



PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

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Mr Gerry McInally
Committee Secretary
Red Tape Committee
Department of the Senate
PO Box 6100
Canberra ACT 2600
By email: redtape.sen@aph.gov.au

Effect of restrictions and prohibitions on business (red tape) on the economy and community – tobacco retail

Dear Mr McInally

Thank you for inviting us to make a submission to this inquiry. We welcome the opportunity to share our thoughts on how red tape impacts our vision for a smoke-free future and prevents millions of Australians from switching to less harmful alternatives to cigarette smoking.

Our vision and commitment

Philip Morris International (PMI) intends to lead the development of a smoke-free future, where smoke-free products will replace cigarettes.

To date, we have:

- Invested over USD 3 billion developing and testing products that deliver nicotine without the harmful smoke of cigarettes, employing over 400 world-class scientists, engineers, and technicians.
- Developed a portfolio of these breakthrough products that are smoke-free, enjoyable and being made available around the world today. IQOS (the first of our smoke-free products) will be launched in over 30 markets by the end of this year.
- Made it possible for over 1.8 million people to give up smoking and switch to our new products, and this is just the beginning.
- Submitted a 2 million page Pre-Market Tobacco Application to the US Food and Drug Administration (FDA), where the FDA determines whether the product is appropriate for the protection of public health.
- Commenced the process of significantly re-engineering our business to meet the needs of our customers and deliver our smoke-free objectives.

Our smoke-free vision is grounded in the reality that people, unless provided with credible smoke-free alternatives, will continue to smoke. The World Health Organization estimates that over 1 billion people will continue to smoke around the world by 2025, over 2.1 million of those

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in Australia.¹ Most Australian smokers are asking for the opportunity to switch to smoke-free alternatives and for us to do whatever it takes to make them available.

Alternative approaches are needed to complement existing supply and demand measures intended to prevent initiation, encourage cessation, and reduce consumption of conventional, combustible products.

Indeed, Article 1 of the World Health Organization Framework Convention on Tobacco Control² defines 'tobacco control' as:

a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.

A common-sense approach for public health would be to encourage the development and commercialisation of better, more satisfying Reduced-Risk Product (RRP)³ alternatives for the greatest number of smokers.

More information about Philip Morris, our smoke-free vision, and innovation-driven efforts to develop and make available RRP's can be found in the Appendix to this letter.

Australia's red tape challenge

The manufacture, importation and sale of cigarettes into Australia is highly regulated, but nevertheless tobacco products for smoking are widely available. Perversely, we cannot introduce smoke-free alternatives and Australian retailers cannot make them available to their customers due to government regulation, meaning the policy environment overseen by the Department of Health protects and comparatively promotes only the most harmful products in this category.

Recent evidence suggests that the Department hopes to prevent the introduction of less harmful smoke-free alternative products in Australia. Indeed, the Assistant Health Minister, The Hon Dr David Gillespie was recently interviewed Fairfax press and speaking specifically about IQOS said:

... Dr Gillespie made clear the tobacco company was unlikely to get permission to sell the new cigarette in Australia under current regulations.

"The commercial supply of nicotine is effectively prohibited in Australia via state and territory poisons legislation, with some exceptions, such as for tobacco prepared and packed for smoking, and certain nicotine replacement therapies," the minister said in a statement to Fairfax Media.

*"The department is of the view that these exemptions would not likely apply to heat-not-burn products as the nicotine in them would not be in the form of tobacco prepared and packed for smoking. Australia also has a comprehensive set of tobacco control measures, a number of which may apply to heat-not-burn products. For instance, the Tobacco Plain Packaging Act 2011 and the Tobacco Advertising Prohibition Act 1992 would likely apply to heat-not-burn products."*⁴

¹ World Health Organization (2015), WHO global report on trends in prevalence of tobacco smoking 2015, available [here](#).

² World Health Organization (2003), WHO Framework Convention on Tobacco Control, available [here](#).

³ Reduced-Risk Products (RRPs) is the term we use to refer to products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continued smoking.

⁴ Wright, Tony, Philip Morris's 'smoke-free' cigarette seems unlikely to ignite in Australia (2017), The Sydney Morning Herald, available [here](#).

Experts agree that nicotine, while addictive, is not the primary cause of smoking related diseases, for example:

*The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.*⁵

And the UK Royal College of Physicians:

*Nicotine is not, however, in itself a highly hazardous drug...it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.*⁶

As such, there is growing support for the opportunity smoke-free products provide to improve public health.

Countries like the US and the EU have already adopted new frameworks that treat RRP differently than cigarettes. Canada and New Zealand have also recently announced their intention to make a range of smoke-free products available to reduce the harm of cigarette consumption.

Locally however:

- Current Australian regulation prevents adult smokers from switching to less harmful products. Indeed, Schedule 7 of the Poisons Standard⁷ bans nicotine as a dangerous poison except “in tobacco prepared and packed for smoking”. Australia also bans smokeless tobacco products pursuant to Consumer Protection Notice No. 10 of 1991 issued by the then Minister of State for Justice and Consumer Affairs on 3 June 1991;⁸
- Current advice from Australian public health officials and agencies discourages adoption of smoke-free alternatives such as e-cigarettes,⁹ reinforcing the message that those who cannot or will not quit without such products should instead continue smoking;
- Selling smoke-free products such as e-cigarettes is illegal for Australian businesses, but there is no practical impediment to the same products being sold by foreign businesses from overseas.

Less harmful products represent a new and quickly evolving category of consumer goods that require a unique regulatory framework. Such rules should be inspired by some key principles:

- Define specific regulations to encourage smokers to switch to smoke-free products, including different rules for use in public places, communication to consumers and tax levels, which apply only to products that are proven to be less harmful to encourage smoker adoption.
- Require that any claim that a product is less harmful be scientifically substantiated.
- Encourage product innovation and investment in scientific assessment.
- Restrict access to adults by setting minimum age requirements and other laws to prevent youth access.
- Provide consumers with confidence that the products meet quality manufacturing standards.

⁵ National Center for Chronic Disease Prevention and Health Promotion (US) Office on Smoking and Health, The Health Consequences of Smoking — 50 Years of Progress: A Report of the Surgeon General (2014)

⁶ Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction (2016)

⁷ The Standard for the Uniform Scheduling of Medicines and Poisons, available on the Australian Government Federal Register of Legislation [here](#)

⁸ Australian Competition and Consumer Commission for Product Safety Australia, detail available [here](#).

⁹ Statement from the CEO of NHMRC on E-Cigarettes, available [here](#).

Conclusion

In general terms, red tape of the type described above prevents tobacco harm reduction, banning e-cigarettes and other smoke-free products while protecting the most harmful.

Red tape denies the opportunity for tobacco retailers to sell less harmful products and hurts consumers by preventing access to less harmful alternatives that would positively impact individual and public health.

Australian governments have the opportunity to re-shape an environment that benefits individual and public health by researching, regulating, and making available smoke-free alternatives to cigarettes.

We thank the Red Tape Committee for the opportunity to make a submission.

Yours sincerely

Philip Morris Limited

Appendix

About Philip Morris

PMI is the **world's leading international tobacco company**, with a diverse workforce of around 80,000 people who hail from every corner of the globe. Philip Morris Limited is our local affiliate, including our operations in Australia, New Zealand and the Pacific Islands.

We are committed to being a great employer and a good corporate citizen. We strive to be environmentally and socially responsible. We are dedicated to fighting the illegal cigarette trade. And we proudly support the communities where we source tobacco and where our employees live and work.

We're dedicated to doing something very dramatic – replacing cigarettes with the smoke-free products that we're developing and selling.

That's why we have a total of over 400 dedicated scientists, engineers, and technicians developing less harmful alternatives to cigarettes at our two Research & Development sites in Switzerland and Singapore.

It's the biggest shift in our history. And it's the right one for our consumers, our company, our shareholders, and society.

Our Mission: Designing a Smoke-Free Future

How long will the world's leading cigarette company be in the cigarette business?

We've built the world's most successful cigarette company, with the world's most popular and iconic brands.

Now we've made a dramatic decision.

We will be far more than the leading cigarette company. We're building PMI's future on smoke-free products that are a much better choice than cigarette smoking.

Indeed, our vision – for all of us at PMI – is that these products will one day replace cigarettes.

Why are we doing this?

Because we should...

We understand the millions of men and women who smoke cigarettes. They are looking for less harmful, yet satisfying, alternatives to smoking. We will give them that choice.

We have a commitment to our employees and our shareholders. We will fulfil that commitment by pursuing this long-term vision for success.

Society expects us to act responsibly. And we are doing just that by designing a smoke-free future.

and because we now can.

Success in the cigarette business gives us the resources to pursue our ambitious vision.

Thanks to the imagination and perseverance of thousands of people at PMI, we have developed breakthrough products that are smoke-free and enjoyable.

And, we are selling them today. Over a million people have already given up smoking and switched to our new products, and this is just the beginning.

We're investing to make these products the Philip Morris icons of the future.

A future PMI that's known for replacing cigarettes with a portfolio of revolutionary products.

In changing times you can always choose to do nothing. Instead, we've set a new course for the company. We've chosen to do something really big.

A Common-Sense Approach for Public Health

Making better, more satisfying alternatives for the greatest number of smokers

The World Health Organization estimates that there will be over a billion smokers by 2025.¹⁰ With so many people choosing to smoke, it makes sense that they should have less harmful alternatives to cigarettes. Why would anyone deny them this opportunity?

A few important steps are needed to make this **common-sense approach** a reality for millions of smokers.

First, you need to invent less harmful alternatives to cigarettes. Second, these alternatives should be appealing to smokers: they should deliver a taste and sensory experience that leads smokers, who would otherwise continue to smoke, to switch. We can achieve a significant public-health benefit only when a large number of these smokers switch from cigarettes to better products.

We're investing people, resources, time, and money to develop and assess the risk-reduction potential of these new products. Our innovation pipeline includes four product platforms that can meet the varying preferences of adult smokers and hence help them to switch.

In pursuing our vision of RRP, we are eager to see measures introduced that drive large-scale switching as quickly as possible. We are confident that the right mix of government leadership and commercial initiative will dramatically accelerate efforts to reduce the health burden of smoking.

¹⁰ Bilano V, Gilmour S, Moffiet T, d'Espaignet ET, Stevens GA, Commar A, Tuyl F, Hudson I, Shibuya K. (2015) Global trends and projections for tobacco use, 1990–2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control. Lancet 385:966–76.

Science and Innovation

Our vision is to offer smokers a better choice

How are we making this vision a reality?

The answer is that we are **developing and testing products** that deliver nicotine **without the harmful smoke** of cigarettes – yet that consumers will find satisfying. Since 2008, we've invested over USD 3 billion, employing over 400 world-class scientists, engineers, and technicians.

We're already making these new products available. Over 1.8 million consumers have switched to the first of our smoke-free products.

Our priority is clear – to switch, as quickly as possible, hundreds of millions of adult smokers to less harmful alternatives than continued smoking.

These new products are only intended for adult smokers and not for those who have never smoked or are former smokers.

Our Findings to Date

Studies are well advanced and the results are encouraging. What is the science telling us?

Our studies on our most advanced smoke-free alternative product, the Tobacco Heating System (THS), are progressing rapidly. PMI's studies support the following for the THS (when used as intended):

- It generates no combustion and no smoke.
- According to laboratory tests, its aerosol has significantly lower levels of harmful and potentially harmful constituents (HPHCs) and is much less toxic than cigarette smoke.
- One 90-day study in the United States and one 90-day study in Japan reported that smokers who switched completely to the THS reduced their exposure to selected HPHCs (based on the measurements of biomarkers of exposure). These levels of reduced exposure approached those observed in people who quit smoking for the duration of the studies.
- According to air-quality tests, the aerosol does not negatively impact indoor-air quality.
- Our research shows negligible interest in the THS among people who have never smoked or who have quit smoking and substantial potential for full switching among adult smokers.

The studies to date indicate that the THS has the potential to present less risk of harm compared to continued smoking for adult smokers who switch to it completely.

PMI has filed a Modified Risk Tobacco Product Application (MRTPA) for the THS with the U.S. FDA (the U.S. FDA has not yet reviewed or reached any conclusions about our data. The THS is not for sale in the United States or Australia, but we plan to make IQOS available in key cities in over 30 countries by the end of 2017).

What steps are we taking to independently verify our scientific data?

We **are committed to seeking independent verification** of the scientific data we have generated on our RRP. There are several components to this verification:

- Published over 170 peer-reviewed articles in the last five years
- Conducting an in-depth analysis of study reports by independent experts
- Developed the [sbvIMPROVER.com](https://sbvimprover.com) platform. sbvIMPROVER is a methodology applied through crowd-sourcing, which enables the verification of research methods and study results
- Launched an investigator-initiated studies program that supports external scientists who can conduct independent research related to our RRP through the provision of products, equipment, and financial or technical support

Heated Tobacco Products

Heating tobacco to release flavours and nicotine without combustion

While the idea of heating tobacco (instead of burning it) has been around for more than two decades, it's only now that we have managed to find a way to heat tobacco that results in a product that is satisfying to adult smokers.

Through intensive research and development, we have managed to create two breakthrough heated tobacco products, each of which heats the tobacco in a distinct way. One product uses an electronically controlled heater, and the other uses a carbon heat source.

Tobacco Heating System – IQOS

At the heart of *IQOS* are sophisticated electronics that heat specially prepared and blended tobacco. *IQOS* heats the tobacco just enough to release a flavourful nicotine-containing vapour but without burning the tobacco.

Here's the key point: the tobacco in a cigarette burns at temperatures in excess of 600°C, generating smoke that contains harmful chemicals. But *IQOS* heats tobacco to much lower temperatures, below 350°C, **without combustion, fire, ash, or smoke**. The lower temperature heating releases the true taste of heated tobacco. Because the tobacco is heated and not burned, the levels of harmful chemicals are significantly reduced compared to cigarette smoke.

What is there? A nicotine-containing vapour – not smoke – that makes *IQOS* a smoke-free product that is appealing to smokers.

How does *IQOS* work?

IQOS is a tobacco heating system with three main components – a tobacco stick (called *HEETS* or *HeatSticks*), an *IQOS* holder, and a charger:

1. **The tobacco stick** contains a uniquely processed tobacco plug designed for heating, not for smoking. The tobacco plug is made from tobacco leaves, which are ground and re-constituted into tobacco sheets, called cast-leaf. These sheets are then crimped and made into a tobacco plug.
2. **The holder**, into which the tobacco stick is inserted, heats the tobacco in the tobacco stick via an electronically controlled heating blade. The blade simultaneously heats the tobacco to temperatures below 350°C, while monitoring its temperature to ensure a consistent taste experience and to avoid burning. It also has an over-heating protection mechanism, which turns itself off if necessary. The holder supplies heat to the tobacco stick via the heating blade for six minutes or 14 puffs, whichever comes first.
3. After each tobacco stick experience, the small battery in the holder needs to be recharged. **The charger** houses a bigger battery that stores enough energy to recharge the holder approximately 20 times and can be recharged from household power sockets.

To use *IQOS*, a consumer inserts the tobacco stick into the *IQOS* holder. The *IQOS* holder contains the electronically controlled heater that heats the tobacco stick. The consumer pushes a button to turn on the heater, and then draws on the tobacco stick to enjoy the real taste of heated tobacco. Once the tobacco stick is finished, the consumer removes it from the holder, and the tobacco stick can be disposed of safely in a waste bin. When needed, the consumer recharges the holder by inserting it into the charger.