critical attention being focussed on the necessity, appropriateness, justification and basis for regulation by such bodies as the Office of Regulatory Review, the High Court, and Senate Standing Committees. In addition, further regulation needs to be considered in the context of Australia's international obligations regarding free trade under the General Agreement on Tariff and Trade (GATT), and our obligations under international covenants such as the Paris Convention for the Protection of Industrial Property, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).*

[107] http://www.dfat.gov.au/ip/index.html

[108] See, e.g. Australia-United States Free Trade Agreement, chapter 17; Thailand-Australia Free Trade Agreement, chapter 13.

[109] See, e.g., Department of Foreign Affairs and Trade, Australia-China FTA Conference in Shenzhen, *Intellectual Property Protection: A win-win strategy for the Australia-China FTA.*

To date, generic packaging of tobacco products has not been implemented anywhere in the world. As such, there is no international experience of the effect of generic packaging on consumer behaviour. In addition, there is limited primary research on the potential effect of generic packaging on the factors underlying or relevant to the uptake and cessation of tobacco consumption."

Government Response to the Report of the Senate Community Affairs Reference Committee The Tobacco Industry and the Costs of Tobacco-Related Illness at 30 (1997)

4.2 Health warning messages should rotated and periodically refreshed

The Technical Report recommends increasing the size of current government-mandated health warning messages on tobacco product packaging,[110] and putting in place "*a new system for providing consumer product information which ensures that package health warnings are reviewed much more regularly and are amended where necessary to maintain their effectiveness*."[111] It recommends complementing pack warnings with bulletins from a designated authority.[112]

Australia currently requires the world's largest health warnings, with two different sets of seven graphic and text messages appearing in alternate years. PML supports clear warning messages on all consumer packaging of tobacco products. We defer to the government on the content of those warnings, but warnings should be used to inform and remind smokers of the health effects of smoking. They should not be used to demonise tobacco companies, expropriate trademarks, or coerce smokers into quitting.

We agree that health warning messages should "rotate" (with several different health warnings appearing on products at any given time), and health warning messages should be refreshed periodically. We do not support establishing new health warnings "much more regularly" than every five years, as has been the practice over the last twenty years. The *Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004* recognise that changing consumer product packaging takes time. With a variety of warning messages already being presented across a two-year period, requiring entirely new warnings on a more frequent basis is unduly burdensome or infeasible – particularly since the key message, that smoking causes fatal diseases and is addictive, is clear.

Warnings should not change in format, in content or in style simply because advocates reckon that larger or different warnings would somehow be "better." Alternating defined warnings every two years should be sufficient, with warning content re-assessed and refreshed if needed every five years, particularly since a variety of other media exist for sharing new or emerging science. Sufficient time should be allowed to implement packaging changes.

[110] The proposal to increase health warnings to 90% of the front and 100% of the back of tobacco packages is tantamount to mandating plain packaging, and the analysis of the previous sections would apply equally to it.

[111] Technical Report, p. 22.

[112] Ibid.

4.3 Descriptors should be consistently regulated

The Technical Report recommends prohibiting the commercial supply of tobacco products in packs displaying descriptors it characterises as misleading such as "light," "mild" and similar terms as well as colours, brand names, "milder taste" or any other device to suggest lower yields.[113]

We support regulations that would ban the use of descriptors such as "light" and "mild." PML and the other major tobacco manufacturers have entered into binding Undertakings with the Australian Competition and Consumer Commission in which PML refrains from using the terms "light" or "mild" and from using any means to connote that a cigarette is safe or safer.[114] The terms of those undertakings should be incorporated into regulations that would apply to all manufacturers and importers of tobacco products.

We do not support a ban on the use of colours on tobacco product packaging to differentiate brand extensions, which (as discussed in the previous sections) form an essential, legally protected part of the visual elements that help consumers distinguish among brands, identify our brands, and allow us to compete.

4.4 Yield numbers should be prohibited from tobacco product packaging

We support legislation prohibiting manufacturers and importers from incorporating tar, nicotine, or CO numbers in a tobacco product's brand name or printed anywhere on the products, packaging or in trade or consumer communications. Bans should likewise apply to statements relating to the yields of other smoke constituents.[115]

[113] Technical Report, p. 24.

[114] Undertaking to the Australian Competition and Consumer Commission given for the purposes of Section 87B of the Trade Practice Act 1974 by Philip Morris, 10 May 2005.

[115] An exception to this general rule should be made for substantiated, approved statements about potential reduced risk products. Communicating reduced smoke constituents related to those products could play an important role in furthering the goal of harm reduction provided they are made pursuant to requirements described in Section 6.

5 Retailers should continue to be permitted to display the products they sell

The *Tobacco Advertising Prohibition Act 1992* (Cth) recognises States' and Territories' authority to regulate tobacco advertising and display inside retail shops. Every State and Territory already prohibits tobacco advertising within retail shops; each State and Territory also regulates the size and location of tobacco product displays. Two States and one Territory have passed laws which will prohibit retail displays of tobacco products, but none of those laws has yet been implemented.

> WHAT'S PROPOSED? Amending Federal law to revoke State and Territory authority over retailers; prohibiting retailers from displaying the tobacco products they have for sale.
>
> PML'S VIEW: Prohibiting retailers from displaying the products they sell is anti-competitive, and display bans in other jurisdictions have not been effective at reducing smoking prevalence.

The Technical Report recommends abrogating States' authority and "*amend[ing] the Tobacco Advertising Prohibition Act to prohibit the display of tobacco products in all states and territories.*"[116]

The Technical Report supports its proposal with speculative and theoretical studies, but fails to mention that evidence from the few jurisdictions which have banned displays does *not* support display bans. The recommendation to implement a nationwide ban on tobacco displays should be rejected.

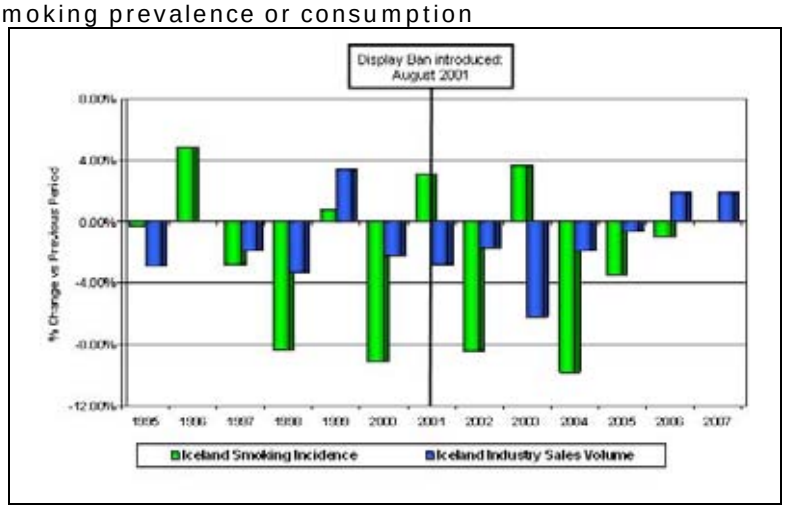
5.1 Display bans have not been demonstrated effective

Although a number of Australian jurisdictions have passed laws that will prohibit retail display of tobacco products, none of those laws has been implemented yet. There are therefore no Australian data on the purported effectiveness of a display ban.

Experience and data from the only country to have implemented a national display ban, Iceland, does not demonstrate that retail display bans are effective at reducing smoking prevalence in adults or in youth, as illustrated in *Figure 7*.

[116] Technical Report, p. 18 (citations omitted).

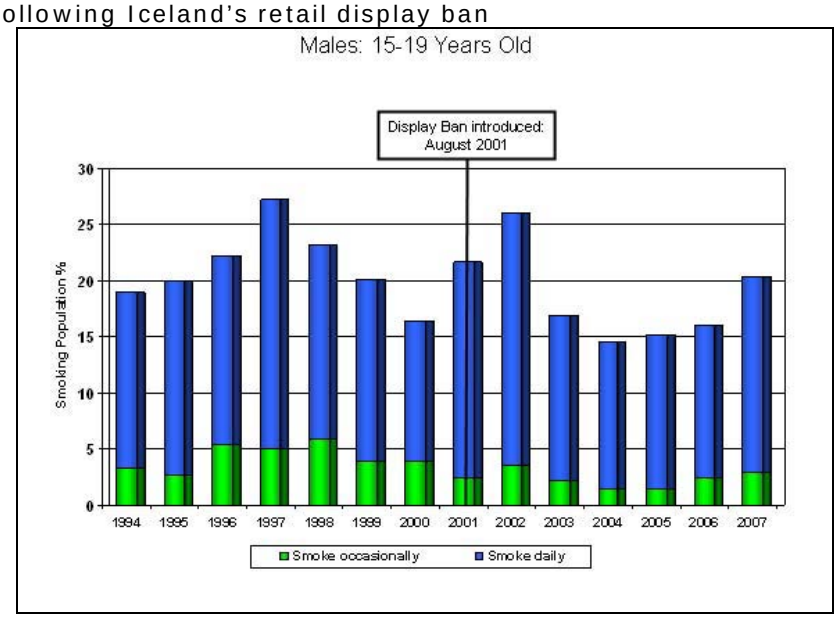
Fig. 7: Iceland's retail display ban has had no clear effect on smoking prevalence or consumption



Source: Sales Data: Icelandic Alcohol and Tobacco Monopoly. Smoking Incidence: Statistics Iceland - Statistical Yearbook of Iceland 2007

Iceland has seen both decreases and increases in the incidence of daily and occasional smoking among minors (15 to 19 year old males and females) in individual years following its display ban. In fact, as *Figure 8* illustrates, incidence of male smokers aged 15 to 19 was highest in 1997 – four years before the ban – and 2002 – one year after the ban. Incidence for the same group grew marginally from 2004 to 2006 and spiked in 2007 to levels approximately equal to those reported for 1995 and 1999. For females aged 15 to 19, incidence of daily and occasional smokers in 2003 was reportedly above that reported for 2000 and while not reaching that level since has declined and increased every other year from 2004 to 2007.[117]

Fig. 8: Male youth smoking prevalence increased in the year following Iceland's retail display ban



Source: Smoking Incidence: Statistics Iceland - Statistical Yearbook of Iceland

Commenting on the data from Iceland, the Norwegian Ministry of Health noted that although overall smoking prevalence in Iceland declined from 2001 to 2005,

[117] Public Health Institute of Iceland, Statistical Yearbook of Iceland 2007, Table 17.18, *Smoking habits of 15–79 years old by sex 1987–2006*.

"*there are no indications to prove that this reduction is a result of the ban, more than other tobacco preventive measures introduced at the same time*."[118]

Other jurisdictions have recognised that claims that a retail display ban advances public health objectives are speculative and unproven. For example, while Canadian provinces were implementing tobacco display bans, the Canadian federal government's Department of Health (Health Canada) noted that "*It is possible that restrictions on tobacco displays will have an impact on this trend [smoking incidence], but this remains very speculative at this time*."[119]

Moreover, *no* studies have examined the various impacts of display bans on our business or on the diverse retail universe.

It would be unreasonable, and contrary to the Government's commitments to the States, Territories and the public, to deprive businesses of a core means of competition if it has not been demonstrated that the regulatory intervention will advance the Government's health objectives.

5.2 Studies don't support display bans

The Technical Report cites "additional evidence" to support the proposition that tobacco displays indirectly increase the likelihood that young people will start smoking, encourage smokers to buy more tobacco products and make it harder for quitters to stay quit.[120]

None of the studies cited in the Technical Report establishes that prohibiting retail tobacco display would result in fewer minors starting to smoke or more adults successfully quitting.

For example, a 2006 study cited in the Technical Report measured 605 teenagers' self-reported "*predisposition*" to smoke following exposure to photographs of in-store advertising and point of sale displays. After showing those teenagers photographs of stores with and without advertising and product display, the researchers concluded that "*advertising and bold displays may help to pre-dispose them to smoking*."[121] It never found that tobacco displays actually influenced their beliefs or actions.

In fact, the study found the contrary. Although it found higher brand recall and perceived ease of access to tobacco products among students who viewed photos of stores with product display, the researchers concluded: "*Exposure to point of sale advertising, but not display, tended to weaken students' resolve not to smoke in the following year. Findings also indicate that exposure to advertising, as opposed to pack display on its own, influenced whether students would*

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[118] Norwegian Ministry of Health and Care Services, *Public Hearing of A Proposal on A Ban Against Visible Display of Tobacco Products at Point of Sale, As Well As Certain Other Changes to the Tobacco Damage Act and the Advertising Regulation*, March 2007, p. 5 (Norwegian Consultation Document).

[119] Health Canada, *A Proposal to Regulate the Display and Promotion of Tobacco and Tobacco-related Products at Retail: Consultation Document*, 2006.

[120] Technical Report, p. 17.

[121] M Wakefield, et al., "An Experimental Study of Effects on Schoolchildren of Exposure to Point of Sale Cigarette Advertising and Pack Displays", *Health Education Research* , vol. 21, 15 May 2006, pp. 338-347, 338 (emphasis added), cited in Technical Report, p. 17 & reference number 147.

accept a cigarette from one of its friends if they offered."[122] The same researchers found that product display had *no impact* on peer approval of smoking, positive attributes being ascribed to smokers, or perceptions about overall harm from smoking.[123]

Similarly, although another study cited in the Technical Report found that some adult smokers may make "impulse" purchases when they see tobacco products displayed, the study never suggests that those adults would not have purchased those same tobacco products otherwise.[124]

There insufficient evidence to support a prohibition on tobacco displays rather than less restrictive, evidence-based options.

5.3 Proponents of tobacco display bans ignore the fact that most youth who smoke do not buy cigarettes from retail shops. Broad community initiatives are needed to prevent youth smoking

If the Government's aim is to reduce youth smoking, banning retail tobacco displays misses the mark.

Australian Government research indicates that minors obtain cigarettes significantly more frequently from friends, siblings or even parents than they do from retail shops. For example, the *2004 National Drug Strategy Household Survey* found that "*two in three (68.8%) smokers and three in four (73.9%) ex-smokers aged 12-15 years obtained their first cigarette from a friend or acquaintance*."[125] Another study found that 77% of adolescents identified as "current smokers" did not buy their last cigarette.[126] While 12% of those surveyed had obtained tobacco products from parents (8%) and siblings (4%) and 5% had taken tobacco products from home, most adolescents had acquired their cigarette from friends (41%) or by asking someone else to buy it for them (16%).[127]

Although those surveys highlight the need for stronger enforcement of existing laws (since it is illegal to sell tobacco products to – or purchase tobacco products on behalf of - a person aged less than 18 years), *they also demonstrate that retail regulations are only part of the equation*. While preventing youth access to tobacco at the point of retail remains vital, the responsibility for preventing youth smoking needs to be shared across different sections of the community: parents, friends, siblings, doctors, teachers and the individuals themselves.

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[122] Ibid., p. 345 (emphasis added).

[123] Ibid. (emphasis added). It is worth noting that point of sale advertising is prohibited in all States and Territories.

[124] See M Wakefield et al., "The effect of retail cigarette pack displays on impulse purchase", *Addiction*, vol. 103, 2008, pp. 322-28, cited in Technical Report, p. 17 & reference number 148.

[125] Australian Institute of Health and Welfare, *2004 National Drug Strategy Household Survey – Detailed Findings*, Canberra, October 2005, p. 108 (emphasis added).

[126] Drug Strategy Branch, Australian Government Department of Health and Ageing, *Smoking behaviours of Australian secondary students in 2005*, Centre for Behavioural Research in Cancer, Cancer Control Research Institute, The Cancer Council Victoria, June 2006, p. 20.

[127] Ibid., p. 19.

5.4 Prohibiting tobacco product display would significantly distort competition and impact small businesses

Competing manufacturers and retailers use display to present their range of brands to adult smokers, who can then select the brand they prefer within that range. Requiring retailers to hide tobacco products would significantly impair opportunities for manufacturers to introduce new brands or alternative products. Because adult smokers would have no way of knowing that a new brand, new brand variant, or new product is available, a ban on tobacco product display would make it virtually impossible for manufacturers to introduce new products, an essential element of fair, effective competition in a free marketplace.

A point of sale display ban will adversely impact the ability of manufacturers, importers and retailers to compete. For example, in its proposal to ban tobacco product display, the Norwegian government stated there was no "*doubt that … a [display] ban will remove the use of positioning as a competitive measure between the producers*."[128] Display has been at the heart of a number of competition disputes and litigation in other jurisdictions.[129] Retail display of consumer goods is similarly a key factor in competition in the retail marketplace in Australia.

Some proponents of display bans have suggested that tobacco product display is unnecessary, because up to 90% of adult smokers know their brands. Even if that number is accurate (and we have no basis to know whether it is), that 10% of adults who smoke but who have not decided on their preferred brand represents the key to our ability to compete and succeed.[130]

It's true that most adult smokers know their preferred brand and, in Australia, the leading tobacco brand is made by one of our competitors. If adult smokers never see PML's brands when they buy their products, odds are they will never switch to them, and adults who smoke our brands may switch to better-known brands. Banning display of tobacco products would give, in effect, a regulated competitive advantage to brands with existing market shares and established consumer recognition.

A ban on display of tobacco products also risks distorting competition in the retail universe. Display bans may encourage consumers to shift tobacco purchases to large stores rather than small retailers, as consumers may believe that such retailers are likely to stock a wider range of products.[131] Businesses where display bans have been implemented have expressed significant concerns about that happening.[132]

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[128] Norwegian Consultation Document, p. 5.

[129] In the EU, for example, courts, governments and manufacturers have stressed the importance of access to display in retail to the ability to enter into and compete in a market. See, e.g., European Court of Justice Case C-405/98 Konsumentombusdmannen v Gourmet International Products Aktiebolag (2001), Decision of the Court paras 19-21, 38, 39 and Opinion of Advocate General Jacobs, paras 35, 36.

[130] PML's business succeeds when adult smokers switch to our brands and don't switch to competitors'. Last year, while adult and youth smoking rates in Australia fell to record lows, we increased our market share by 1% and generated an 8.9% increase in operating revenues.

[131] Approximately 34,000 retail businesses in Australia sell tobacco products.

[132] See, e.g., [Canadian] National Association of Convenience Stores, "Tobacco display ban will close 30% of Canadian c-stores, warns top industry executive", *Global Convenience Store Focus*, 4 November 2008.

5.5 Banning retail display is inconsistent with the Competition Principles Agreement

The Competition Principles Agreement between the Commonwealth and each of the State and Territory Governments requires that regulations not restrict competition unless:

> (c) the benefits of the restriction to the community as a whole outweigh the costs; and
>
> (d) the objectives of the legislation can *only* be achieved by restricting competition.[133]

It has not been demonstrated that display bans are the only means of reducing smoking and preventing youth smoking. On the contrary, experience does not support a display ban; the estimated effectiveness of a display ban at reducing youth smoking is speculative; and less restrictive, evidence-based options are both available and likely to further advance policy objectives. Competition principles embodied in State, Territory and Commonwealth law therefore suggest pursuing less restrictive options than a complete ban on retail display of tobacco products.

[133] Clause 5 (emphasis added).

6 Tobacco product regulation should be included in government strategies to reduce harm

Over three million adults in Australia currently use tobacco products. Even if the target of 9% smoking prevalence is reached by 2020, more than one million adults will continue to smoke.[134] While marketing, packaging and sales are strictly regulated, tobacco products themselves are not regulated. One expert observed, "*Given Australia's exemplary role in the regulation of cigarette marketing, it is bizarre that no regulations at all are applied to the product or its emissions*."[135]

> WHAT'S PROPOSED? Legislation authorizing the Government to establish tobacco product standards.
>
> PML'S VIEW: Tobacco products should be comprehensively regulated, and the government should be authorised to establish science-based standards for all tobacco products based on the principle of harm reduction.

The Technical Report recognises that tobacco product regulation can play a role in reducing harm for those adults who continue to smoke. It recommends "*introduc[ing] legislation that gives the government powers to ban, specify or mandate any particular tobacco product constituents, emissions, additives or other aspects of manufacture and design*."[136]

We support the Government establishing science-based standards for tobacco products to reduce harm. We recommend several specific regulatory steps to reach that objective.[137]

6.1 Establishing an expert regulatory agency is key to successful, evidence-based product regulation

Given the complex issues raised by tobacco harm reduction, it is essential that the appropriate resources and expertise are provided to support the development of comprehensive, evidence-based regulations and to implement rigorous testing and performance standards for tobacco and nicotine products. We strongly

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[134] Technical Report, p. 1.

[135] NJ Gray, "The modern cigarette, an unregulated disaster", *Medical Journal of Australia*, vol. 187, no. 9, 5 November 2007, pp. 502-03.

[136] Technical Report, p. 25.

[137] As the Technical Report does not make detailed recommendations on product regulation, our comments in this Section do not contain our complete views (or responses to on-going debates in the public health literature) on the complex issues of tobacco product regulation. PMI provided more detailed views on tobacco product regulation in a recent submission to the European Commission, attached as Annex 2. In the event of a concrete proposal or consultation on any of these or other product regulatory issues, we will provide more detailed additional comments.

support the Technical Report's recommendation that an Agency should be created or empowered with that responsibility.[138]

6.2 Tobacco companies should be required to test and report cigarette ingredients and ingredient toxicity

Every tobacco product manufacturer or importer should be required by law to provide the Government with comprehensive information about the ingredients it adds to its products. Since 2001, we have annually provided information regarding our ingredients to the federal Department of Health. All companies should be required to do so, and disclosure should be mandatory for all tobacco products (including accessories such as cigarette papers).

We support regulation that would permit regulators to ensure that an ingredient does not meaningfully increase the toxicity or addictiveness of tobacco smoke compared to tobacco products on the market without the ingredient. This approach was advocated by the US Institute of Medicine in 2001, which suggested that cigarette ingredient toxicology should be assessed "*with the objective of identifying those ingredients that add no significant toxicity to tobacco products and therefore can be considered safe in the context of its use*."[139]

Adopting regulation in this area is possible, but several scientific and policy issues remain open. For example, the Conference of the Parties Working Group on product regulation has noted the lack of standardised testing for tobacco product ingredients.[140]

We therefore recommend that an expert agency (1) establish the required test methods and require manufactures to conduct assessments of the ingredients they use and to report those assessments to the Government, and (2) establish clear, objective, science-based performance standards (i.e., the level at which an ingredient would be permitted for use).

6.3 The critical focus of regulation should be on emissions

WHO's Scientific Advisory Committee on Tobacco Product Regulation emphasised in 2002 that "*For tobacco products intended to be smoked, the manufactured product needs to be differentiated from the product actually intended for consumption which is its emission ('smoke') and the critical force of regulation*

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[138] Technical Report, p. 25.

[139] K Stratton, P Shetty, R Wallace, S Bondurant, eds. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction National Institutes of Health*, Institute of Medicine, Washington, D.C.: National Academies Press, 2001 (IOM Report), p. 224.

[140] In its 2007 Progress Report, the Working Group stated, "*[T]esting and measuring of toxicity of cigarette contents [e.g., ingredients]…is an emerging field…*," and refrained from recommending a course of action pending "*more work to develop a better understanding of these issues*." *Elaboration of Guidelines for Implementation of the Convention; Article 9: Product Regulation*, 26 April 2007 ("2007 Working Group Progress Report"). The Working Group also stated, "*the concept of testing and measuring the … dependence-producing properties of various tobacco products is fairly new and its application to tobacco product monitoring in particular has yet to be identified. Although the working group believes this area to be very promising, it is of the opinion that there is insufficient knowledge to move forward with guidelines at this time*." Ibid.

must be on the emissions."[141] We agree, and recommend regulatory actions the government should take now.

6.3.1 Tar, nicotine and carbon monoxide emissions should be measured and reported to the Government

Tar, nicotine and carbon monoxide are three commonly regulated components of cigarette smoke. A number of governments, including every EU Member State, require manufacturers or importers to report tar, nicotine and CO yields to the government each year, and we recommend that Australia require that as well.

Currently tar, nicotine and CO are commonly measured using test methods developed by the International Organization for Standardization (ISO). There has been significant debate over the public health benefits of testing tobacco products in this way. We share concerns about the limitations of the ISO test method – or any machine-based test – to reflect actual smoker intake, as individuals do not smoke like machines.

The debate over the ISO test method has been on-going for several years. At one point, the WHO supported supplementing the ISO method with the more intensive method used in Canada – the "Health Canada method."[142] PMI supported this proposal and communicated its support for this proposal to the WHO, as well as to ISO and the Federal Department of Health.[143] The WHO subsequently withdrew its proposal, pending further consideration of the issue by the FCTC's Conference of the Parties Working Group on product regulation. We understand that the Working Group is recommending that both ISO and Health Canada methods be used as smoke test methods. As before, we support that proposal.

Our support of the WHO's proposal also reflects our view, based on data we and others have generated, that the Health Canada intensive method provides a potential upper range for tar, nicotine and carbon monoxide yields. While no machine-based measurement can accurately represent human smoking behaviour in all cases and under all circumstances, a range better illustrates the wide variability in tar, nicotine and carbon monoxide intake, depending upon how an individual smokes a cigarette. Thus, until more meaningful standardised measures of actual human smoker exposure are developed, we believe the Health Canada intensive method is an appropriate complement to the current ISO method.[144]

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[141] World Health Organization, Scientific Advisory Committee on Tobacco Product Regulation (SACTob) Recommendation on Tobacco Product Ingredients and Emissions, November 2002 (SACTob Recommendation on Ingredients and Emissions), p. 3. SACTob later became the Study Group on Tobacco Product Regulation, TobReg.

[142] Health Canada, *Tobacco Industry Reporting Regulations*, Part 3, Section 14(6)(b).

[143] Letter from David Davies to Dr. Yomiko Mochizuki, Director, WHO Tobacco Free Initiative, 5 December 2005; Letter from Dr. Matthias K. Schorp to Mr. Rolf Duus, Secretary ISO/TC 126 WG9, 1 December 2005.

[144] The Government should note, however, that cigarette designs could be developed, such as new means of ventilation or filtration, with which the Health Canada intensive method would not reflect an upper range of smoker intake. For that reason, governments should continuously monitor the relevance of the Health Canada method to new cigarette designs and technologies. To assist this process, manufacturers should be required to disclose information to governments about new designs and technologies.

6.3.2 Other smoke emissions should be measured and reported to the Government

Thousands of chemicals have been identified in cigarette emissions and dozens have been classified as harmful or potentially harmful.

Knowing the yields of a range of smoke constituents in conventional tobacco products is an important step in developing a better understanding of the relationship between tobacco use and disease and in establishing a baseline against which to assess novel products that have the potential to reduce the risk of disease. We therefore support a requirement for manufacturers to report by-brand information on yields of smoke constituents other than tar, nicotine and CO that have been identified as likely causes of tobacco related diseases.

Adopting regulation in this area is possible, but several scientific and policy issues remain open. *First,* no clear scientific consensus exists on which specific constituents to regulate[145]; *second*, analytical methods for measuring individual constituents must be developed and/or validated; *third*, only a handful of laboratories in the public or private sector have the ability to test for smoke constituents other than tar, nicotine and CO, which is needed to monitor industry compliance; and *fourth*, the frequency of by-brand testing for other smoke constituents must be considered in the context of the public health purpose of the testing.

The most prudent approach in light of these open issues is to identify, based on objective scientific evidence and with the assistance of a tobacco-specific regulatory agency

- the specific smoke constituents for testing and reporting,
- the smoke test method to be applied (e.g. ISO, Health Canada),
- the analytical methods to be used for testing those constituents,
- the details of the reporting requirements,
- a plan to establish laboratory capacity, including laboratory qualification criteria, and
- the frequency with which the testing should be carried out.

We do not support communicating quantitative yields of specific constituents to consumers, other than pursuant to a substantiated claim for a reduced risk product, which we discuss in Section 6.4.4. However, the government could determine that communications about emissions on a qualitative basis are needed and can be provided through educational programs, on-line communications or through the mandated on-pack health warnings.

[145] In August 2008, the Conference of the Parties Working Group identified nine smoke constituents for which "*methods for testing and measuring in mainstream smoke (analytical chemistry) should be validated as a priority*." FCTC/COP/3/6, Elaboration of Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC, 21 August 2008, p. 3. The Working Group stated that it could take four years to validate analytical methods. Ibid., p. 4. However, in 2007, the Working Group suggested 44 smoke constituents based on the "Hoffman list." 2007 Working Group Progress Report. Another frequently cited list is the one used by Health Canada. *Health Canada Tobacco Industry Reporting Regulations*, Part 6, Schedule 2.

6.4 Regulation should empower an agency to assess products with the potential to reduce the harm caused by smoking conventional cigarettes

By considering regulation of alternative tobacco products, the Technical Report offers a compelling vision of Government tobacco strategy that, in addition to appropriately maintaining its focus on preventing initiation and encouraging cessation, would address the reality that millions of adults in Australia currently use tobacco products and will continue to do so even if ambitious targets for reducing smoking prevalence are met.

Alternatives to cigarettes should play a part in the Government's long-term strategy of reducing the harm caused by tobacco consumption. "*There is no scientific doubt that there is a vast continuum of risk depending upon how someone obtains nicotine*," according to one tobacco control expert.[146] In his view, "*if all smokers obtained their nicotine from medicinal or low-toxicity non-combustion products, the health concerns about the drug would approach those associated with the contemporary use of caffeine*." Indeed, several have suggested that governments should, as a matter of human rights, take steps to ensure that such products – and accurate information about them – are available to the public as an alternative to cigarettes.[147]

We would support a single, broad regulatory framework covering both tobacco and nicotine products. Some public health groups have referred to this as regulation along a "risk continuum" – essentially establishing regulations of increasing (or decreasing) restrictions based on the risk presented by the product with, hypothetically, conventional cigarettes at one end and nicotine replacement therapies at the other.[148]

6.4.1 Electronic cigarettes and other alternatives to cigarettes should be regulated as pharmaceutical products or medical devices until a more coherent regulatory framework is established

The Technical Report notes "*a proliferation of new devices providing nicotine in products other than those that need to be lit and inhaled have been launched into various markets around the world*."[149] A number of those products are reportedly sold in Australia.[150]

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[146] Sweanor, p. 1602.

[147] See, e.g., ibid., p. 1603 ("*The failure to accept harm reduction strategies as part of its regulatory armamentarium has also sacrificed the moral high ground on the issue of the human rights of smokers*."); L Kozlowski et al., "Some practical points on harm reduction: what to tell your lawmaker and what to tell your brother about Swedish snus", *Tobacco Control*, vol. 12, 2003, pp. 372-73 ("*Individuals who do use or who are thinking of using cigarettes have a right to know that smokeless products are safer than cigarettes … Public health concerns should trump individual rights only when there is clear and convincing evidence of harm to society. Lacking that evidence, individual rights should prevail*.").

[148] See, e.g., Sweanor, p. 1602: "*There is no scientific doubt that there is a vast continuum of risk depending upon how someone obtains nicotine … [A] critical question for future policy directions is just how quickly tobacco control efforts can evolve to become more pragmatic rather than dogmatic*."

[149] Technical Report, p. 26.

[150] PML and PMI recently commented on a proposal to the National Drugs and Poison Schedule Committee to amend the scheduling of nicotine which would effectively permit the sale of e-cigarettes. Our comments are attached as Annex 3.

The "electronic cigarettes" mentioned in the Technical Report are designed to physically resemble cigarettes and are marketed to and understood by consumers as cigarette substitutes, purportedly providing consumers with a pleasurable alternative to cigarettes; reduced risk of disease; or effective smoking cessation therapies.[151] Because the electronic cigarettes do not contain tobacco, they cannot be regulated under current tobacco regulations. Even though the products are similar to pharmaceutical nicotine cessation therapies, such as nicotine inhalers, many countries have been slow to regulate them as pharmaceutical products.

The Technical Report highlights the dilemmas under Australian law:

> *"If e-cigarettes are marketed as an aid in withdrawal from smoking they will be considered a therapeutic good, and would have to be listed on the Australian Register of Therapeutic Goods before they could be imported and retailed in Australia. It seems unlikely that they would meet standards for safety and efficacy. If, on the other hand, e-cigarettes are marketed exclusively as recreational devices, they may not meet the definition of therapeutic use. The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) currently categorises all nicotine products that are not tobacco products or are used for NRT as falling under Schedule 7, which covers Dangerous Poisons. Therefore, at present, such products (not being clearly a tobacco product or NRT) would probably not satisfy the stated exceptions, and could not be retailed under state and territory legislation."*[152]

We believe that pharmaceutical regulation appears to be the only viable option for such products today. Several EU Member States have recently taken that approach,[153] as has the U.S. Food and Drug Administration.[154]

Our support of pharmaceutical regulation for products such as electronic cigarettes is not intended to place unreasonable or undue regulatory burdens on the marketing of legitimate smoking cessation products or products that have the potential to offer consumers safer alternatives to cigarettes. However, it is not

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[151] For example, the manufacturer of *Ruyan* has in the past stated in consumer communications that the product "*means healthier smoking*" and that "*painless smoke abstention can be realized within a certain period of time, after carrying out the smoke abstention scheme recommended by Ruyan*."

[152] Technical Report, p. 26. See, e.g., Government of Victoria Media Release, "Victorian ban on battery-powered cigarette," 31 December 2008.

[153] For example, in a letter sent out to its counterparts, the Dutch Health Minister concluded that electronic cigarettes were a medicinal product but would "withhold a final decision on the status of the product until the EU Member States have reached a more uniform position."

[154] In July 2002, the FDA granted a petition filed by, among other, the American Lung Association and Campaign for Tobacco Free Kids, to designate a product called Nicotine Water as an unapproved new drug. FDA concluded that "*Based on several factors…this product should be regarded as an unapproved new drug*" and also stated that "*Because the nicotine and nicotine polacrilex in Nicotine Water are both active ingredients in FDA-approved drugs (such as* Nicoderm CQ*,* Prostep*,* Habitrol*, and* Nicorette*) Nicotine Water cannot be marketed as a dietary supplement*." The FDA also issued warning letters to manufacturers of nicotine lollipops and lip balm, citing claims that the products were a "*'convenient and tasty way' to replace the cigarette habit*."

tenable to permit products that deliver nicotine – whether marketed with or without claims – to be sold without meaningful regulatory oversight.

Nevertheless, we recognise the imbalance between regulation of tobacco products and that of pharmaceutical products providing nicotine, especially products intended (and substantiated) as nicotine replacement therapies or safer alternatives to conventional cigarettes. One possible way of addressing this dilemma in the long term is to revise the pharmaceutical regulatory framework to accommodate tobacco harm reduction by liberalizing the restrictions on nicotine pharmaceutical products, such as was recently done in Sweden.[155] Longer-term, the government could establish a single, broad regulatory framework covering all tobacco and nicotine consumer products.

6.4.2 Australia should permit and regulate the commercial import and sale of snus

Like all tobacco products, Swedish-style moist snuff – *snus* – causes disease and is addictive. However, the data from Sweden suggest that snus has far fewer adverse health effects than cigarettes. In fact, scientists and public health advocates have reported that snus is substantially less harmful than cigarette smoking, essentially eliminating the risk of lung cancer and other lung diseases and reducing by as much as 50% or more the risk of many other major tobacco related diseases.[156]

In fact, in 2003 a panel of leading EU tobacco control experts recommended that the EU's ban on snus be lifted. According to the panel, smokeless tobacco and snus were "*at least 90% less hazardous than cigarette smoking*," and there were "*very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco.*"[157]

Respected scientists have pointed out in a recently published commentary, "*whatever the true overall hazard, use of low nitrosamine smokeless products is clearly substantially less harmful than tobacco smoking.*"[158] The Tobacco Advisory Group of the Royal College of Physicians stated in its 2007 report that *"[t]he epidemiology of tobacco use in Sweden suggests that if the public is offered a substantially less harmful smokeless tobacco product along with access to accurate information on relative risks, a substantial portion can switch to the less harmful product. This has clear implications for public health*."[159]

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[155] See UK Consultation Paper, p. 54.

[156] See, e.g., European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks, *Health Effects of Smokeless Tobacco: Preliminary Report*, June 2007, p. 107; J Luo et al., "Oral Use of Swedish Moist Snuff (Snus) and Risk for Cancer of the Mouth, Lung, and Pancreas in Male Construction Workers: A Retrospective Cohort Study", 10 May 2007; C Bates et al., "European Union Policy on Smokeless Tobacco: A Statement in Favor of Evidence-based Regulation for Public Health", *Tobacco Control*, vol. 12, 2003, pp. 360-67, 361 ("*smokeless tobaccos are not associated with major lung diseases, including…COPD and lung cancer*").

[157] European Commission, *Health Effects of Smokeless Tobacco*, p. 107.

[158] J Britton et al., "Tobacco Smoking, Harm Reduction and Nicotine Product Regulation". *Lancet*, vol. 371, 2 February 2008.

[159] Royal College of Physicians, *Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit. A Report by the Tobacco Advisory of the Royal College of Physicians*, October 2007, p. 167 (Royal College of Physicians Report) (emphasis added). The Report noted that all of the health hazards presented by snus "*are of a lower magnitude than those associated with cigarette smoking*;" that "*smokeless products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer*;" that "*in Sweden, the*

In May 2007, Australian health researchers published a study that modelled the health impact of legalizing snus in Australia.[160] They concluded that "*Individual smokers who switched to snus instead of continuing to smoke and new tobacco users who only used snus rather than smoking would achieve large health gains compared to smokers*."[161] They also predicted, as have many other researchers, that snus would likely provide a net benefit to the public health.[162]

Currently smokeless tobacco products may not be commercially imported or sold in Australia, although a limited quantity can be imported for personal consumption.[163] Although that may technically permit savvy consumers to somehow learn about and snus, it deprives Australian adult smokers of information and access to less harmful tobacco products. They should have that right.

We therefore urge the government to lift Australia's *de facto* ban on snus. Today, millions of Australian adults use conventional lit tobacco products. Those adults should have the informed option of purchasing snus, an alternative tobacco product that reduces the risk of disease without undermining the public health goals of prevention and cessation. The public health concerns about snus should be addressed through regulation rather than de facto prohibition.[164]

6.4.3 A product regulatory framework should recognise that other tobacco products can also potentially reduce the harm of smoking

A number of public health experts have opined that it is conceivable for other tobacco products to be developed which could measurably reduce the risk of smoking compared to conventional cigarettes, and that making such products available and understood by consumers could reduce societal harm.[165] A regulatory framework should recognise that possibility, and set clear rules for developing and selling such products.

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available low-harm smokeless products have been shown to be an acceptable substitute for cigarettes to many smokers, while 'gateway' progression from smokeless to smoking is relatively uncommon;" and that therefore, snus "has potential application as a lower hazard alternative to cigarette smoking." Ibid. However, the report noted that "the applicability of smokeless tobacco as a substitute for cigarette smoking if made available to populations with no tradition of smokeless use is not known." Ibid.

[160] CE Gartner et al., "Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study", *Lancet,* published online 10 May 2007.

[161] Ibid., p. 3 (emphasis added).

[162] Ibid., p. 1.

[163] Technical Report, p. 26.

[164] We believe, therefore, that concurrent with the lifting of the ban, Australia should adopt a regulatory framework for snus For example, regulations could mandate that consumers are told that snus is not a safe or risk-free alternative to cigarettes. Regulations can also create mechanisms to monitor the actual impact of snus on the prevalence of overall tobacco use and tobacco related diseases. This will allow policy changes to be made if and when necessary.

[165] For example, the US Institute of Medicine concluded in 2001 that "*for many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible*." IOM Report, p. 5.

Broadly speaking, the law should explicitly *prohibit* manufacturers from making any reduced risk claim about a tobacco product *unless* the claim is substantiated by a designated regulatory agency, under a rigorous pre-market review process. As with the other products discussed in this section, *if a product is proven to have the potential to reduce risk of disease compared to conventional cigarettes, that fact should be communicated to consumers*.[166]

In order to substantiate a claim, the manufacturer or importer should be required to establish through reliable scientific data that the product will result, or is reasonably likely to result, in a substantial reduction in risk of one or more tobacco related diseases compared to a conventional combustible tobacco product on the market. Elaboration on the data needed to support this standard should be established by the Government with the assistance of a scientific committee of experts. The data should be generated from non-clinical investigation (smoke chemistry, *in vitro* and *in vivo* assays) and clinical investigations.[167]

Achieving the appropriate balance between the objective of communicating benefits of new products and the objective of preventing initiation and encouraging cessation can be done. As the United States Institute of Medicine (IOM) stated in a seminal report on regulating reduced risk tobacco products, "*The problem of conveying balance in communicating health benefits and risks is not unique to tobacco-related PREPs, and the large body of experience in other areas of health and safety regulation may be applicable to these products as well*."[168]

For example, the Agency should develop rules regarding pre-market testing of consumer perception of claims.[169] Manufacturers and importers could be required to inform consumers that smoking a reduced risk product, albeit substantiated by

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[166] Although the Technical Report would empower the regulator with "*authorising the form and content of all communication with consumers about the contents and toxicity of cigarettes*," which we support, it then paradoxically suggests that product regulation should be preceded by a total ban on any product communication. Technical Report, p. 25. We disagree. We do not suggest that tobacco advertising prohibitions should be repealed. Rather, consumers must have a meaningful ability to learn about the availability and benefits of cigarette alternatives. See, e.g., Royal College of Physicians' Report, pp. 209-210 ("*The principles of autonomy and individual rights are that adults should have knowledge of and access to less hazardous forms of nicotine in case they want to choose to use them. If significantly less hazardous means exist to satisfy nicotine-addiction, honest information and availability are ways to respect individual rights…it is arguable that consumers have a right to know salient information about the products they wish to use, and about products which the may wish to use but are prevented from using on public health or product safety grounds*.").

[167] In addition to statements that one product is safer, i.e., presents a reduced risk of one or more tobacco related diseases than other products on the market, the following other statements should be subject to pre-market review: (1) a product reduces or eliminates the levels of one or more smoke constituents and (2) a product reduces or eliminates the user's exposure to one or more smoke constituents. Such statements should be subject to pre-market review whether or not the manufacturer states that the reduction in yield or exposure reduces the risk of disease.

[168] IOM Report. "PREPs" is the acronym for what the Report calls Potential Reduced Exposure Products, which, for simplicity's sake, we refer to here as reduced-risk products.

[169] DK Hatsukami et al., "Methods to assess potential reduced exposure products", *Nicotine & Tobacco Research* , vol. 7, no. 6, 2005, pp. 827-44, 829-30 ("*The purpose of consumer product testing is to ensure that claims and marketing of a product will lead the consumer to make an informed decision based on an accurate understanding of valid information, and to ensure that the product does not appeal to youth, those who would have quit otherwise, or those who have previously quit*").

expert authorities, is not an alternative to quitting and that the best way to reduce risk of tobacco-related disease is to stop using tobacco products. Depending on the data provided, a claim could be accompanied by a statement that the health consequences of the change are unproven. It is also important that substantiated claims do not imply that the product has been endorsed by the Government, is an alternative to quitting, or is safe to use.

6.4.4 Informing cigarette smokers about the potential benefits of safer alternative products is a crucial component of a harm reduction strategy

The Technical Report recognises that there would be "*few public health benefits [to having less harmful alternatives to cigarettes] unless large numbers of … smokers knew about such alternative products and were willing to try them*."[170] Without meaningful access to information, smokers will never know that potentially less harmful alternatives to cigarettes are available, nor will those who are aware of such products be able to make informed decisions about which products to choose.

Today, it is illegal for anyone (including government agencies) to publicise or promote any tobacco product, including those demonstrated less risky than conventional cigarettes. Nicotine replacement therapies can only be advertised according to laws on therapeutic goods. Non-tobacco, non-therapeutic nicotine is in a grey area.[171]

Several prominent tobacco control experts have suggested that rules on communication should be based on scientifically substantiated risk assessments rather than on product content. One prominent tobacco control advocate for example, suggested that "*a regulatory strategy could include advertising less toxic tobacco products to current smokers as an alternative to cigarettes, mandating smoker-friendly package messaging aimed directly at facilitating cessation…*"[172] Regulating (and communicating) along such a risk continuum will require a significant re-assessment of the government's current all-or-nothing approach.

We recognise that many public health advocates are legitimately concerned that marketing products with claims, even substantiated ones, may increase overall harm to the population by causing fewer people to quit or more people to initiate tobacco use. While pre-market testing can provide important information upon which to predict consumer use and behaviours, these issues are essentially unknowable before marketing the product. For that reason, population harm is best assessed through post-marketing monitoring and studies, rules about which should be developed by a responsible agency. The IOM's 2001 report commented on this issue:

> *"Regulation cannot assure that the availability of risk-reducing PREPs will lead to reduced tobacco-related harm in the population as a whole. However, a regulatory agency can assure that data are gathered that would permit population effects to be monitored. If tobacco use increases or tobacco-*

[170] Technical Report, p. 27.

[171] See, e.g., National Drugs and Poisons Schedule Committee, Proposal to Amend the Scheduling of Nicotine in Relation to Use In Electronic Cigarettes, Item 5.1 in the Pre-October 2008 Scheduling Meeting Notice.

[172] Sweanor, p. 1602.

> *related disease increases, these data would serve as a basis for developing and implementing appropriate public health interventions*."[173]

A regulatory framework for cigarette alternatives can build a solid basis for tobacco product harm reduction in the Australia without undermining the goals of preventing initiation and encouraging cessation.

[173] IOM Report, p. 6 (emphasis added); see also WHO Scientific Advisory Committee on Tobacco Product Regulation, Statement of Principles Guiding the Evaluation of New or Modified Tobacco Products, 2002, p. 7 (post-marketing surveillance will allow the assessment of the impact of the product "*on rates of smoking initiation and cessation*" which are "*important measures of its net harm to the population*").

7 Tobacco advertising is already banned; the Technical Report's recommendations to ban other so-called 'advertising' serves no valid public health purpose

The *Tobacco Advertising Prohibition Act 1992* (Cth) prohibits anything which gives publicity to or otherwise promotes smoking, tobacco use, a tobacco product or a tobacco brand. The prohibition extends to any form of communication, and applies to any person or group. It is so broad that specific exemptions were needed to allow for the publication of recall notices and for tobacco company employees to have (unbranded) business cards.

> WHAT'S PROPOSED? Prohibiting internet sales; prohibiting normal, essential commercial and competitive practices; and discouraging charitable contributions and responsible conduct.
>
> PML'S VIEW: Internet sales should be restricted but not prohibited. Commercial practices are essential business tools that cannot be outlawed. The suggestion of banning charitable contributions and discouraging responsible conduct by tobacco companies has no rational relationship with the objective of reducing smoking prevalence.

The Technical Report recommends "modernising" the Act, banning internet sales, prohibiting normal trade relations, and adopting wholesale the recommendations of guidelines recently adopted at the FCTC Conference of Parties ("COP Guidelines").[174]

The Technical Report does not explain that the COP Guidelines go well beyond what is necessary or effective for reducing smoking incidence, and in some instances are outrageous and unlawful. The Government should reject the proposal to extend an already complete tobacco advertising ban in a way that would prevent well-controlled sales, distort normal commercial practices, and selectively demonise Australian businesses.

7.1 Internet sales should be regulated not banned

The Technical Report recommends banning internet sales to retail purchasers of tobacco products, which the COP Guidelines assert "*inherently involve tobacco advertising and promotion.*"[175]

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[174] Technical Report, p. 18, referring to and incorporating the COP Guidelines for Article 13 of the Framework Convention on Tobacco Control.

[175] Technical Report, p. 15. We assume that the proposal is to ban internet retail sales. PML uses secured internet sites to sell to its commercial customers, and would strongly oppose prohibiting that.

A complete ban on consumer internet marketing and sales of tobacco products is disproportionate and unwarranted. Marketing over the internet can be achieved safely and securely. Appropriate technology exists to implement robust age verification procedures. Appropriate IP filtering technology exists to limit access to adult smokers resident in a particular country. In fact, the internet can provide one of the most secure ways to limit communications about tobacco products to adult smokers.

Selling tobacco products over the internet should likewise be permitted provided that there is reliable age verification, the product is in compliance with all applicable product regulations, and the manufacturer, seller and purchaser pays all applicable duties and excise taxes.

7.2 Normal trade relations, including competitive wholesale trading terms, are essential, protected competitive tools and should continue to be permitted

The Technical Report vaguely recommends prohibiting tobacco "*payments to retailers*" by tobacco product manufacturers.[176] The COP Guidelines go farther, and suggest banning "*various sales and/or distribution arrangements …For instance, incentive schemes for retailers…*"[177]

Tobacco product manufacturers should be able to continue to provide rebates, discounts, incentives, and other trade programs in exchange for the services they render in stocking and selling their brands. Such trade practices are a normal – and essential – part of doing business, and are particularly important for small businesses.

The retail trade is highly competitive and retailers seek incentives from all suppliers, not just tobacco manufacturers and their distributors. Incentives are used to compete for the ability to stock and place products in preference to the products of a competing manufacturer, to ensure product quality and freshness stock, to reward shelf replenishment and cleanliness, and cooperation to prevent illicit trade.

Preventing tobacco companies from participating in this part of the normal retail trade will directly limit our ability to compete fairly, but there is no evidence it would help reduce smoking prevalence. Trade incentives do not promote the use of tobacco. Instead they are designed to use the strength of our relationships with retail partners to gain a competitive edge against other tobacco companies – a fundamental principle in free and competitive markets.

7.3 The Government should not discourage responsible business practices nor selectively prohibit companies from making charitable contributions

The Technical Report's recommendation to amend the law in line with the COP Guidelines incorporates a recommendation to ban contributions of any kind by any person who earns money from tobacco sales.

The COP Guidelines state that "*Some tobacco companies make financial or in-kind contributions to organizations, such as community, health, welfare or environmental organizations … Such contributions fall within the definition of*

[176] Technical Report, p. vii.

[177] COP Guidelines para 8 & footnote 1

tobacco sponsorship … and should be prohibited as part of a comprehensive ban, because the aim, effect or likely effect of such a contribution is to promote a tobacco product or tobacco use either directly or indirectly."[178]

The COP Guidelines further state that "*Tobacco companies may also seek to engage in 'socially responsible' business practices (such as good employee-employer relations or environmental stewardship), which do not involve contributions to other parties. Public dissemination of such information should be prohibited, except for purposes of required corporate reporting (such as annual reports) or necessary business administration (e.g. for recruitment purposes and communications with suppliers)*."[179]

We agree that public communications about charitable contributions should not be used to promote tobacco brands, and the law already ensures that.

However, it is outrageous to suggest that the Government should outlaw "*contributions to organizations, such as community, health, welfare or environmental organizations*" and discourage a company from adopting "'*socially responsible' business practices (such as good employee-employer relations or environmental stewardship*." There is no conceivable basis (and certainly no evidence in the Technical Report) for suggesting that adopting such punitive laws would do anything to reduce smoking prevalence in Australia.

[178] COP Guidelines para 26.

[179] COP Guidelines para 28.

8 Conclusion: Industry inclusion results in better regulation

An alliance comprising organisations led by NPHT members and others has recommended jettisoning principles of good governance from tobacco policymaking altogether:

> *"[W]e urge Parties [to the FCTC] to eliminate references to 'good governance' from the draft guidelines. This is a term which means different things in different places, but often involves consulting all 'stakeholders' to minimise the negative impacts of proposed new policies. This gives the industry the opportunity to delay urgently needed measures and a soapbox to trumpet its groundless economic arguments…"*[180]

Although that approach seems to have already been applied by the NHPT,[181] the Government should not take that approach.

Excluding PML because we don't endorse everything proposed by the NPHT misunderstands our views and misses the point: PML can succeed in a rigorous regulatory environment, and we support further regulation. But regulation that advances no public health interest but hurts us, our employees, and our customers is bad policy.

Including companies and people who make and sell tobacco products in the policy-making process is important for a number of reasons.

First, although it may be convenient to perpetuate the image of "Big Tobacco" in order to present policy options as simple, black-and-white choices, the so-called tobacco "industry" isn't an industry at all. Tobacco products sold in Australia are made by nearly a dozen companies, not just PML, and all manufacturers are not alike. Tobacco products are sold by over 25,000 large and small businesses across Australia. Their views should not be reduced and ignored for the sake of demonizing "Big Tobacco." Millions of Australians smoke, and millions more do not. Australia has a tobacco control community that is experienced and influential within Australia and beyond. The views of all of those stakeholders should be solicited and considered. But neither "best practice regulation" nor fundamental concepts of individual liberty permits policy making by popularity poll.

Second, limiting our ability to participate in the process of developing tobacco regulations is contrary to the Australian Constitution, long established principles of participatory democracy, and good governance rules. Australian governments should continue to follow those principles, including meaningful consultation of all affected parties.

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[180] Framework Convention Alliance Bulletin, 20 November 2008, pp. 1, 3 (emphasis added).

[181] See Discussion Paper, p. xi; see also the "by invitation only" consultation schedule posted on the NPHT's website, http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/engagement-and-consultation-1lp

Third, better policy results from consulting with *all* stakeholders, even unpopular ones. If 10 like-minded people were asked to develop policy on tobacco, they would likely have similar views.[182] That's true whether those people are from the tobacco control community or from a tobacco company. *Group-think is unlikely to represent the views of the 2 million adults who smoke or of Australians at large*, and is not the best way for the Government to develop policies that work best for the people it represents.

Broad, inclusive consultation and open-minded consideration of all the evidence is the only way to achieve that. For example, tobacco retailers have substantial expertise to help legislators and regulators understand (and better regulate) the tobacco retail business. Their views should not be the only ones considered, but their experience should be a factor in guiding legislators on their quest for rational regulation of the retail trade. Similarly, given the complexities of tobacco regulation, especially in areas such as illicit trade prevention, fiscal policy, and product regulation, the evidence and experience of tobacco companies can help develop regulation that is technically viable, practically workable, enforceable, and with a minimum of unintended consequences.

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Moorabbin, Victoria
2 January 2009

[182] See, e.g., Centre for Independent Studies, "Six Social Policy Myths", *Policy*, Autumn 2008. ("*The core beliefs and assumptions of this group of 'experts' are rarely challenged, and when they are, the challenge is generally ignored or waved away as self-evidently absurd and wrongheaded. This is not because these people consciously act in bad faith. They genuinely believe they are open to ideas and that they are self-critical, even impartial. But when everybody around them thinks as they do, and sees the world as they see it, it is difficult for them to take contrary 'definitions of the situation' seriously when they occasionally encounter them*.")

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Annexes

ANNEX 1: COMPARISON OF TAX INCIDENCE AND RETAIL PRICE OF CIGARETTES IN CALIFORNIA AND AUSTRALIA

AUSTRALIA		
Peter Jackson 30s	**Status quo**	**$0.075 / cigarette increase**
RRP per pack	$ 13.50	$ 15.975*
Excise yield per cigarette	$ 0.2545	$ 0.3295
Excise yield per pack	$ 7.635	$ 9.885
Excise incidence	56.56 %	61.88 %
GST	10.00 %	10.00 %
Total tax yield per cigarette	$ 0.27995	$ 0.3779*
Total tax yield per pack	$ 8.862	$ 11.3372*
Total tax incidence	65.65 %	70.97%

*assumes, for argument sake, that excise tax increase fully passed on in RRP, and does not account for any potential additional increases due to retail margin or mark-ups.

CALIFORNIA	
***Basic* 30s**	
RRP per pack	$10.23**
Excise yield per cigarette	$ 0.0959***
Excise yield per pack	$ 2.8776
Excise incidence	28.13 %
State sales tax	7.250 %
Los Angeles County sales tax	8.250 %
Total tax yield per pack	$ 3.8170
Total tax incidence	37.32%

****** Cigarettes are not sold in packs of 30 in California. *Basic* 20s, a leading value brand in California, was calculated as a 30-pack for comparison purposes as follows: US$ $4.48 / pack of 20 = US$ 0.224 / cigarette = US$ 6.72 / 30 cigarettes = A$ 10.23 / packet of 30. *Source*: telephone call on 15 December 2008 to *Vons Sunset Vista Supermarket*, 2511 Daly Street, Los Angeles, CA 90031, tel. (+1 323) 662-8107.

******* State excise tax of US$ 0.87 / pack of 20
Federal excise tax of US$ 0.39 / pack of 20
Total excise; US$ .063/ cigarette = US$ 1.89 / pack of 30 = AU$ 2.8776 / pack of 30

Exchange rates
$1 = € 0.5159
$1 = US$ 0.6568

ANNEX 2: PMI SUBMISSION TO EUROPEAN UNION ON IMPLEMENTATION OF TOBACCO PRODUCT DIRECTIVE

Philip Morris International's (PMI) Comments on the "Second Report on the Application of the Tobacco Products Directive" and Potential Future Amendments to the Directive

1. Expanding the Commission's Authority and Establishing an EU Tobacco Agency

The Commission recommends amending the Directive to broaden its regulatory authority. This is essential and can be achieved by expanding the matters that the Commission is permitted to address through the comitology process currently provided for in Articles 9 and 10 of the Directive.

In addition to expanding the Commission's authority, we suggest creating a Community tobacco agency, or alternatively a scientific advisory committee to support the Commission, the Council, the European Parliament and the Member States. However, although the Commission and the comitology process can be supported by scientific committees, the establishment of an agency specifically dedicated to the regulation of tobacco products is, we believe, a better alternative.

An agency staffed by policy and scientific experts would be able to develop complex science-based test methods and standards (including new measurement methods for smoke constituents, ingredients testing methods, performance standards for conventional products, and the development of a rigorous process for evaluating potentially reduced risk products), sustain long term research and monitoring, and fulfil the role of a "*coordinating mechanism or focal points for tobacco control*" in the EU.[1]

An agency has also been called for by other organisations such as the European Network for Smoking Prevention, which stated in their response to the Consultation on Health in Europe: A Strategic Approach that: "*there is a need for greater capacity dedicated to tobacco control at both EC and Member State level. It is in particular the capacity to assess and regulate nicotine and tobacco products at EC level that is needed. At European level an extension of existing capacity within the European Commission or the establishment of a European tobacco and nicotine products regulatory agency could fill this need.*"[2]

2. Regulating Tar, Nicotine and CO Yields

2.1 Tar, Nicotine and CO Yields on Packs and in Consumer Communications

Public health advocates have called for a ban on printing yield numbers on packs.[3] We agree that the Directive should be amended, and consistent with its ban on descriptors, prohibit manufacturers and importers[4] from printing tar, nicotine and CO yields on packs.

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[1] See FCTC Article 5(2)(a).

[2] European Network for Smoking Prevention (ENSP) response to the consultation on Health in Europe: A Strategic Approach, page 2 http://ec.europa.eu/health/ph_overview/strategy/docs/R-063.pdf

[3] PMI has expressed its view that machine-based yield numbers do not necessarily reflect the amount of tar, nicotine or CO an individual consumer will actually inhale. In fact, actual deliveries of these constituents can vary widely, depending upon how an individual smokes a cigarette.

[4] Throughout this paper when we refer to manufacturers we also cover importers because products that are imported but not manufactured in a particular Member State must be subject to the same regulatory requirements and standards.

We understand, however, that the FCTC's Conference of the Parties Working Group on product regulation is recommending that both ISO and Health Canada methods be used as smoke test methods.[5] As before, we support this proposal.[6] If adopted, manufacturers could be required to print a range of numbers (ISO and Health Canada) on-pack, providing consumers with two sets of tar, nicotine and CO yield numbers, reflecting a range of smoke intake.[7]

Manufacturers should also be prohibited from incorporating tar, nicotine, or CO numbers in a tobacco product's brand name or anywhere on the packaging.[8] This should likewise apply to on-pack statements or numbers relating to the yields of any other smoke constituent.

An exception to this general rule should be granted to numbers or on-pack statements relating to potential reduced risk products as discussed in Section 7.1 below. Specifically, the product must be substantiated by an appropriate government authority to result, or be reasonably likely to result, in a substantial reduction in risk of one or more tobacco related diseases compared to commercial combustible products on the market. On-pack communication of reduced smoke constituents related to those products can play an important role in furthering the goal of harm reduction provided such communication is made as described in Section 7.1.

2.2. Reporting Yields to Governments and Compliance with Ceilings

We agree with the Commission that manufacturers should continue to report ISO-measured tar, nicotine and CO yields to governments, and that those yields should continue to be the basis for the Directive's maximum yields for tar, nicotine and CO. [9]

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[5] FCTC/COP/3/6, *Elaboration of Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC*, (21 Aug. 2008) (Working Group 2008 Progress Report).

[6] The debate over the ISO test method has been on-going for several years. At one point, the WHO supported supplementing the ISO method with the more intensive method used in Canada – the "Health Canada method." Health Canada, Tobacco Industry Reporting Regulations, Part 3, Section 14(6)(b). PMI supported this proposal and communicated its support for this proposal to the WHO, as well as to ISO and the European Commission. Letter from David Davies to Dr. Yomiko Mochizuki, Director, WHO Tobacco Free Initiative (5 Dec. 2005); Letter from Dr. Matthias K. Schorp to Mr. Rolf Duus, Secretary ISO/TC 126 WG9 (1 Dec. 2005). The WHO subsequently withdrew its proposal, pending further consideration of the issue by the Working Group.

Our support of this proposal reflects our view, based on data we and others have generated, that the Health Canada intensive method provides a potential upper range for tar, nicotine and CO yields. While no machine-based measurement can or is meant to accurately represent human smoking behaviour in all cases and under all circumstances, a range better illustrates the wide variability in tar, nicotine and CO intake, depending upon how an individual smokes a cigarette. Thus, until more meaningful standardised measures of actual human smoker exposure are developed, we believe the Health Canada intensive method is an appropriate complement to the current ISO method.

[7] Of course, any yield information provided to consumers would need to be explained in a way that is clear and conveys the limitations of machine-based measurements and additionally discloses the purpose and limits of a dual rating system, including that low and high ends of the "range" do not bracket the full range of human smoke intake.

[8] Similarly, we would also support Member State action to prohibit manufacturers from making statements relating to tar, nicotine, or CO yields in advertisements or other non-packaging related consumer communications.

[9] We note that existing ISO-based ceilings should remain based on ISO measurements. If not, the result would be a de facto ban on virtually all products. For example, today all countries in the European Union

However, Article 4 of the Directive, which governs testing for tar, nicotine and CO yields, should be amended to incorporate the Commission's *Practical Guide on Cigarette Yield Measurement*, making it binding throughout the EU. The *Practical Guide* was intended to resolve questions from the Member States about the application of the ISO confidence intervals to the EU mandated ceilings, *i.e.*, whether variances or fluctuations were permitted around the ceilings.[10] If applied by all Member States, the *Practical Guide* can align the application of the ceilings across Member States, which, as the Directive clearly states, is needed for the proper functioning of the internal market.

3. Regulating Other Smoke Constituent Yields

3.1 Reporting Yields to Governments

The Commission raises the possibility of requiring manufacturers to report other smoke constituents for their tobacco brands in addition to tar, nicotine and carbon monoxide ("*the Hoffmann list of analytes*").

We support amending Article 4 of the Directive to require manufacturers to report by-brand information on yields of smoke constituents that have been identified as likely causes of tobacco related diseases. Knowing the yields of a range of smoke constituents in conventional tobacco products is an important step in developing a better understanding of the relationship between tobacco use and disease and, most importantly, in establishing a baseline against which to assess novel products that have the potential to reduce the risk of disease. However, before elaborating specific testing and reporting requirements, several fundamental issues must be resolved.

First, no clear scientific consensus exists on which specific constituents to regulate. In April 2007, the FCTC's Conference of the Parties Working Group on Product Regulation referred to the "Hoffmann list" as a "sound basis" for regulation and identified approximately 44 smoke constituents as a "preliminary list" for possible regulation.[11] But at least three "Hoffmann lists" exist, with the latest list published identifying 82 constituents.[12] Other public health advocates

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have established ISO measured limits of 10 milligrams of tar. Under Health Canada's intensive method, products that measure 1 milligram of tar under the current ISO method would yield approximately 20 milligrams of tar, and those that measure 10 milligrams of tar would yield approximately 30 milligrams of tar. Until more meaningful measurements of actual human exposure are developed and until the potential benefits of ceilings under the Canadian intensive method are examined, we believe that legislation on maximum yields should continue to be based on the existing ISO method. This is particularly important because the Canadian intensive method may only be an interim step until a new test method is established that provides more meaningful information.

[10] The Commission clarified that the ISO confidence intervals apply to the maximum permitted yields of tar, nicotine and CO. However, while yields could "fluctuate" around the ceiling, they must remain within the confidence interval and could not be "repeatedly" above the ceiling.

[11] WHO Conference of the Parties to the FCTC Second Session, *Elaboration of guidelines for implementation of the Convention; Article 9: Product regulation)*. (26 April 2007) ("COP 2007 Article 9 Progress Report").

[12] Hoffmann D., Hoffmann I., *Tobacco Smoke Components*, Letters to the Editor, Beitr Tabakforsch Int 18: 49-52 (1998); Hoffmann D., Hoffmann, I., *The Changing Cigarette, 1950-1995*. *J Toxicol Environ Health* 50: 307-364 (1997); Hoffmann D., *Analysis of Toxic Smoke Constituents*, Consumer Product Safety Commission (1993).

and regulators have identified different lists of smoke constituents for regulation.[13] In August this year, the FCTC's Conference of the Parties Working Group on Product Regulation issued a Progress Report, which identified nine smoke constituents ("emissions")[14] for which "*methods for testing and measuring in mainstream smoke (analytical chemistry) should be validated as a priority*."[15]

Second, analytical methods for measuring individual constituents must be developed and/or validated. In its 2007 Progress Report, the Conference of Parties Working Group stated, "*[n]o [analytical] methods have yet been validated"* except for tar, nicotine and carbon monoxide.[16] The Working Group confirmed that it was undertaking to "*review the structure and completeness of identified methods and to support the development of new methods where they are lacking,"* but noted that this process could take several years to complete.[17] It also referred to the "*contentious issue*" about which smoke test method to use (Health Canada, ISO or another method).[18] As we stated above, no machine based test method today accurately represents the amount of tar, nicotine, CO, or other smoke constituent inhaled by each smoker. In its 2008 Progress Report, the Working Group stated that the WHO Tobacco Laboratory Network has submitted a proposal to validate methods for testing and measuring emissions. According to the Report, the development of methods for emissions "*is estimated to take five and a half years.*"[19]

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[13] *See, e.g.*, Health Canada Tobacco Industry Reporting Regulations, Part 6, Schedule 2; *IARC Monographs on the Carcinogenic Risk of Chemicals to Humans – Tobacco Smoking (38)* (IARC 1986); *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans -- Tobacco Smoke and Involuntary Smoking (83).* (IARC 2004); U.S. Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette, A Report of the Surgeon General* (1981).

[14] The constituents are: 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), *N*-nitrosonornicotine (NNN), acetaldehyde, acrylaldehyde (acrolein), benzene, Benzo[a]pyrene, 1,3-butadiene, carbon monoxide and formaldehyde. (Elaboration of guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control, Progress Report of the Working Group, FCTC/COP/3/6, 21 August, 2008) http://www.who.int/gb/fctc/PDF/cop3/FCTC_COP3_6-en.pdf

[15] The Working Group 2008 Progress Report does not make any suggestion regarding the development of regulations other than establishing validated test and analytical methods to measure these emissions. However, the nine priority constituents are the same constituents that have been identified by the members of the WHO Study Group on Tobacco Product Regulation (TobReg) for the creation of performance standards (*i.e.*, ceilings). See, *e.g.*, Burns DM. et al. *Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal*, Tobacco Control 2008; 17; 132-141 (2008). Although, as stated above, PMI supports the testing and regulation of smoke constituents, we do not support arbitrary performance standards, such as those proposed by TobReg, that are not likely to reduce the risk of tobacco related diseases.

[16] Working Group 2007 Progress Report. The Working Group stated, "*Validation is an essential process in the development of a method in order to demonstrate the method in question is suitable for its intended purposes*." Id. at p. 5. The Group has said that before guidelines can be adopted by the Conference of the Parties, the test methods and procedures must be validated.

[17] Id. Health Canada has published analytical test methods for measuring several mainstream smoke constituents. See Health Canada Tobacco Industry Reporting Regulations. However, the Canadian methods are not considered to be internationally validated methods.

[18] Id.

[19] Working Group 2008 Progress Report.

Clarification is also needed regarding which smoke test method should be used.

Third, only a handful of laboratories in the public or private sector have the ability to test for smoke constituents other than tar, nicotine and CO. The development of appropriately qualified and certified laboratories in the EU is, of course, an important factor to be considered, especially for Member States who will need to monitor industry compliance (and for manufacturers who will need to obtain laboratory capacity to conduct testing to fulfill their reporting requirements).

Fourth, the frequency of by-brand testing for other smoke constituents must be considered in the context of the public health purpose of the testing. As we understand it, that purpose is to establish a baseline of specific constituents or chemicals in the smoke of commercial tobacco products. This baseline can serve as a basis for regulation, in particular as a measure for performance standards for reduced risk products. This purpose does not require by-brand testing of all brands on the market on an annual basis because the variation in smoke constituents in a single brand of cigarettes is unlikely to change from year to year outside of expected and insignificant variation (*e.g.*, production variability, natural agricultural variability, and normal testing variability associated with the relevant testing methods) unless substantial changes in design or materials occur. Moreover, as recognized by many public health researchers and scientists, all commercial conventional combusted tobacco products present essentially the same risk of disease.[20] Requiring annual by brand testing therefore is unlikely to produce useful data in the context of protecting public health and an alternative should be considered.

Therefore, in our opinion, the most prudent approach in light of these open issues is to amend the Directive to mandate the Commission to direct a tobacco agency or an expert scientific committee to recommend (1) specific smoke constituents for testing and reporting, (2) the smoke test method to be applied (*e.g.*, ISO, Health Canada), (3) the analytical methods to be used for testing those constituents, (4) the details of the reporting requirements, (5) a plan to establish laboratory capacity, including laboratory qualification criteria, and (6) the frequency with which the testing should be carried out. The Commission should be granted implementing powers pursuant to comitology to adopt the recommendations made by the agency or committee.

Recognizing that information about smoke emissions is a core basis for comprehensive product regulation and that Member States and the Commission may wish to proceed with regulation in this area in an expedited time frame, we would suggest an initial regulatory proposal for by-brand smoke constituent testing as follows:

- Manufacturers would be required to test for the 40 plus smoke constituents recommended in the FCTC Conference of the Parties Working Group on Product Regulation 2007 Progress Report or the constituents required under Health Canada's reporting regulations, although regulation should specify that the lists should be amended (deleted or added to) if warranted by new scientific knowledge.

- Until internationally validated methods are developed, manufacturers should be permitted to measure constituents using Health Canada's or other analytical methods, as long as the method used is disclosed, along with evidence of its validation and

[20] See, e.g., Hammond, et al. "*Revising the machine smoking regime for cigarette emissions*" Tobacco Control 16(1):8-14 (2007) ("Most within the public health community would argue that there are no meaningful differences in risk between conventional cigarette brands to begin with. So long as this is the case, there is little or no point in making distinctions between brands that are already on the market.").

information on its measurement uncertainties (*e.g.*, reproducibility and repeatability). As new and more reliable methods become available, they should be mandated.

- The initial year of testing should require testing of all brands on the market. Subsequently, brands should be tested only once every three to five years, provided that manufacturers can certify that a brand's design (*e.g.*, components) and performance characteristics (*e.g.*, tar, nicotine and carbon monoxide yields) have not materially changed from the prior year. However, if changes are made to a brand that would materially alter its characteristics, such as a substantial change in smoke constituents, or if a new brand is introduced on the market, full brand testing would be required for the altered or new brand.

- If several brands are substantially equivalent, manufacturers should be required to test only one brand, and should certify that the other brands are equivalent in design (*e.g.*, components) and performance characteristics (*e.g.*, tar, nicotine and carbon monoxide yields) subject to existing ISO tolerances.

Finally, because the Directive reserves the sole authority to establish requirements for tar, nicotine and CO reporting and performance standards (ceilings) to the EU, we recommend that the Directive mandates that authority to establish testing and reporting requirements for other smoke constituents also be reserved to the EU.[21]

4. Regulating Ingredients

4.1 Adopting the Commission's Common Reporting Format for Ingredients

We agree with the Commission's proposal to amend the Directive to incorporate the Common Reporting Formats for by-brand ingredient disclosure in the Commission's *Practical Guide: Reporting on Tobacco Product Ingredients* (May 2007), thus making their use legally binding throughout the EU.[22] In addition, the reporting formats should be made mandatory for all tobacco products (including accessories used for fine cut products, such as filter tubes). To provide for potential future changes, the Commission's authority under comitology should be broadened to cover ingredients reporting.

A further amendment to the Directive should clarify that the confidential reports for regulators contain trade secrets which Member States need to protect to the fullest extent possible under

[21] Regulation of smoke constituents must take place at EU level in order to ensure a smooth operation of the internal market. The Directive explicitly makes this point regarding carbon monoxide and nicotine ceilings: "*Differences in rules concerning carbon monoxide are likely to constitute barriers to trade and to impede the smooth operation of the internal market.*" Directive 2001/37/EC at Recital 7. *See also* Recital 9 ("*There are differences between…the Member States on the limitation of the maximum nicotine yields of cigarettes. Such differences are liable to constitute barriers to trade and to impede the smooth operation of the internal market.*")

[22] PMI used these formats for filing the 2007 ingredient reports in almost all EU Member States. However, we have learned that many Member States have not sent this information on to the Commission, contrary to what is foreseen by the Directive, Article 6. We hope that Member States will forward this information to the Commission going forward as it is our understanding that this information is to form the basis of the creation of a common list of ingredients, as called for by the Directive's Article 12.

their national legislation. Today, significant differences exist in how trade secrets are protected under national freedom of information laws.

4.2 Testing and Standards for Use of Ingredients

While we believe the regulatory focus should be on emissions, we nonetheless fully support that the use of ingredients in all tobacco products should be regulated based on scientific standards, which should be applied equally to all manufacturers and all types of tobacco products. If an ingredient is found, based on an objective scientific standard, to make the smoke from a tobacco product more toxic or addictive than smoke from current similar products without that ingredient, then the ingredient should be banned.

PMI supports amending the Directive to improve ingredient regulation to permit regulators to ensure that an ingredient does not materially increase the toxicity or addictiveness of tobacco smoke compared to tobacco products on the market without the ingredient. This approach was advocated by the United States Institute of Medicine in 2000: Cigarette ingredient toxicology review should be conducted "*with the objective of identifying those ingredients that add no significant toxicity to tobacco products and therefore can be considered safe in the context of its use*."[23] We recommend amending the Directive to (1) require manufacturers to conduct assessments of the ingredients they use and to report those assessments to the Member States and the Commission, (2) establish clearly defined standards for permitting and banning the use of ingredients, and (3) as currently required under Article 12, provide a uniform list of permitted ingredients common for all EU Member States to improve the functioning of the internal market.

However, as with smoke constituent regulation, before specifying regulatory requirements or even banning certain ingredients, several scientific and public health issues remain open that must be resolved. Most important, there are no internationally validated methods for testing ingredients or standards for their use. For example, the FCTC Conference of the Parties Working Group on Product Regulation's 2007 Progress Report stated, "*[T]esting and measuring of toxicity of cigarette contents [e.g., ingredients]…is an emerging field…*,"[24] and refrained from recommending a course of action pending "*more work to develop a better understanding of these issues*."[25] Similarly, the Working Group stated, "*the concept of testing and measuring the … dependence-producing properties of various tobacco products is fairly new and its application to tobacco product monitoring in particular has yet to be identified. Although the working group believes this area to be very promising, it is of the opinion that there is insufficient knowledge to move forward with guidelines at this time.*"[26] The Commission echoed concerns about the lack of

[23]Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.* National Institutes of Health, Institute of Medicine (Washington, D.C.: National Academies Press 2001) at 224.

[24] Working Group 2007 Progress Report.

[25] The Working Group also stated, "*In vitro and in vivo methods are generally well established, but their use for testing tobacco product contents … has been quite limited…. Important development and validation work will be needed before any guideline can be submitted to the COP for adoption.*"

[26] Commenting on this fact in 2004, the ASPECT Report stated, "*Methodologies for assessing addictiveness are not well developed and not applicable to routine, large-scale monitoring and it may take years for them to be agreed."* ASPECT Report at 180.

specific methods to asses ingredients in its Report, stating that "*meaningful work on specific ingredients requires human and financial resources that are currently not yet available*."

In the 2008 Progress Report, the FCTC Conference of the Parties Working Group on Product Regulation identified three "priority" tobacco product "contents" for testing and measuring: nicotine (which is a natural compound in tobacco leaf), ammonia (which can be an ingredient[27] and also a natural compound in tobacco leaf) and three humectants (which are ingredients). The Working Group stated that the WHO TobLab Network will develop test methods to measure these compounds and expected the process to take five and a half years.[28]

Our recommendation is to mandate the Commission to direct a tobacco agency or scientific committee to develop the required test methods and performance standards which ultimately would lead to the creation of a common list of ingredients authorized in the EU for use in tobacco products. The Commission should be granted implementing powers pursuant to comitology to adopt the recommendations from the agency or committee.

In developing ingredient testing and performance standards, regulators should consider several fundamental principles which are raised either directly or indirectly in the Report:

First, regulation must focus on the impact of the ingredient on the tobacco product's emissions or smoke as opposed to the ingredient itself. WHO's Scientific Advisory Committee on Tobacco Product Regulation (the predecessor of TobReg) emphasized in 2002, "*For tobacco products intended to be smoked, the manufactured product needs to be differentiated from the product actually intended for consumption which is its emission ('smoke') and the critical force of regulation must be on the emissions*."[29]

Second, the only viable standard for determining whether to permit the use of an ingredient is whether the use of an ingredient materially increases the toxicity or addictiveness of smoke as compared to similar commercial products without the ingredient. Under any other standard, eliminating ingredients may have no material impact on the toxicity or addictiveness of smoke and therefore no impact on individual risk or public health -- an inference repeatedly made by public health groups. For example, WHO stated in 2006 that "all natural" cigarettes without ingredients have "*never been demonstrated to be less dangerous or addictive than … cigarettes [with additives]. In fact, tests on some [all natural] brands indicate higher levels of tar and nicotine delivery than those produced by conventional brands [with additives] …*"[30]

Further, in many countries, such as the United Kingdom and Ireland, the vast majority of smokers smoke Virginia-style cigarettes which are manufactured without or with very few ingredients. Data show no significant differences in smoking incidence, cessation rates, youth smoking rates,

[27] PMI does not add ammonia as an ingredient to its conventional combustible tobacco products.

[28] Working Group 2008 Progress Report at p. 3-4.

[29] World Health Organization, Scientific Advisory Committee on Tobacco Product Regulation (SACTob) Recommendation on Tobacco Product Ingredients and Emissions, November 2002 ("SACTob Recommendation on Ingredients and Emissions") at 3.

[30] WHO, *Tobacco: deadly in any form or disguise. World No Tobacco Day 2006.* It is notable that two pages before this statement WHO criticized the use of ingredients as increasing toxicity and addictiveness.

or prevalence of smoking related diseases in these countries compared to countries where the vast majority of cigarettes smoked contain flavoring ingredients.[31]

Other standards suggested in the Report or by public health advocates appear to overlook some important factors and therefore would be likely to result in unintended consequences. One such standard is recommended by the European Parliament, which argues that an ingredient should be banned if, when pyrolyzed, the ingredient produces carcinogens or toxins, wholly apart from whether the ingredient, when added to tobacco, increases the overall levels of toxins or carcinogens in the tobacco smoke. This standard is inappropriate because *any* organic material produces toxins and/or carcinogens when pyrolyzed or burned. Thus, if applied strictly, this standard could lead to a ban on all ingredients added to cigarettes. In fact, because all cigarettes and cigarette papers contain *some* ingredients, the standard could, if carried to its extreme, result in a ban on the manufacture, import and sale of all cigarettes in the EU. We do not believe that this was the intention of the Parliament.

Another standard suggested by many public health advocates is to ban ingredients that make tobacco products more palatable or acceptable to consumers. However, the assumption that banning ingredients would make cigarettes unacceptable or less attractive and thereby lead to a reduction in consumption or an increase in cessation is based on supposition and is not supported by data. On the contrary, as noted above, millions of smokers in many countries around the world (including the UK and Ireland in the EU and Australia, China, and India) overwhelmingly prefer Virginia-style cigarettes made without or with very few flavoring ingredients.[32] In these countries, American blended cigarettes, which are characterized by greater amounts of flavor ingredients, have much smaller market shares. This is inconsistent with the position that ingredients are a material factor in driving initiation and consumer preference. Moreover, under a standard based on reducing palatability, in these markets *adding* ingredients would appear to reduce palatability. Obviously, a standard premised on subjective consumer appeal is not a reliable basis for regulation. Nor is there any evidence to support the belief that consumers who smoke predominantly American blended cigarettes with flavorings will choose to stop smoking rather than switch to Virginia cigarettes or that fewer people will begin to smoke because cigarettes do not contain flavorings.

Taking the foregoing into account, if the Commission and Member States decide to promulgate ingredients testing and performance standards without waiting for the recommendation of an agency or scientific committee, we would support an amendment to the Directive which would require the following:

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[31] Statistics from the WHO Regional Office for Europe indicate comparable percentages of smoking-related mortality in blended and Virginia markets in Europe. Moreover, according to WHO EU Region, the United Kingdom, where smokers prefer Virginia style cigarettes, has higher total adult smoking prevalence (26%) than Czech Republic, Denmark, Finland, France, Italy, Romania, Sweden, and Switzerland – all countries in which cigarettes containing higher amounts of flavor ingredients dominate the marketplace. In the same report, the UK's total youth smoking prevalence (24.1%) was reported to be higher than in the following countries where most smokers use cigarettes with greater amounts of added flavor ingredients: Belgium, Denmark, Greece, Italy, Netherlands, Poland, Portugal, and Sweden. China, which has the largest population of smokers in the world and a smoking incidence of approximately 31.4%, is a predominantly if not exclusively Virginia market (Source: WHO *M*power Report 2008).

[32] Other countries that are predominantly Virginia markets include Canada, Nigeria, Kenya, Pakistan and South Africa.

- Manufacturers should be required to conduct testing to determine whether the ingredient(s) materially increase(s) the overall toxicity of tobacco smoke compared to similar commercial cigarettes without the ingredient(s) and, if internationally accepted test methods are available, whether the ingredient(s) increase the addictiveness of smoke compared to similar commercial cigarettes without the ingredient(s).

- Pending the development of internationally recognized toxicity standards (or recommendations from an EU agency or expert committee), manufacturers should have the flexibility to select specific toxicity tests, provided they are recognised by credible scientific organisations such as the U.S. FDA, U.S. EPA, WHO and OECD, and relevant to cigarette smoke/tobacco toxins.

- We do not see how a requirement to conduct an assessment of an ingredient's impact on addictiveness can be implemented without science-based standards to measure and compare addictiveness.[33] We therefore suggest that no requirements be imposed regarding measurements for addictiveness pending the development of internationally recognized and validated methods to assess the impact of ingredients on the addictiveness of tobacco smoke.

- Testing should be conducted in appropriately qualified laboratories and manufacturers should disclose the methods used, evidence of their validation, and information on measurement uncertainties (*e.g.*, reproducibility and repeatability).

- While not suitable to a bright line standard, it may be appropriate on a case-by-case approach to prohibit the sale of predominantly confectionary flavoured tobacco products where the candy flavour overwhelms the tobacco taste and the product is sold in a manner inconsistent with a product intended for adult use.

Finally, the Directive should clarify that testing and performance standards for ingredients should be determined at the EU level. Different and potentially conflicting product requirements could have a significant impact on the internal market, hindering the ability of manufacturers to operate efficiently within the EU. See footnote 21 above.

5. Regulating Tobacco Leaf

The Commission has said that it will consider amending the Directive in order to regulate the "*tobacco leaf and other natural or unprocessed tobacco plant parts*" used in tobacco products. While we do not dispute that regulation should cover tobacco leaf and its compounds, we repeat the admonitions of public health groups that product regulation should be centered on product emissions, not what goes into the cigarette. Moreover, we disagree with the Commission's

[33] Subjective measures for assessing addiction potential have been proposed for use in clinical research. These measures are based on criteria like smoker preferences, palatability, sensory effects, and "extent of feeling dependent." These highly subjective measures can differ from country to country and, within a country, from person to person – and are incapable of providing a rational and consistent basis for international regulatory standards. In addition to subjective measures such as these, various animal models have been used to study the abuse liability of drugs. As a practical matter, animal models that have been used to study nicotine (*e.g.*, self-administration, discrimination) cannot be used to compare the addictiveness of different types of cigarette.

suggestion that the regulation of tobacco leaf can best be accomplished by expanding the definition of the term "ingredients." Instead, we propose that the Directive be amended to establish a separate provision regulating tobacco leaf.

Ingredient regulation serves the purpose of informing regulators and the public about ingredients – materials that are added to tobacco products – and assessing whether they increase the toxicity and addictiveness of tobacco smoke. Tobacco is not an "ingredient" added to tobacco products; it is the base of the product itself. Thus, it would be illogical to assess whether tobacco increases the toxicity and addictiveness of tobacco, particularly since it is already established and well known that combusted tobacco is toxic and addictive.

Testing and the development of standards for tobacco leaf, including testing of specific compounds in the tobacco leaf and standards relating to crop protection agents is, like smoke constituent and ingredient assessment, a new and complex area of regulation.[34] Accordingly, we suggest that the Directive requires that the Commission mandate this matter to a tobacco agency or a scientific committee, whose recommendations should be taken into account by the Commission and the comitology committee.

6. Harmonizing Regulation of Fine-Cut Tobacco Products

The Commission says that Member States have underscored the fact that sales and consumption of roll-your-own cigarettes (RYO) "*are dramatically increasing*," attributing this dynamic to tax-driven price gaps. Of particular concern is the impact on youth smoking. The Commission states its intent to become more involved in the revision of the taxation framework to address the matter. The Commission also notes that until recently, no ISO standard for measuring constituents existed for RYO and suggests that it would be possible to adopt those standards under the existing comitology procedure under Articles 9 and 10 of the Directive.

The Commission and Member States' concern is valid. Consumption of fine cut tobacco products, including both roll-your-own (RYO) and make-your-own (MYO) products, has increased significantly in a number of Member States. This has been driven primarily by tax and price gaps when compared to manufactured cigarettes. In Germany, for example, the RYO and MYO share of the total market for hand-made and manufactured cigarettes increased by approximately 14 percentage points between 2002 and 2007. Today, RYO accounts for a quarter of the total German hand-made and manufactured cigarette market. In Belgium, Luxembourg and the Netherlands, RYO products account for approximately half of this market.[35]

Despite the growing number of EU smokers who use RYO and MYO products, many provisions of the Directive do not apply to these products. The following are just a few examples:

[34] Several proposals, including by the Conference of Parties Working Group on Product Regulation, have been made regarding testing and reporting of compounds in tobacco leaf, but like smoke constituents, there is no internationally accepted list of those compounds or validated analytical methods to measure them. See Working Group 2007 and 2008 Progress Reports. As with smoke constituents, the Working Group has suggested that several years of research are needed prior to adopting guidelines in this area of regulation. Id.

[35] See Annex 1 to this document

- Fine-cut products are not required to comply with tar, nicotine and CO ceilings, and many exceed those ceilings as measured under the current ISO standard for fine-cut products.[36] In fact, RYO cigarettes currently sold in the EU have ISO yields of up to 21 mg tar and 1.8 mg nicotine (at 750 mg of tobacco) and up to 15 mg tar and 1.2 mg nicotine (at 400 mg of tobacco).

- There is no requirement that fine-cut products bear health warnings comparable to those for cigarettes. Thus, in Belgium, where fine cut accounts for over half of the tobacco market, only manufactured cigarettes are required to have graphic health warnings.

- The Directive regulates non-tobacco components used in manufactured cigarettes, including ingredients added to filters, tipping paper and cigarette paper. But similar materials used to assemble fine-cut tobacco products, such as filter tubes, are not covered by the Directive.

The Directive therefore should be amended to apply the same or equivalent product regulatory requirements to fine-cut products that apply to manufactured cigarettes. To the extent that this will require the development of new standards, the Directive should empower the Commission with the authority to do so, through comitology and, where necessary, with guidance from a tobacco agency or a scientific committee.

7. Regulating Novel Products with Claims

In the Report, the Commission recognizes that the emergence on the market of "novel products" raises regulatory challenges. Specifically, the Commission emphasizes the need to take regulatory action at the Commission level to address "*new tobacco and/or nicotine products marketed*" "*to serve the public health and internal market objectives*."

Specific action is needed now for the up-coming revision of the Tobacco Products Directive, because most of these novel products, whether containing tobacco, nicotine or neither (as in the case of herbal cigarettes[37]), are sold with explicit or implicit claims that they are safer alternatives to conventional cigarettes and/or are effective smoking cessation therapies. Although some manufacturers of these products have abandoned such claims and now market the products purely as pleasurable alternatives to cigarettes, the public health ramifications of these products warrant regulatory action now.

[36] The ISO standard for measuring tar and nicotine for RYO was published in 2003. ISO 15592-3 (2003).

[37] Herbal cigarettes, a growing category in the EU, have been shown in studies (see "Guide to Smoke-free Environments Act 2003, New Zealand 2004) to generate similar levels of certain toxic substances as conventional cigarettes, such as carbon monoxide and tar. We recommend that the Directive be amended to add herbal cigarettes to its scope. This is consistent with a 2006 ruling by the European Court of Justice, (Case C-495/04, A.C. Smits-Koolhoven v Staatssecretaris van Financien, 30 March 2006) on the excise tax status of herbal cigarettes. In that case, the Court held that *"cigarettes without tobacco which do not contain substances having a medical effect but which are presented and marketed as an aid to giving up smoking are not 'used exclusively for medical purposes' within the meaning of [the EU excise tax directives]."* Article 9 of the Directive should be amended to provide the Commission the authority through comitology (and assisted by an agency or scientific committee) to adapt the Directive's regulatory requirements, where needed, to address the unique features of herbal cigarettes.

7.1 Tobacco Products Marketed with Reduced Risk Claims

The Directive should be amended to explicitly prohibit manufacturers from making a reduced risk claim about a tobacco product ***unless*** the claim is substantiated. This could be accomplished either by adding a new provision to the Directive or by amending Article 7.[38]

In order to substantiate a claim, the manufacturer must prove that the product will result, or is reasonably likely to result, in a substantial reduction in risk of one or more tobacco related diseases. Elaboration on the data needed to support this standard should be within the powers of the Commission to establish through comitology. However, as this is a complex scientific matter, the Commission should be able to direct a tobacco agency or a scientific committee to develop specific details on the nature of the data needed to substantiate a reduced risk claim. The data should be generated from state of the art scientific experimental methods including, for example, non-clinical investigation (smoke chemistry, *in vitro* and *in vivo* assays) and clinical investigations. Evidentiary standards should be flexible to account for developments in the science of risk assessment.

In addition to statements that one product is safer, *i.e.*, presents a reduced risk of one or more tobacco related diseases than other products on the market, the following other statements should be subject to pre-market review: (1) a product reduces or eliminates the levels of one or more smoke constituents; and (2) a product reduces or eliminates the user's exposure to one or more smoke constituents. Such statements should be subject to pre-market review whether or not the manufacturer states that the reduction in yield or exposure reduces the risk of disease.

The important point about regulation of claims is that (1) they are not permitted unless substantiated under a pre-market review process and (2) their content is accurate and conveyed in a manner that allows consumers to understand their significance. Achieving an appropriate balance between the objective of communicating benefits of new products and the objective of preventing initiation and encouraging cessation can be done. As the United States Institute of Medicine (IOM) stated in its seminal report on regulating reduced risk tobacco products, "*The problem of conveying balance in communicating health benefits and risks is not unique to tobacco-related PREPs, and the large body of experience in other areas of health and safety regulation may be applicable to these products as well.*"[39]

For example, rules can be developed regarding pre-market testing of consumer perception of claims.[40] Further, manufacturers could be required to inform consumers that smoking a reduced

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[38] Article 7 currently prohibits the use of any "texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products." The Article would have to be amended to provide for an exemption subject to substantiation. Such amendment would be consistent with both Recital 27 of the Directive and Article 11 FCTC, which make clear that only such descriptors should be banned which may "mislead the consumer into the belief that such products are less harmful." (emphasis added)

[39] Stratton, K.; Shetty, P.; Wallace, R.; Bondurant, S., eds. Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction National Institutes of Health, Institute of Medicine at 218 (Washington, D.C.: National Academies Press 2001) (IOM Report).

[40] Hatsukami, D.K., et al., *Methods to assess potential reduced exposure products.* Nicotine & Tobacco Research 7(6): 827-44, 829-30 (2005) ("*The purpose of consumer product testing is to ensure that claims and marketing of a product will lead the consumer to make an informed decision based on an accurate*

risk product is not safe nor an alternative to quitting and that the best way to reduce risk of tobacco-related disease is to stop using tobacco products. Depending on the data provided, a claim could be accompanied by a statement that the health consequences of the change are unproven. It is also important that substantiated claims are not worded in a manner that would imply that the product has been endorsed by the EU or a public health authority.

Finally, the unique characteristic of these products both in performance standards and likely design characteristics suggest that the Directive may need to be modified to provide for effective and operational regulatory requirements. The Commission therefore should have the authority through comitology to modify the Directive's requirements. For example, if, contrary to the evidence, ingredients were banned for conventional cigarettes, there is a compelling public health interest in preserving the right to use flavors in products that have the potential to reduce risk because flavorings can be critical to compensate for loss of tobacco flavor. The assessment of ingredients must be defined in the context of this strategy.[41]

We recognize that one of the concerns of the public health community is the impact of reduced risk products on tobacco initiation and cessation. Many public health advocates are concerned that the introduction on the market of products that are marketed with claims, even if substantiated, may cause overall harm to the population by causing fewer people to quit or more people to initiate tobacco use. While pre-market testing can provide important information upon which to predict consumer use and behaviors, these issues are essentially unknowable prior to the marketing of the product.

For this reason, harm to the population is best assessed through post-marketing surveillance and studies, rules about which should be developed by the Commission with the assistance of a tobacco specific agency or scientific experts. The IOM's 2001 report commented on this issue:

> *"Regulation cannot assure that the availability of risk-reducing PREPs will lead to reduced tobacco-related harm in the population as a whole. However, a regulatory agency can assure that data are gathered that would permit population effects to be monitored. If tobacco use increases or tobacco-related disease increases, these data would serve as a basis for developing and implementing appropriate public health interventions."*

Thus, the amendment of the Directive, as described, can build a solid basis for tobacco product harm reduction in the EU without undermining the goals of preventing initiation and encouraging cessation.

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understanding of valid information, and to ensure that the product does not appeal to youth, those who would have quit otherwise, or those who have previously quit.").

[41] *See, e.g.*, WHO Tobacco Free Initiative, *Advancing Knowledge on Regulating Tobacco Products* at 37-38 (2000) (*"a completely 'safe' cigarette that is smoked by only 1% of the smoking public has less preventative value than a cigarette with some adverse effects that is smoked by 90% of that public."*).

7.2 Non-Tobacco Products Containing Nicotine

Other products seen with increasing regularity in the EU are "electronic cigarettes" and similar products that provide nicotine to consumers but do not contain tobacco.[42] As the Commission stated, the regulatory status of these products is unclear. Although these products are similar to pharmaceutical nicotine cessation therapies, such as nicotine inhalers, they have not been approved for use as pharmaceutical products (either medicines or medical devices). At the same time, many are designed to physically resemble cigarettes and are marketed to and understood by consumers to be cigarette substitutes, providing one or more of the following benefits: pleasurable alternative to cigarettes, reduced risk of disease, or effective smoking cessation therapies.[43] Because they do not contain tobacco, they cannot be regulated under the current scope of the Directive.

Member States have slowly begun to assert that these products meet the definition of pharmaceutical products or medical devices and are blocking or limiting their sale without appropriate pharmaceutical approvals**.**[44] We agree. Pharmaceutical regulation appears to be the only viable option for them today.[45] Our support of pharmaceutical regulation for products such as electronic cigarettes is not intended to place unreasonable or undue regulatory burdens on legitimate smoking cessation products or products that have the potential to offer consumers safer alternatives to cigarettes. However, it is not tenable to permit products marketed with claims on the market without any regulatory oversight.

Nevertheless, we recognize the imbalance between regulation of tobacco products and that of pharmaceutical products providing nicotine. One possible way of addressing this dilemma would be to revise the pharmaceutical regulatory framework to accommodate tobacco harm reduction by liberalizing the restrictions on nicotine pharmaceutical products, such as was recently done in Sweden. Another possibility in the long term would be to develop a single, broad regulatory framework covering both tobacco and nicotine products. Some public health groups have referred to this as regulation along a "risk continuum" – essentially establishing regulations of increasing (or decreasing) restrictions based on the risk presented by the product with, hypothetically, conventional cigarettes at one end and nicotine replacement therapies at the other.

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[42] For example, so-called "electronic cigarettes" that deliver nicotine in an aerosol along with other substances have been sold in various Member States including Austria, Belgium, Germany and the Netherlands. Examples of such products include *Ruyan*, which is characterized as a "tobacco-free electronic cigarette" in which users place "nicotine containers", and *Supersmoker*, which the manufacturer describes as an "alternative cigarette" that uses an "atomizer" to deliver nicotine.

[43] For example, the manufacturer of *Ruyan* has in the past stated in consumer communications that the product "*means healthier smoking*" and that "*painless smoke abstention can be realized within a certain period of time, after carrying out the smoke abstention scheme recommended by Ruyan*."

[44] For example in Austria. See: *Expert Opinion of the Advisory Council for Classification Criteria, pursuant to § 49a of the {Austrian} Medicinal Products Act ("AMG"), on Nicotine Inhalators, in particular, electrically operated or similar products (e.g., RUYAN — the Electrical Cigarette; RUYAN Atomizing Electronic Cigarette, and RUYAN Atomizing Tobacco Alkaloid Liquid Container).* The Advisory Council for Classification Criteria at the Austrian Federal Ministry for Public Health, Family, and Young People Expert. March 6, 2007.

[45] Directive 2001/83/EC.

Expanding the Tobacco Products Directive in this manner would be a long term solution that the Commission and Member States should consider.[46]

8. Lifting the Ban on Snus

Like all tobacco products, snus causes disease and is addictive. However, scientists and public health advocates have reported -- and the data show -- that snus is substantially less harmful than cigarette smoking, essentially eliminating the risk of lung cancer and other lung diseases and reducing by as much as 50% or more the risk of many other major tobacco related diseases.

In fact, in 2003 a panel of leading EU tobacco control experts recommended that the EU lift its ban on snus. According to the panel, smokeless tobacco and snus were "*at least 90% less hazardous than cigarette smoking*," and there were "*very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco.*"[47]

More recently, scientists and public health advocates have reached similar conclusions. In 2007 researchers concluded, "*Current smokers who switch to using snus rather than continuing to smoke can realize substantial health gains.…[T]here is extensive epidemiological evidence that snus is much less hazardous than smoking.*"[48] And in 2006, the American Council on Science and Health stated, "*The health risks associated with smokeless tobacco are much less extensive than those associated with cigarette smoking…. Overall, the use of smokeless tobacco confers only 2% of the health risks of smoking*."[49]

This was confirmed by the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in its recent final report on the Health Effects of Smokeless Tobacco. According to the SCENIHR, the overall reduction in risk for an individual who switches to snus from cigarettes is approximately 90%.[50]

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[46] Consistent with the view of many in the public health community about snus, as discussed in section 8, consumers should have the knowledge that other products have the potential reduced risk of tobacco related disease compared to cigarettes, provided that such products have been reviewed by appropriate regulatory authorities under the procedures noted above. Communications about risk reduction is particularly important when it is likely that such products will have a deficit in taste and sensory aspects compared to conventional tobacco products. Exemptions or preferential treatment in the areas of marketing, sales, and taxation are some of the areas that could be considered.

[47] Bates, C, et al., *European Union Policy on Smokeless Tobacco: A Statement in Favor of Evidence-based Regulation for Public Health* Tobacco Control 12:360-367 (2003).

[48] Gartner CE, et al., *Assessment of Swedish Snus for Tobacco Harm Reduction: An Epidemiological Modelling Study* The Lancet 369:2010-14, 2010, 2013 (2007).

[49] Meister K., *Helping Smokers Quit: A Role for Smokeless Tobacco?* American Council on Science and Health, at 5 (October 2006).

[50] In its report, SCENHIR stated, "*[t]he balance of the benefits and risks … will vary according to circumstances of individuals and population groups. However, for those who substitute smoking by [smokeless tobacco products] the benefits outweigh the risks*." SCENHIR Final Report at 118. Further, SCENHIR stated, "*The data indicate that the health benefit experienced by a smoker who switches to snus but would otherwise have quit smoking is substantially greater than the risk of snus use, and that whilst snus use among people who would have never have used a tobacco product will have a detrimental effect on individual and public health, this effect is relatively small*." Id. at 117.

Despite these data, the WHO, the International Agency for Cancer Research and other prominent public health organizations argue that smokeless tobacco products, including snus, should not be viewed as "safer" alternatives to cigarettes because they can cause disease. And despite its findings that snus substantially reduced risk compared to cigarettes, the SCENIHR concluded that snus caused disease and suggested that it was not possible to extrapolate the public health impact of lifting the ban in the EU from the experience in Sweden.

We disagree. We urge the Commission and the EU Member States to lift the ban on snus for three reasons.

- While harmful and addictive, snus significantly reduces the risk of tobacco related diseases compared to cigarettes.

- The data from Sweden suggest that snus will not undermine the public health goals of prevention and cessation.

- Regulation can address public health concerns while simultaneously allowing adult consumers who want to continue to use tobacco the benefits of snus (as compared to smoked tobacco products).

Today, many forms of tobacco products, including chewing tobacco, manufactured cigarettes and fine-cut tobacco, are used by millions of adults throughout the EU. Those adults should have the informed option of purchasing snus, an alternative tobacco product that has the potential to reduce the risk of disease.[51]

9. Health Warnings

Although we believe that textual warnings are sufficient, we would not oppose an amendment to the Directive requiring all Member States to mandate graphic or pictorial health warnings. To the extent that graphic health warnings are required, they should apply to all tobacco products, not just to manufactured cigarettes as is the case in Belgium today.

We do not support an increase in the current warning size which range from 30% front/40% back to 35% front/50% back. That is larger than the minimum mandated size in the FCTC (30% front/30% back). Increasing the size would diminish the already limited space for our trademarks and would encroach on the ability of consumers to distinguish our brands from those of our competitors.

10. Generic Packaging

The Commission stated in the Report, "In order to reduce the smoking initiation and to protect EU consumers on an equal basis in all Member States the introduction of generic (black and white) standardised packaging could be explored as a possibility to reduce the attractiveness."

[51] We also suggest that Article 9 of the Directive should be amended to provide the Commission the authority to adapt, through comitology (and assisted by a tobacco agency or scientific committee), the Directive's regulatory requirements where needed to address unique features of snus. For example, the labelling requirements may be amended as recommended by some in the public health community. Further, ingredients used in snus are not combusted and thus a food based ingredient model may be more appropriate for these products.

The possibility of generic or "plain" packaging has been raised by public health advocates and recently by the Department of Health in the UK in its consultation on the future of tobacco control.[52] Philip Morris Limited - PMI's affiliate in the UK - provided an extensive response to this consultation, including its discussion of generic (plain) packaging. We have attached a copy of those comments to this submission as Annex 3.

In short, we believe that plain or "generic" packaging would be an extreme and disproportionate measure. There is no sound evidentiary basis to conclude that generic packaging will achieve its stated public health objective. The result will be to make all cigarette packs look the same, stripping manufacturers of one of their last remaining means of competing in the vast majority of Member States and amounting to expropriation of extremely valuable property rights. While PMI supports regulation based on principles of harm reduction, particularly regulation intended to prevent youth smoking, we do not believe that the Commission should pursue generic packaging as there is no basis to believe it will reduce smoking prevalence and is a violation of fundamental legal principles in the European Union. Indeed, eliminating one of the last remaining forms of product differentiation – and competition -- in many EU Member States can only be reconciled with a strategy of preventing tobacco manufacturers from engaging in legitimate commerce.

First, there is no evidentiary basis to conclude that plain packaging will deter young people from taking up smoking or prevent adult smokers from quitting (or relapsing once they have quit). In fact, the UK Department of Health conceded this point: "*the research into this initiative is speculative, relying on asking people what they might do in a certain situation. The assumption is that changes in packaging will lead to changes in behaviour*."[53] In many studies (including the most widely cited) the underlying data confirm that pack design – or "brand appeal" -- does not play a role in uptake of smoking or continued smoking. In fact, the majority of adolescents interviewed in these studies said that plain packaging will have no impact on youth smoking. Thus, one study concluded:

> *"It is clear that in most first trials there are little package, brand or brand promotion elements. Most kids receive their first cigarette from friends. There is no brand choice – the choice is simply to smoke or not to smoke. Therefore, in the uptake process brand and package are very minor components. This means that changing the package will not have any major effect on the decision(s) to smoke or not to smoke."*[54]

On the other hand, experience shows that overall tobacco consumption is not likely to be affected by plain packaging. As we have seen in other situations, smokers are likely to shift consumption. They may choose to purchase plain packs at retail or may choose other sources for purchasing. The view that consumers will be less likely to smoke because of a lack of branded packaging is belied by the example of single stick sales in many countries where low income levels make pack purchases unaffordable for adult smokers. Another example is in Canada, where 20% of the cigarette market is estimated to consist of illicit cigarettes. 70-80% of the illicit trade consists of

[52] Consultation on the Future of Tobacco Control, UK Department of Health, May 31, 2008.

[53] Id. at p. 41 (emphasis added).

[54] Expert Panel Report for Health Canada, *When Packages Can't Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products* National Survey of Teens: Knowledge, Attitudes, Beliefs and Smoking Behaviours at 184 (March 1995) (emphasis added).

cigarettes that are sold in clear plastic bags. Again, packaging without branding does not deter consumption.

Second, the speculative benefit of generic packaging to prevent youth smoking must also be weighed against its impact on illicit trade and price competition. As we show in our submission to the UK Department of Health, an increase in both are likely outcomes of generic packaging.

- The Consultation Paper concedes that "*Plain packaging may force tobacco companies to compete on price alone, resulting in cigarettes becoming cheaper*." We would go further: plain packaging will reduce overall cigarette prices. Imposing generic packaging to reduce youth smoking rates which is based purely on speculation while knowing that generic packaging is certain to increase what is generally accepted as one of, if not, the most important factors affecting youth smoking: cheap cigarettes defies common sense and is poor public policy.

- Generic packaging offers two significant incentives to counterfeiters. First, it creates a much easier and thus lucrative market for counterfeiting domestic product given that all legal domestic brands will be virtually identical and thus cheaper to replicate. Second, there is no doubt that a market will develop for branded packaging. While the evidence does not suggest that consumers will reduce smoking because of generic packaging (see discussion above), it is likely that when presented with a choice between branded illicit packs and legitimate plain packs, a smoker will choose the branded pack which would convey through the branding the impression (albeit incorrect) of providing higher quality tobacco products. Finally, plain packaging may lead consumers to opt for more generic illegal alternatives such as cigarettes sold in plastic bags, such as are popular in Canada.

The Commission and the public health community are well aware that both are factors that lead to increases in smoking prevalence, especially among youth. Thus, generic packaging will not only fail to achieve its stated objectives, but will actually work against them.

Third, generic packaging is an unjustified restriction of competition and a breach of obligations under EU law and international trade agreements. Generic packaging will effectively eliminate the use of brands and trademarks in relation to tobacco products. This in turn will eliminate the well known advantages trademarks create in a free market society – advantages of paramount importance not just for brand owners but for consumers and competition as well.

The European Court of Justice summarized the significance of trademark rights for consumers and competition as follows:

> *"[T]rade mark rights … constitute an essential element in the system of undistorted competition which the [EC] Treaty is intended to establish. In such a system, undertakings must be able to attract and retain customers by the quality of their products or services, which is made possible only by distinctive signs allowing them to be identified."*[55]

Generic packaging will severely undermine these important functions of trademarks, thereby harming both consumers and competition. By foreclosing use of distinctive visual elements,

[55] C-349/95 *Frits Loendersloot v. George Ballantine & Son. Ltd. And Others* (11 November 1997)

generic packaging would invite consumer confusion by destroying unique brands through its mandated mix of visual elements (standardized design, colors, and font). Consumers will no longer be able to easily distinguish between brands on sale. Restricted to displaying packs that are virtually indistinguishable from one another, manufacturers will find it difficult – if not impossible – to launch new products or line extensions of existing brands. New companies, without the ability to distinguish their products through trademarks, will face enormous difficulties in entering the market. Indeed, manufacturers will be limited to pricing to attract consumers to new products, and, as discussed above, low price tobacco products are recognized as undermining public health objectives.

The failure to protect intellectual property, including trademarks, would have severe negative consequences for fair competition and free trade. Mindful of this, international treaties such as the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) and the Paris Convention for the Protection of Industrial Property impose obligations on the signatory countries to follow minimum standards concerning the availability, scope and use of intellectual property rights. Generic packaging will squarely conflict with these treaty obligations. Generic packaging not only unjustifiably encumbers the use of a trademark,[56] it also violates the principle that the nature of the goods to which a trademark is applied shall in no case form an obstacle to the registration of the trademark.[57] In short, plain packaging would install a dual-class system of trademarks – one class for tobacco products and one class for other goods. Such a dual-class trademarks system puts the EU Member States completely out of step with the rest of the world and places the EU Member States in breach of their obligations under both TRIPs and the Paris Convention.

Fourth, generic packaging amounts to expropriation of long held and extremely valuable intellectual property rights. In fact, generic packaging is contrary to a 2002 European Court of Justice decision on the rights of tobacco manufacturers to display their trademarks on product packaging.[58]

In that case, which involved a challenge by some Member States against the Directive's ban on descriptors and expanded health warning sizes, the Member States argued that those provisions of the Directive violated the principle of proportionality and the right to property. Opposing the challenge, the Commission and other Member States argued that the Directive was legal because it allowed a "*cigarette manufacturer to continue to use its trade mark by distinguishing it from others by means of words, signs, colours and drawings which are particular to it and which it could present on the available surfaces of the tobacco products.*"[59]

The Court agreed, noting that despite the descriptor ban, a manufacturer "*may continue to distinguish its product by using other distinctive signs*."[60] On health warnings, the Court found that "*the only effect produced by…the Directive is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets…to show their trade marks,*

[56] TRIPs, Article 20.

[57] TRIPs, Article 15.4; Paris Convention for the Protection of Industrial Property ("Paris Convention"), Article 7.

[58] Case C-491/01 *R v Secretary of State for Health ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*. (10 December 2002)

[59] Id. at para 146.

[60] Id. at para 152.

without prejudicing the substance of their trade mark rights."[61] More specifically, the Court held that the increased size requirements were still "*in a proportion which leaves sufficient space … to affix other material, in particular concerning their trade marks*…."[62]

The Court concluded that because the Directive did not impair "*the very substance"* of manufacturers' trademark rights, the legislature *"has not overstepped the bounds of discretion which it enjoys in this area*."[63] This is obviously not true for generic packaging which obliterates the "*very substance*" of manufacturers' trademark rights.[64]

A trademark that cannot be affixed to the product packaging is effectively rendered worthless. By taking away the very substance of trademark rights and effectively commoditizing the tobacco market, plain packaging amounts to nothing less than the expropriation of manufacturers' valuable brands. It will destroy the value of the brands and the large investments manufacturers have made to build up and maintain the goodwill associated with their brands.

Therefore, even if the EU could demonstrate that generic packaging were a proportionate and legal measure (which it is not) the EU will be required to compensate manufacturers for the value of the expropriated trademarks. As recognized consistently, the value of tobacco manufacturers' trademarks, brand logos and pack designs are enormous, including some of the most valuable commercial brands in the world.

Fifth, although beyond the scope of the Directive, there are numerous steps that the EC and Member States can take to address the serious problem of youth smoking and smoking prevalence that have proven to be effective. We have addressed some of these in detail in our submission to the UK Department of Health's Consultation. Pursuing generic packaging would be wholly and utterly inappropriate even if such measures did not exist, but the fact that they do would make a future proposal for generic packaging disproportionate in the extreme.

In conclusion, generic packaging is unsupportable in light of the lack of evidence that it would have any impact on youth smoking rates and weighed against the unquestionable harm it would cause to competition and the damage it would inflict on manufacturers including but not limited to the expropriation of their extremely valuable intellectual property rights. On the contrary, there is a very real and substantial risk that plain packaging would undermine public health objectives.

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[61] Id at para 150.

[62] Id at para 132.

[63] Id. at para 153.

[64] In his Opinion, the Advocate General suggested that the results of a proportionality test would be different where "*normal usage is no longer possible*" and consequently "*the substance of the [trademark] right*" is compromised. The only reason he gives as to why the "*substance*" of the right was not compromised by the Tobacco Products Directive is that the "*trademark can still be displayed on the packaging*" and that *"[o]nly part of the packaging*" is taken up with health warnings and other officially mandated information. A plain packaging requirement would remove even this residual ability to use some part of the packaging for trademarks and would thus fail the Advocate General's "*very substance*" test and suggest a conclusion of a disproportionate interference with intellectual property rights.

ANNEX 1

EU Member State 2007 market share estimates for roll-your-own (RYO) and make-your-own (MYO) as a percentage of the total hand-made and machine-made cigarette market

The information is provided in cigarette sticks equivalent, using a conversion rate of 0,75 grams of RYO/MYO equals 1 manufactured cigarette.

Source: PMI estimates, based on duty-paid in-market sales.

Share of RYO/MYO as a percentage of the total hand-made and machine-made cigarette market	**2007 estimates**
Austria	4%
Belgium	45%
Cyprus	n.a
Czech Republic	5%
Denmark	7%
Estonia	0.4%
Finland	17%
France	15%
Germany *	27%
Greece	5%
Hungary	9%
Ireland	3%
Italy	1%
Latvia	1%
Lithuania	0%
Luxembourg	51%
Malta	6%
Netherlands	50%
Poland	2%
Portugal	3%
Slovak Republic	1%
Slovenia	1%
Spain	4%
Sweden	11%
UK	11%
Bulgaria	0%
Romania	n.a.
Norway	36%
Switzerland	4%

* For Germany, the 2002 estimate was 11%

ANNEX 2

Information concerning PMI's tobacco purchases, GM prevention program and Crop Protection Agent Management System

Philip Morris International (PMI) does not own any tobacco farms. Instead we buy our tobacco from leaf merchant companies and farmers from many countries, including Brazil, Argentina, Greece, Italy, Malawi, Poland, Thailand, Turkey and the US. Approximately 92-93% of the tobacco is purchased from farmers under a contract scheme, while approximately 7-8% is purchased from tobacco auctions in Malawi and India.

Irrespective of whether the tobacco is purchased from contracted farmers or at auction, PMI applies the same criteria concerning 1) preventing genetically modified (GM) tobacco from being used in our products, and 2) ensuring that residue of crop protection agents in the raw tobacco is in accordance with established maximum residue limits (MRL).

Below are summaries of the procedures we apply to the raw tobacco that we purchase for GM prevention and for crop protection agent residue management:

GM Prevention: The Tobacco Identity Preservation Program (TIPP)

PMI believes that advances in modern biotechnology achieved in accordance with sound science and appropriate regulation offer potential benefits to consumers, the agricultural community, the environment and society as a whole. However, for the time being, PMI purchases only conventional tobacco for use in the company's tobacco products.

In order to prevent genetically modified tobacco from being used in PMI's tobacco products, PMI uses a system known as the "Tobacco Identity Preservation Program" (TIPP).

TIPP is a traceability system with documented sampling and testing for GM tobacco. PMI applies the TIPP Program to all tobacco purchased worldwide, irrespective of whether it is purchased through a contract farming scheme or at tobacco auctions. This program supports and promotes the use of certified and tested seed and monitors the portion of the global crop destined to PMI to detect genetically modified tobacco.

Participation in TIPP is a requirement for all leaf suppliers to PMI. All countries where PMI purchases tobacco are included in the PMI TIPP program. TIPP involves sampling and testing of seeds and processed tobacco. Thousands of samples are tested every year.

Crop Protection Agent Management System (CPA-MS)

PMI has developed a Good Agricultural Practices (GAP) program that encourages growing practices that minimize the impact on the environment, promote worker safety, enhance product integrity and improve crop sustainability.

As with any other agricultural crop, tobacco growers apply crop protection agents (CPAs) to tobacco plants to protect them from pests and diseases. One of the key parts of GAP is Integrated Pest Management (IPM) that promotes limiting the use of CPAs to only when needed and in accordance with the manufacturer's instructions and applicable regulations. IPM programs include pest threshold levels to determine whether and when CPA treatment is needed, and promotes the use of effective alternative biological CPAs.

In order to monitor CPA residues and compliance with CPA regulation, PMI has developed a program to sample and test every lot of raw tobacco that PMI purchases. Under this program which we refer to as the CPA-Management System (CPA-MS), CPA sampling and testing is carried out by our leaf suppliers and results of the analysis are submitted to PMI prior to the shipment of tobacco. Suppliers are required to deliver tobacco that meets certain conditions, including that it does not exceed established CPA residue limits. All testing for CPA residues must be conducted in ISO 17025 certified laboratories.

Tobaccos must comply with CPA regulations and maximum residue limits (MRLs) at the place of origin and in the country of destination. In the absence of regulations at origin and/or destination, PMI follows MRLs that have been established based on MRLs existing in other jurisdictions as well as CORESTA Agrochemical Guidance Residue Levels.

Tobacco growers, suppliers and PMI share the objective of further improving sustainable tobacco production, farmer safety, as well as conserving biodiversity. We are fully committed to continue working on reducing the number of CPAs used in tobacco production and the CPA residue levels. To achieve this objective we believe it is necessary to develop a regulated sampling, testing and reporting CPA program at the EU level, with harmonized MRLs that manufacturers and importers have to comply with, based on residues found when the crop is treated according to good agricultural practices, including integrated pest management.

PMI's Agricultural Programs Department would be happy to provide more in-depth information on the above matters. We trust that you understand that some of this information is confidential.

ANNEX 3: PML AND PMI SUBMISSION ON e-CIGARETTE SCHEDULING

PHILIP MORRIS LIMITED AND PHILIP MORRIS INTERNATIONAL MANAGEMENT SA's SUBMISSION TO THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE ON THE PROPOSAL TO AMEND THE SCHEDULING OF NICOTINE IN RELATION TO USE IN ELECTRONIC CIGARETTES

10 September 2008

Philip Morris Limited and Philip Morris International Management SA[1] offer these comments to assist the National Drugs and Poisons Schedule Committee (NDPSC) in considering a proposal to amend the scheduling of nicotine in relation to use in electronic cigarettes.[2] Because Philip Morris does not have information on the specific nature of the product under consideration by the NDPSC, or of the specific nature of the scheduling proposed, our comments are premised on our understanding of electronic cigarettes currently advertised or marketed in Australia and elsewhere.

Those products do not contain tobacco but rather provide nicotine to consumers by generating an inhalable aerosol using a battery-like energy source. Such products are seen with increasing regularity in various countries around the world. They are widely available via the Internet[3], and various claims are made about their benefits. For example, electronic cigarettes are purported to "provide similar enjoyment of smoking without tar and carbon monoxide and the other dangerous substances that are released in the burning of tobacco"[4], and are claimed to allow both smokers and non-smokers to "smoke anywhere free-risk" and "smoke without fire."[5] Other consumer communications suggest that these products could aid in quitting smoking ("quit smoking easier") and present the product as being "100% healthy."[6] Many of those products are designed to physically resemble cigarettes and may be marketed to and understood by consumers as cigarette substitutes that provide one or more of the following benefits: pleasurable alternative to cigarettes; reduced risk of disease; safe and effective smoking cessation therapies.

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[1] Philip Morris Limited manufactures and sells cigarettes and other tobacco products in Australia. Philip Morris International Management SA provides administrative support to Philip Morris International Inc. and its affiliated companies worldwide. For the purposes of this submission, they will be referred to as Philip Morris. For more information on Philip Morris International and its affiliates, see http://www.philipmorrisinternational.com/

[2] Item 5.1 in the Pre-October 2008 Scheduling Meeting Notice, http://www.tga.gov.au/ndpsc/gazette/g0810pre.pdf

[3] *See, e.g.,* "Crown 7" homepage, http://www.crown7.com/ (site accessed 5 September 2008; page print attached); "Rutoo" homepage, http://www.rutoo.co.uk/ (site accessed 5 September 2008; page print attached).

[4] http://www.ruyan.com.cn/operNews.do?action=l&id=17 (site accessed 5 September 2008; page print attached).

[5] http://www.ruyanhealth.com/blog/ (site accessed 5 September 2008; page print attached).

[6] http://ruyan.offerchina.com/ (site accessed 5 September 2008; page print attached).

Electronic cigarettes have been described recently in Australian media. For example, the *West Australian* reported on 19 August 2008 that "Electronic ciggies 'beat smoke bans'".[7] The article stated that manufacturers "market them as the healthier alternative to smoking" and "spruik[ ] them as a device to sidestep smoking bans." An article in *The Age* said that although the device "is not intended as a nicotine replacement therapy," the product's distributor stated that the e-cigarette is "'much more effective' than any other quit product."[8] The products are reportedly already being sold in Australia. A caller to a morning radio programme in June 2008 said "I just bought one … a week ago, and I'm – yeah. I'm addicted…It looks like smoke, tastes like smoke. You get the same nicotine hit. But you can smoke it indoors …. "[9] In New Zealand, an electronic cigarette is reportedly being tested in clinical trials in order to assess the product's safety and efficacy.[10]

Regulatory assessment is needed to ensure that statements about these products are substantiated by sound scientific data and that consumers receive appropriate information about the risks, if any, posed by these products. However, it has not yet clearly been established which regulatory scheme – e.g., tobacco products or therapeutic goods – should apply to electronic cigarettes.

On the one hand, electronic cigarettes cannot be regulated under tobacco product regulations in many countries, including Australia, because they do not contain tobacco and thus fall outside of the scope of tobacco product regulation. On the other hand, despite the fact that electronic cigarettes are similar to smoking cessation therapies, particularly nicotine inhalers, in that they deliver nicotine to consumers, many countries have not sought to regulate them under pharmaceutical regulations based in part on confusion about whether the products are being sold for therapeutic purposes.

Recently a number of European governments have concluded that electronic cigarettes should in fact be regulated as pharmaceutical products or medical devices and have taken action to limit or prevent their sale until appropriate regulatory approvals have been obtained.[11] We believe that for products such as electronic cigarettes that deliver

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[7] Andrew Tillett, *Electronic ciggies 'beat smoke bans'*, The West Australian, 19 August 2008, p. 15 (attached).

[8] Cameron Houston, *The bluff puff, but it's not the full quit*, The Age, 2 June 2008 (attached).

[9] Transcript, Nova 100.3 Breakfast Programme, 30 June 2008 (attached).

[10] Ian Steward, *Cigarette substitute set for trials,* The [Christchurch, NZ] Press, 30 April 2008, p. 7 (attached). *See also* Laugeson et al., *How safe is an e-cigarette? The results of independent chemical and microbiological analysis*. 2008 (attached); SmokeLess New Zealand e-news (describing product's purported safety, efficacy, dosimetry, and legal status), http://www.smokeless.org.nz/ecigarette.htm (site accessed 8 September 2008, page print attached).

[11] Austria is one such example. *See, e.g.,* The Advisory Council for Classification Criteria at the Austrian Federal Ministry for Public Health, Family, and Young People, *Expert Opinion of the Advisory Council for Classification Criteria, pursuant to § 49a of the {Austrian} Medicinal Products Act ("AMG"), on Nicotine*

nicotine but do not contain tobacco, this is the most appropriate option for regulation today.

Our support for such oversight for electronic cigarettes is not intended to place unreasonable or undue regulatory burdens on the marketing of legitimate smoking cessation products or products that have the potential to offer consumers safer alternatives to cigarettes. However, it is not tenable to permit products that deliver nicotine and are marketed with claims on the market without any regulatory oversight.

Nevertheless, we recognize the imbalance between regulation of tobacco products and that of pharmaceutical products providing nicotine, especially products intended (and substantiated) as nicotine replacement therapies or safer alternatives to conventional cigarettes. One possible way of addressing this dilemma in the long term is to revise the pharmaceutical regulatory framework to accommodate tobacco harm reduction by liberalizing the restrictions on nicotine replacement therapies, as was recently done in Sweden.

Another approach suggested by some public health advocates would be to develop a single, broad regulatory framework covering both tobacco and nicotine products. Some public health groups have referred to this as regulation along a "risk continuum" – essentially establishing regulations of increasing (or decreasing) restrictions based on the risk presented by the product with, hypothetically, conventional cigarettes at one end and nicotine replacement therapies at the other.

Philip Morris strongly supports efforts to develop and market products that may reduce the harm of tobacco use. A science-based regulatory framework could support this development by establishing clear rules for the manufacture and scientific assessment of novel products in order to obtain authorization to market these products with claims.[12] This framework should also outline requirements regarding communication and labelling of novel products as well as require post-marketing surveillance of these products once on the market.

We believe government oversight is needed to ensure that claims made by manufacturers are substantiated by sound scientific data and that consumers receive appropriate information about the risk, if any, posed by the products.

We recognise the technical, scientific, resource and enforcement challenges such a science-based regulatory framework would entail. However, the current availability of various new products, including electronic cigarettes, demonstrates the need for

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Inhalators, in particular, electrically operated or similar products (e.g., RUYAN — the Electrical Cigarette; RUYAN Atomizing Electronic Cigarette, and RUYAN Atomizing Tobacco Alkaloid Liquid Container). 6 March 2007 (courtesy translation attached).

[12] In our view a "claim" includes any statement made in the labelling or advertising of the product or in any other communication made or directed to be made by the manufacturer that would reasonably be expected to result in consumer believing that a product presents a lower risk of disease or is less harmful than one or more commercially marketed tobacco products.

regulation that would provide for assessment standards for new products and determine the most appropriate regulatory requirements that would apply to them.

We would appreciate the opportunity to share further information about similar products that we have encountered in several countries around the world, as well as our thoughts on a science-based regulatory framework for products with the potential to reduce the risk of tobacco related disease.

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REFERENCE MATERIALS CITED

Footnote 3

PML SUBMISSION
ANNEX 3

Crown7 products and Website are intended for audiences of a legal smoking age. By entering this site you verify that you are of legal smoking age.

What is a Crown7 Smoking Device?

Crown7 is a battery operated Art Deco styled tube which contains a cartridge and rechargeable battery. The cartridge contains water, propylene glycol, nicotine, and a tobacco flavor. One Crown7 cartridge is the equivalent to about two packs of cigarettes. It is a wonderful invention that allows a person to virtually smoke anywhere! It contains nicotine, but does not pollute the environment, nor offend people in the surrounding area, bar, home, workplace, car, any situation which would be a public place.

Crown7 is committed to quality and safety. Extensive testing and investment has been to make sure there are no harmful substances associated with our product. 1 year guarantee if your Crown7 stops working due to manufacturer defects.

Features & Benefits of Owning a Crown7 Cigar - Cigarette - Pipe

Emits a Harmless Vapor That Simulates Smoke yet Satisfies the Nicotine Urges & Cravings

Use Crown7 in Any Situation Where Smoking is Prohibited - Our Product is Non-Offensive

Rechargeable Battery for Endless Hours of Enjoyment and Smoking Pleasure

No Offensive Smoke... Only a Harmless Vapor is Emitted

Perfect Solution to Smoking in a Casino or Pool Hall - Prevents Noxious Odors by Never Creating Them

Sophisticated Design, Sleek Art Deco Look & Feel

No Residual Clothing or Room Odor Now that's a Real Benefit!

Battery Operated, Simple to Manipulate in all Situations Where Smoking Cigarettes has been Prohibited

Replaceable Filter Cartridges - Click

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ANNEX 3

Search:

RuToo
e-Sigarets manufacturer

Become
Click here

Footnote 4

PML SUBMISSION
ANNEX 3

Come Visit

Search

HOME > ABOUT US > What is RUYAN?

What is RUYAN?

RUYAN electronic cigarettes, cigars and pipes and their pleasures of smoking without the associated dangers. **R** experience and are far more appealing than any of the e provide similar enjoyment of smoking without tar and ca that are released in the burning of tobacco.

RUYAN was deemed one of the best 10 business ideas

Our latest products, **RUYAN** *Vegas*® and **RUYAN** *e-G* RUYAN's development in fast-moving consumer goods. bars, restaurants and other businesses, to take advanta price-points and other appealing features, partners have **RUYAN** *e-Gar*®, and sales are ramping up quickly.

Ruyan is the original inventor of the e-cigarette and has to form the idea for the electronic cigarette in 2000. In 2 registered in the same year in China. The company has toxicology) in both developed economies and in China, a are safe under normal use.

To date, Ruyan has sold more than one million units of e America, the United Kingdom and Ireland, the Benelux, Romania and here in China.

, **RUYAN**® and

Footnote 5

- Ruyan, Like smoking
- About

- **Categories**
  - Academic articles for free-smoking
  - Electronic cigarettes
  - Health Care
  - Knowledge
  - Mini e-cigarettes
  - News
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About E-cigarette Blog

Buy Mini E-Cigarette NOW ONLY 38 USD.

Smoke in the office, on the train, in a restaurant, even on a plane! With e-cigarette you can smoke anywhere free-risk!

Inhale and exhale what looks & feels EXACTLY like real smoke - it's fantastic!

The e-cig is a high tech product developed to provide smokers with a clean alternative to smoking. It contains no tar, no carbon monoxide and no cancer-causing chemicals. The device is packed with electronic gadgetry, enabling it to produce water vapour rather than producing smoke. The battery is rechargeable. Even the mouthpiece can be changed and shared between various people.

Do I have to be a smoker to enjoy the e-cigarette?

No, you can still have just as much fun with the e cig without the nicotine capsule. Just walk into any bar, club, office, restaurant or shop and puff away… The end lights up when you inhale (just like hot ash) and you can safely exhale clean water vapour that looks just like you are smoking. The rest we can leave to your imagination. It is hilarious!

Apart from the health benefits, it's the 'must have' gadget for any smoker (or non-smoker) this Xmas!

The e-cigarette can allow smokers to enjoy the same pleasure as that of traditional cigarettes when inhaling, imitating the whole process of smoking. e-cigarettes create a healthy smoking experience but are far more fun than other products and have become known as the most perfect alternative to smoking so far. You are simply inhaling and exhaling water vapour with the added advantage of a replacement capsule if required! (refills can be purchased online for as little a (£10 for the equivelant of 200 cigarettes).

Testimonials

"*This is exactly what you hoped someone would invent one day and now they have!! It's fantastic.* "
– **Jürgen Walter**

"*That's brilliant! I have to have one.* "
– **Daan Faber**

" *I got the funniest looks on the tube. I was even asked to put my e-cig out on two occasions!* "
– **Elisabeth Nacheva**

"*The comedy value is superb! Inhale and exhale loads of SAFE smoke!* "
– **Judith Hackl**

" I tried to give up with patches without much luck but the e-cig looks and feels the part - maybe this will work! "
– **Hans, The Queens**

Smoke without fire with the e-cigarette!

Why buy another smoke alarm or fire alarm when you could smoke without fire? All the enjoyment of smoking without the worry of burning your clothes, your carpet or even your house. A simple atomizing cigarette is surely the answer. And consider the health benefits!

China moves to curb smoking before Olympics

Posted by admin

BEIJING — Li Zhigang inhaled deeply from a cigarette while sitting on his haunches near the Beijing Railway Station before deciding there was no way that tighter smoking regulations would change where or when he'd grab a smoke.

Li, 30, a real estate salesman, said he began smoking several years ago because he saw virtually all the people around him lighting up. He said he could support tighter rules, at least in theory, but could not see himself changing his smoking habits.

"I'm not that addicted, but it's also not so easy to stop," Li said. "The only answer would be if they stopped making cigarettes completely."

As part of a bid to create a "smoke-free Olympics," new regulations effective Thursday in Beijing require separate smoking and nonsmoking areas in bars, restaurants, hotels, parks, Internet cafes and airport lounges. There's an outright ban in places such as offices, hospitals, sports stadiums, museums and universities.

The results will probably be most obvious at Olympic sites as the Chinese government, with the Beijing Games beginning Aug. 8, goes into overdrive to curb littering, spitting, walking around without a shirt and cutting in line, a bid to project a favorable image to the world.

The tighter rules, which apply only to Beijing and a few other cities, replace less stringent, rarely enforced, measures in place since 1995. The government is counting on newfound cooperation from smokers as well as enforcement by way of 100,000 voluntary monitors and fines of up to $700 for companies that don't comply.

In 2009, cigarette packs are supposed to have health warnings cover at least one-third of their surface.

With about 350 million smokers, China is the world's largest producer and consumer of cigarettes and has a deeply entrenched smoking culture.

Outside the Yuyang Hotel in central Beijing, dozens of migrant workers offered one another cigarettes on their lunch break from their construction jobs Thursday as, nearby, waiting taxi drivers gossiped in a cloud of smoke near a businessman who stopped at the crosswalk to light up between conversations on his cellphone.

At the Dongzhimen Bus Station, Zhang Qinglin sat in his car smoking. He smokes 10 relatively expensive "Zhonghua" cigarettes a day as a way to break up the monotony of long drives or to enjoy a moment with friends. His wife and his 18-year old son don't like second-hand smoke, so he avoids bothering them at home.

"Even if they make it tougher, I don't think I'll stop," he said a few yards from the Beijing Tobacco Monopoly Co. headquarters. "If you really want to smoke, you'll smoke."

Whether Beijing can curtail all the huffing and puffing remains to be seen, but activists note that anti-smoking campaigns in New York and Paris were also met with skepticism initially, but have been a success.

Chinese officials hope the efforts in Beijing will inspire the country to meet nationwide commitments aimed at curtailing tobacco use under a U.N. convention it ratified in 2005. They include pledges to ban tobacco advertising, post prominent health warnings on cigarette packs, step up education and support smoking cessation programs nationwide by 2011.

Critics of the new regulations say that China has a long history of campaigns that peter out. A recent China Youth Daily poll found only 22% of respondents thought a smoking ban would be effective.

A security ban on cigarette lighters when passing through metal detectors at stadiums should help efforts to curb smokers, said Susan Lawrence, head of China programs at the Washington-based Campaign for Tobacco-Free Kids, a civic group.

And text messages delivered to cellphones and warnings splashed across giant screens at venues will reinforce the campaign, said Sarah England of the World Health Organization in Beijing. Early test runs at the "Water Cube" swimming venue and "Bird's Nest" National Stadium found no-smoking signs prominently posted and staff trained to warn anyone caught smoking to snuff it out, she said.

But changing the culture in a country with a third of the world's smokers, including some boys who start as young as 10, won't be easy.

"It's difficult to have a smoke-free Olympics," said Li Xiguang, journalism school dean of Beijing's Qinghua University, who runs an anti-tobacco media awareness program. "It's so deeply rooted in

ordinary life and business."

Indeed, in China it's customary to offer a cigarette as a sign of hospitality, and many business deals are hammered out over long, boozy dinners in a tobacco haze. Smokers range from those wealthy enough to afford $35 packs to the rural poor who turn to state tobacco monopolies capable of producing cigarettes starting at 20 cents a pack.

"Those who don't smoke and drink aren't real men," according to a popular expression.

China's two top leaders from the late 1940s to the early 1990s, Mao Tse-tung and Deng Xiaoping, were both heavy smokers, and students sent to the countryside during the Cultural Revolution grabbed a smoke to escape the drudgery, even if it meant rolling up dried vegetables. "With all the books burned, it was a way to fight boredom," said Zhang Zuhua, a constitutional researcher in Beijing.

Li, the journalism school dean, said his father was a senior engineer during the disastrous 1958-60 Great Leap Forward, a position that entitled him to a carton of cigarettes a month at a time when many people were starving. Initially he wasn't interested in the cigarettes, until he realized they were worth a year's salary for an ordinary worker. In November, he died of lung cancer, Li said, joining the 1 million Chinese who die annually of smoking-related illnesses.

Although health awareness is growing, more than half of Chinese doctors smoke, in part because relatives of their patients often ply them with cigarettes during pre- and post-operation consultations.

"And if senior doctors smoke, junior doctors follow suit," said Wang Ke-an, a physician and director of ThinkTank Research Center for Health Development. "If you're offered a cigarette and decline, you're still seen as rude. We need to change this custom."

If you enjoyed this post, make sure you subscribe to my RSS feed!

- May 1st
- No Comments
- Filed under: News

Ruyan e-cigarette reviews

Posted by admin

I would like to see a review or at least what Ruyan e-cigarette did for someone, i know its new, but somebody.

it cost a little over 200 bucks so i want to know what someone whos tried it thinks, so please someone with a little insight into electronic cigarettes please give assistance.

If you enjoyed this post, make sure you subscribe to my RSS feed!

- April 18th
- 1 Comment
- Filed under: Ruyan e-cigarette

Carlsbad needs smoke-free areas

Posted by admin

This is to all the citizens of Carlsbad who are wondering why Carlsbad has not passed a smoke-free ordinance like many other cities in San Diego County. I am really wondering, too.

I am the one who made a presentation more than a year ago to the Carlsbad parks and recreation commissioners to do so. They unanimously passed my proposal and promised me that they would work on an agenda bill, pass it to all the pertinent departments within the city, and then present it to the Carlsbad City Council for approval.

My sister and I have been working on encouraging the city to pass such an ordinance for almost three years.

I am tired of hearing that there are more important items on the city council agenda. What could be more important than protecting its citizens from secondhand smoke and litter?

Just to let you know, the majority of Carlsbad's beaches are state controlled, therefore Carlsbad has no legal jurisdiction over those beaches. So we took the position of encouraging the city to restrict smoking in the areas that it does control: more than 30 parks and recreational areas.

But listen, I have just been promised by the Parks and Recreation Department that in May, this smoke-free ordinance will be placed on the agenda to be voted on by the city council.

Here is where I need the citizens of Carlsbad to help. We recently celebrated Earth Day with a wide variety of programs in Carlsbad and across the county. Call or write the Carlsbad mayor and the city council members to let them know that you want the city to step up and be really concerned about our health and environment by providing smoke-free parks and recreational areas.

With memories of Earth Day still in our minds and the positive things that event stands for, I hope that Carlsbad will soon join other cities in California who have provided smoke-free areas for their citizens, even if we are one of the last coastal cities to join that distinguished list of participants.

If you enjoyed this post, make sure you subscribe to my RSS feed!

- April 17th
- No Comments
- Filed under: News

Students aim to make parks smoke free

Posted by admin

A group of Rosemount High School students is trying to clear the air in the city's parks.The students, members of the student council and SADD, attended Monday night's meeting of the Rosemount Parks and Recreation Commission to propose a policy prohibiting smoking in all city parks.

The park commission did not take any action Monday. Commissioners asked parks and recreation director Dan Schultz to look into what other cities in the area have done.

Ruyanhealth.com monday's presentation was the end — or at least the next big step — for the RHS students who made it. They've been working since October on the information they presented this week. They researched smoking policies in other Dakota County cities and circulated a petition looking for support. They got 367 signatures.On April

22 — Earth Day — the students spent part of their afternoon picking up trash in four Rosemount parks. They filled two large jars with the cigarette butts they found.Those butts, as much as the quality of the air, are the reason the students made their presentation Monday. They worry about the environmental impact of the cigarette filters many smokers leave behind and about children or animals picking them up or eating them.

“The children find the butts on the ground.They’re young, so they’re sticking the cigarette butts in their mouths saying, ‘What’s this?’” RHS student Tanner Little said.

Students said they’re also concerned about younger children seeing teens smoking in the park and choosing to emulate the activity.

The RHS group is the latest in a series of student groups to approach city officials looking for limits on smoking in parks. Pat Stieg, community health specialist with the Dakota County Public Health Department, has worked with groups in Mendota Heights, West St. Paul, Hastings and Lakeville, among others.

“We found it has been a good experience for them to learn more about the issue and more about how public policy gets made,” Stieg said. “I think they enjoy it and appreciate it more after the fact. In Hastings they talked about how, after the city put up signs to let people know about the policy, they felt a sense of pride when they saw the signs.”

Stieg met with the RHS students once a month as they prepared their presentation. He was there last Thursday as the students made a final run-through. Standing behind a counter in a science classroom at RHS — the words “Smoking is icky” scrawled on a whiteboard behind them — they ran through their presentation. When they were done they got tips on posture, pacing and diction from an RHS speech teacher.

Schultz said the students did well with their performance. He expects the parks commission will make a decision at its next meeting.

Students in several other cities have had success with their presentations. Hastings currently has a no-smoking policy in place in its parks, as does West St. Paul.

Not all groups have done so well, though. The Farmington City Council failed to act earlier this month on its own version of a park smoking ban.

Whatever happens, the students at RHS seem to have enjoyed the experience of putting their presentation together.

“It was fun, and we learned how much cigarettes are at parks,” student Jasmine Hunt said. “I’m not that great of a public speaker but I’m trying to help the environment.”

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- April 17th
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Spit It Out and Keep It Out

Posted by admin

Myths About Smokeless Tobacco

Which of the following is true?

1. Smokeless tobacco is a safe alternative to smoking.
2. Smokeless tobacco is not as habit forming as cigarettes.
3. Smokeless tobacco is not a problem except among cowboys and farmers.

If you answered true to #1 - wrong!

If you answered true to #2 - wrong again!

If you answered true to #3 - you strike out!

It has taken a long time for the public to finally realize that smoking is a major health hazard. It's becoming less and less acceptable or chic for people to smoke. Recently, however, another tobacco-related public health menace has begun to surface - smokeless tobacco, that is chewing or sniffing tobacco. This is not just a problem in rural America, but is being used throughout the U.S, mostly by teenagers. Sixteen percent of all males between 12 and 17 used smokeless tobacco in 1985, and the number is increasing rapidly. The tobacco industry has succeeded in duping the youth of this country into thinking that by using smokeless tobacco instead of cigarettes, they are exercising a "safe alternative." Make no mistake about it, it is the young people of this country to whom this industry has directed its efforts - for example in some state surveys, more than 50% of those who use smokeless tobacco developed the habit before they were 13 years old.

Let's Talk About Chemicals

Let's talk about chemicals–smoking, chewing or sniffing tobacco all cause physical feelings; this is not a mental high. Nicotine and related chemicals are found in *all* forms of tobacco, and how you take it is not important. We're talking chemical stimulation of the brain, blood vessels, heart and other organs. That's why getting rid of the habit is so hard; it is not just mind

over body–not just willpower. It's a physical dependency that makes the whole body crave more of the chemical. These chemicals are in all tobacco. When smoked, these substances are absorbed through the lungs, into the blood, and they are distributed to all body parts. When chewed or dipped, the chemicals are absorbed through the mouth and the stomach. It takes a little longer for this absorption, but the final concentration in the blood is just as high as with smoking. And guess what, the concentrations of the cancer causing chemicals in smokeless tobacco are much higher than in cigarette tobacco.

Now you may say to yourself that if you don't smoke these chemicals, you avoid cancer-you re wrong again! You're only swapping lung cancer for mouth cancer! You see, the body tissues, whether its lungs or membranes in the mouth, don't like tobacco byproducts; they cause them to develop cancer.

Effects of Smokeless Tobacco

The effects of smokeless tobacco include:

- Increased heart rate caused by nicotine in the blood stream releasing hormones (such as adrenaline).
- Increased blood pressure caused by nicotine in the blood stream. Can cause irregular heart

beats as well.
- Constricted blood vessels: nicotine constricts the blood vessels, slowing down the circulation of oxygen-rich blood to the organs.
- Cancer of the mouth (including the lip, tongue, and cheek): mouth cancer is 1 of the 10 most common cancers in the world. The risk of mouth cancer is four times greater for the smokeless tobacco user. It is particularly high where the tobacco is placed.
- Cancer of the throat: the risk of oral cancer is up to 50 times greater for the person who chews tobacco. The longer smokeless tobacco is used, the greater the risk.
- Discoloration of teeth: the products in smokeless tobacco *permanently* stain teeth.
- Halitosis: Bad breath caused by chewing tobacco is socially unacceptable and offensive.
- Gum recession: The direct and repeated contact of tobacco with the gum tissue causes the gums to recede from the teeth. This eventually can lead to the loss of teeth.
- Tooth decay: Smokeless tobacco contains high quantities of sugar. This sugar mixed with the plaque on your teeth forms acids that eat away at the tooth's enamel, causing cavities.

Let's Talk Money

You may not think about the cost of sickness when you're young, but the problems will be obvious when you start paying taxes and wondering where your hard earned money goes. Every year in the U.S., 320,000 people die from diseases that are directly related to tobacco use. Lung cancer alone kills 136,000 citizens yearly, and most of those got the disease from smoking. Can you imagine how much money it takes to care for the 30,000 new mouth cancer patients every year. The overall numbers are staggering.

The cost of smoking to the economy ranges from $30 to 95 billion, with a middle estimate of $65 billion. This amounts to $2.17 in lost productivity and the treatment of smoking-related diseases for each pack of cigarettes sold.

You might say that health insurance pays for much of this–well that insurance costs employers and employees alike. And for those who are not insured by private carriers, programs such as Medicare and Medicaid pick up the bill. Smoking's adverse health consequences cost nation's taxpayers $65 billion each year in increased medical bills, premature death and time lost from work. You see, there is no such thing as free health care–we all end up paying for the problems caused by tobacco use.

Let's be even more practical, when you are a teenager, you may not think of chewing tobacco as a disgusting habit, but in a few years, after you are addicted, you'll find it is not so socially acceptable. You may even find that your career opportunities are limited because of it.

Tips To Quit

Many smokeless tobacco users say it is even harder to quit smokeless tobacco than cigarettes. Chewing tobacco and snuff contain nicotine and are addictive. A recent study showed that nicotine in the blood stream was actually twice as great for smokeless' tobacco as for cigarettes. Trying to quit can be difficult, but not impossible. Here are some tips to spit it out and keep it out!

1. Think of reasons why you want to quit. You may want to quit because:

    - The people around you find it offensive.
    - You don't like having bad breath after chewing and dipping.
    - You don't want stained teeth.
    - You don't want to risk getting cancer.
    - You don't like being addicted to nicotine.

- You want to start leading a healthier life.

2. Pick a quit date and throw out all your chewing tobacco and snuff.
3. Ask your friends, family, teachers, and coaches to help you kick the habit by giving you support and encouragement. Tell friends not to offer you smokeless tobacco. You may want to ask a friend to quit with you.
4. Ask your doctor about a nicotine chewing gum tobacco cessation program.
5. Find alternatives to smokeless tobacco.
6. A few good examples are sugarless gum, pumpkin or sunflower seeds, apple slices, or raisins.
7. Find activities to keep your mind off of smokeless tobacco.
8. You could ride a bike, talk or write a letter to a friend, work on a hobby, or listen to music. Exercise can help relieve tension caused by quitting.
9. Remember that everyone is different, so develop a personalized plan that works best for you. Set realistic goals and achieve them.
10. Reward yourself. You could save the money that would have been spent on smokeless tobacco products and buy something nice for yourself.

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- April 16th
- No Comments
- Filed under: News

Smoking ban in all pubs and clubs

Posted by admin

MPs have voted by a huge margin to ban smoking from all pubs and private members' clubs in England. Health Secretary Patricia Hewitt said the change, expected to take effect in summer 2007, would "save thousands of people's lives".

Ministers have argued about the extent of a ban

Ministers gave a free vote amid fears Labour MPs could rebel against plans to exempt clubs and pubs not serving food.

The Commons decided by a margin of 200 to impose a ban on smoking in all enclosed public spaces.

Cabinet votes

The Cabinet was split on how far restrictions - set out in the Health Bill - should go, with Conservatives calling government policy a "shambles".

Prime Minister Tony Blair, Chancellor Gordon Brown and Home Secretary Charles Clarke all voted for a blanket ban.

But Deputy Prime Minister John Prescott, Culture Secretary Tessa Jowell, Defence Secretary John Reid and Education Secretary Ruth Kelly opposed it.

A total smoking ban is due to come

> **This is really going to affect**

into force in Scotland next month, and Northern Ireland is set to follow suit in April, next year.

The Health Bill gives the Welsh Assembly the right to decide for itself whether to implement a ban it has already twice approved in principle.

Ms Hewitt, who voted for a total ban for England, told the BBC: "I'm absolutely delighted. This is really a historic day for public health."

She added: "This is going to save thousands of people's lives."

'Illiberal'

Elspeth Lee, of Cancer Research UK, said: "This is really going to affect generations to come and make the nation a lot healthier."

However, Simon Clark, director of smoking support group Forest, said: "This is a double whammy and an unnecessary and illiberal piece of legislation that denies freedom of choice to millions of people.

"The Government should educate people about the health risks of smoking but politicians have no right to force people to quit by making it more difficult for people to consume a legal product."

Earlier, health minister Caroline Flint said fines for failing to stop people smoking in restricted areas would go up by more than ten times from £200 to £2,500.

She said: "I am confident that these increased fine levels will result in better compliance with smoke-free legislation, which of course, will make enforcement easier."

"generations to come and make the nation a lot healthier"

Elspeth Lee, Cancer Research UK

Reaction to the votes

How Labour MPs voted

Q&A: Smoking ban

"About one third of people who smoke more than 20 cigarettes a day will have their first within five minutes of waking"

Feature: The way we smoke

The Cabinet originally proposed prohibiting smoking only in pubs serving food, in line with Labour's election manifesto.

A free vote was offered after many Labour MPs, fearing a partial ban could increase health inequalities among customers and staff, threatened to rebel.

Ministers came up with three choices: a total ban; exempting private clubs; or exempting clubs and pubs not serving food.

Many MPs opposed a smoking ban on civil liberties grounds.

'Good news'

The government predicts an estimated 600,000 people will give up smoking as a result of the law change.

Conservative MPs were offered a free vote on the issue.

Shadow health secretary Andrew Lansley said ministers had "put forward proposals which their own backbenchers thought were completely unworkable".

But it was “a very important step”, he added there “had to be a culture that encourages better health”.

Liberal Democrat health spokesman Steve Webb said: “This legislation is good news for tens of thousands of bar staff up and down the country.

“The key issue has always been the health and safety of people who work in public places.”

Tory leader David Cameron missed the vote following the birth of his third child, a son, earlier on Tuesday.

In a recent report, the Commons health select committee said a total ban was the “only effective means” of protecting public health.

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- April 15th
- No Comments
- Filed under: News

E-cigarette in New Zealand

Posted by admin

Read the article, then place your vote!

As of today, all cigarette packaging in New Zealand will come complete with graphic images depicting the horrific fate which awaits you if you are a smoker. I don’t know about you, but there’s something not quite right with this picture.

Personally, it wouldn’t bother me if the entire cigarette package was covered in images of ruptured arteries and amputated toes - hell, I probably wouldn’t even be too worried about an actual artery hanging out the bottom of my packet. I would still smoke. I’d just transfer the cigarettes from the packet to one of the nice tins which the tobacco companies brought out in anticipation of this move a few months back. I just don’t get it.

Now, we have something which so obviously removes the harm associated with cigarette smoking - and, I’m only advocating this for people who are already addicted to nicotine. We have something that will clear the air for those around the smoker - those who would otherwise be subjected to second-hand smoke. The innocent children who, because their parents smoke, become addicted before they even know what the word “addiction” means.

If the New Zealand government were really serious about harm reduction around those who already smoke, it’s quite simple. I have one word for them - “**E-cigarette**“.

Let it be sold freely at the local dairy or tobacconist. I am completely on the side of Dr Murray Laugeson and others who are advocating for cigarette displays at shops to be removed. That’s absolutely fine, and would be a great way of reducing the numbers of kids taking up smoking, but at the same time, we have a generation of smokers here and now, who are addicted and who need a way out. I say, let’s give smokers easy access to e-cigarette products and watch the smoking-related hospital waiting lists dwindle down to nothing.

It’s common knowledge that nicotine is the addictive substance in cigarettes - no-one is denying that.

But, nicotine is harmless when compared to the other (approximately) 4000 chemicals found in a typical cigarette.

How many smokers have tried all other methods to quit, without success? I know I have. I've even tried lung surgery.

So, the government makes a big fuss about all the amazing things they are doing to reduce the harm caused by cigarettes - banning it in a public place. Okay, that's good for the non-smoker. Putting horrific images on the packets. Doesn't work for existing smokers - *might* work for the kids who are thinking about starting.

The e-cigarette is NOT a quit smoking device. It is a replacement for those who would like to reduce the harm that their smoking is causing to themselves and others around them. That is so simple that it's not even funny.

My suggestion to the government would be this - if you are so serious about reducing the harm that cigarettes cause, allow the sale of e-cigarette products by tobacconists and other retail outlets. What harm can this possibly cause? I know that it would reduce a huge amount of harm - massive.

Every smoker who I have spoken to about, and shown the e-cigarette to so far, has ordered one directly from the manufacturer - that is a huge vote of confidence in this life-saving invention.

If you enjoyed this post, make sure you subscribe to my RSS feed!

- April 14th
- No Comments
- Filed under: Electronic cigarettes

When the Smoke Cleared

Posted by admin

SHOULD employers have the right to punish workers who smoke when they are not working?

Skip to next paragraph

Alex Eben Meyer

The question is a troublesome one, with persuasive arguments on both sides. Employers that provide health insurance have an interest in the health of their workers. But workers do not want their employers regulating their private behavior.

Under its previous ownership, the Tribune Company fined workers $100 a month if they smoked while enrolled in the company's health plan. This week, under the new owner, Samuel Zell, the company ended the practice, which had taken effect on Jan. 1 (**chicagotribune.com**). In an e-mail message to employees this week, Gerry Spector, executive vice president, said the fine was "inconsistent with the new culture."

"We'd rather you use your own judgment when it comes to tobacco use, not impose ours upon you," he wrote. Employees who had paid fines would be reimbursed, he said. And the company would continue to offer smoking-cessation programs to employees at no cost.

When the fine was imposed, Mark Lacter of the blog LAObserved (**laobserved.com**) wrote that it was "another example of why companies have no business dealing with people's health care coverage."

One argument against fines or other sanctions is that a better approach would be for companies to offer incentives for employees to quit smoking or take other steps to improve their health. But that can be problematic, too. This week, Whirlpool suspended 39 employees who had claimed to be nonsmokers to get a $500 discount on their health insurance. They were seen smoking outside a Whirlpool factory in Evansville, Ind. (**abc news.com**)

In a statement, Whirlpool said that it was among "a growing number of companies waging war on unhealthy habits."

The suspensions prompted another plea for decoupling health insurance from employment, this time from Laurie Ruettimann of the human resources blog Team Building Is for Suckers (**laurieruettimann.com**). "Imagine how much more competitive American corporations could become if we focused on products, services, profitability and employee development, and not on reducing & containing health care costs," she wrote.

COMFY FLYING Delta Air Lines is planning to install seats that it says are more comfortable in the coach sections of some of its planes. Wired.com's Gadget Lab**(blog.wired.com/gadgets)** has pictures of the seats, which are positioned diagonally to offer more legroom. "The only problem," wrote Charlie Sorrel on Gadget Lab, "might be in holding a conversation with your neighbor."

For travelers not interested in the life stories of strangers, that might not be a problem.

THE PORN INDICATOR Peter Bart, a columnist for Variety, suggests that the downturn in the pornography industry may serve as an economic indicator (**variety.com**).

Mr. Bart argued that falling sales of pornography DVDs may signal "a true plunge in consumer confidence." As for online pornography, he said, it was "lofty in traffic" but did not bring in revenue.

The fact is, the pornography industry is struggling with a problem that has little to do with the overall economy — a problem that began well before the current downturn and is shared by most other media industries. The Internet has created a vast oversupply, leaving consumers to wonder why they should pay someone for something they can get free.

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- April 14th

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- Filed under: Knowledge

Efficial time of e-cigarette

Posted by admin

We all know that smoking isn't that great for our health, and we all (should) know that the e-cigarette is essentially a replacement for smoking, rather than a method of quitting. My personal experience, however, shows that even without trying, e-smoking is effective in reducing the number of cigarettes I smoke, and judging by the experiences of others, this is clearly the likely outcome.

What then can you look forward to on taking up e-smoking as an alternative?

- **In 20 minutes** - your blood pressure will return to normal
- **In 8 hours** - The carbon monoxide (a toxic gas) levels in your blood stream will drop by half, and oxygen levels will return to normal
- **In 48 hours** - Your chance of having a heart attack will begin its long decline. All nicotine will have left your body (if you're e-smoking 0% cartridges or liquid). Your sense of taste and smell will return to a normal level
- **In 72 hours** - Your bronchial tubes will relax, and your overall energy level will rise
- **In 2 weeks** - Your circulation will increase, and it will continue to improve for the next 10 weeks
- **In 3-9 months** - Coughs, wheezing and breathing problems will dissapate as your lung capacity improves by 10%
- **In 1 year** - Your risk of having a heart attack will have now dropped by half
- **In 5 years** - Your risk of having a stroke returns to that of a non-smoker
- **In 10 years** - Your risk of lung cancer will have returned to that of a non-smoker
- **In 15 years** - Your risk of heart attack will have returned to that of a non-smoker

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- April 13th
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- Filed under: Electronic cigarettes

electronic cigarettes in USA

Posted by admin

A smoking alternative, popular overseas, has made landfall here and is raising some eyebrows in the process. The E Cigarette was brought to the United States by Cape Coral resident and Germany native Dieter Fiebbig. After his wife of 41 years lost her fight with lung cancer, he was inspired to help smokers quit.

The device, which costs around $100.00, operates on a re-chargeable battery, which powers a red light that glows on the tip. When you inhale, the E Cigarette emits an virtually odorless vapor that simulates actual smoke.

So far, no major American health organization has endorsed the product, but the company offers incentive to customers: Quit within three weeks of buying E Cigarette and get a $100.00 rebate.

E Cigarettes are already popular smoking alternatives in Europe and China…but will they work

here? www.ruyanhealth.com

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Footnote 6

PML SUBMISSION
ANNEX 3

IMPORTANT NOTICE We have changed the name from *ruyan.OfferChina.com.com* into *eCigarettes.Of*

RUYAN NO.1

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THE ELECTRONIC CIGARETTE
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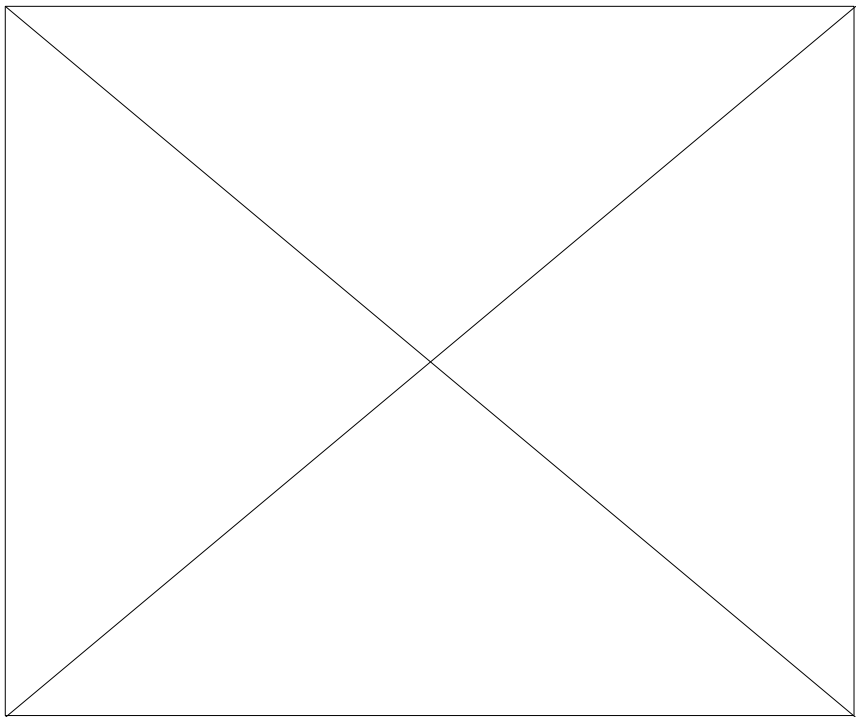

The Electronic Cigarette looks, feels and tastes exactly like a cigarette or cig
the reduced health risk, freedom to smoke anywhere, no second hand smoke

makes it better than a cigarette or a cigar.

The non-flammable Electronic Cigarette is driven by modern microelectronic technology, a small battery and a unique, safe replaceable cartridge containing water, propylene glycol, nicotine, a sc a tobacco flavor and a membrane to suspend the ingredients. When using the Electronic Cigarett inhaling or smoking it produces the tactile and craving satisfactions traditional smokers seek, and vaporizing process that releases a simulated smoke that is actually a vapor mist that harmlessly the air within a few seconds.

Cigarette smoke contains about 4,000 chemical agents, including over 60 carcinogens including s as carbon monoxide, tar, arsenic, cyanide, benzene, formaldehyde, methanol, acetylene, ammon cause CANCER.

ELECTRONIC CIGARETTE	Versus	CIGARETTES
100% Healthy, Only Contains Nicotine		CAUSES CANCER and KIL
NO Chemical Agents		4,000 Chemical Agents
NO Carcinogens		60 Carcinogens
NO Carbon monoxide, NO Tar, NO Arsenic		Carbon Monoxide, Tar, Ars
NO cyanide, NO Benzene, NO Ammonia		Cyanide, Benzene, Ammo
Smoke Anywhere You Want		No Smoking in Airports, Restauran Trains and Buses
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Save:

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Save:

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~~$230.00~~ $170.00
Save: 26% off

Ruyan E-Cigarette V8 Brown
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Save: 26% off

Mini E-Cigarette Car
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Footnote 7

MEDIA MONITORS

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MTWTFS-

Electronic ciggies 'beat smoke bans'

ANDREW TILLETT

Smokers could soon be able to switch on battery-powered "cigarettes" to get a nicotine fix without falling foul of smoking bans, with the Federal Government considering allowing the sale of electronic cigarettes.

The Government's peak drugs advisory body is examining who should be able to buy the so-called e-cigarettes and where they would be sold, the Therapeutic Goods Administration has confirmed.

Electronic cigarettes are not available on Australian shelves because of their nicotine content but a loophole exists allowing individuals to order them over the internet.

The devices, which look like traditional cigarettes, use a small heater to vaporise liquid nicotine into a fine mist for smokers to inhale. Instead of smelly smoke, smokers exhale steam.

A starter kits costs $75 while cartridges, which are equivalent to a pack of 20 cigarettes, sell for $5.

Manufacturers market them as the healthier alternative to smoking because they do not contain the other harmful chemicals found in conventional cigarettes such tar and carbon monoxide.

"We don't claim to be curing smoking. Most people will probably continue smoking but we're delivering clean nicotine," distributor Albert Nisman told *The West Australian*.

Mr Nisman, who wants to sell them in pharmacies and is already distributing them online, also spruiks them as a device to sidestep smoking bans.

Mr Nisman claims because the cigarettes do not emit second-hand smoke or smell, they can be used in smoking prohibited areas.

A TGA spokeswoman said no application to sell electronic cigarettes had been lodged but there had been inquiries.

She said provisional advice to the agency indicated they should be classified as a dangerous poison and be heavily controlled.

Australian Council on Smoking and Health president Mike Daube said people might try electronic cigarettes but would ultimately switch back to conventional cigarettes because they would miss the other elements of smoking, such as the smell of tobacco and the social interaction.

"Smoking these is like saying jumping off the 10th floor of a building is healthier than jumping off the 40th floor," he said.

A WA Health spokeswoman said there had been no applications to sell electronic cigarettes. Officials were investigating whether their sale would break the State's anti-tobacco laws.

Footnote 8

The Age
2 June 2008

The bluff puff, but it's not the full quit

By **CAMERON HOUSTON**
CITY REPORTER

HEALTH organisations have blasted the new electronic cigarettes and cigars being promoted as a way to beat the bans in pubs, offices and public transport.

The battery-powered Egar is touted as a "healthy alternative to smoking" and delivers nicotine through an atomiser that creates puffs of vapour that resembles cigarette smoke.

"You can still have the sensation of smoke but you are not inhaling all the toxic chemicals associated with tobacco," said Albert Nisman, who has distribution rights for the controversial device in Australia. "There is no harm to others around you, as it is smoke free, and with the proposed new laws banning smoking in a car with children this product will definitely be a benefit."

The device, sold overseas as Gamucci, is not intended as nicotine replacement therapy, according to a company website, despite claims by Mr Nisman that it was "much more effective" than any other quit product.

Quit executive director Fiona Sharkie said the product was a gimmick that deliberately flouted the spirit of tobacco bans.

"One of the many benefits of a ban on smoking in bars in clubs is that it encourages people to quit smoking or smoke less," she said. "This product is clearly marketed in a way to get around these bans.

"We doubt that such an awkward, novelty-style device would be popular in Australia."

VicHealth chief executive Todd Harper said health claims regarding the product were dubious. "To suggest this is a legitimate way to give up smoking is ridiculous and possibly dangerous," he said. "The packing of the product to resemble a cigarette blatantly extends the association."

Last year, the tobacco giant Philip Morris launched a similar electronic device. It claimed the hand-held device would usher in a "new movement in smoking, where art meets technology", but it failed to make an impact on younger smokers.

It also falls down because it heats specially designed cigarettes that emit some smoke.

LINKS

- www.quit.org.au
- www.egar.com.au

The Egar, promoted as a "healthy alternative to smoking".

Footnote 9

MEDIA MONITORS

Transcript

Station:	**NOVA 100.3**	Date:	**30/06/2008**
Program:	**BREAKFAST**	Time:	**08:19 AM**
Compere:	**DAVE HUGHES AND KATE LANGBROEK**	Summary ID:	**M00031206253**
Item:	**COMPERES TAKE CALLS FROM LISTENERS DISCUSSING WHAT THEY THINK ABOUT SMOKER'S BREATH.** **INTERVIEWEES: CALLER JARROD; CALLER LUKE; CALLER SAM; CALLER LACHLAN**		

Demographics:	Male 16+	Female 16+	All people	ABs	GBs
	61000	53000	114000	41000	36000

DAVE HUGHES: Yeah, well, I tell you the problem with smokers is, they stink.

KATE LANGBROEK: Oh, Hughesy. That's just terrible. That's so harsh.

DAVE HUGHES: Well, we'll put it to the smokers. Give us a call. What do you reckon?

KATE LANGBROEK: Okay. Who we got?

DAVE HUGHES: We've go...

KATE LANGBROEK: Got a full board.

DAVE HUGHES: We do have a full board. Jarrod, maybe wants to have a crack at having a go.

KATE LANGBROEK: Breathless and angry.

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DAVE HUGHES: What do you want to say, Jarrod?

CALLER JARROD: How you doing guys?

DAVE HUGHES: Yeah, we're okay.

CALLER JARROD: Yeah, well Hughesy. I've got a bit of a thing for you, mate, because I know for a fact you used to be a smoker. So...

DAVE HUGHES: I did.

KATE LANGBROEK: Yes. We all know that, Jarrod. Yes.

CALLER JARROD: So it's no use pointing the finger at people that are smokers and have got bad breath. We didn't ask for bad breath when we take a c...

[Laughter]

[Inaudible due to mobile phone connection] smell minty and fresh and everything like that.

KATE LANGBROEK: That's true. That's why we should all make the switch to Alpines, Jarrod.

CALLER JARROD: Yeah. Well, yeah. If we're all [indistinct] we could do that.

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DAVE HUGHES: All right. So, but you - so you're not denying the truth of what I've said, though. You're just saying I shouldn't say it. Is that right Jarrod?

CALLER JARROD: Yeah. Exactly right.

DAVE HUGHES: All right. Thank you.

That's about as far as we've got with smokers. They're all like - let's listen to Luke's story. Luke, you're a smoker.

CALLER LUKE: Yeah, no, I totally agree with you mate.

KATE LANGBROEK: Oh, Luke.

CALLER LUKE: Smoke stinks, your breath stinks; you should always eat chewy and put deodorant on afterwards.

DAVE HUGHES: And what do you s...

KATE LANGBROEK: What, you put deodorant on after a cigarette?

CALLER LUKE: Yeah, bloody oath. It gets all over your clothes.

KATE LANGBROEK: No. Don't you be one of those people overusing the Lynx(*) effect, Luke.

DAVE HUGHES: Hang on. But what do you say about girls who smoke, Luke?

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CALLER LUKE: Ah - I wouldn't - my girlfriend's a non-smoker.

DAVE HUGHES: Would you go out with a smoking girl.

CALLER LUKE: No. I'd try and get her to quit.

KATE LANGBROEK: Hey listen, dude. You know that girls who smoke are into oral gratification. That's all I'm going to tell you.

[Audio]

MALE SPEAKER: Massive generalisations that are probably true.

[End of audio]

KATE LANGBROEK: Well no, that's true. It's an oral gratification thing.

DAVE HUGHES: What you're saying is that smoking girls are...

KATE LANGBROEK: No I'm not. I'm saying they're into or...

DAVE HUGHES: ... tramps. I was going to use the s word, but I thought that's a bit...

KATE LANGBROEK: No, not tramps.

DAVE HUGHES: So I see a girl with smokes, and I think, all right. She'll smoke anything.

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KATE LANGBROEK: You know what. You know that she's got a certain attitude to life.

DAVE HUGHES: Oh, for God's sake. All right.

KATE LANGBROEK: You know. She's here for a good time, not necessarily a long time.

DAVE HUGHES: Now, I believe that smokers are onto themselves.

Sam - what did you used to do?

CALLER SAM: I was a smoker, and I haven't had a cigarette for six months, and now - smell of it just stinks. Anyone that has a cigarette, it just reeks.

But I didn't realise how bad it was.

DAVE HUGHES: Yeah. Exactly. Now you're from a bit of distance. People, you've just got to give up. It's just n... there's no thing for it.

KATE LANGBROEK: There's got to be something good. Lachlan's got a different way.

DAVE HUGHES: What's Lachlan saying?

CALLER LACHLAN: Hughesy, I'm a smoker. And my breath does not smell like smoke. I challenge you. I challenge you to be able to tell the difference between me and a smoker. I - between me and a non-smoker.

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DAVE HUGHES: You and a non-smoker.

KATE LANGBROEK: Yeah.

CALLER LACHLAN: There's a trick to it. Electronic cigarettes.

DAVE HUGHES: All right.

CALLER LACHLAN: It basically gives you vapour - not smoke.

KATE LANGBROEK: What?

CALLER LACHLAN: Yeah.

DAVE HUGHES: Well, I want Lachlan - I want you to come into Nova 100 and br...

KATE LANGBROEK: Yeah. But he's not a smoker, Hughesy.

CALLER LACHLAN: I am.

KATE LANGBROEK: He's smoking something called an electronic cigarette. He's a freak.

CALLER LACHLAN: Electronic cigarette. You get...

KATE LANGBROEK: What are you talking about, Lachlan?

CALLER LACHLAN: It looks like smoke, but it's a vapour.

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COMPERE: Isn't that the thing they bring in to try and get people to quit smoking, so that you get...

CALLER LACHLAN: Exactly.

KATE LANGBROEK: But it's not smoking a cigarette.

CALLER LACHLAN: Tastes like cigarettes.

DAVE HUGHES: Well is there smoke involved?

CALLER LACHLAN: It's a vapour, though. Completely healthy.

KATE LANGBROEK: What? Healthy? What is it?

CALLER LACHLAN: No cancer.

KATE LANGBROEK: What do you mean...

CALLER LACHLAN: Google it. Seriously. Google it.

KATE LANGBROEK: Are you from the company that makes them, Lachlan?

CALLER LACHLAN: No.

DAVE HUGHES: Does it look like...

CALLER LACHLAN: I just bought one, like, a week ago, and I'm - yeah. I'm addicted.

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KATE LANGBROEK: Where did you get it from? He's addicted.

CALLER LACHLAN: Online. Electronic cigarettes.

KATE LANGBROEK: Who knew - a smoker, addicted.

CALLER LACHLAN: Just google for it.

DAVE HUGHES: Does it look like smoke?

CALLER LACHLAN: It looks like smoke, tastes like smoke. You get the same nicotine hit. But you can smoke it indoors.

DAVE HUGHES: Well, I need to see it.

FEMALE COMPERE: But it's probably not going to leave your breath as...

DAVE HUGHES: Yeah, but I still want to - I still want...

KATE LANGBROEK: What flavour is it, Lachlan?

CALLER LACHLAN: You can get apple, tobacco flavour, caramel and...

KATE LANGBROEK: What - what flavour do you smoke?

CALLER LACHLAN: Tobacco flavour, of course.

KATE LANGBROEK: Who would smoke caramel flavour?

CALLER LACHLAN: Well, [indistinct] caramel flavour.

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MALE COMPERE: Just buy a packet of fags.

DAVE HUGHES: What is - and how do you smoke it?

CALLER LACHLAN: How do you smoke a normal smoke? You breath in.

DAVE HUGHES: So it looks like a normal cigarette.

CALLER LACHLAN: Yep. It's got a light up thing on the end.

KATE LANGBROEK: Do you light it?

CALLER LACHLAN: Yeah - oh, no. You don't light it.

KATE LANGBROEK: Do you pretend to?

CALLER LACHLAN: There's no flame.

DAVE HUGHES: So it's like a little - it emits a sort of an orange light, or something?

CALLER LACHLAN: We smoked this in a hospital.

KATE LANGBROEK: In a hospital.

DAVE HUGHES: Well, we need to get it.

CALLER LACHLAN: Lachlan, have you done that?

DAVE HUGHES: We need to get it.

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CALLER LACHLAN: No. I was [indistinct] in the food court at [indistinct].

DAVE HUGHES: Where do I get it? I need it now. Where are you, Lachlan. Where do you live?

CALLER LACHLAN: Ringwood East, mate.

DAVE HUGHES: Where - are you there right now?

CALLER LACHLAN: Yep.

DAVE HUGHES: Oh.

KATE LANGBROEK: I want you to go to a hospital and smoke and I want you to smoke your electronic cigarette in the hospital.

DAVE HUGHES: Yeah, but I want it in here.

KATE LANGBROEK: You've still got the smokers cough - I'm happy to hear.

DAVE HUGHES: Oh, well that's intriguing.

KATE LANGBROEK: All right. You've thrown us a curve ball, Lachlan.

DAVE HUGHES: There's no doubt about it.

MALE COMPERE: Thanks Lachlan.

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DAVE HUGHES: Yeah.

MALE COMPERE: We'll research the electronic cigarette.

* * END * *

TRANSCRIPT PRODUCED BY MEDIA MONITORS
target-monitor-analyse

AGENCY REPORT For private research and not to be disseminated. Every effort made to ensure accuracy for the benefit of our clients but no legal responsibility is taken for errors or omissions. (*) - Indicates unknown spelling or phonetic spelling. Metro TV demographics are supplied by OzTAM, Radio and Non-Metro TV demographics are supplied by Nielsen Media Research.
ABs = Managers, administrators, professions. GBs = Grocery buyers.

Footnote 10

MEDIA MONITORS

back

Press, The
30/04/2008
Page: 7
General News
Region: Christchurch Circulation: 92465
Type: Metro
Size: 449.04 sq.cms
MTWTFS-

Cigarette substitute set for trials

Ian Steward

You suck on it, it smokes, the end glows and it gives you nicotine — but it's not a cigarette.

Christchurch smokers may get the chance to try the Ruyan e-cigarette, a Chinese smoking substitute that delivers nicotine in a harmless mist through a cigarette-like device, this year.

Christchurch doctor and anti-smoking campaigner Murray Laugesen has been testing the device for its Chinese manufacturers in preparation for a launch in this part of the world.

He is planning clinical trials on the device that would involve "hundreds of people".

Activated when the smoker sucks on the end, the electronic cigarette glows at the tip, produces harmless theatrical smoke and conveys nicotine from a reloadable cartridge to the smoker's lungs.

Laugesen has completed the first of several trials for Ruyan to test the product's efficacy and safety.

The tests found the e-cigarette decreased cigarette cravings as effectively as the Nicorette inhaler already on the market, but most smokers preferred the e-cigarette's taste and said they would recommend it to a friend, Laugesen said.

The device has been on sale in China since 2004 and in the United States this year, but was only in the first stages of New Zealand testing.

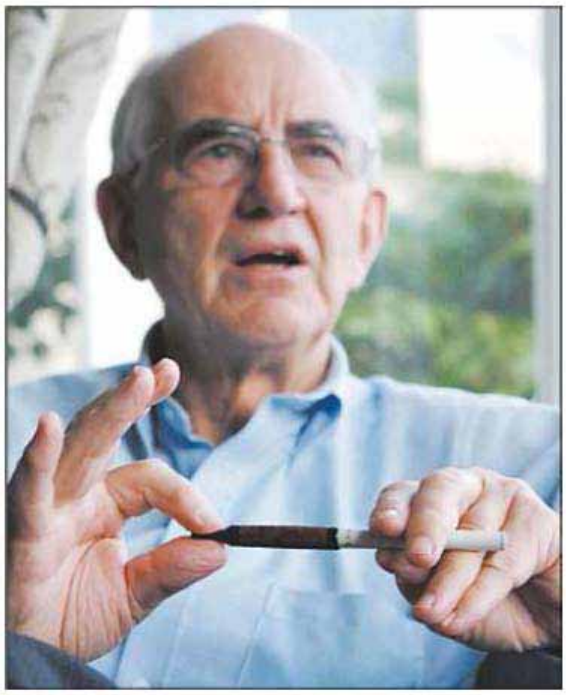
Laugesen's first impressions of the e-cigarette were positive.

"It's the first product I've seen that looks as if it can compete with tobacco," he said.

"It's interesting watching smokers. Usually on about the third puff, a look of surprise comes over their face because they get light-headed."

The device sells in the US for about $US200 ($NZ256), with refills, which last between one and four days, selling for $US5 ($NZ6.40) each.

It contains a microchip that senses pressure on the mouthpiece and warms the nicotine mist. The nicotine canisters must be certified as a medicine and such aspects as shelf life would have to be tested before it could be sold in New Zealand.



Safer: anti-smoking campaigner Dr Murray Laugesen believes the e-cigarette will help smokers to quit.

New device: the e-cigarette glows, produces harmless smoke and conveys nicotine to the user's lungs. Photos: Dean Kozanic

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HOW SAFE IS AN E-CIGARETTE?

THE RESULTS OF INDEPENDENT CHEMICAL AND MICROBIOLOGICAL ANALYSIS

Murray Laugesen*
Simon Thornley#
Hayden McRobbie**
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The Ruyan e-cigarette

Inventor: Hon Lik, of Ruyan Holdings Ltd, Beijing

Conflict of Interest and Disclosure statement

This work is part of a research contract between the Health New Zealand Ltd and Ruyan Group Holdings, Beijing.

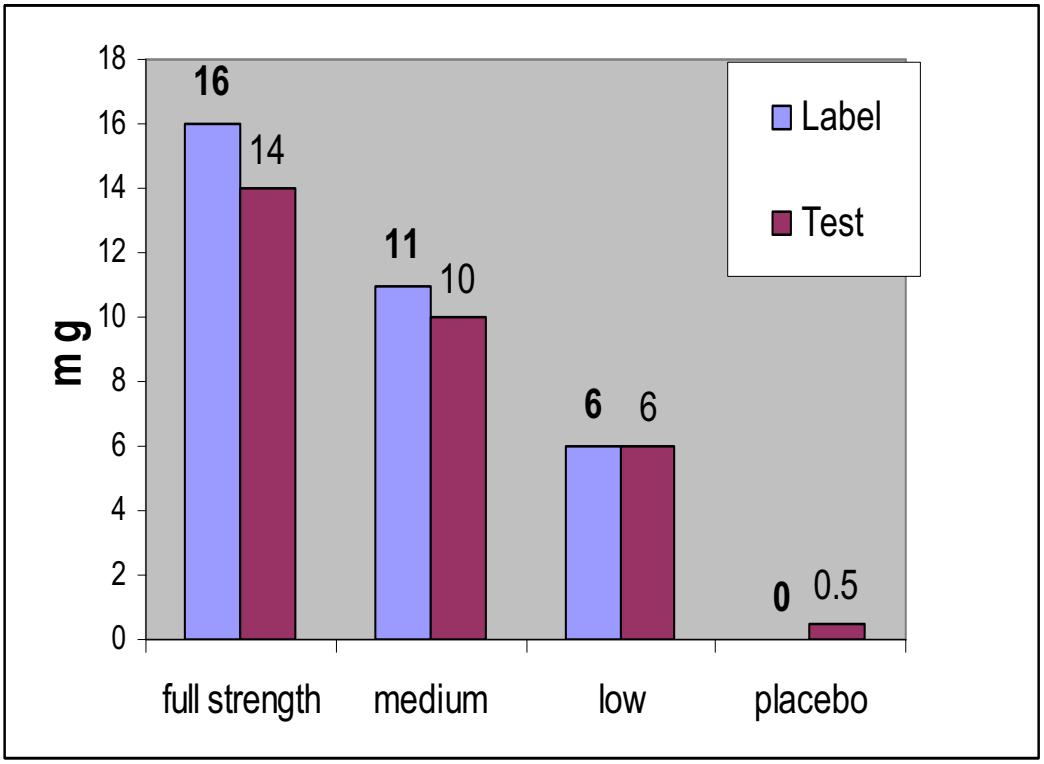
No financial benefit accrues and no Ruyan stock is held by Health New Zealand Ltd or the author

The research was planned by Health New Zealand Ltd

Ruyan have not placed any bar on publication

Results of all completed tests have been disclosed.

Nicotine Content of the The Ruyan cartridge



Conclusion

- The labeling is similar to actual content.
- Batch to batch and within-batch variations were not studied.

Risk of microorganisms in cartridge liquid

Samples: One unused cartridge
One repeatedly used cartridge

Tests:	cfu/mL
Aerobic plate count 35 °C	<10
Anaerobic	<10
Legionella	<10

Conclusion

No tendency for microorganisms to grow in the liquid

Laboratory: ESR , a Crown Research Institute, Porirua, NZ.

Metals mg/Kg (ppm)

Samples: Liquid in unused cartridges

Sb (antimony)	**< 1**
As	**< 0.1**
Cd	**< 0.01**
Cr	**< 0.2**
Co	**< 0.5**
Cu	**< 0.3**
Pb	**< 0.1**
Mn	**< 0.1**
Ni	**< 0.2**

Conclusion:

Metals all < 1 ppm: Not a risk

Is this a tobacco product?

Test samples: with and without nicotine

Fragrance/odour	**Yes**
Tobacco -specific Nitrosamines	**8 ppb (ng/g)**
For comparison	
NRT gum[1]	**8 ng/g)**
Unburnt cig. Tobacco[2]	**1200 ng/g)]**
Cigarette smoke[3]	**to 500 ng /cigarette**
MAO inhibition:	
Of MAO A	**no sig. effect**
Of MAO B	**no sig. effect**

1. Stepanov I, Jensen J, Hatsukami D, Hecht SS. Tobacco-specific nitrosamines in new tobacco products. Nicotine Tobacco Research 2006; 8: 309-313.

2. TSNAs in NZ cigarette tobaccos www.smokeless.org.nz/snuffregulations.htm at Table 2.

3. Counts ME, Morton MJ, Laffoon SW, *et al.* Smoke composition and predicting relationships for international commercial cigarettes smoked with three machine smoking test mode. *Regulatory Toxicol Pharmacol* 2005;**41**:185–227.

Volatile smoke toxicants (VOCs)

SIFT-MS headspace analysis of the Ruyan e-Cigarette cartridge (mean of two replicates).

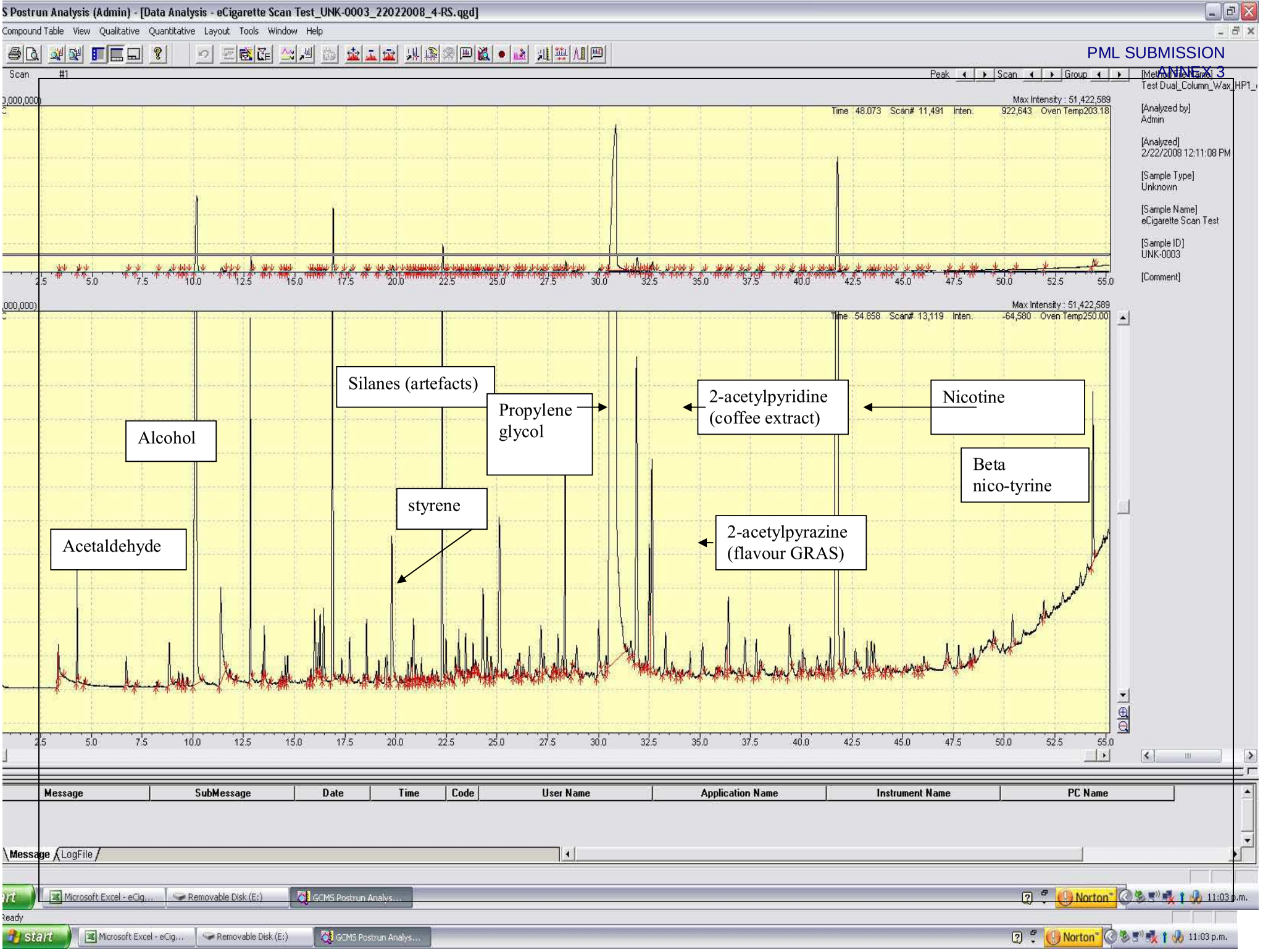
Toxicant (LOQ=0.3 ppm)	Concentration in blank (parts per million; ppm)	Concentration in headspace of cartridge: parts per million; ppm
Acetaldehyde	<LOQ	**9.40**
Benzene	<LOQ	**1.50**
Acrolein	<LOQ	**1.30**
Cresols (total m-, o- and p-)	<LOQ	**0.49**
1,3-Butadiene	<LOQ	<LOQ
Hydrogen cyanide	<LOQ	<LOQ
Acrylonitrile	<LOQ	<LOQ
Propylene oxide	<LOQ	<LOQ
Diethylene oxide	<LOQ	<LOQ

To convert from ppm at 25degC to mg/m3 or to ug/ml =ppm x MW/24.45

Due to interference in ion measurements from alcohol:

- **VOCs detected as > LOQ should be verified by GC-MS type methods.**
- **Values are upper limits**

In the e-cigarette, smoke toxicants such as HCN, Butadiene and acrylonitrile are below 0.3 ppm


S Postrun Analysis (Admin) - [Data Analysis - eCigarette Scan Test_UNK-0003_22022008_4-RS.qgd]
Compound Table View Qualitative Quantitative Layout Tools Window Help
Scan #1
Peak Scan Group
Max Intensity : 51,422,589
Time 48.073 Scan# 11,491 Inten. 922,643 Oven Temp203.18
Max Intensity : 51,422,589
Time 54.858 Scan# 13,119 Inten. -64,580 Oven Temp250.00
Test Dual_Column_Wax_HP1_
[Analyzed by]
Admin
[Analyzed]
2/22/2008 12:11:08 PM
[Sample Type]
Unknown
[Sample Name]
eCigarette Scan Test
[Sample ID]
UNK-0003
[Comment]
Silanes (artefacts)
Propylene glycol
2-acetylpyridine (coffee extract)
Nicotine
Alcohol
Beta nico-tyrine
styrene
2-acetylpyrazine (flavour GRAS)
Acetaldehyde
Message
SubMessage
Date
Time
Code
User Name
Application Name
Instrument Name
PC Name
Message
LogFile
Microsoft Excel - eCig...
Removable Disk (E:)
GCMS Postrun Analys...
Norton
11:03 p.m.
Ready
start

Further VOCs detected in head space of e-cigarette cartridge liquid by HS-SPME

(Headspace Scan/Solid Phase MicroExtraction)

Acetone	0.5 to 1 ppm minimum
Styrene	0.5 to 1 ppm minimum
Xylene	0.5 to 1 ppm minimum

After drawback on the e-cigarette, the vapourised mist needs to be measured by GC-MS to allow for the higher temperature during vapourisation.

—

Inhalation safety levels for acetaldehyde

Concentration in cartridge headspace: 9.5 ppm

OSHA permits concentrations of 100 ppm (average) for workplace air across one 8-hour shift, 40 hours per week, for 1 year duration or more.

If the e-cigarette smoker smoked one cartridge (300 breaths) during one 8-hour shift, e-cigarette smoking would comprise 5% of workplace breaths taken.

Thus if a workplace was acetaldehyde-free to begin with, the e-cigarette smoker would have to inhale vapour with a concentration of 2000 ppm to equal what OSHA permits for average workplace air levels.

This is 200 times the 9.5 ppm measured by SIFT-MS in the headspace of the Ruyan cartridge.

- Acetaldehyde should be re-measured in the mist inhaled from the drawback.
- Better, the source of the acetaldehyde in the cartridge liquid should be detected and eliminated if at all possible.

Carcinogens, non-volatile

Samples: cartridge liquid, not head space

TSNAs (nitrosamines) 8 ng / cartridge as above

BENZO ALPHA PYRENE < 1 ng / cartridge
(< LOD)

- **In an inhaler, the non-volatile compounds are not likely to be inhaled.**
- **However the e-cigarette relies on a higher temperature to vapourise nicotine**
- **A scan of the vapourised mist from the e-cigarette is required to check what else has been vapourised.**

1 Fowles J and Dybing E. Application of toxicological risk assessment principles to the chemical constituents of cigarette smoke. Tob Control 12 (4): 424. Web-only table from EPA California. http://tobaccocontrol.bmj.com/cgi/data/12/4/424/DC1/1

Risk of contamination from mouthpiece

Risk:

Meningococcal meningitis, tuberculosis.

Public health advice is to avoid sharing glasses and cigarettes.

Sharing the e-cigarette mouthpiece is inadvisable.

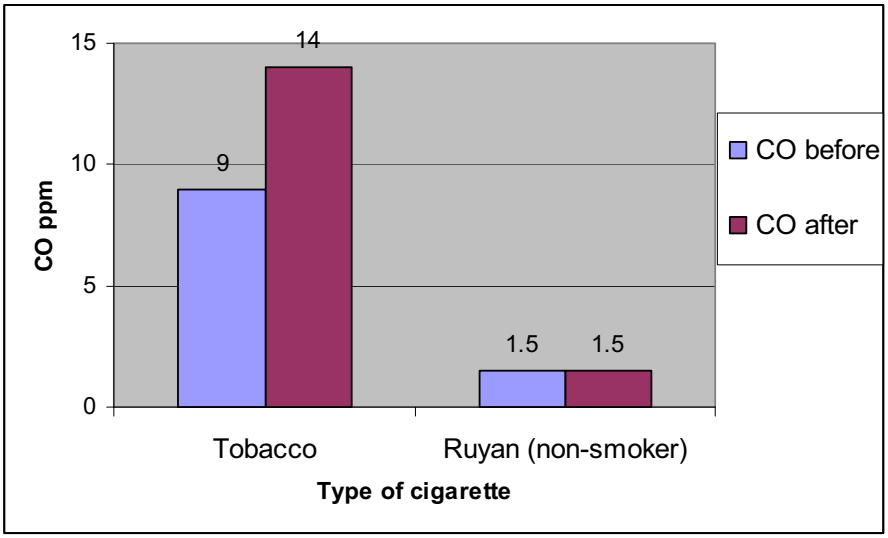
The risk is largely eliminated by separate mouth pieces for different users.

(The black mouthpiece is detachable from the white nicotine-containing cartridge.)

Safety of e-cigarette 'smoke' for bystanders

The 'smoke' is propylene glycol – virtually non-toxic, does not contain gases of combustion.

Carbon monoxide in exhaled breath, before and after the first cigarette of the day



- CO is a marker gas for combustion.
- The e-cigarette does not increase CO in breath.
- Smoking the e-cigarette would not be restricted

  The NZ Smoke-free Environments Act only restricts tobacco and marijuana smoke.

The e-cigarette reduces second-hand smoke

1) by replacing the lighting up of tobacco, and

2) by not producing second-hand smoke itself.

PML SUBMISSION
ANNEX 3

SmokeLess New Zealand e-News

www.smokeless.org.nz info@smokeless.org.nz

9 April 2008

The Ruyan® (nicotine) e-cigarette

This nicotine inhaler mimics the smoking experi closely than any smokeless product to date and p nicotine hit, without causing smokers to cough. I and functions like a cigarette.
It gives the satisfaction of drawback, and gives a effect within seconds, rather than minutes requir from oral nicotine medications. It is likely to be nicotine alternative to smoking among those kee smoking.

Description The Ruyan® e-cigarette is a battery-operated nicotine delivery device, without the carci white segment contains a re-chargeable battery (charged overnight from the mains), the dark coloure vapourising chamber. Near the mouthpiece a replaceable cartridge contains a nicotine-containing solv

Marketing. For a You-tube depiction of the e-cigarette in action see:
http://www.google.com/search?q=Ruyan+cigarette&rls=com.microsoft:en-nz:IE-SearchBox&ie 8&sourceid=ie7&rlz=1I7WZPA Ruyan® prefers to market its e-cigarette as a cigarette substitute, to continue to enjoy the act of "smoking", but without the risks. Most countries, however, only provic as an aid to quitting.

Cost As a cigarette substitute it is sold in China (300,000 sold pa) and from 2008 in the United States Turkey. The e-cigarette as of 9 April 2008 sells on the internet at US208. (http://www.ruyanchina.cor US $90 for 50. The manufacturer states that each cartridge provide 300 to 350 puffs. The rechargeabl puffs.

Mechanism. Lip pressure on the mouthpiece activates the electric circuit, sparking vapourisation of r propylene glycol, an FDA approved solvent. Flavour essence makes up 0.6% of its weight, and it is t vapour mist exhaled is not smoke, so it can be "smoked" indoors. An artificial red light glow at the ti drawback.

Table 1 Nicotine doses deliverable from a tobacco and a Ruyan® nicotine cigarette

	Per puff	Per 15 puffs	Per 300 puffs
Manufactured tobacco cigarettes	0.1 mg	1.5 mg (1 cigarette)	30 mg (20 cigarett
Ruyan® 16 mg cartridge	0.05 mg	0.8 mg	16 mg
Ruyan® 11 mg cartridge	0.04 mg	0.6 mg	11 mg
Ruyan® 6 mg cartridge	0.02 mg	0.3 mg	6 mg
Ruyan® 0 mg cartridge	0.0 mg	0.0 mg	0 mg

- Ruyan® , nicotine content confirmed by ESR.

Dosimetry. It is available from China in pipe and cigar forms. The nicotine in the cartridge comes in 11 mg, 6 mg and 0 mg nicotine content. Allowing 10% residual and 300 drags per tube, compared w mg of nicotine from a tobacco cigarette, then at 16 mg cartridge strength, two e-puffs equal one tobac

Biological effect. On drawback, nicotine is apparently inhaled into the lungs within a few breaths to effect within 20 seconds.

Legal status. New Zealand does not (yet) have Nicotine Regulations to permit sale as a cigarette subs not encompass the concept of pleasurable, largely harmless nicotine, only of nicotine as an aid to achi Ministry of Health (Medsafe) ruled (August 2007) that the Ruyan® e-cigarette is a medicine, a type cannot be sold in New Zealand unless it meets Medicines Act requirements for registration as a medi

general sale, then it will be permissible to advertise it, as is the case for other nicotine inhalers.

Safety A range of safety tests are being carried out by Health New Zealand Ltd at various New Zeala

Efficacy Clinical testing has been completed at Clinical Trials Research Unit, University of Aucklanc decide whether to apply for registration as a medicine.

Contra-indications:

Non smokers**.** Nicotine-naïve non-smokers may experience the same effects as first-time smokers. Th the throat, and if they inhale into the lungs, nausea, dizziness and possibly vomiting might occur

Pregnancy As this device can deliver high doses of nicotine, it is contra-indicated in pregnancy, unles able to quit smoking by other means.

Cardiovascular disease**.** Nicotine in high dose may trigger heart beat irregularities.

Children. It is difficult to unscrew, but once unscrewed a child could be at risk of nicotine poisoning their mouth. Children can also be poisoned by the nicotine in cigarettes. The lethal dose for a child is one manufactured cigarette contains 13 mg of nicotine, and a hand-rolled cigarette contains 9 mg nicc

<script src="http://www.google-analytics.com/urchin.js" type="text/javascript"></script><script type="text/javascript">_uacct = "UA-3289734-1"; urchinTracker();</script>

© SmokeLess New Zealand

Footnote 11

The Advisory Council for Classification Criteria at the Austrian Federal Ministry for Public Health, Family, and Young People

Expert Opinion of the Advisory Council for Classification Criteria, pursuant to § 49a of the {Austrian} Medicinal Products Act ("AMG"), on Nicotine Inhalators, in particular, electrically operated or similar products (e.g., RUYAN — the Electrical Cigarette; RUYAN Atomizing Electronic Cigarette, and RUYAN Atomizing Tobacco Alkaloid Liquid Container),

prepared in the course of the provision of advice to the Federal Minister of Public Health, Family, and Young People, as well as the Federal Office for Safety and Security in the Public-Health System, pursuant to § 49a of the {Austrian} Medicinal Products Act ("AMG"), Federal Law Gazette, No. 185/1983, as amended.

1. A Brief Description

In multi-level marketing, so-called "electrical cigarettes" (also known as e-pipe, e-cigarette, etc.) are being distributed. Time and again, AGES-PharmMed[1] receives inquiries about imports and the application of the nicotine cartridges that come with those cigarettes.

The products consist of two components each:

— a nicotine storage container (nicotine cartridge);

— an inhalator unit with an electrically-operated atomizer for the nicotine (the energy source may be, for instance, a rechargeable lithium ion battery). One product has a red indicator light at the front end of the cigarette-like inhalator unit.

2. Nature of Inquiry

"Does RUYAN — the Electrical Cigarette come under the definition for medicinal products pursuant to § 1 of the AMG?"

[1] An organization created by the Austrian legislator which is *inter alia* in charge of ensuring the safety of medicinal products and medical devices.

3. Findings

3.1 A Brief Description of the Product

By way of example, the RUYAN product is dealt with below (PharmMed is in possession of a product sample).

The product consists of two components:

— a nicotine storage container (nicotine cartridge);
— an inhalator unit with an electrically-operated atomizer for the nicotine.

3.2 Product Composition

According to the declaration on the pack, the cartridges contain 0 mg, 12 mg, or 16 mg of nicotine.

3.3 Dosage and Method of Application

Application: for the inhalation of nicotine

Dosage: according to the advertisement, one nicotine cartridge contains the "typical" quantity equivalent to the nicotine contents in a pack of cigarettes.

There are also cartridges on offer which are intended to simulate "light, medium-strength, and strong" cigarettes.

3.4 Labeling on the Outer Packaging

The outer packaging has been designed as follows:

An embossed-leather cassette; Chinese characters in gold blocking; the name of RUYAN in red color; a seal with Chinese characters (no translation of meaning is given).

3.5 Labeling on the Primary Packaging

A nicotine cartridge with cover and seal (with Chinese characters, no translation of meaning given).

3.6 Instructions for Use

Printed on both sides, in the Chinese and English languages, no German-language instructions for use available.

In the instructions for the use of the nicotine cartridges (RUYAN Atomizing Tobacco Alkaloid Liquid Container {ATALC}), reference is made to "medi-

cine alkaloid" and the addictive potential of nicotine. Similarly, there is a description of withdrawal treatment through changing to lower-strength cartridges, with the 0 mg-cartridge to be used last.

Invoking the WHO's cessation program, the instructions for use declare that he product has been developed for weaning smokers [away from nicotine] ("Theory of abstention from smoking: RUYAN ATALC is designed according to 'Nicotine replacement theory' recommended by World Health Organization {WHO}. It will let smokers gradually step-down the quantity of nicotine they absorb. Smokers who decide to quit smoking can adopt RUYAN Atomizing Electronic Cigarette to fulfill their purpose"[2]).

3.7 Miscellaneous

Since the present case is about the application of nicotine as a substance, the Tobacco Act (Federal Law Gazette, No. 431/1995 as amended) will not be applicable.

4. Expert Opinion (including a statement on the sources of information used)

This Expert Opinion has been prepared using as a basis the available samples and the following information:

> Sources of information (date: March 1, 2007): www.ruyan.tk, www.ruyan.dk, www.rauchfrei.de/nikotin.htm

Nicotine is an alkaloid that has a direct parasympathomimetic effect. Irrespective of the type of intake and the source (cigarette, chewing gum, nicotine patch, or inhalation), nicotine is quickly absorbed into the bloodstream, and reaches the brain within a few seconds.

The activation of various transmitter substances, such as dopamine and noradrenaline, creates a feeling of wellbeing and attentiveness. In a smoker, this will result in the positive effect maintained by a steady supply of nicotine. That effect, then, will occur irrespective of the way in which nicotine has been taken in. Similarly, it will be of no significance whether nicotine is supplied by way of a nicotine-substitution therapy or by way of a cigarette without harmful side effects caused by smoke ingredients.

[2] As in the original text, this has been quoted *verbatim* from the manufacturer's instructions.

- Nicotine increases both heart and respiratory rates
- Nicotine causes vasoconstriction and a rise in blood pressure
- Nicotine causes circulatory disturbance through skin cooling
- Nicotine lowers the depth of respiration because of impaired oxygen transport
- Nicotine increases the production of gastric juice, and peristalsis
- Nicotine releases adrenaline (increases the metabolic rate, and has a lipocatabolic effect)
- Nicotine increases general metabolic activity
- Nicotine releases noradrenaline, beta-endorphin, and vasopressin
- Nicotine increases the concentration of cortisol, prolactin, and somatotropin in the blood

Even irrespective of whether it is advertised for the therapy of addiction to nicotine or not, the RUYAN product — the electrical cigarette, and similar products such as the e-cigarette — may, with regard to its pharmacological efficacy, be compared with medicinal specialty products, particularly with nicotine inhalators for the promotion of smoking cessation. Obviously, RUYAN's dosage recommendation (cartridges of various strengths are on offer, as well as placebos without nicotine) also provides for application as a nicotine-substitute therapy.

§ 1 of the AMG defines medicinal products as follows:

§ 1. (1) "Medicinal products" are substances or preparations of substances which, in the general opinion of market participants, serve the purpose of, or are by the type and form of their marketing intended, if applied to or within the bodies of humans or animals, for —

1. curing, alleviating, preventing, or identifying disease, suffering, physical injury, or medical disorders;
2. giving insight into the quality, condition, or functions of the body, or into mental conditions;
3. replacing agents or body fluids produced by the bodies of humans or animals;
4. fending off, eliminating, or rendering innocuous disease-causing agents, parasites, or substances extraneous to the body; or
5. influencing quality, condition, or functions of the body, or mental conditions.

From a professional point of view, the nicotine cartridge of the product, RUYAN — the electrical cigarette, comes under the definition of medicinal products pursuant to § 1 of the Medicinal Products Act.

Since with the product, RUYAN — the electrical cigarette, the nicotine cartridge may be replaced or refilled, and is or may hence be distributed separately, the inhalator unit comes under the provisions of the Medical Devices Act ("MPG"; No. 657/1996 as amended); the wording of § 5,, Clause 1, of the MPG reads: "Medical devices which at the time of sale do not contain a medicinal product but are intended to apply a medicinal product for the purposes of the Medicinal Products Act shall be subject to the provisions of this Federal Statute (MPG) notwithstanding the AMG's provisions relating to such medicinal product." Pursuant to the classification rules prescribed by the Medical Devices Classification Ordinance (Federal Law Gazette, II, No. 56/2004) and Annex IX to Directive 93/42/EEC, provision 11, the medical device shall be classified as an active medical device of Class IIa (or possibly IIb). Thus, a designated passage from the conformity assessment for this product by the manufacturer is to be used as well.

In accordance with the described properties and effects of nicotine as a substance, the nicotine-containing part of the RUYAN product would have to be defined as a medicinal product, and the inhalator unit as a medical device.

5. Summary

From a professional point of view, the nicotine in the electrically-operated nicotine inhalators (e.g., RUYAN) comes under the definition for medicinal products pursuant to § 1 of the Medicinal Products Act.

The inhalator unit of the electrically-operated nicotine inhalators (e.g., RUYAN), accordingly, is to be defined as a medical device pursuant to § 5, Clause 1, of the Medical Devices Act.

Enclosures: none

This Expert Opinion is comprised of 4 (translation: 5) pages.

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