PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

28 June 2019

The Hon Ken Wyatt AM, MP
Minister for Indigenous Australians
Parliament House
CANBERRA ACT 2600

Dear Mr Wyatt

Congratulations on your appointment as Minister for Indigenous Australians. I wish you every success in your role and look forward to working constructively with you in the future to address policy issues of mutual interest and concern.

The 46th Parliament will present you with a wide range of social and economic policy challenges to address. Few will be more important than the need to address the stagnation of smoking prevalence rates in Australia and the impact this has on the lives of Australia's almost 3 million smokers, their loved ones and public health more broadly.

Earlier this month, the Australian Institute of Health and Welfare released *Australia's health 2018*, its biennial report on the health of Australians. In relation to smoking, it highlights:

- that past declines in daily smoking have slowed;
- the significant health inequalities facing Australia's smokers; and
- the burden of disease caused by smoking.

This is even more concerning as Australia's approach to addressing smoking is now at odds with other developed nations that commonly experience declining smoking prevalence.

It is no coincidence that they embrace tobacco harm reduction policies by making less harmful products available to adult smokers in a controlled, regulated way. All OECD nations except for Australia and Turkey have now embraced this approach.

Much new evidence has emerged since the House Standing Committee on Health, Aged Care and Sport and both the Senate Economics References and Community Affairs committees each last considered this matter. While tobacco harm reduction remains controversial in Australia, it is the law overseas with bipartisan support, backed by government policy and the Department of Health in other comparable countries. In many cases, support for quitting and switching to less harmful products is proactively supported and promoted through national government advertising campaigns.

The United Kingdom, Europe and the United States have long endorsed tobacco harm reduction principles as a meaningful way to reduce smoking rates and placed vaping at the centre of their approach. Most recently, the Trudeau Government in Canada has legalised and regulated vaping, and the Ardern Government in New Zealand is in the process of doing so, and even though the law is not yet updated, they are still actively encouraging Kiwis to switch from cigarettes to less harmful, smoke-free alternatives.

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In reading this, you will likely have doubts, both about the message and the messenger. However, as Australia's progress in reducing smoking stalls, other countries are acting. With Australia due to update the National Tobacco Strategy this year, I ask you to develop your own independent understanding of the latest evidence on this important policy topic and how we can get the policy settings right.

A good starting place is the New Zealand Ministry of Health vaping website launched earlier this month (www.vapingfacts.health.nz) which sets out the facts on vaping and notably states:

Vaping has the potential to help people quit smoking and contribute to New Zealand's Smokefree 2025 goal.

Philip Morris is also committed to securing a Smoke-Free Future, as the greatest real-world contribution we can make to society is to replace cigarettes with smoke-free products (SFP) which are a less harmful alternative to smoking, thereby minimising the negative impact of smoking on public health.

This will seem incredible to some, however, in only a few years we have made progress in achieving this transformation. In 2018, SFPs represented 13.8% of our total net revenues, up from nothing only a few years before. In three countries, such revenues exceeded those of our combustible products and 6.6 million people have stopped smoking and switched to *IQOS*, our most advanced SFP. However, while these products remain banned in Australia, nearly 3 million smokers are without new alternatives to smoking cigarettes.

On 30 April 2019, the world's toughest and most respected regulator, the US Food and Drug Administration (FDA), finalised its rigorous science-based review through the premarket tobacco product application pathway for *IQOS*. This legislated mechanism doesn't exist in Australia, but enabled the FDA to determine that "authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." The FDA also found that "few non-tobacco users would be likely to choose to start using *IQOS*, including youth."[1]

I trust you will agree that this is an important development and deserves consideration in the Australian context. Indeed, we are now presented with an enormous public health opportunity: to allow adult smokers who would otherwise continue smoking, the chance to switch to a scientifically-substantiated less harmful alternative.

To discuss this further, s 47F Manager Public Policy and I would like to arrange to meet with you in the sitting weeks commencing 22nd and 29th July 2019 or otherwise at a convenient time at your electorate office. To arrange a meeting, please contact s 47F

Best wishes for all your endeavours throughout the 46th Parliament. I look forward to speaking with you soon.

Yours sincerely

s 47F

Director External Affairs AU NZ & PI

Ps. Following the FDA decision (media release attached), it is significant that NZ is acting in large part to address indigenous smoking.

[1] *FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway*, US FDA Media Release, 30 April 2019. Available here: https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

FDA NEWS RELEASE

FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway

Agency places stringent marketing restrictions on heated tobacco products aimed at preventing youth access and exposure to the new products

For Immediate Release:

April 30, 2019

The U.S. Food and Drug Administration today announced it has authorized (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders) the marketing of new tobacco products manufactured by Philip Morris Products S.A. for the IQOS "Tobacco Heating System" – an electronic device that heats tobacco-filled sticks wrapped in paper to generate a nicotine-containing aerosol. The FDA has placed stringent marketing restrictions on the products in an effort to prevent youth access and exposure.

Following a rigorous science-based review through the premarket tobacco product application (PMTA) pathway, the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes. The products authorized for sale include the IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks. While today's action permits the tobacco products to be sold in the U.S., it does not mean these products are safe or "FDA approved." All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to. Additionally, today's action is not a decision on the separate modified risk tobacco product (MRTP) applications that the company also submitted for these products (/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications) to market them with claims of reduced exposure or reduced risk.

"Ensuring new tobacco products undergo a robust premarket evaluation by the FDA is a critical part of our mission to protect the public, particularly youth, and to reduce tobacco-related disease and death. While the authorization of new tobacco products doesn't mean they are safe, the review process makes certain that the marketing of the products is appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole. This includes how the products may impact youth use of nicotine and tobacco, and the potential for the products to completely move adult smokers away from use of combustible cigarettes," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "Importantly, the FDA is putting in place postmarket requirements aimed at, among other things, monitoring market dynamics such as potential youth uptake. We'll be keeping a close watch on the marketplace, including how the company is marketing these products, and will take action as necessary to ensure the continued sale of these products in the U.S. remains appropriate and make certain that the company complies with the agency's marketing restrictions to prevent youth access and exposure. As other manufacturers

seek to market new tobacco products, the FDA remains committed to upholding the vital public health standards under the law and using all the tools at our disposal to ensure the efficient and appropriate oversight of tobacco products."

Under the PMTA pathway (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), manufacturers must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products. Importantly this includes youth. The agency's evaluation includes reviewing a tobacco product's components, ingredients, additives and health risks, as well as how the product is manufactured, packaged and labeled. The review for the IQOS products took into account the increased or decreased likelihood that existing tobacco product users will stop using tobacco products, and the increased or decreased likelihood that those who do not use tobacco products will start using them.

In particular, through the FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources, the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke. For example, the carbon monoxide exposure from IQOS aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66% to 91% lower than from combustible cigarettes, respectively.

Additionally, IQOS delivers nicotine in levels close to combustible cigarettes suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively. Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth.

While these non-combusted cigarettes may be referred to as "heat-not-burn" or "heated" tobacco products, they meet the definition of a cigarette in the Federal Food, Drug and Cosmetic Act. Therefore, these products must adhere to existing restrictions for cigarettes under FDA regulations, as well as other federal laws that, among other things, prohibit television and radio advertising. In addition, to further limit youth access to the products and exposure to their advertising and promotion, the FDA is placing stringent restrictions on how the products are marketed – particularly via websites and through social media platforms – by including requirements that advertising be targeted to adults. The company must also give notification to the FDA of, among other things, its labeling, advertising, marketing plans, including information about specific adult target audiences, and how it plans to restrict youth access and limit youth exposure to the products' labeling, advertising, marketing and promotion. The agency has issued a document (https://www.fda.gov/media/124174/download) providing its rationale for these postmarket requirements, which highlight important considerations for reviewing the company's applications as well any potential future PMTAs for other products.

The FDA also is requiring all package labels and advertisements for these products to include a warning about the addictiveness of nicotine, in addition to other warnings required for cigarettes, to prevent consumer misperceptions about the relative addiction risk of using IQOS compared to combusted cigarettes.

With the authorization of these products, the FDA will evaluate new available data regarding the products through postmarketing records and reports required in the marketing order. The company is required to report regularly to the FDA with information regarding the products on the market, including, but not limited to, ongoing and completed consumer research studies, advertising, marketing plans, sales data, information on current and new users, manufacturing changes and adverse experiences. The FDA may withdraw a marketing order if it, among other reasons, determines that the continued marketing of a product is no longer appropriate for the protection of the public health, such as if there is an uptake of the product by youth.

The FDA is continuing its substantive scientific review of the company's MRTP applications. The company would need to receive an MRTP order from the FDA before they could market a tobacco product with any implicit or explicit claims that, among other things, a product reduces exposure to certain chemicals or that use of the product is less harmful than another tobacco product or would reduce the risk of disease. If a company markets a tobacco product as an MRTP without authorization, the company would be in violation of the law and may face FDA advisory or enforcement actions.

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Inquiries

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Related Information

- Premarket Tobacco Product Marketing Orders (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders)
- Premarket Tobacco Product Applications (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications)
- Modified Risk Tobacco Products (Modified Risk Tobacco Products)
- Market and Distribute a Tobacco Product (/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product)
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