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立法會秘書處

致《2019 年吸煙(公眾衞生)(修訂)條例草案》委員會:

全面禁止所有另類吸煙產品，保障全港市民健康

香港大學護理學院支持全面禁止所有另類吸煙產品，包括電子煙、加熱煙及草本煙，並期望立法會能從速通過《2019 年吸煙(公眾衞生)(修訂)條例草案》，保障香港市民健康。

本學院的研究亦發現加熱煙與電子煙無助本港的吸煙人士戒煙。[1,2,3]任何形式的煙草產品均損害健康，包括電子煙或加熱煙。世界衞生組織早已指出電子煙毫無疑問對健康有害，並重申加熱煙的危害並不低於傳統捲煙，釋出有害物數量減少不等於降低健康危害的風險。

科學研究證實電子煙可增加患上心血管疾病、中風、慢性阻塞性肺病、閉塞性細支氣管炎(不可逆轉的肺病)等的風險。2018 年中至 2020 年初，美國已錄得超過 2,800 宗電子煙相關嚴重肺病(EVALI)，當中更有 68 人死亡。吸食電子煙會增加氧化壓力，增加患上胸口痛、心悸、冠狀動脈病、心律失常等心血管疾病的風險。每天吸食電子煙的人士更容易患上心臟病。

加熱煙主要以煙草製成，本身具有毒性，即使是天然形式也含致癌物質，部分有毒或致癌物質是沒有安全水平的，危害健康。煙草業標榜加熱煙「較少危害」的說法只是基於比較傳統煙中的主要有害物質。有研究指出加熱煙的部分有害物質比傳統煙含量較高，當中包括致癌物苊、丙

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烯醯胺及苯甲醛。加熱煙亦含有尼古丁，與傳統煙一樣會令吸食者上癮、損害血管，更可引致血壓上升、心跳加速、心肌梗塞、腦中風及冠心病等。本學院的研究亦發現本港使用電子煙的青少年較多有呼吸系統病徵。[4]由此可見，所謂另類吸煙產品能夠「減害」的說法只是煙草商企圖藉此誤導公眾，對其真正的禍害掉以輕心，從而吸引不吸煙人士尤其青少年吸食。

另類吸煙產品設計新穎，被宣傳為潮流產品。電子煙推出過萬種口味，加熱煙亦混入不同水果口味，宣傳推廣策略針對不吸煙人士和年輕人，將產品營造為時尚和有生活品味的用品，企圖吸引年輕人嘗試。本學院對本港青少年的研究[5]及外國研究早已證實電子煙及加熱煙會成為青少年開始吸煙的入門，而單憑規管並不能阻止情況發生。

我們絕不贊同將《修訂條例》分拆審議的建議，亦懇請立法會切勿接納有關建議。此建議變相默許加熱煙之安全及認受性，與保障市民健康的宗旨背道而馳，更會向市民傳遞錯誤信息，讓煙草商趁機利用加熱煙開拓年青人及非吸煙人士市場，令更多不吸煙市民染上另類煙癮。

公共衞生健康乃任何政策制定之首要考慮，立法會應從速通過《2019 年吸煙(公眾衞生)(修訂)條例草案》，並採取最嚴格的措施，禁止所有另類吸煙產品在本地進口、製造、售賣、分發和宣傳。

林佳靜教授
香港大學護理學院院長

二零二一年一月五日

CCL\KW/yw

[4] Wang MP, Ho SY, Leung LT, Lam TH. E-cigarette use and respiratory symptoms in Chinese adolescents in Hong Kong. JAMA Pediatrics 2015; 170 (1):89-91.
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香港吸煙與健康委員會
HONG KONG COUNCIL ON SMOKING AND HEALTH

香港中區立法會道 1 號
香法特別行政區立法會
《2019 年吸煙（公眾衞生）（修訂）條例草案》委員會

主席及全體委員：

促請果斷全禁另類吸煙產品
以免妨礙控煙進程及衍生其他社會問題

香港近年控煙力度不足，導致吸煙率跌勢停止，2019 年的吸煙率（10.2%）更較 2017 年微升 0.2 百分點。另一方面，煙草商不斷推銷另類吸煙產品（另類煙），不但減低吸煙人士的戒煙決心，更會令不吸煙人士尤其年輕人染上煙癮。面對傳統捲煙造成每年近 7 千人死亡及 56 億經濟捐損失的威脅，以及煙草商的攻勢，實在沒有空間亦絕不應該讓任何吸煙產品流行，承受吸煙率回升的風險。香港吸煙與健康委員會（委員會）促請立法會以整體公眾健康為依歸，果斷地通過《2019 年吸煙（公眾衞生）（修訂）條例草案》，全面禁止所有另類吸煙產品。

減害成效存疑

科學證據對另類煙的減害聲稱尚未有定論，醫學界亦不認可有關聲稱，多個國際權威公共衞生機構及醫學組織如世界衞生組織、歐洲呼吸學會、國際防癆會等都建議禁止電子煙及加熱煙。就加熱煙而言，其**減害聲稱不但沒有獲外國衞生部門認可**（如美國食品藥物管理局 (FDA)、意大利衞生部、澳洲衞生部），**甚至連煙草商的研究都未能證實加熱煙比傳統捲煙對人體危害較少**（附件一）。必須重申，美國 FDA 雖然同意加熱煙釋出傳統煙中常見有害物質的濃度較低，但不認可加熱煙的相關健康風險較低、非較少害，**FDA 強調加煙熱不安全，有關產品不能以「減害產品」作宣傳**，其報告亦指出**加熱煙煙霧含有多種獨有或含量比傳統捲煙煙霧高的化學物質，包括縮水甘油、氯丙二醇等潛在致癌物**。

不能幫助戒除或減少吸食傳統捲煙

大部分另類煙使用者**同時吸食傳統捲煙**，這些雙重使用者有可能因而接觸到更多尼古丁及其他有害物質。日本及韓國數據均顯示大部分加熱煙使用者並沒有放棄傳統捲煙，而韓國及香港都有研究指出**加熱煙減低吸煙人士戒食傳統捲煙的機會**。相反，最近一項日本研究指出加熱煙**增加從不吸煙人士開始吸煙及已戒煙人士復吸的機會**。香港大學護理學院的本地研究發現，在使用加熱煙的人士當中，六個月成功戒煙的機率沒有提高，而且在肺炎疫情期間有更多人在家中吸食加熱

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煙。因此，使用加熱煙並不能幫助戒煙或減輕煙癮。

透過電子電子裝置違法宣傳及銷售

加熱煙的電子裝置設有晶片，偵測吸煙時間、頻率、次數等使用習慣資料，煙草商利可這些數據，研發迎合不同使用者的吸煙產品，從而令吸煙人士持續使用煙草，亦引誘不吸煙的人士嘗試。部分加熱煙品牌推出相關的電話應用程式和電子平台，直接向使用者溝通和發放產品資訊等信息，變相成為煙草推廣。即使現時法例禁止所有煙草宣傳及廣告，**這種形成點對點通訊方法，可成為法律漏洞讓煙草公司不受監管地向吸煙人士、甚至不吸煙人士或青少年宣傳吸煙產品**。有應用程式更設有加熱煙訂購功能及顯示附近的零售點，促進和便利購買煙草產品。**煙草商雖然聲稱加熱煙幫助戒煙，實際卻提示使用者要繼續吸煙，同時令使用者對尼古丁上癮持續或加深。**

衍生私穩問題

記錄使用資料的電子裝置，亦可以透過藍芽技術連結至其他電子產品及平台，並將資料傳送至煙草商。有些裝置甚至可**過度取得使用者與吸煙無關的資料**，例如有電子煙會向使用者收集樣貌、地點資料等，更有可能向其他使用者曝露其位置和其他資料。**煙草商會否與第三方分享所得資料或保護不足以致個人資料外洩是另類煙影響公共衞生以外的一大隱憂。**

歐洲呼吸學會指出「肺部是用來呼吸清新的空氣，而非呼吸『較少的毒素或致癌物』」。吸煙人士應戒掉所有有害的吸煙產品，而非尋求所謂「減害」產品或比較有害程度。事實上，致癌物質和大部分有害物質並沒有安全水平，委員會促請立法會果斷通過全禁另類煙的法案，亦建議政政持續加強的控煙政策及訂立全面禁煙的時間表，以保障公眾健康。

主席

湯修齊 MH 太平紳士

2021 年 3 月 26 日

總幹事

黎慧賢

副本送：食物及衞生局局長
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Research paper

PMI's own in vivo clinical data on biomarkers of potential harm in Americans show that IQOS is not detectably different from conventional cigarettes

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ABSTRACT

Introduction New 'heated tobacco products' are being marketed in several countries with claims that they expose users to lower levels of toxins than conventional cigarettes which could be read as being less likely to cause health problems than conventional cigarettes. In the USA, Philip Morris International (PMI) has submitted an application to the Food and Drug Administration for permission to market its heated tobacco product, IQOS, with reduced exposure and reduced risk claims.

Methods Analysis of detailed results on 24 biomarkers of potential harm in PMI studies of humans using IQOS compared with humans using conventional cigarettes.

Results Among American adults, there is no statistically detectable difference between IQOS and conventional cigarette users for 23 of the 24 biomarkers of potential harm in PMI's studies. In Japan, there were no significant differences between people using IQOS and conventional cigarettes in 10 of 13 biomarkers of potential harm. It is likely that some of the significant differences are false positives.

Conclusion Despite delivering lower levels of some toxins than conventional cigarettes, PMI's own data fail to show consistently lower risks of harm in humans using its heated tobacco product, IQOS, than conventional cigarettes.

INTRODUCTION

Nicotine is the addictive drug in tobacco. Burning the tobacco generates an aerosol of ultrafine particles that carries nicotine deep into smokers' lungs, where it is absorbed and rapidly reaches the brain. That burning yields toxic chemicals that cause disease. Ever since people started understanding in the 1950s that smoking kills, millions have struggled to stop smoking. The tobacco companies, desperate to keep and expand their customers, have been trying to make 'safer cigarettes' since the 1960s.[1] They have also developed products that avoided burning, including e-cigarettes,[2] nicotine replacement therapy,[3] and products that heat the tobacco without setting it on fire. As of January 2018 all the major multinational tobacco companies had developed, or were in the process of developing, so-called 'heated tobacco products' (HTP; also called 'heat-not-burn' tobacco products). Because these devices generate their nicotine aerosols by heating a stick of ground tobacco and chemicals without setting the tobacco on fire, they generally produce fewer toxic chemicals than a conventional cigarette, which is promoted as meaning or implying that these products are not as dangerous as conventional cigarettes.

In 2015, Philip Morris International (PMI) started test marketing its IQOS HTP outside the USA on the grounds that it is not as bad as a cigarette because 'the tobacco is heated and not burned, the levels of harmful chemicals are significantly reduced compared to cigarette smoke.'[4]

Because IQOS is a new tobacco product, PMI needs to obtain premarket authorisation from the US Food and Drug Administration (FDA) to sell it in the USA. In particular, PMI wants to market IQOS with reduced risk claims, what US law calls a 'modified risk tobacco product' (MRTP). To obtain authorisation to market IQOS with reduced risk claims, PMI submitted an application to the FDA in December 2016.[5] As required by law, FDA has made most of the application available for the public to review. The application includes comparisons of the levels of 24 biomarkers of potential harm in human smokers, including comparisons with people who smoke conventional cigarettes. These biomarkers include measures of inflammation, oxidative stress, cholesterol and triglycerides, blood pressure and lung function. This paper uses information in the PMI application to evaluate this comparison and concludes that in people who actually use IQOS, the levels of these biomarkers of potential harm are not detectably different from conventional cigarettes.

METHODS

The results analysed in this paper are from PMI's 'Three-month Reduced Exposure in a confined and ambulatory setting' studies (ZRHR-REXA-07-JP in Japan and ZRHM-REXA-08-US in the USA) that present human clinical studies of non-cancer biomarkers of potential harm presented in PMI's MRTP application's[5] Executive Summary, Module 6: Summaries of All Research Findings, and Module 7.3.1: Scientific Studies and Analyses (Studies in Adult Human Studies: Clinical Studies), specifically the data on 24 biomarkers of potential harm *in human users* derived from two of their 'Reduced Exposure' studies: ZRHR-REXA-07-JP in Japan and ZRHM-REXA-08-US in the USA.

As described in Section 6.1.4.3.2 of the application, cigarette smokers were randomised, controlled, open-label, three-arm parallel group studies in which smokers were randomised to IQOS (menthol), continued smoking their current brand of cigarettes or smoking abstinence. Baseline data were collected on day 0 immediately before randomisation, people were held during a 5-day confinement period then released to the ambulatory setting and observed at 90 (±3 (range)) days

after randomisation. (Some variables were measured during confinement and before 90 days, but are not considered in this analysis.) During the confinement period, product use was directed and monitored by the study staff and participating smokers were controlled for product compliance. Subjects assigned to conventional cigarettes or IQOS used the products without restriction (ad libitum) during an extended daily time window (16 hours); dual use of conventional cigarettes and IQOS was not permitted. The 3-month ambulatory phase was designed to reflect a near real-world environment where dual use of IQOS and conventional cigarettes or other tobacco products could occur. PMI selected a 3-month extended ambulatory follow-up period so that the study would be long enough to assess the initial changes in some of the clinical risk endpoints that have been shown to be reversible within 2 weeks to 3 months.

The final sample (table 1) consisted of people who were adherent with their assigned study product and without major protocol deviations that impacted the validity of the evaluation of the study results. This sample was designed to assess the maximum exposure reduction achievable (what PMI characterised as the 'optimal effect') in subjects who were using IQOS ad libitum and exclusively or at least predominantly, rather than the effect in the full population representing a heterogeneous exposure (eg, as mixed product use, or non-use of the assigned product).

The point estimates and 95% confident intervals (CIs) at day 90 were computed using least squares means from an analysis of covariance with study arm as a factor adjusting for baseline value, sex and average daily conventional cigarette consumption over the last 4 weeks as reported during screening. (Thus, the width of the CIs for the differences between IQOS and conventional cigarette use in table 1 benefits from the information in the smoking abstinence group even though those subjects are not directly involved in the point estimates being compared.) Endpoints that were not normally distributed were log-transformed (base e) prior to analysis, then back-transformed to calculate least squares means ratios to compare IQOS with conventional cigarettes.

Both trials were registered with ClinTrials.gov.

Specific results are based on measures of inflammation in Section 6.1.4.4.2; cholesterol, triglycerides and physiological measures related to heart disease in Section 6.1.4.4.4; and lung function in Section 6.1.4.4.5.

RESULTS

Among American adults, there is no statistically detectable difference between IQOS and conventional cigarettes for 23 of the 24 biomarkers of potential harm in PMI's studies (table 1). This is indicated by the fact that 23 of the 95% CIs include zero (ie, no statistically significant difference). Moreover, when using the conventional 95% confidence standard for statistical hypothesis testing, one would expect 5% of the tests to yield false positives. Five per cent of 24 tests is 1.2 tests, which means that one would expect one false positive result. PMI had one positive result (soluble intercellular adhesion molecule (ICAM)), which is what one would expect by chance.

PMI also reported the results on 13 biomarkers of potential harm among Japanese people (table 1). There were significant improvements in 4/13 of these biomarkers, 3 markers of inflammation (white cell count, prostaglandin F2 alpha and soluble ICAM) and 1 measure of cholesterol (high-density lipoprotein cholesterol). When using the conventional 95% confidence standard one would expect 0.65 positive tests, which means one would expect one false positive test.

Table 1 Summary of Philip Morris studies of changes in biomarkers in IQOS users compared with conventional cigarette smokers after 90 days of product use (95% CIs in parenthesis)

	Japan	USA
Inflammation (6.1.4.4.2**)		
White cell count	**−0.57 GI/L (−1.04 to −0.10)**	0.17 GI/L (−0.47 to 0.81)
C-reactive protein (CRP)	6.41% ↓ (−40.75 to 37.77)	16.23% ↓ (−21.69 to 42.33)
Soluble ICAM (sICAM-1)	**8.72% ↓ (2.05 to 14.94)**	**10.59% ↓ (4.03 to 16.71)**
Fibrinogen	5.42% ↓ (−1.80 to 12.13)	1.63% ↓ (−6.42 to 9.08)
Oxidative stress (6.1.4.4.3)		
Prostaglandin F2 alpha (8-epi-PGF2α)	**12.71% ↓ (2.55 to 21.81)**	13.46% ↓ (−1.95 to 23.61)
11-dehydrothromboxane B2 (11DTXB2)	5.42% ↓ (−1.80 to 12.13)	3.56% ↓ (−23.31 to 24.57)
Cholesterol and triglycerides (6.1.4.4.4)		
High-density lipoprotein cholesterol (HDL-C)	**4.53 mg/dL (1.17 to 7.88)**	1.4 mg/dL (−2.3 to 5.0)
Low-density lipoprotein cholesterol (LDL-C)	0.87 mg/dL (−6.55 to 8.30)	−3.3 mg/dL (−12.0 to 5.4)
Total cholesterol	2.00 mg/dL (−6.68 to 10.67)	−4.0 mg/dL (−13.3 to 5.2)
Triglycerides	−6.25 mg/dL (−21.20 to 8.69)	0.9 mg/dL (−12.8 to 14.6)
Apolipoprotein A1 (apoA1)	NA	3.1 mg/dL (−4.6 to 10. 7)
Apolipoprotein B (apoB)	NA	−1.6 mg/dL (−7.24 to 4.03)
Physiological measures		
Systolic blood pressure	−0.59 mm Hg (−3.80 to 2.62)	−0.7 mm Hg (−4.5 to 3.1)
Diastolic blood pressure	−0.68 mm Hg (−3.04 to 1.69)	0.2 mm Hg (−3.7 to 4.0)
Lung function (6.1.4.4.5)		
Forced expiratory volume in 1 s (FEV_1)	1.91 %Pred (−0.14 to 3.97)	0.53 %Pred (−2.09 to 3.00) 0.05 L (−0.06 to 0.15)
FEV_1/FVC (forced vital capacity)	NA	0.00 (−0.02 to 0.02)
Mid-expiratory flow (MEF 25–75) (L/s)	NA	−0.67 (−6.33 to 4.99)
Diffusion capacity for lung CO (DLCO) (mL/min/mm Hg)	NA	0.31 (−1.09 to 1.72)
Rate constant of CO (KCO) (mmol/min/kPa/L)	NA	0.05 (−0.02 to 0.12)
Total lung capacity (TLC) (L)	NA	0.09 (−0.25 to 0.43)
Functional residual volume (FRV) (L)	NA	−0.09 (−0.31 to 0.13)
Inspiratory capacity (IC) (L)	NA	0.21 (−0.08 to 0.51)
Vital capacity (VC) (L)	NA	0.10 (0.00 to 0.21)
Summary		
Number of biomarkers tested	13	24
Number significantly improved	3	1
Number expected by chance	1	1

Continued

Table 1 Continued

	Japan	USA
Sample sizes		
IQOS	70	47†
Conventional cigarettes	41	32‡
Smoking abstinence	37	9§

The results are either IQOS:CC or IQOS-CC (conventional cigarettes).
Bold results are statistically significant differences (p<05).
*Section of Philip Morris International's Modified Risk Tobacco Product application.
†n=45 for fibrinogen, 8-epi-PGF2α, 11DTXB2, systolic blood pressure, diastolic blood pressure, DCLO and KCO.
‡n=30 for FEV_1, FEV_1/FVC, MEF 25–75, DLCO, KCO, TLC, FRV, IC and VC.
§n=8 for DLCO and 7 for KCO.
ICAM, intercellular adhesion molecule; NA, not applicable.

DISCUSSION

These human data are important information because they represent direct evidence on how IQOS affects people who use the product. They show that, despite the evidence that PMI submitted that the levels of some toxins in IQOS aerosol are lower than in conventional cigarettes,[5] fewer toxic chemicals, however, do not necessarily translate into lower harm when people use the product.

In its MRTP application, PMI did not discuss the results of the conventional statistical tests described in the Results section, which are routine for such scientific analysis. Rather, they simply emphasise the direction of changes while ignoring the fact that these differences are within what would be expected based on simple randomness. No tobacco company would tolerate such assertions made by the FDA or other public health authorities.

The results reported in PMI's application (and in a published paper[6]) for Japan are slightly more positive for IQOS, with 4 of 13 biomarkers showing differences from conventional cigarettes (where one would expect one false positive by chance). These results are not strong enough to warrant drawing a conclusion of reduced risk. The conclusion of no significant difference on biomarkers of potential harm is based on taking PMI's results at face value despite the tobacco companies' (including Philip Morris) long record of manipulating the design, analysis and presentation of their published scientific studies <<ED: Citation should be "7-12" no "7-13".>>.[7–13]

Like cigarettes (and e-cigarettes), IQOS uses an aerosol of ultrafine particles to deliver the nicotine. These ultrafine particles cause heart and lung disease. The adverse health effects of these particles and many of the other toxins do not drop in proportion to reducing the dose, so even low levels of exposure can be dangerous.[13] This effect is why smoke-free environment laws are followed by big drops in heart attacks and other diseases despite the fact that secondhand smokers breathe in much less smoke that the smokers.[14] In addition, while the IQOS does not set the tobacco stick on fire, it heats it to 350°C (660°F), which is still hot enough to cause pyrolysis. There is already independent evidence that IQOS compromises functioning of arteries,[15] a key risk factor for heart disease and heart attacks, as badly as a cigarette.

The clinical studies that PMI reported appropriately did not include cancer because carcinogenic effects take much longer to be manifest than cardiovascular and pulmonary effects. Even if the levels of carcinogens delivered by IQOS are lower than conventional cigarettes on a per-puff basis, these lower exposure levels may not yield proportionately lower cancer risks because both the intensity and duration of exposure impact cancer risk.[16–18]

The purpose of this paper is to assess the data on biomarkers of potential harm of the Philip Morris IQOS HTP system in people who were actually using the system compared with people who smoke conventional cigarettes based on the information submitted to the US FDA in PMI's MRTP application for IQOS. On 31 March 2018, the author conducted a PubMed search using the search term '(IQOS or 'heat not burn' or 'heated tobacco product') and (health or harm) and (human or clinical)'. This search returned 33 papers, none of which reported on comparisons of in vivo biomarkers of potential harm in people using IQOS (or any other HTP system) compared with conventional cigarettes. Thus, as of 9 July 2018, the data in the PMI MRTP application remained the only publicly available evidence on the in vivo human clinical effects of IQOS compared with conventional cigarettes.

While this analysis is limited to the data presented in PMI's IQOS MRTP application to the FDA, it is likely that the effects of other HTPs being developed by other tobacco companies will have similar effects because the fundamental principles behind all these products are the same.

On 15 June 2018, PMI issued a press release, 'Philip Morris (PM) Announces Positive Results from New Clinical Study on IQOS,'[19] that said, 'all eight of the primary clinical risk endpoints moved in the same direction as observed for smoking cessation in the group who switched to IQOS, with statistically significant changes in five of the eight endpoints compared with on-going smoking.' While PMI did not release any detailed results, examining the protocol (on ClinicalTrials.gov) revealed that this new study only examined six clinical measures, compared with the 24 in MRTP application (table 1). (The other two were biomarkers of exposure.) PMI did not say which of the changes were statistically significant, raising the possibility that the protocol and analysis were manipulated to achieve positive results.[8 9] PMI increased the sample size from 88 in the original US study to 984. While bigger studies are better, the fact is that making the sample size big enough will increase the power to the point that almost any difference will reach statistical significance regardless of whether it is clinically significant or not. The true measure of reduced risk would be statistically significant changes that were large enough to be clinically significant in enough biomarkers of potential harm to be meaningful.

PMI's failure to show significant improvements in these biomarkers of potential harm is consistent with the data PMI reported on the levels of toxicants in IQOS mainstream aerosol compared with mainstream smoke of 3R4F reference cigarettes.[20] While many toxicants were lower in IQOS aerosol, 56 others were higher in IQOS emissions and 22 were more than twice as high, and 7 were more than an order of magnitude higher.

In short, PMI's results in humans failed to meet the legal requirement that IQOS 'as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual users' that US law requires before the FDA can approve a reduced risk claim. In the USA, PMI wants to sell IQOS with claims that 'Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases' and 'Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes'[5]; these claims are not substantiated by PMI's own data.

On 25 January 2018, based in part on the information in this paper (which had been submitted to FDA as a public comment) showing gaps in PMI's scientific evidence, the FDA's Tobacco Products Scientific Advisory Committee voted that PMI had failed to demonstrate that its proposed modified (reduced) risk labelling and advertising claims for IQOS were demonstrated by scientific evidence.[21]

What this paper adds

- Heated tobacco products are being marketed in several countries with claims of reduced exposure to toxins compared with conventional cigarettes.
- Studies conducted in people using Philip Morris International's IQOS heated tobacco product did not reveal detectably better measures of biomarkers of potential harm than conventional cigarettes in human tests.
- These products should not be permitted to be marketed with claims that state or imply reduced risks compared with conventional cigarettes.

Based on the data in the PMI MRTP application for IQOS, neither the US FDA nor comparable authorities elsewhere in the world should permit such claims to be made. All companies wishing to market HTPs with reduced risk claims should be held to the same standard, and their claims independently verified.

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