

International Union Against Tuberculosis and Lung Disease Health solutions for the poor

THE UNION'S POSITION ON HEATED TOBACCO PRODUCTS (HTP)

January 2018

The Union's Position on Heated Tobacco Products

The new generation of tobacco products

Tobacco use causes more than 7 million preventable deaths each year. (1) The tobacco industry has a long history, dating back decades, of stoking the smoking epidemic by introducing "reduced risk" products, beginning with filtered cigarettes in the 1920s with intensive promotion that started in the 1950s, followed by "low tar" cigarettes and a variety of other product modifications to allay the rising public concerns about the dangers of smoking. All these products were introduced and promoted to maintain industry profits, including Electronic Nicotine Delivery Systems (or ENDS, mainly e-cigarettes). (2, 3)

The tobacco industry has now started marketing heavily the latest generation of Heated Tobacco Products (HTP). HTP heat sticks made of compressed processed tobacco and other chemicals to a high enough temperature to generate an inhalable aerosol that contains nicotine along with many other chemicals. Such products are often promoted by the tobacco industry as heat-not-burn tobacco products. As one recent study revealed that the smoke generated by the so-called heat-not-burn tobacco products bears strong resemblance with the smoke of conventional cigarettes, (4) we will use Heated Tobacco Products in this statement. HTP differ slightly from ENDS, which create a nicotine aerosol by heating a liquid. Both HTP and ENDS are designed to deliver an aerosol of nicotine deep into the lungs using a behaviour that mimics the physical act of smoking. The ultrafine particles that comprise the aerosol that delivers nicotine increase the risk of lung and heart diseases. (5, 6)

There are currently no independent estimates of the number of consumers using HTP. Phillip Morris International (PMI) claims that iQOS (PMI's flagship HTP) has more than 1.4 million regular users. (7) PMI also claims that since the launch of iQOS in the UK in December 2016, 70 % of its users have been able to quit cigarettes. (8)

Tobacco companies are adding HTP to their portfolio of nicotine delivery products and are aggressively promoting these as products of "lower risk" and as devices for cessation. PMI has included harm reduction as a core corporate strategy (9) and claims that adopting new technologies such as HTP could save lives of millions of current smokers in the future. British American Tobacco (BAT) launched its latest HTP brand glo in Japan in 2016, claiming that it produces 90% less toxicants than a conventional cigarette. (10) R. J. Reynolds was the first tobacco company to produce a HTP brand Premier in 1988 and the brand was subsequently relaunched in several

variations. BAT saw its acquisition of R. J. Reynolds in 2017 as an opportunity to create "a stronger, global tobacco and Next Generation Products company committed to delivering sustained long-term profit growth and returns." (11) Japan Tobacco International is also aggressively promoting its new product Ploom Tech to gain a share of the market in Japan, which it lost to PMI. (12)

PMI claims that in the future it plans to replace conventional cigarettes with reduced risk products such as HTP. It also launched the "Foundation for a Smoke-free World" to support research on harm reduction with the ultimate goal of "eliminating smoking worldwide" (13) primarily by promoting these new products. It has been well documented that PMI and other tobacco industry actors have for decades been establishing similar entities to protect themselves from litigation threats and government regulation by distributing questionable science to distract from the irrefutable evidence of the death and disease caused by tobacco. (14) PMI and other tobacco companies' assurances that they want to reduce use of combusted cigarettes ring hollow while they continue to aggressively promote cigarette smoking and block the implementation of the WHO Framework Convention on Tobacco Control (FCTC) (15) around the world. (16)

Industry research dominates published literature on HTP

The current published literature on the health impact of HTP is dominated by Industry-sponsored research that unequivocally concludes that HTP pose a lower risk than cigarettes. These studies claim that, under experimental settings, HTP release as much as 90 to 95% less harmful and potentially harmful constituents. (17, 18)

A peer-reviewed paper published in September 2017 by investigators independent from the tobacco industry found that the aerosol released from IQOS had higher levels of harmful constituents than PMI reported. (4) True to the industry's behavior in the past, PMI attacked this research and the institutions where the researchers were based. (19)

Another peer-reviewed independent publication investigated the health effects of HTP. This case study reported details of a patient who contracted acute eosinophilic pneumonia (AEP) two weeks after increasing the smoke amount from 20 to 40 HTP cigarettes per day. The authors attributed the patient's AEP to the rapid increase in the amount of HTP aerosol inhalation and associated antigens. (20) This finding raises a potential risk of HTP that has not yet been identified in studies presented by the industry. Prior studies of past HTP (such as RJR's Eclipse) done independently of the tobacco company found no evidence that they were less harmful than combustible cigarettes. (21)

An independent study of second-hand emissions from HTP shows that, while at lower levels than a conventional cigarette, HTP still pollute the air around people using the products, creating second-hand exposure. (22)

Legislation and Regulatory Responses

There have been a range of policy responses to HTP across the world, ranging from no regulations, softer variations than tobacco regulations, similar regulations as tobacco products and complete bans.

One example of current legislation is New Zealand, where the sale and distribution of HTP are prohibited. This has been achieved by categorizing HTP as non-smoked items under oral tobacco products, which are banned under New Zealand law. (23) In Germany, HTP can be purchased and are categorised under the legislation for pipe tobacco as, unlike cigarettes, they require a device to be used. The pipe tobacco category has a 75% lower tax rate than cigarette tax and does not require a graphic health warning on packaging. On the other end of the spectrum, Japan – unlike their stance on ENDS, which are prohibited – HTP can be legally sold and distributed, are not regulated and can be used in smoke-free areas.

The European Union (EU) has not yet adopted a policy on HTP. According to the EU, HTP heat sticks are considered to be tobacco products and therefore advertising for heat sticks (but not heating devices) should be prohibited. (24) However, the EU are reviewing the decision as to whether HTP should be classified as smoking products or novel tobacco products. If HTP are accepted as novel tobacco products after review, they will not be subject to restrictions on flavors and packaging, and will be subject to softer health warnings than conventional cigarettes. However, if HTP are classified as smoking products, regulations will prohibit flavors, enforce plain packaging and place a restriction on emissions including carbon monoxide and tar. (25)

The Union's position

 The potential benefits and risks from HTP to the public health remain undetermined but early independent research indicates that the tobacco companies are understating the risks. The Union recommends that governments apply the precautionary principle to the regulation of HTP. Countries should wait for independent assessment of the health effects of HTP and not simply take industry assertions at face value before allowing the sale of these products.

- Governments should ban indoor HTP use because the aerosol released from HTP contain many of the harmful constituents found in cigarette smoke. There are likely health risks from being exposed to second-hand aerosol of HTP.
- Advertising, promotion, and sponsorship activities of HTP should be banned as they have the potential to glamorize cigarette smoking. Children and adult non-smokers are at the risk of being led into nicotine addiction and subsequently smoking cigarettes or using other tobacco products.
- 4. HTP should be incorporated in the regular monitoring framework of tobacco use in the country.
- 5. In countries where HTP are already available, governments should also prohibit claims that these products assist in smoking cessation until independent evidence at both individual and population levels is available that this claim is accurate. The potential of HTP to reduce willingness to quit smoking and the impact of dual use with cigarettes should also be independently assessed.
- Tobacco industry should not be involved in the discussions of HTP policies or any other tobacco control policies. Such involvement is a violation of the WHO FCTC Article 5.3 and its Guidelines.

(This position statement is prepared by Pranay Lal, Daouda Adam, Anne Jones, Rana Singh, Tara Bam, Fouad Aslam, Syed Mahbubul Alam, Michelle Reyes-Palmones, Hanbing Guo, Mirta Molinari, Nadia Freeman, Mithun Nair, and Gan Quan. We would like to thank the contribution by Mairi Benson and Angela Jackson-Morris to an early draft and the review by Stanton Glantz, Pamela Ling, Mike Daube, and Maciej Goniewicz.)

References:

1. World Health Organization. WHO report on the global tobacco epidemic, 2017: monitoring tobacco use and prevention policies. Geneva: 2017

2. Dutra LM, Grana R, Glantz SA. Philip Morris research on precursors to the modern e-cigarette since 1990. 2017;26(e2):e97-e105.

3. National Cancer Institute (US). Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. Bethesda, MD: 2001

4. Auer R, Concha-Lozano N, Jacot-Sadowski I, Cornuz J, Berthet A. Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name. JAMA internal medicine. 2017;177(7):1050-2.

5. Hom S, Chen L, Wang T, Ghebrehiwet B, Yin W, Rubenstein DA. Platelet activation, adhesion, inflammation, and aggregation potential are altered in the presence of electronic cigarette extracts of variable nicotine concentrations. Platelets. 2016;27(7):694-702.

6. Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. Tobacco control. 2017.

7. Gillette F, Kaplan J, Chambers S. Big Tobacco Has Caught Startup Fever. Bloomberg. 2017.https://www.bloomberg.com/news/features/2017-03-08/big-tobacco-has-caught-startup-fever

8. Reuters. Tobacco Group Philip Morris sees iQOS as key to smokeless future in UK. 2017.https://uk.reuters.com/article/uk-philipmorris-britain/tobacco-group-philip-morris-sees-iqos-as-k ey-to-smokeless-future-in-uk-idUKKBN19L1G9

9. PMI Science. Learn more about the science behind RRPs.^https://www.pmiscience.com/welcome

10.British American Tobacco. Harm reduction, the opportunity. 2017 [cited 2017 5 October
Available2017].Available

http://www.bat.com/group/sites/UK 9D9KCY.nsf/vwPagesWebLive/DO9DCGG2.

11. BAT Completes Acquisition of Reynolds [press release]. 2017.

12. Ploom TECH, a new state-of-the-art tobacco vaporizer to be launched online nationally and at certain stores in Fukuoka City, from early March. [press release]. 2016.

13. Foundation for a Smoke-free World. Foundation for a Smoke-free World. 2017 [cited 2017 5 October]. Available from: https://www.smoke-freeworld.org/our-work/support-global-research.

14. Naomi Oreskes, Erik M. Conway. Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming2011.

15. WHO Framework Convention on Tobacco Control, (2003).

16. Reuters. Special Report: Inside Philip Morris' campaign to subvert the global anti-smoking treaty.

2017.https://www.reuters.com/article/us-pmi-who-fctc-specialreport/special-report-inside-philip-morri s-campaign-to-subvert-the-global-anti-smoking-treaty-idUSKBN19Y18T

17. BAT. Developing less risky products. New products, safer choices?^<u>http://www.bat.com/productrisk</u>

18. PMI Science. Heat-Not-Burn Products: Scientific Assessment of Risk Reduction.^https://www.pmiscience.com/system/files/publications/presentation moira gilchrist gtnf _2015a.pdf

19. William Wong. Big Tobacco's new cigarette is sleek, smokeless — but is it any better for you? Washington Post.

2017.https://www.washingtonpost.com/national/health-science/big-tobaccos-new-cigarette-is-sleeksmokeless--but-is-it-actually-healthier/2017/08/11/60e9fe5a-763e-11e7-8839-ec48ec4cae25_story.h tml?utm_term=.ace697d4a8fa

20. Kamada T, Yamashita Y, Tomioka H. Acute eosinophilic pneumonia following heat-not-burn cigarette smoking. Respirology case reports. 2016;4(6):e00190.

21. Slade J, Connolly GN, Lymperis D. Eclipse: does it live up to its health claims? Tobacco control. 2002;11 Suppl 2:ii64-70.

22. Ruprecht AA, De Marco C, Saffari A, Pozzi P, Mazza R, Veronese C, et al. Environmental pollution and emission factors of electronic cigarettes, heat-not-burn tobacco products, and conventional cigarettes. Aerosol Science and Technology. 2017;51(6):674-84.

23. New Zealand Ministry of Health. Heat Not Burn' tobacco products [cited 2017 5 October]. Available from:

http://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/heat-not-burn-toba cco-products.

24. European Parliament. Parliamentary questions. 2017 [cited 2017 4 October]. Available from: http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2016-009704&language=EN.

25. European Union. Directive 2014/40/EU of the European Parliament and of the Council. 2014 [cited 2017 5 October]. Available from: https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf.