

To: Mr. MK Yaakov Litzman  
Minister of Health, Israel

Mr. Moshe Bar Siman Tov  
Director General  
Ministry of Health, Israel

CC: Mr. Moshe Kahlon  
Minister of Finance, Israel

Mr. Moshe Asher  
Director of Tax Authority, Israel

21 June 2017

Dear Minister Litzman

**Policy on taxation of tobacco and nicotine products – relative risk of heated tobacco products compared to smoking**

We write as longstanding supporters of rational tobacco and public health strategy, including the use of ‘harm reduction’ approaches in public health, specifically in addressing the harms of smoking. That includes adopting a tax philosophy that reflects differences in risk among products. Our focus is on reducing smoking-related diseases and we do not speak for any of the industries involved.

Further to a letter we addressed to the Ministry of Finance on 8 May 2017<sup>1</sup>, we understand some progress has been made in developing a rational and efficient framework for taxation of tobacco and nicotine products. We understand that a separate category is to be established for heated tobacco products. This is a welcome and sensible move as these products have completely different physical, chemical and risk characteristics to cigarettes and may provide public health benefits.

However, we also understand that the Ministry of Health does not consider there to be sufficient evidence to differentiate taxation levels between cigarettes and heated tobacco products on the basis of risk to health. We disagree with this assessment. In our view, it is beyond reasonable doubt that the heated tobacco products will be much safer than combusted products.

It is inevitable with any new product that we will not have complete long-term data for many decades. However, that does not mean we know nothing or that we should be unable to make judgements in the face of some inevitable uncertainties. In our view, we have a lot of knowledge of these products and there are sufficient data to justify a marked difference in tax treatment.

There are three broad strands of evidence to draw on:

**1. The physical and chemical process involved are completely different**

Heated tobacco products have an inherently different design to cigarettes and operate at much lower temperatures. The heated product design allows for electrical heating of a liquid infused into the tobacco to reach 250-350°C. This heated liquid condenses to form a nicotine-containing aerosol to be inhaled. This compares to high temperature combustion reactions taking place at 600-900°C in the burning tip of a cigarette that create the mixture of solid and liquid particles (sometimes referred to as ‘tar’) and toxic gases that constitute cigarette smoke. This lower temperature range is designed to avoid triggering combustion processes and therefore to avoid the creation of products of combustion. It is clear beyond reasonable doubt that products of combustion dominate the harms caused by smoking<sup>2</sup>, so avoiding combustion processes will reduce the toxicity of the aerosol<sup>3 4</sup>.

Heated tobacco products and cigarettes are completely different in concept. The heated products are designed to reduce or eliminate the main harmful agents associated with smoking, namely the products of combustion. There is no basis at all to make an expert judgement that they should be assumed to have similar risk to cigarettes in the absence of any other data.

## **2. The toxicity of the heated tobacco aerosol is far less than cigarette smoke**

There has been extensive measurement of the characteristics of the aerosol delivered by heated tobacco products and comparisons with cigarette smoke. The aerosol and cigarette smoke can be subjected to a battery of tests to analyse composition and presence of harmful or potentially harmful constituents, cytotoxicity, mutagenicity, and oxidative stress and other indicators of risks. There is extensive testing of the nature published in the peer-reviewed, which an expert review could easily access. It is not our role to provide a full systematic literature review, but we can provide some insights from the literature that suggest there is no basis to assume that heated tobacco products and cigarette have equivalent toxicity. For example, Poynton et al (2017) found<sup>5</sup>:

For nine toxicants mandated by the WHO Study Group on Tobacco Product Regulation for reduction in cigarette emissions, the levels were 91%-99% lower per puff in the hybrid tobacco product aerosol than in 3R4F [cigarette] smoke.

Breheeny et al (2017) found<sup>6</sup>:

The hybrid tobacco product tested negative across the in vitro assays including mutagenicity, genotoxicity, cytotoxicity, tumour promotion, oxidative stress and endothelial dysfunction. All the THPs tested demonstrated significantly reduced responses in these in vitro assays when compared to 3R4F [cigarette].

Schaller et al (2016) found<sup>7</sup>:

The low operating temperature of [Tobacco Heating System 2.2] caused distinct shifts in the aerosol composition compared with 3R4F [cigarette]. This resulted in a reduction of more than 90% for the majority of the analyzed harmful and potentially harmful constituents (HPHCs), while the mass median aerodynamic diameter of the aerosol remained similar. A reduction of about 90% was also observed when comparing the cytotoxicity determined by the neutral red uptake assay and the mutagenic potency in the mouse lymphoma assay. The THS2.2 aerosol was not mutagenic in the Ames assay.

## **3. The markers of toxic exposure measured in the bodies of users are much lower**

A further set of insights comes from looking at markers of exposure to hazardous agents measured in the bodies of users. This approach takes the toxicology a step further by allowing for how the products are used in practice. Again, the results suggest much lower exposures, close to the levels associated with smoking abstinence. Again, we provide some examples from the literature.

Haziza et al (2016) conducted a randomised reduced exposure study of Polish users and found<sup>8</sup>:

Biomarkers of exposure, except those associated with nicotine exposure, were significantly reduced in the [Tobacco Heating System] group compared with the [Combustible Cigarette] group, and approached the levels observed in the [Smoking Abstinence] group.

Haziza et al (2016) also studied a Japanese group and found<sup>9</sup>:

...the magnitude of exposure reduction observed was close to that which was seen in participants who abstained from smoking for 5 days, while nicotine uptake was maintained

And Lüdicke et al (2016) found<sup>10</sup>:

Biomarkers of exposure to tobacco smoke toxicants which inform product risk assessment were significantly reduced with [Tobacco Heating System] use compared to the [Combustible Cigarette] group.

#### 4. Overall view

There are many studies available that would inform a judgement on relative risks and all draw conclusions that would be consistent with the result set out above. Most of these studies have been conducted by the manufacturers as part of their regulatory science initiatives, often prior to product availability. They are published in respected peer reviewed journals and reflect demanding standards expected by regulators.

It is our view that a genuinely neutral and objective assessment of the available data could only conclude that heated tobacco products pose substantially lower risks to health than cigarettes. The products are completely different in their basic chemistry and physics, the toxicity of the heated tobacco aerosol is much less than cigarette smoke, and exposure to harmful agents as measured in the body is much lower and approaches that found for smoking cessation.

Based on these insights *from what we do know*, we think it is impossible to conclude that the risks of heated tobacco products would be the same as cigarette smoking and that it is more reasonable to conclude as a working basis for policy-making that the risks would be very much lower.

We should not wait to act on such insights for many decades until the risks are known with complete certainty. The danger of such an approach to risk and uncertainty is that we implicitly encourage continued smoking – something that we know with great confidence to be highly dangerous.

We hope you will take these views into account as you develop Israel's approach to regulation and taxation of novel tobacco products.

Yours sincerely,

**Clive D. Bates**

Director,  
The Counterfactual  
Former Director Action on  
Smoking and Health (UK)  
London, United Kingdom

**Martin Jarvis**

Emeritus Professor  
Department Behavioural  
Science and Health  
University College London  
United Kingdom

**Mark A.R. Kleiman**

Professor of Public Policy  
NYU, Marron Institute of  
Urban Management  
New York  
United States

**Sally L. Satel**

Resident Scholar  
American Enterprise Institute  
Lecturer, Yale University  
School of Medicine  
United States

**Jeff Stier**

Senior Fellow,  
National Center for Public  
Policy Research  
Director, Risk Analysis Division  
Washington DC, United States

**David T. Swenor J.D.**

Adjunct Professor,  
Faculty of Law,  
Centre for Health Law, Policy  
& Ethics  
University of Ottawa, Canada

## References, sources and links

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