

Introduction:

The Coalition of Asia Pacific (Tobacco) Harm Reduction Advocates (CAPHRA) submits this white paper to specifically address the issues presented by the government of the Kingdom of Thailand and its ancillary agencies in response to the call to ban all Safer Nicotine Products (SNP) such as electronic cigarettes, nicotine e liquid, Heat Not Burn products and snus, whilst leaving combustible tobacco products legally available.

This policy paper aims to address the issues that have arisen since the implementation of the ban, as well as to provide scientific evidence/references to address the concerns that were presented as justification for the ban, as well as evidence to instead support the Kingdom to implement risk proportionate regulation so that tobacco harm reduction (THR) is available freely to all adults within the Kingdom of Thailand.

Background:

We are aware that, as of 2018, there are approximately 10.7 Million combustible tobacco users (Smokers) in Thailand and another 17 Million Thai citizens who are exposed regularly to the second hand effects of smoking.

However, personal vaporizers (e-cigarettes) and Heat not Burn (HnB) products are currently banned in Thailand due to a ban notification by the Ministries of Commerce, influenced by Ministry of Public Health, and that owning a device for personal use, by either a citizen of the Kingdom, or the importation of device for personal use by a visitor/tourist, is a criminal offense with the possibility of a fine and/or jail time.

The justification for the ban, was that anti-Tobacco groups (Ash Thailand & TRC) strongly advocate that e-cig is more dangerous than combustible cigarette, and that these products act as a gateway to combustible cigarette, especially among youth.

Recently, with growing evidence, these same groups started to admit that e-cigarettes are less harmful than combustible tobacco, however they still believe that they are a



gateway to smoking initiation and that the ban must remain in order to protect the youth of the Kingdom.

The global push for tobacco harm reduction (THR):

There have been numerous studies done overseas that have proven the effectiveness and harm reduced qualities of Safer Nicotine Products. These studies have provided the background for many countries - including the United Kingdom, New Zealand, and UAE to promote their use as an alternative for combustible tobacco smokers and for these governments to introduce and finalise risk proportionate regulation.

Best practice towards implementation of risk proportionate regulation:

We at CAPHRA, in our experience in other countries in region, know that a transparent and inclusive public consultation, together with a regulatory impact assessment, which objectively analyses and reviews the currently available scientific evidence, should be conducted by the Kingdom of Thailand Government before any legislation is amended, benchmarking good policy-making practices internationally.

An example of this is New Zealand, where the Ministry of Health collaborated with not only the medical profession and public health authorities and experts in country, but also with those overseas. Most importantly however was the inclusion of consumers of SNP to provide input and guidance with regards to best practice regarding regulation, manufacturing, access and availability of the products and accessories to ensure that the narrative was inclusive and comprehensive.

As a signatory to the FCTC, New Zealand understood that access to SNP for adults who wish to utilise them in lieu of combustible tobacco is a human right. This right is outlined on the human right to health embodied in Article 12 of the International Covenant on Economic, Social and Cultural Rights, this article contends that international law supports a harm reduction approach to tobacco control.

The article specifies that "the work of the parties needs to be about 'emphasizing the



special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts." ¹

We have taken the liberty to present and address some of the issues that have been presented to justify bans of safer nicotine products (SNP) in Kingdom of Thailand, as well as other recent issues in tobacco harm reduction (THR) and the use of safer nicotine products (SNP) to provide the scientific evidence to alleviate concerns around these issues.

Issues & Concerns around SNP:

1. Youth Vaping and the "Gateway Effect" the presumption that youth who vape will go on to using combustible tobacco.

According to Dr. Linda Bauld, who is the lead researcher for the Cancer Research Council and Public Health England on the use of electronic cigarettes in youth and by pregnant women, the data do now show that youth vaping is an "epidemic" as has been touted in the media. Also, youth who vape are coming to vaping FROM smoking, not the other way around. ²

Dr Bauld has stated - repeatedly - that youth and pregnant women are more inclined to switch to vaping from smoking and not the other way around. There is no evidence that youth are using vaping as a gateway to smoking. There is no evidence that the nicotine in electronic cigarettes has the same detrimental effect on pregnant mothers and their children as does smoking during pregnancy. ³

Smoking, due to combustion and the 7000 chemicals contained therein, cause health issues. Where there is no "smoke/fire" there are none of the issues that arise from combustion.



Another study, done in the US entitled "Adolescents and e-cigarettes: Objects of concern may appear larger than they are" by Kozlowski and Warner stated ⁴ unequivocally that "The role of e-cigarettes in the future of youth smoking has yet to be definitively assessed. Prospective studies - the only evidence that e-cigarette use might lead to smoking - do not yet persuade that e-cigarettes are a substantial causal gateway to cigarettes. At best, they support that a minority of the relatively small number of e-cigarette triers - who haven't also been experimenting with other tobacco products already - will go on to some experimentation with cigarettes"

Expert: Linda Bauld, PhD (Scotland)

2. Cardiovascular/Cerebral Health Harms (Heart Attack/Stroke) from Vaping. Recently there was a study on electronic cigarette users to determine their risk for heart attack and stroke. "Daily e-cigarette use, adjusted for smoking conventional cigarettes as well as other risk factors, is associated with increased risk of myocardial infarction.". In the media, coverage of the conference abstract mention: "E-cigarettes linked to higher risk of stroke, heart attack, diseased arteries." This study , published by the University of Southern California had ⁵ major flaws in methodology and reporting.

Action on Smoking and Health UK even commented on the problems with the study and conclusions stating "This study does not establish a causal relationship between heart attacks and the use of e-cigarettes. Rather it shows that at the point they were surveyed people who smoked and/or vaped were more likely to have had a heart attack in their lifetime. The study was not able to determine when the heart attack took place, whether it followed or preceded use of an e-cigarette. It is therefore inaccurate to say this research shows that vaping leads to an increased risk of a heart attack. The link between tobacco smoking and heart attacks is well established."

According to Dr. Konstantinos Farsalinos, a cardiologist and researcher from Greece, "Increasing the risk" means that someone is FIRST exposed to a condition (in this case, exposed to e-cigarette use) and THEN, BECAUSE OF THIS EXPOSURE, he/she develops disease. Both studies CANNOT provide any of this information to substantiate an increased risk. Both are cross-sectional surveys, meaning that they asked participants if they have heart disease and if they use e-cigarettes.



The studies provide no information on whether e-cigarette use was initiated before (and how long before) or after the development of disease. What if participants used e-cigarettes after they developed the disease in order to quit smoking?

In conclusion, both studies provide no information about any risk associated with the use of e-cigarettes. They do not prove an increased risk and of course they do not prove that no such risk exists. They simply cannot address the question of whether e-cigarettes increase the risk for heart disease or not. I am confident that the authors of the published study and the American Heart Association, which released the press statement for the conference abstract, are very well aware of these basic epidemiological principles. This is simple, basic knowledge for a medical student, let alone for acknowledged scientists. And they know that the statements about "increased risk" are wrong."

A five year study done by Dr. Riccardo Polosa, in Italy found that non smokers who vaped, had no increases in markers of cardiovascular risk, lung function and or symptoms of respiratory disease. ⁶

Another study done by Dr. Polosa in smokers suggested that E-cigarette (EC) use may ameliorate objective and subjective COPD outcomes and that the benefits gained may persist long-term. EC use may reverse some of the harm resulting from tobacco smoking in COPD patients. These include reduced blood pressure, fewer exacerbations of chronic obstructive pulmonary disease (COPD) and improvements in asthma symptoms. ⁷

In the United States, the National Academy of Sciences, Engineering and Medicine published their own report entitled "Public Health Consequences of E-Cigarettes" ⁸ where they stated clearly that "There is insufficient evidence that e-cigarette use is associated with long-term changes in heart rate, blood pressure, and cardiac geometry and function."

Experts: Konstantinos Farsalinos, MD (Greece) & Riccardo Polosa, MD (Italy)

3. Concerns around Effects of Second/Third Hand Exposure of Vapour/Aerosol. According to experts at the US Department of Health and Human Services, there are no



quantifiable harms from second/third hand vapour/there is no additional harms from vaping in those who have been exposed. This has been studied extensively by a few different researchers in different projects.

The first presented is that done by the US Department of Health and Human Services entitled "Evaluation of Chemical Exposures at a Vape Shop" The work ⁹ involved "Our primary objective was to evaluate employees' potential exposures to chemicals associated with vaping in the shop. Our work involved (1) sampling air for specific flavoring chemicals associated with respiratory disease; (2)sampling air for nicotine, propylene glycol, formaldehyde, and other VOCs; (3)sampling work surfaces for metals and nicotine; and (4) observing work practices." The conclusion from the study states "Employees were exposed to detectable levels of diacetyl and 2,3-pentanedione in the air while working in the vape shop. Although the measured concentrations were below all applicable OELs..."

Expert: US Department of Health and Human Services (USA)

4. Evidence of Harm Reduction in users of Safer Nicotine Products. Evidence of Harm Reduction has been scientifically proven, most notably those done and reviewed Public Health England - the National Health Service, the Royal College ¹⁰ of Physicians (United Kingdom) and University College and King's College London ^{11 12}. The Royal College of Physicians have shown a 95-98% reduction in the harm compared to that of combustible tobacco. As Michael Russell said over 30 years ago, it is the TAR that kills, not the nicotine. Alternative nicotine products do not involve combustion, which is what creates TAR.

These studies have been followed up and reviewed regularly by Public Health England, in 2015, 2016 and most recently in 2018. This is the basis for the National Health Service promoting the use of Alternative Nicotine Products in lieu of smoking on hospital grounds in various locations throughout the country, the promotion and use of Alternative Nicotine products within their smoking cessation programs and also the provision of these products in prisons to alleviate the currency of tobacco, as well as the health harms of smoking, to the prisoners and staff.

Expert: Royal College of Physicians, United Kingdom, UK Centre for Tobacco and Alcohol Studies



(UK)

In conclusion, we implore all the involved public health officials and government ministers to consider the scientific evidence and facts when making the decision to regulate Safer Nicotine Products. We remind them that their mandated responsibility is to promote the health and well being of all the citizens of Kingdom of Thailand. Lastly, we offer our assistance to them, to provide information, expert advice and guidance in developing regulation, which it is hoped will be risk proportionate and progressive, instead of implementing an outright ban, which will not best serve the public health of the citizens of Kingdom of Thailand.

Please find an addendum with statements regarding the issues presented from Internationally respected authorities on the issues presented herein.



REFERENCES:

- ¹ World Health Assembly Resolution 56.1. Retrieved 8 Jan 19 from: www.who.int/tobacco/framework/final_text/en/index2.html
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- ³ BMC Pregnancy and Childbirth201818:233 https://doi.org/10.1186/s12884-018-1856-4
- ⁴https://www.buffalo.edu/content/dam/www/news/documents/ Study%20PDFs/Kozlowski-Warner-DAD-201 7-inpress.pdf, accessed 14Mar19.
- ⁵ Talal Alzahrani, Ivan Pena, Nardos Temesgen, Stanton A. Glantz. Association Between Electronic Cigarette Use and Myocardial Infarction. *Am J Prev Med* 2018; DOI information: 10.1016/j.amepre.2018.05.004.
- ⁶ Polosa, Riccardo, et al. "Health Effects in COPD Smokers Who Switch to Electronic Cigarettes: a | COPD." *International Journal of Chronic Obstructive Pulmonary Disease*, Dove Press, 22 Aug. 2018, www.dovepress.com/health-effects-in-copd-smokers-whoswitch-to-electronic-cigarettes-a-r-peer-reviewed-articl e-COPD.
- 7 ibid.
- ⁸ "Public Health Consequences of E-Cigarettes." *Public Health Consequences of E-Cigarettes*, 19 Oct. 2018, nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx. Accessed 14Mar19.
- ⁹https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf, accessed 14Mar19



- ¹⁰ Public Health England. "E-Cigarettes and Heated Tobacco Products: Evidence Review." *GOV.UK*, GOV.UK, 2 Mar. 2018, www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review.
- 11 "Nicotine without Smoke: Tobacco Harm Reduction." *RCP London*, 25 July 2017, Accessed 14 Mar 19 https://www.rcplondon.ac.uk/file/3563/download?token=Mu0K_ZR0
- ¹²"Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-Sectional Study." *Annals of Internal Medicine*, American College of Physicians, 21 Mar. 2017.



ADDENDUM:

American Cancer Society, February 15, 2018 "Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes, but the health effects of long-term use are not known." "Many smokers choose to quit smoking without the assistance of a clinician and some opt to use e-cigarettes to accomplish this goal. The ACS recommends that clinicians support all attempts to quit the use of combustible tobacco and work with smokers to eventually stop using any tobacco product, including e-cigarettes. Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products."

Link: https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-sta tement.html

American Heart Association, 24 August 2014 "If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt." Link: https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000107

American Association of Public Health Physicians, 2 April 2010 "AAPHP favors a permissive approach to E-cigarettes because the possibility exists to save the lives of four million of the eight million current adult American smokers who will otherwise die of a tobacco-related illness over the next twenty years." "E-cigarettes can and should be marketed as a substitute for conventional cigarettes for smokers unable or unwilling to quit."

Link:

https://www.aaphp.org/special/joelstobac/2010/harmredcnupdatejuly2010.html

National Academies of Sciences, Engineering and Medicine, 2018 "E-cigarette aerosol contains fewer numbers and lower levels of most toxicants than does smoke from combustible tobacco cigarettes."

"Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-



term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes."

Link: https://www.nap.edu/read/24952/chapter/2

Public Health England, 6 February 2018 "Risks of cancer, cardiovascular disease, and respiratory diseases due to ECs are expected to be reduced compared with smoking because toxicants and carcinogens present in cigarette smoke are absent or present at much lower concentrations in EC aerosols.4,16 Although not without risk, the overall risk of harm is estimated at less than 5% of that from smoking tobacco;4 the risk of cancer has been calculated to be less than 1%.16"

Link: https://www.gov.uk/government/news/phe-publishes-independent-expert-ecigar ettes-evidence-review

PATH study by FDA in the US (prospective study of using e-cigarettes and subsequent change in smoking status) "After adjusting for covariates, cigarette smokers who initiated e-cigarette use between waves and reported they used e-cigarettes daily at wave 2 had 7.88 (95% CI 4.45 to 13.95) times the odds of 30-day cigarette cessation compared with non-users of e-cigarettes at wave 2. Cigarette smokers who began using e-cigarettes every day and did not achieve cessation had 5.70 (95% CI 3.47 to 9.35) times the odds of reducing their average daily cigarette use by at least 50% between waves and compared with e-cigarette non-users." Link: 2 https://www.ncbi.nlm.nih.gov/pubmed/29986104