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PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

Minister for Health

22 JUL 2019

Reply by: Minister / Chief of Staff / Adviser
Action: Response / Phone Call / Information
Department / Urgent by
Other: Campaign / Consituent / Background Information Required / Refer to
Comments:

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29 JUL 2019

Division: Minister: Milestone: 10 15 20
INFO VIP PM

The Hon Greg Hunt MP
Member for Flinders
PO Box 647
SOMERVILLE VIC 3912

Dear Mr Hunt,

On 30 April 2019, the US Food and Drug Administration (FDA) authorised for sale Philip Morris International's (PMI) pioneering heat-not-burn product, *IQOS*, in a **major step forward for adult US smokers seeking to replace cigarettes with a less harmful product.**

In making its determination, the FDA, one of the pre-eminent regulatory bodies in the world charged with ensuring the safety and efficacy of new and innovative products in the US, **recognised that *IQOS* is appropriate for the protection of public health.**

***IQOS* differs from combustible cigarettes in that it heats tobacco, rather than burning it,** to produce a nicotine vapour and give smokers the feel of smoking but without tar and other carcinogens. Studies have recognised that by removing the smoke, ***IQOS* is up to 95 per cent less harmful than combustible cigarettes – a fact recognised by the FDA.**

The FDA notes:

> *"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."*

Commercialisation guidelines are clearly and comprehensively set out by the FDA to give smokers the best chance to switch from cigarettes, while preventing non-smokers and youth from taking it up and PMI fully supports this objective.

The FDA authorisation adds to the growing body of evidence, more than 60 peer-reviewed studies, pointing to the fact that smoke-free products are significantly less harmful than smoking.

Public Health England has recognised vaping is up to 95 per cent less harmful than smoking and the National Health Service Long Term Plan hails vaping to save 500,000 lives over the next ten years. A study conducted by Australian and New Zealand academics found that a permissive regulatory environment around smoke-free products in New Zealand could add more than a quarter of a million quality-adjusted life-years to the lives of New Zealanders and save more than NZ$3.6bn.[1]

[1] Petrović et al, 'Potential Country-Level Health and Cost Impacts of Legalizing Domestic Sale of Vaporized Nicotine Products' (2019) 30(3) *Epidemiology* 396.

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The United States joins 47 other countries including New Zealand, Canada, the United Kingdom, the European Union, Israel and Japan in giving smokers the choice to access a less harmful product. Unfortunately, Australia's 'quit or die' legislative approach continues to prohibit smoke-free products, denying Australia's almost 3 million adult smokers the opportunity to improve their health.

Of all 36 OECD countries, Australia and Turkey are the only nations where smoke-free products are banned outright with no foreseeable reform to the law.

Smoking rates in Australia have barely moved since 2013 despite plain packaging, increasing taxes, graphic warnings on packaging and millions in taxpayers' money spent on anti-tobacco advertising.

Smoking kills. At PMI we acknowledge the best thing anyone can do for their health is to never start smoking. The next best is to quit. Some will do that, but many won't. Smoke-free products offer those people a far less harmful alternative to cigarettes.

With sensible regulation, we can prohibit young people from accessing tobacco products, and at the same time give adult smokers access to better alternatives proven to reduce their risk of harm and help them give up smoking for good. We certainly would welcome progressive regulation like that designed by the Ardern Government in New Zealand, or recommended by progressive think-tank, the McKell Institute.

The FDA is just the latest in a long line of governments, professional medical bodies, and public health organisations to recognise the public health benefit of smoke-free products, while Australian regulations fall further behind.

Australia cannot afford to ignore the rest of the world on this issue any longer. We need action now.

Yours sincerely

s 47F

Managing Director AU, NZ and Pacific Islands

MEDIA RELEASE

PHILIP MORRIS
AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

Australian smokers left behind as US decision brings the world closer to being smoke-free

2 May 2019

Philip Morris Australia is calling for Australian policy makers to urgently review the evidence supporting smoke-free products, following yesterday's historic decision in the United States.

The US Food and Drug Administration (FDA) has authorised the sale of Philip Morris International (PMI)'s smoke-free product, *IQOS*, determining it is "appropriate for the protection of public health".

The decision follows PMI's 2017 application to the FDA, supported by millions of pages of scientific evidence, including peer-reviewed published literature and other sources.

In welcoming the FDA's decision to authorise *IQOS* in the US, Philip Morris Australia Managing Director Tammy Chan said:

"Our vision as a company is to stop selling cigarettes. We are now one step closer. However, while 40 million American smokers now have the opportunity to give up smoking by switching to a less harmful alternative, Australian smokers are still being denied that option," Ms Chan said.

"Australian smokers who don't quit are essentially condemned to only smoking cigarettes, even though there are less harmful alternatives available elsewhere. The law in Australia only allows the sale of products that produce smoke, which we know is the leading cause of serious illnesses among smokers, such as lung cancer and heart disease.

"Health, is a key issue in this federal election campaign and meaningfully addressing the issue of smoking could go a long way in improving public health in Australia.

"Unlike in the US, there is no process or regulatory mechanism in Australia that would allow us to submit an application for similar review to that conducted by the FDA to allow the sale of specific smoke free products, without additionally requiring a change to the laws governing nicotine-containing products. Despite this, we have sent a summary of the scientific evidence presented to the FDA to various health departments across Australia. We are not aware of any review being undertaken.

"Furthermore, we have invited public health bodies to discuss our science and the enormous public health opportunity that is before us. We are yet to receive a response.

"Australia must catch up to the rest of the world and change its laws, as it is the only OECD country other than Turkey to have not moved to make smoke-free products available to adult smokers who would otherwise continue to smoke.

"Together, we can achieve a smoke-free world. We are ready to our part," Ms Chan said.

Please see the full text of the FDA decision here.

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IN THIS SECTION

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/tobacco-product-review-evaluation/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/tobacco-product-review-evaluation/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)
- Modified Risk Tobacco Products (/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products)

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