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PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

Minister for Rural Health
Minister for Sport

02 MAY 2019

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

4 April 2019

Senator the Hon Bridget McKenzie
Minister for Regional Services
The Senate
Parliament House
PO Box 6100
CANBERRA ACT 2600

RECEIVED
02 MAY 2019
Division: PHSD
Minister: BM
Milestone: 10 ☐ 15 ☐ 20 ☑
INFO ☑ VIP ☐ PM ☐

Dear Minister,

RE: STUDY ON THE SAFETY PROFILE OF E-CIGARETTES

During March 2019 PMI released findings of a landmark six-month study to evaluate the impact of e-cigarette vapour on the risks of heart and lung disease.

The study concluded that switching to smoke-free e-cigarettes, whether the product was with or without nicotine, was less harmful than continuing to smoke cigarettes and resulted in less risk associated with both diseases.[241] The full results of this study will be submitted for publication in a peer-reviewed journal.

These results are a powerful addition to the growing body of international peer reviewed evidence that shows switching to smoke-free alternatives is less harmful for adult smokers and their families.

The University of Melbourne recently published a study that shows access to smoke-free products has helped New Zealanders gain around 236,000 years of healthy life.[242]

Research by Public Health England says smoke-free products are 95 per cent less harmful than cigarettes and twice as likely to help smokers quit for good compared to nicotine patches and gum.[243]

Our vision for a Smoke-Free Future

At Philip Morris International, we want to offer adult smokers who would otherwise continue to smoke, less harmful alternatives, such as e-cigarettes, personal vaporisers and heated tobacco products.

Our ultimate goal as a company is to stop selling cigarettes. Change of this magnitude cannot be achieved overnight, as some may have you believe. Smoking is addictive and people who smoke would simply switch to other brands.

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[241] https://www.pmiscience.com/library/publication/a-six-month-inhalation-study-in-apoe-mice
[242] Frederieke S. Petrović-van der Deen et al. Potential country-level health and cost impacts of legalizing domestic sale of vaporized nicotine products, *Epidemiology*
[243] Hajek et al. 2019, New England Journal of Medicine

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Australia has some of the strictest tobacco control measures in place. Despite this, three million Australians continue to smoke, and that number has remained "relatively similar" since 2014, according to the Australian Bureau of Statistics[244].

We believe smoke-free products are a complementary addition to tobacco control measures and hold huge potential for people who would otherwise continue to use cigarettes. Australia is one of only three OECD countries to outright ban smoke-free products, while smokers in the US, UK, Canada, European Union and New Zealand are already seeing the benefits.

I would be pleased to share our views on how Philip Morris plans to achieve our smoke-free vision and provide further details on the findings of this study.

Yours sincerely,

s 47F

Managing Director Australia, New Zealand and Pacific Islands

Encl.

[244] http://www.abs.gov.au/ausstats/abs@.nsf/mf/4364.0.55.001

PMI study – Impact of e-cigarette vapour on the risk of heart and lung disease

Factsheet

- The landmark six-month study adds to the existing evidence that e-cigarettes are less harmful and pose less risks associated with heart and lung disease than cigarettes.
- This first-of-its-kind study evaluated the impact of e-cigarette vapour, with and without nicotine, on the risks of heart and lung disease in a mouse model.
- The study exposed groups of mice to e-cigarette vapours (with and without nicotine and flavour) and the other to cigarette smoke and assessed the biological responses.
- Female mice were exposed to air, cigarette smoke or one of the three formulations of e-cigarette vapours, (nicotine-free, 4% nicotine, or 4% nicotine and flavours) for three hours a day, five days a week for six months.
- After six months the study concluded e-cigarette vapour with and without nicotine and flavour, when compared to regular cigarettes, resulted in:
  - Lower levels of lung inflammation, structural damage and molecular changes,
  - induced lower atherosclerotic plaque formation, meaning less plaque formation inside the arteries, reducing the risk of heart attack and stroke, and
  - lower molecular changes in aorta and heart tissue.
- The study also detected that e-cigarette vapour had significantly less impact on pulse wave velocity than cigarettes, which simply means less pressure on the body's cardiovascular system.
- The result findings were recently presented at the 58th Annual Society of Toxicology meeting in Baltimore.
- The World Health Organisation estimates more than one billion people worldwide smoke cigarettes. In Australia, three million people smoke despite strict control measures.
- These results add to the existing body of peer-reviewed evidence that shows smoke-free products are less harmful and a better alternative for current adult smokers than cigarettes.
- Nicotine is addictive; however, it is the other toxicants produced by burning tobacco that cause the most harm and smoke related disease.
- Tobacco harm reduction through smoke-free alternatives can play an important role by supplementing existing tobacco control strategies aimed at helping people give up smoking.
- The full results of this study will be submitted for publication in a peer-reviewed journal.
- For more information, see: www.pmiscience.com

GROWING GOVERNMENT SUPPORT FOR SCIENCE BACKED SMOKE-FREE PRODUCTS

World Health Organization

Prediction: There will continue to be **over 1 billion smokers into 2025** and beyond

United States

Supporting an **appropriate regulatory framework** for new product innovations

U.S. FOOD & DRUG ADMINISTRATION

Scott Gottlieb
FDA Commissioner

Recognises that the root of the harm from smoking is burning, not nicotine

"It's not the nicotine that kills you, it's all the other carcinogens in lighting tobacco on fire"

Interview on Squawk Box, CNBC
August 24, 2017

"Appropriate product regulation, new technology, and product innovation... could present an opportunity for smokers to quit combustible tobacco and stay quit."

Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap
January 11, 2018

United Kingdom

Department of Health welcomes **science-backed innovations** for smokers

Department of Health

Five-year tobacco plan:

12% smoking rate by 2022

"We welcome innovation that will reduce the harms caused by smoking"

Department of Health
July, 2017

'If demonstrated as less harmful, to "maximize the availability of safer alternatives to smoking" coupled with "providing clear communication about what is known and unknown... of using different products relative to smoking."'

New Zealand

Supports smokers' switch to "significantly **less harmful alternatives**"

23 November 2018

Government plan with dual aims:

Improve smokers access to quality vaping and **smokeless products**

Improve publicly available **information on vaping**

"Many people want to quit smoking, but this can be difficult, especially for those who face complex challenges in their lives. However, many smokers who find it hard to quit may be able to switch to much less harmful alternatives, such as vaping"

Official website of the New Zealand Government
November, 2018

European Union

Introduced **measures** for e-cigarettes **to reduce the number of smokers**

Italy

Passed a law **in favor of harm reduction products** pending scientific review by the Higher Institute of Health and the Ministry of Health

May, 2018

Iceland

Study from Iceland's Directorate of Health shows the **smoking rate fell to 9%** with evidence **e-cigarettes contributed to the national decrease**

May, 2018

Tobacco Products Directive (TPD)

Introduced specific measures for e-cigarettes to reduce the number of smokers and ensure that citizens are aware of the harmful effects of tobacco use. **The TPD represents a reversal of policy to accept e-cigarettes and classify them as something different to conventional cigarettes**

May, 2016

Growing Government Support for Science-Backed Smoke-Free Products

The WHO predicts that there will continue to be over 1 billion smokers into 2025 and beyond. That means many smokers will not benefit from tobacco control measures to curb adoption and increase quitting. A growing number of governments are now complementing these traditional measures with a harm reduction approach: providing smokers with scientifically substantiated less harmful products.

United States – Supporting an "appropriate regulatory framework for new product innovations"

Since its policy announcement in July 2017, the FDA has been outspoken about its support for alternatives to cigarettes for adults who want access to nicotine through less harmful products. It recognizes that the root of the harm from smoking is burning, not nicotine.

- ***"Nicotine, while not an entirely benign substance, is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year."***

- ***"It's not the nicotine that kills you, it's all the other carcinogens in lighting tobacco on fire."***

Scott Gottlieb, FDA Commissioner, Interview, Squawk Box, CNBC. August 24, 2017.
https://partner.criticalmention.com/app/#/clip/slim/ededee82a-4b17-4090-b39c-d4eb134f946f

The agency has been clear that measures intended to more drastically reduce smoking should be complemented by providing smokers who would otherwise continue with better, innovative, science-backed alternatives:

- ***"...the Agency must also take a fresh look at products that can deliver satisfying levels of nicotine to adults who want access to it without burning tobacco."***

- ***"With appropriate product regulation, new technology, and product innovation...could present an opportunity for smokers to quit combustible tobacco and stay quit."***

US Food and Drugs Administration, Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap. January 11, 2018.
https://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm591993.htm

UK – Welcoming less harmful innovations

Also in July 2017, the UK Department of Health released its five-year tobacco plan for England, in which it aimed for a 12% smoking rate by 2022. To help achieve this objective, the government acknowledged the role that science-backed innovations can play in helping to achieve that objective, by helping smokers switch away completely from cigarettes.

- ***"We welcome innovation that will reduce the harms caused by smoking"***

- **The government *"will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers."***

- **And if demonstrated as less harmful, to *"maximize the availability of safer alternatives to smoking"* coupled with *"providing clear communication about what is known and unknown about the short and long term risks of using different products relative to smoking"***

UK Department of Health, July, 2017. https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england

New Zealand – Government publishes plan incorporating smoke-free products into smoke-free efforts

On 23 November 2018, the New Zealand government published a plan for risk proportionate regulation for smoke-free products in order to support smokers switch to "significantly less harmful alternatives." The plan has as its **dual aims to improve**:

- **smokers' access** to quality vaping and smokeless products
- **publicly available information** on vaping.

This incorporates the development of product safety requirements to be set for vaping and smokeless tobacco products to ensure consistency in quality, and a public information campaign on the benefits of switching to vaping for those who don't quit, particularly for high smoking-rate communities.

- ***"Many people want to quit smoking, but this can be difficult, especially for those who face complex challenges in their lives. However, many smokers who find it hard to quit may be able to switch to much less harmful alternatives, such as vaping."***

- ***"The tar and toxins in tobacco smoke, rather than the nicotine, are responsible for most of the harm associated with tobacco use. Vaping and smokeless tobacco products do not combust and are, therefore, highly likely to be much less harmful than smoking."***

The Official website of New Zealand Government, November 2018.
https://www.health.govt.nz/system/files/documents/pages/supporting-smokers-switch-to-significantly-less-harmful-alternatives-21nov2018-redacted.pdf

Italy – Government permits science-backed communications on relative risk and harmful chemicals of novel tobacco products

In August 2017, Italy passed a law in favor of harm reduction products. The pathway permits scientifically substantiated novel tobacco products to communicate about the reduction of toxic components and/or the potential risk reduction compared to combustible tobacco products pending scientific review by the Higher Institute of Health and the Ministry of Health.

European Union – Supporting "special rules for electronic cigarettes"

In May 2016, the Tobacco Products Directive (TPD) introduced specific measures for electronic cigarettes to reduce the number of tobacco users across the EU and to ensure that citizens are fully aware of the harmful effects of tobacco use.

Before TPD, electronic cigarettes were banned or effectively banned across nearly half of the EU. The TPD represents a reversal of that policy to instead accept electronic cigarettes, and to classify them as something with differential regulation to conventional cigarettes.

EU - Iceland Health Directorate study shows e-cigarettes helped lower smoking rates

A new study from Iceland's Directorate of Health shows that smoking in Iceland is on the decline, with evidence that the use of e-cigarettes are contributing to a decrease in the consumption of traditional cigarettes. The study indicates that last year daily smoking fell to 9% of population, a drop of 5% in three years while daily e-cigarettes use reached 4%.

- ***"There's no other way to interpret these figures than increasingly, people are quitting smoking and starting to vape."***

Guðmundur Karl Snæbjörnsson, Doctor from Iceland's National Institute of Health, May 2018.
http://icelandreview.com/news/2018/05/03/vaping-linked-decrease-cigarette-smoking

OVERVIEW OF INDEPENDENT RESEARCH ON IQOS

Over the last year several independent studies have confirmed that IQOS emits reduced levels of toxicants compared to cigarettes. This document summarizes the independent research on IQOS to date.

Many government bodies have conducted literature reviews or performed research on heated tobacco products, finding that they expose users to significantly lower levels of harmful chemicals.

- Public Health England (PHE) recently published a review of the evidence on e-cigarettes and heated tobacco products, and stated that heated tobacco products are likely reduce user's and bystander's exposure to harmful compounds compared to cigarettes.
- The US Food and Drug Administration (FDA), in a recent briefing document, reviewed PMI's data supporting *IQOS* and the available independent literature about *IQOS*. The briefing document included a section explaining the results of the FDA's *IQOS* aerosol chemistry measurements.
- The UK Committee of Toxicity conducted a review of available evidence on two heated tobacco products, one of which is *IQOS*, and concluded that these products "*are likely to reduce risks for smokers.*"
- The Dutch National Institute for Public Health and the Environment (RIVM) published a Factsheet on novel tobacco products that are heated, and an English language summary. They concluded that "*The use of heatsticks with the iQOS is harmful to health, but probably less harmful than smoking tobacco cigarettes*," based on their aerosol chemistry measurements, which are "*of the same order of magnitude as in the data of Philip Morris.*"
- The German Federal Institute for Risk Assessment (BfR), conducted laboratory studies which found that reductions in selected toxicants measured by the Institute "*are likely to reduce toxicant exposure.*" The study states that while further studies are required to address the magnitude of exposure reduction, the measured reductions *"lead to the relevant questions of putatively reduced health risks."*
- Two government-commissioned studies were conducted by independent scientists in Russia, confirming that *IQOS* aerosol contains an average of 90% reduced levels of harmful chemicals compared to cigarette smoke, and that *IQOS* has a minimal effect on biological processes in people compared to smoking. This report is not published yet, though the researchers have made some public statements. (Rossiyskaya Gazeta)

The reports described above survey a wide range of publications on IQOS and other heated tobacco products. Listed below is a selection of publications which focused exclusively on IQOS:

- Research by Japanese Department of Environmental Health, National Institute of Public Health, compared selected chemicals in the aerosol generated by IQOS and in smoke from

reference cigarettes. The research shows significant reductions in the levels of several chemicals, in line with those found by PMI's research. (Bekki et al, 2017)

- The China National Tobacco Quality Supervision and Test Centre, a member of the WHO Tobacco Laboratory Network, published an independent study comparing the harmful chemicals present in IQOS aerosol and cigarette smoke, which generally agree with PMI's results. (Li et al, 2018)

- One of Ukraine's leading research institutes conducted a six-month clinical study on IQOS which was published in prominent national medical periodical Ukrainian Health, showing no significant adverse effect on users of smoke-free products. (Kvasha et al, 2018)

- Research by cardiologist and leading e-cigarette researcher Dr. K. Farsalinos on *IQOS* was presented at Global Forum on Nicotine, not yet published in a peer-reviewed journal, with results in line with PMI's own research.

- Researchers at the University of St. Andrews, Scotland calculated that IQOS aerosol has "*lower cancer potencies than tobacco smoke by at least one order of magnitude, but higher potencies than e-cigarettes.*" (Stephens et al., 2018)

A letter to the Journal of the American Medical Association (JAMA) published in May 2017 by Auer et al, describes a study whose findings confirm a significant reduction in harmful compounds in the IQOS aerosol compared to cigarette smoke, but with different values than the ones found in independent lab tests.

- PMI voiced its concerns over the lack of methods validation or consistency with previous research in a reply letter published in JAMA, which we believe are the cause of the differences in results.

Independent reviewers had similar concerns:

- The FDA unambiguously stated that the study indeed has many flaws and does not bear on its assessment of IQOS in its briefing to its scientific advisory committee (pg 13, here). The FDA wrote in their briefing document that:

> *"The data published is not considered adequate for comparing the levels of HPHCs between the IQOS products and combusted cigarettes. There are significant analytical issues in the Auer et al. study, such as lack of testing reference samples, low number of replicates, lack of selectivity on some analytical methods. In comparison, we have not identified specific issues with the applicant's [PMI's] methods."*

- The FDA also reviewed other studies including Farsalinos et al. (2017) and Bekki et al. (2017) and found no similar concerns for these independent studies.

- Dr. R. Polosa, a medical doctor who frequently publishes on e-cigarettes, has also voiced "serious doubts about the quality of the analytical data" in the study.

Both Public Health England and the US FDA have compiled compilations of research published to date on *IQOS*.

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SCIENTIFIC UPDATE FOR SMOKE-FREE PRODUCTS

MARCH 2019 • ISSUE 07
Past issues can be found here

This Scientific Update provides an overview of the most recent **scientific developments behind PMI's approach to achieving a smoke-free future** through a range of alternatives to cigarettes that do not burn tobacco. The following pages include our **product development and assessment efforts, our initiatives to share** our methodologies and results, as well as independent research and government reports. More detailed information can be found at www.pmiscience.com.

WHAT'S INSIDE: