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RESEARCH ON REGULATION OF HEAT-NOT-BURN PRODUCTS IN HONG KONG

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Section 1 – Introduction

Smoking is one of the biggest public health threats the world has ever faced, and the largest single preventable cause of many chronic diseases. Out of 8 million killed by related causes around the world each year, more than 7 million are smokers, while around 1.2 million are the result of non-smokers being exposed to secondhand smoke (WHO, 2019). The debilitating effects of tobacco smoking affect the quality of life of not only smokers, but everyone, in all parts of the world.

While the harmfulness of cigarette smoking and the addictiveness of nicotine is widely acknowledged, there has been an emerging consensus that most of the harm associated with conventional cigarettes is caused by the tar and toxic gases released from combustion while the tobacco is burning. Studies reported that adverse health outcomes, particularly cancer and cardiovascular and pulmonary diseases, are caused by the complex chemical mixture of combustion compounds in tobacco smoke (CDC, U.S., 2010). Since smokers smoke for the nicotine but not the combustion by-products, the tobacco industry is transformed by the development of “reduced-risk products”, also known as “smokeless smoking”, which the combustion process is eliminated to drastically reduce toxins such as tar and carbon monoxide.

The idea of smokeless products as an alternative to traditional cigarettes has sparked much debate in the science and policy communities in the past few years after gaining popularity internationally. Despite the elimination of carcinogenic tar and combustion by-products, there are still plenty of uncertainties whether there are other harmful side-effects (Cotton, 2018). Cases of illness and deaths related to smokeless products in the recent years have alarmed doctors and governments. Given the lack of long-term data to evaluate impacts on individual users and overall public health, we have yet to see a consistent approach among governments in terms of how to regulate the new products.

Smokeless products currently exist in two main categories: electronic cigarettes and heat-not-burn (HNB) products. Since e-cigarettes work by heating a liquid (may or may not contain nicotine) to produce a vapor that is inhaled by users, it is inherently not a tobacco product. Hence it will not be a focus of this paper.

1.1. What is Heat-Not-Burn (HNB) products

A set of HNB products consists of a battery-powered heating source and specially made tobacco sticks. A tobacco stick is heated to a lower temperature than a combusted cigarette by the heating device, creating aerosols to be inhaled by users. Examples include IQOS from Philip Morris International (PMI), Ploom from Japan Tobacco International, and Glo from British American Tobacco. Since the tobacco is warmed without combusting, it does not release any fire, ash or smoke, hence eliminates the problem of second-hand smoke (Glantz, 2018). While the best way to improve one’s health is to quit smoking and nicotine completely, HNB products are marketed as the next best alternative for those who choose

not to quit, and a less harmful stepping stone that carries a fraction of the risk compared to combustible cigarettes for those who would like to gradually get rid of the bad habit.

HNB products have gained popularity in the past decade and are marketed in more than 40 countries as of July 2019 (WHO, 2019), distributed via various channels including the internet, supermarkets, malls and flagship stores. Despite the absence of combustion, HNB products are by no means risk-free. Tobacco contains carcinogens even in its natural form, and the long-term health effects of any tobacco products should not be underestimated despite some empirical studies favoring HNB products at present stage.

1.2. Research Objectives and Significance

Currently, regulations towards HNB products vary among countries. Some governments, such as in the United Kingdom, categorize HNB products as tobacco under the framework of existing tobacco control legislations as recommended by the WHO; while some countries and regions such as Singapore and Macau implement a total ban on the sale and distribution of HNB products. So far, there is no conclusive data yet to drive a definite answer for how and to what extent HNB products should be regulated.

Last year, the Hong Kong Chief Executive ordered the introduction of Smoking (Public Health) (Amendment) Bill 2019 into the Legislative Council to impose a total ban on all alternative smoking products, including HNB products, which prohibits its import, manufacturing, sale, distribution and advertisement. Any person who commits an offense will be liable to fines or imprisonment. A justification given by the government in support of the ban was the uncertain health impacts associated with alternative smoking products. They worry such products being marketed as less harmful might renormalize smoking behaviors, and eventually become a gateway to cigarette smoking, posing a serious threat to public health (Hong Kong LegCo, 2019). The younger generations are especially at risk given the increasing popularity of related products among teenagers as observed in some countries (Cunningham, 2019). However, the Bill did not successfully pass in the Legislative Council in 2019, and is expected to come back to the agenda in the future. Hence, brainstorming and research at the current stage is important to provide solid grounds for policy discussions on this issue when the topic returns.

The findings presented in this paper are based on three research questions:

1. Comparing the expected benefits and potential risks of a total ban on HNB products, is such a decision justified?
2. What are other alternative ways that can also effectively regulate HNB products?
3. Which approach or a combination of approaches would allow the Hong Kong government to effectively regulate HNB products and bring the most overall benefits?

We consolidated existing medical knowledge of the known effects of HNB products, and studied current international practices for a comparison of their pros and cons. Conducted for our client Philip Morris International (PMI) Hong Kong, the objective of this research is to evaluate possible outcomes of different policy scenarios, to give logical arguments to either support or reject a total ban as proposed by the Hong Kong government. The conclusions

and evidence presented will serve as a basis for PMI's future discussions with the government to support policy makers in making informed and sensible decisions, and provide inputs to what role the company can play to bring positive impacts and promote brand integrity as a responsible market player.

To lay the foundation for policy discussion, section 2 presents a summary of existing literature covering important facts regarding Hong Kong's current tobacco control framework, controversies and criticisms against the use of HNB products, and the dissenting voices in response to the government's proposed ban. Section 3 presents a set of case studies in which we compare and evaluate international approaches in regulating HNB products, followed by a discussion on the pros and cons of different types of policies in Section 4. Lastly, in Section 5, we conclude policy implications and recommendations.

Section 2 - Literature Review

2.1. Current Legal Framework of Traditional Tobacco Control in Hong Kong

Smoking (Public Health) Ordinance (Cap.371) is the major legal framework on tobacco control in Hong Kong, first enacted in 1982 with seven subsequent amendments. This ordinance controls and monitors tobacco use through the prohibition of smoking in public places including all indoor areas and public transport carriers, restriction on sales of tobacco products and restriction on tobacco promotion and advertising.

General restriction on sales includes:

- Sale or possession of any cigarette, cigarette tobacco, cigar, or pipe tobacco for the purpose of sale is prohibited unless in a package of at least 20 sticks within a retail container with health warning and the tar and nicotine yields in the prescribed form and manner;
- Sale of cigarette with a tar yield exceeding 17 milligrams is prohibited;
- Sale of tobacco products from a vending machine is prohibited;
- Selling or giving of tobacco products to any person under the age of 18 years is prohibited;
- Giving of tobacco products for the purposes of promotion or advertisement is prohibited.
- Pictorial health warnings are required for all packets and retail containers of cigarettes, cigars, pipe tobacco, and cigarette tobacco. The warnings must cover at least 85% of both principal display areas, in Chinese on one PDA and in English on the other PDA.
- A sign in English and Chinese is required to be shown in a prominent position in places where tobacco products are sold, to indicate that no tobacco product may be sold or given to any underaged person.

Any violation may be retained in the custody of the Commissioner of Customs and Excise or liable on summary conviction to a fine.

General restriction on advertising includes:

- Printing, publishing, or cause to be published a tobacco advertisement in a printed publication is prohibited, which includes any local newspaper or document printed, published or distributed in Hong Kong;
- Any display of tobacco advertisement in writing or other permanent or semi-permanent form is prohibited;
- Broadcasting of tobacco advertisements by radio, visual images, film, and internet is prohibited.

Under the *Fixed Penalty (Smoking Offences) Ordinance*, any smoker who lights-up in the statutory no-smoking areas will be given a fixed penalty of HKD 1,500.

According to the duty rates prescribed in the Schedule to the *Dutiable Commodities Ordinance (Cap. 109)*, tobacco is subject to tax on general imports. The duty is prepaid by sellers and included in the price. With no duty-free cessation, all Hong Kong residents or

passengers cannot bring in any tobacco products to Hong Kong. Smokers aged 18 or above can be allowed to bring in a small exempted amount for their own consumption, which is equivalent to 19 cigarettes; or 1 whole or 25 grams of cigars; or 25 grams of other manufactured tobacco.

2.2. Controversies over HNB Products

HNB products have been increasingly adopted as an alternative to combustible smoking products, primarily cigarettes. Substantial controversies, nevertheless, accompany their marketing and use in the public health context. HNB products have been marketed as reduced-harm products for both users and bystanders because, as the producers claimed, the technology limits combustion and the generation of toxic compounds (Berthet et al., 2018). The major argument in favor of the development and use of HNB products is the declaration that they are considerably less dangerous than conventional cigarettes (Glantz, 2018). According to an independent study conducted by the Committee of Toxicology in the UK, which compared the number of toxic compounds in the main stroke of conventional cigarettes with that in HNB aerosol, this statement is justified. The study demonstrated that HNB users are exposed to 50 to 90 percent fewer 'harmful and potentially harmful compounds (HPHCs)' than conventional cigarette smokers (UK Committee on Toxicity, 2017). In this regard, HNB products are considered safer than traditional cigarettes.

However, debates continued as their long-term health effects remained unknown (World Health Organization, 2018). Insufficient epidemiological studies on the health effects of HNB products are available since they have been on the market for only five years, which is not long enough to be extensively studied under real-world conditions. Arguments against the use of HNB products are therefore raised based on the concerns of unproven safety. Some studies indicated that HNB products are not completely safe as their aerosols still contain a lot of chemicals that are found in cigarette smoke, although most of these chemicals identified are present at significantly reduced levels. Moreover, levels of nicotine in HNB aerosols are approximately equal to those released by conventional cigarettes (Bekki, Inaba, Uchiyama and Kunugita, 2017). These contradictory results, combined with advocacies by anti-harm reduction organizations and sensationalized media reporting, caused confusion among not only consumers, but also politicians and regulators.

2.3. Evaluation on Major Arguments over HNB Use

According to the Legislative Council Brief 2019, there are three major arguments supporting the proposed ban on HNB products in Hong Kong, including health impacts, gateway effect and renormalization of smoking. Evidence justifying these arguments are evaluated as follows.

Public Health Impacts

It is often claimed that HNB products are not entirely harmless because they still contain nicotine and their long-term health effects are unknown. Restrictions or a total ban should therefore be imposed on these products based on precautionary principles. Although concerning chemicals in HNB aerosols are found at significantly reduced levels compared to cigarettes, there is no data whether this reduced level of chemicals could result in

measurable adverse health impact (Lüdicke et al., 2017). Moreover, even though nicotine is not harmless, it is not responsible for most of the tobacco related diseases. Unfortunately, it has long been associated with these diseases in media campaigns against smoking, which is cited as a counter argument by opponents against the development of harm-reduction alternative products (Cummings, Hyland, Giovino, Hastrup, Bauer, and Bansa, 2004; Siahpush, McNeill, Borland, and Fong, 2006).

Public health impacts of HNB products should not be translated into whether the products are completely safe or not, but whether they are less harmful than traditional cigarettes, and if so, whether they will encourage more current smokers to switch without inducing non-smokers to tobacco smoking. Although limited and contested, some studies have already proven that smokers who switch completely to HNB products are exposed to a lower level of toxins and this is likely to reduce risk of tobacco-related diseases (Nathan et al., 2018), with the possibility of reducing cigarette consumption and producing positive health impacts at population level. Levy et. al. conducted a study to evaluate public health impacts of vaporized nicotine products (VNP), which included e-cigarettes, aerosol nicotine products and HNB products, through comparing patterns of VNPs and traditional cigarette use (Levy, et al., 2018). According to the study, there is a strong potential for VNP use to improve population health by reducing or displacing cigarettes in countries where cigarette prevalence is high, given that smokers are interested in quitting. In the study, it was also highlighted that current smokers were at least 15 times more likely to use VNPs than people who had never smoked.

Many smokers find the process of quitting difficult, relapse rates are high, because smokers are not only dependent on nicotine, but also behaviorally addicted. Currently there are many smoking cessation products in the market including the traditional nicotine replacement therapies (NRTs), which are considered very safe products. However, these products have limited efficacy in smoking reduction and cessation with limited use as they only focus on reducing or replacing nicotine and fail to address the biobehavioral component that is heavily ingrained in most addictive practices (Barbeau, Burda, and Siegel, 2013). In this regard, reduced harm products can be effective alternatives in helping smokers quit and prevent relapsing because they mimic the experience of smoking, allowing smokers to switch to a less harmful replacement tool and thereby maintain cigarette abstinence (Paumgarten, 2018). It is important to find the balance between acceptability and risk, instead of solely looking at safety as the only parameter.

Gateway Effect

Proponents in favor of restrictions or an outright ban on HNB products often claim that nonsmokers will use reduced harm alternatives as a gateway to tobacco smoking, which is backed by some empirical findings. These gateway claims themselves, however, are questionable. According to Carl V. Phillips (2015), the gateway effect, when applied to reduced harm tobacco products, is highly unlikely. First of all, the barriers to start smoking are very low to begin with, so there are no formidable obstacles that might cause potential users to seek a cheaper, more accessible alternative. If anything, the reduced harm tobacco alternatives are more difficult to obtain and even if they are not banned, are more expensive. Secondly, if a person who chooses abstinence over smoking is exposed to a reduced harm

alternative, there is no reason that the person will switch from this product to what has been his/her least-preferred option, smoking. These logics are difficult to conceive and unfortunately, are never explained by those who claim there is such a gateway effect.

As for the empirical studies that indicated a gateway effect occurring among non-smokers, they might be confined to some methodological errors (Lynni and Kenneth, 2017). Usually these studies would conclude that there exists a gateway effect with the observation that a high proportion of reduced harm products users subsequently experimented with conventional cigarettes. However, these studies do not control the fact that some of those who tried cigarette smoking after the use of reduced harm alternatives may have picked up smoking anyway. Moreover, these studies may point to users of the former who have experimented with smoking, even if it is only once or a few times. Furthermore, these studies usually do not control confounding variables, especially the possibility that there are important socioeconomic factors that explain why people smoke. These confounding variables include people's risk-taking propensities, use of other substances, and other potential confounders such as peer and parental smoking. While there is a small possibility of the gateway effect occurring among non-smokers, it is more likely that current smokers would use these alternative products to quit smoking, which is ignored by these studies and gateway effect argument (Carl, 2015).

Meanwhile, current evidence in countries where HNB products have been marketed for a relatively long time, specifically Italy and Japan, demonstrates low uptake by youth and current nonsmokers. According to a longitudinal study involving 8,240 individuals aged from 15 to 69 years old in Japan, during the first one to two years after HNB product IQOS went into the Japanese market in 2014, use by adult former and never smokers was low (1.5% among former smokers and 1.2% among never smokers). Among the survey respondents in 2017, there are 3.6% current IQOS users, of which 1.3% were never smokers, 2.1% were former smokers, and of the 3,6% current users, 18.8% were current smokers with intention to quit, and 10.3% were current smokers with no intention to quit (Tabuchi, Gallus, Shinozaki, Nakaya, Kunugita and Colwell, 2017). In Italy, an offline survey was conducted in 2017 with 3,086 participants aged 15 years old and above selected from the general Italian population. This Italian study also suggests that the prevalence of IQOS use is lower in never and former smokers compared to current smokers (1.7% compared to 0.5% and 5.0%) (Liu, Lugo, Spizzichino, Tabuchi, Pacifici and Gallus, 2018). Additionally, these studies also measured IQOS use among youth. In Japan, 2.0% of those aged 15-19 years reported current use of IQOS in 2017. While in Italy, 0.9% of those aged 15-24 years reported having ever tried IQOS. Both of the Japanese and Italian numbers indicate that the prevalence of current use was lower in youth than that of other aged groups. Overall, the available information demonstrates that those most likely to use HNB products are current smokers, and the low prevalence rates among never smokers and youth suggest that the risks of HNB products becoming a gateway to smoking are minimal.

Renormalization of smoking

Another argument against HNB products is that past efforts to denormalize smoking would be undermined by formal introduction of reduced harm alternatives. This argument does not rely on the claims of gateway between reduced harm products and traditional cigarettes.

Instead, the argument here is that formally introducing these alternative products and allowing them to be marketed as 'reduced harm' or 'reduced risk' may reverse tobacco control successes through increasing the extent to which smoking is once again seen as a 'normal' behavior, and is accepted and accommodated by the non-smoking majority, including young people (Sæbø G, 2017).

This argument, however, is problematic when used to justify a comprehensive ban on HNB products. This is because firstly, the majority of HNB product users treat these products as smoking cessation tools and report that they have been the key to quitting smoking. A study indicates that consumers of HNB products are predominantly current and former smokers, with the majority already quit smoking, and only a small minority are never smokers who do not subsequently initiate smoking (Farsalinos et al., 2019). Secondly, smoking prevalence has not been witnessed to increase dramatically with introduction of HNB products. Taking Japan as an example, a study on whether the introduction of IQOS has affected cigarette sales in a large economy found that cigarette sales began to decline substantially at the time IQOS was introduced in 11 Japanese regions (Stoklosa et al., 2019). When e-cigarettes were introduced in England as a reduced harm alternative, concerns of re-normalization effect arose, as did HNB products. Nevertheless, a study examining whether e-cigarettes renormalized or displaced smoking among young people in England demonstrated that, little evidence suggested renormalization of youth smoking was occurring during a period of rapid growth and limited regulation of e-cigarettes from 2011 to 2015 (Hallingberg et al., 2019). This may not be analogous for HNB products, but a complete ban on reduced harm products is not justified on the basis of renormalization effect. Indeed it cannot state conclusively that renormalization of smoking is not possible even though evidence is limited. The increasing popularity of HNB products among adolescents has raised concerns (Czoli, White, Reid, O'connor and Hammond, 2019), and measures can be taken to control use of reduced harm alternatives among youth. In its statement approving IQOS for sale, the United States Food and Drug Administration (FDA) suggested that "The proposed marketing and advertising restrictions will help ensure lower youth exposure and access to the products. Additionally, the applicant will be required to monitor consumer use patterns and demographic information and provide the FDA with regular reports (U.S. Food and Drug Administration, 2019)".

2.4. Status Quo in Hong Kong and Dissenting Voices

Since HNB products have not yet been legally approved in the Hong Kong market, use of these products is not prevalent. A population-wide study revealed that only 11.3% of surveyed Hong Kong citizens were aware of HNB tobacco products and 1.0% had previously used them. Besides, a higher socioeconomic status (higher educational attainment and monthly household income) was found to be associated with HNB use and the intention of using (Wu et al., 2019).

The particular situations of niche market and elite users, however, turned the proposed ban into a controversial debate among the public. Critics consider an outright ban only on imports and sales but not limiting use of HNB too cursory and extreme to implement.

The first objection questions the government's reasoning for the ban. As the Hong Kong Department of Health (2019) claimed, reduced harm products are promoted in a way that is attractive to youngsters, thus a ban could prevent the underage from picking up the use of any related products. This argument treats all reduced harm products as the same. In fact, different from other reduced harm tobacco products such as e-cigarettes, HNB products mainly target long-term smokers who are trying to quit or wish to reduce damage while still satisfying their cravings. It could be observed that HNB products are generally priced higher than e-cigarettes and traditional cigarettes, which to a large extent excludes young consumers who cannot afford such price. If the proposed ban is implemented, it prevents people from quitting smoking by using HNB products, let alone reducing the overall smoking rate in Hong Kong.

Critics also question the logic and effectiveness if only imports and sales are banned, while uses are still allowed. Inversely, a tough ban could lead to two consequences, first of which, without other options, youngsters could be led directly to traditional cigarettes; second, as the ban only prevents sellers from trading and promoting while placing no restraint on consumers, it might push the transactions under the counter, fuelling illicit markets to flourish. There is evidence that the illicit trade of tobacco products including novel products are increasing in recent year. In 2019, the illicit tobacco product stood for about 43% in Hong Kong (MS Intelligence, 2019). Those illicit trade of tobacco products means a about 3 billion HKD revenues for the government (Nilson, 2020). Additionally, if those illicit trade was regulated legally, it would bring 7.2 billion HKD revenue to Hong Kong retailers (Nilson,2020). Moreover, black markets may worsen the current situation and the regulators further lose the grip of control. Counterfeit products might still circulate while prices could be set unreasonably high, which puts consumers safety at risk and their interests exploited.

The second objection concerns the potential negative economic impacts on trades and job losses. According to the 2018 report of Euromonitor, the global market of new-type tobacco products has reached USD 27.7 billion, growing annually by 60.6%. Among those new-type tobaccos, the market of HNB products is worth USD 11.9 billion, standing for 42.9% of the whole market. Therefore, it is argued by critics that banning imports, sales and promotion of all reduced harm products could be seen as removing competition for any importers, sellers and promoters of traditional cigarettes.

In addition, so far, it has not reached a consensus on the risk of reduced harm products in the field of medicine but it could be ensured that the harm of these products such as e-cigarette is definitely lower than that of traditional cigarettes (Bull World Health Organ, 2014). Therefore, it is unfair to completely ban all reduced harm products while still allowing traditional cigarettes in the market. It is also unfair to trade all reduced harm products without distinction, which deprives customers' freedom of choice. At least for smokers, it is evidence-backed that reduced harm products are effective in aiding smoking cessation compared with other nicotine products (New England Journal of Medicine, n.d.).

For employees in the supply chain of HNB products, the ban could be a nightmare causing massive unemployment. New-type tobacco products contribute to about 20% of a newsstand's revenues in Hong Kong, removing this source of income could be devastating

to newsstands owners (HK01, 2019). Furthermore, the ban would make years of innovation and investigation effort on reduced harm products meaningless, which could be a containment on innovation to some extent.

Section 3 - Case Study

In view of the controversies over HNB products, policymakers are divided on how best to respond. Policy responses across the world range from no regulations, slight variations from tobacco products, resembling regulations as tobacco products, to total bans.

In this section, case studies from Japan, United Kingdom, United States and Singapore will be presented to illustrate how their governments regulate HNB products, as well as examine the harm reduction and cessation aid potential of these products in their jurisdictions. HNB products have been on the market in Japan and the United Kingdom for a comparatively long time, where regulatory frameworks for HNB products have gradually established and improved. While in the United States, IQOS by PMI recently obtained approval to market and sale after rigorous premarket tests in 2019. Singapore is on the other end of the policy control spectrum. In Singapore, vaping and other alternative tobacco products, including HNB products, are completely banned. We believe these countries can provide insights of a wide range of scenarios for the Hong Kong government on how to regulate HNB products in a way that maximizes benefits for public health while minimizing the costs.

3.1. Japan

Japan has been the focal market to test the potential of HNB products as cigarette alternatives due to its regulatory environment and social and cultural factors. In Japan, e-cigarettes are subjected to more regulatory controls compared to HNB products, giving HNB products a very different starting position. In addition, Japanese values cleanliness, fitness and health, and because of social courtesy awareness, many smokers feel shamed for producing harmful substances and ash when smoking. Japanese consumers are also electronic gadgets enthusiasts, therefore tobacco manufacturers aggressively marketed and promoted HNB products in the Japanese market as reduced harm and high-tech products (J.Yoshida, 2018). They have marketed several HNB brands nationwide, including Japan Tobacco's "Ploom TECH" device in March 2016, PMI's "IQOS" device in April 2016, and British American Tobacco's "Glo" device in December 2016 (Du L and Huang G, 2017). Currently Japan is the only country where HNB products are widely sold, accounting for over 90% of the global HNB market, according to Euromonitor. The high cost of traditional tobacco products has made HNB products a more common substitute for cigarettes among smokers in Japan (Caputi, et al, 2017).

Regulation

Regulations on electronic tobacco products vary in Japan depending on whether they use tobacco leaf. Nicotine-containing e-cigarettes are classified as pharmaceutical products in Japan and their sales and use have been banned by the Pharmaceutical Affairs Act since 2010. Non-nicotine e-cigarettes, however, are unregulated and available to the public, even to minors. In contrast, HNB products are sold as tobacco products and regulated under the Tobacco Business Act because they consist of tobacco leaf (Tabuchi et al, 2018). Taxation for HNB products is currently at the same level as pipe tobacco under the Tobacco Tax Act,

which imposes a lower tax rate on HNB products than regular tobacco. Nevertheless, the Liberal Democratic Party is considering raising the tax rate for HNB products (Kyodo, 2017). In addition, sale to minors is restricted in accordance with the Act on Prohibition of Smoking by Minors.

According to the Tobacco Business Act, advertising, promotion, and sponsorship of tobacco products in Japan are largely left to “industry self-regulation.” This means even restrictions on tobacco advertising, promotion and sponsorship do exist in practice, no forms of such restrictions are explicitly prohibited by law. Tobacco companies can therefore set voluntary standards for product advertising and promotion, but they should “be mindful so as not to widely and actively encourage smoking.” HNB products that are marketed to Japanese customers are within this legal context.

Moreover, in Japan HNB products are regulated by the amended Health Promotion Act. The amendments to the Act define smoking to include smoke or vapour from burned or heated tobacco, therefore HNB products are included in the smoking ban stipulated by the amendments. According to the Act, smoking is completely banned in schools, hospitals, children’s facilities, government facilities, passenger cars and planes, but HNB products are allowed indoors and many restaurants have smoking rooms or designated smoking areas. However, there is a push to ban indoor smoking in Tokyo ahead of the 2020 Olympics (Sotaro Yumae, 2018).

Harm Reduction and Cessation Aid Potential

Prevalent use of HNB products has been increasing dramatically in Japan. According to a survey involving 8,240 Japanese respondents between the ages of 15 to 69 in 2015 and 2016, only about 0.3% respondents were current HNB users, whereas in 2017, the current use rate had increased more than 10-fold to 3.6% of all respondents. The survey also demonstrated that current smokers with intention to quit were significantly more likely to use HNB products than current smokers with no intention to quit (18.8% vs 10.3%). The rapid increase in interest and use of HNB products among Japanese are probably triggered by its appearance as a healthier alternative of tobacco products on a popular national entrainment TV show, because HNB use among viewers was nearly four times higher than non-viewers (10.3% vs 2.7%) (Tabuchi et al, 2018). Moreover, this survey along with other studies, indicated that the younger population was more likely to use HNB products (Tabuchi et al, 2018; Hair et al, 2018).

Another study conducted by Stoklosa and his team showed that the introduction of HNB products likely reduced cigarette sales in Japan. Using 2014 to 2018 monthly retailer panel data from Japan, researchers analyzed whether the launch dates of IQOS across different Japanese regions were reflected in the patterns of cigarette sales. They found that cigarette sales began to substantially decline at the time of IQOS launch in each of the 11 Japanese regions, all without a major change in national tobacco control policy (Stoklosa et al., 2019). Even though dropping cigarette sales might not necessarily translate into decreasing cigarette smoking prevalence, smoking rate in Japan has been on the decline since the introduction of HNB products. According to the annual survey on smoking in Japan conducted by Japan Tobacco since 1965, the average smoking rate in Japan continued to

fall and reached the lowest, at 17.9%, in 2018, 27.8% of men and 8.7% of women respectively (Japan Tobacco Inc., 2018).

3.2. United Kingdom

Smoking prevalence in the UK has declined continuously and dramatically over the past 50 years by about two-thirds. In 1974, over 50% of men in the UK were smokers; that had fallen to just 16.5% in 2018. Similarly, just over 40% of women smoked back then; in 2018 it was only 13.0% (UK Office for National Statistics, 2019). While smoking is in terminal decline, it remains the nation's leading preventable cause of illness and premature deaths, so the government plans to further reduce smoking in England, with the aim of creating a smoke-free generation (Department of Health and Social Care, 2017).

The UK has an open mind to innovative technologies that can minimize the risk of harm caused by smoking. After recognizing the potential of e-cigarettes as safer alternatives to smoking, public health policies in England support the use of e-cigarettes as a smoking cessation and harm reduction tool, and promote the availability and acceptability of e-cigarettes (Royal College of Physicians, 2016; Brose, Simonavicius, and Cheeseman, 2018). Use of e-cigarettes as a cessation aid therefore increased rapidly, which appears to have a significant downward pressure on smoking rates. An estimated 7.1% of the adult population amounting to 3.6 million people in the UK currently use e-cigarettes. Over half (54.1%) of current vapers are ex-smokers, and the proportion has grown year on year (Action on Smoking and Health b, 2019). As for HNB products, they are currently sold in the UK, but there is a lack of independent research to validate its use. It is perceived as an opportunity for the government to fill the remaining gaps in evidence on the relative risks of these products, and support a long-term research campaign that would be overseen by public health authorities (House of Commons Hansard, 2019).

Regulation

HNB products are regulated under the Tobacco and Related Products Regulations 2016 as novel tobacco products, and hence are required to be notified to Public Health England before being put on the market. Under the Tobacco and Related Products Regulations 2016, sales of HNB products to those below 18 are prohibited. In addition, the UK is bound by the European Union Tobacco Products Directive and its restrictions on advertising, promotion and sponsorship of tobacco products. HNB are classified as tobacco products and therefore all advertising of these products is banned by default (Public Health England, 2018). For the purposes of taxation, a separate category has been defined for HNB products, which allows for risk-based differentiation. Duty is currently calculated based on the weight of the tobacco inside the product. Usually the price of HNB products like IQOS is about half that of the equivalent cigarettes, because relatively small amounts of tobacco is used in the heated tobacco consumables (UK HM Treasury, 2018).

The impact of Brexit on the UK's tobacco regulations is likely to be minimal. All EU regulations remain binding until Article 50 negotiations are concluded. In addition, many of the tobacco laws in the UK are domestic rather than EU in origin and will therefore survive Brexit intact. These laws include legislation on smoke-free areas and minimum age of sale

for tobacco products and e-cigarettes. Where laws have been transposed from the EU directives, the UK and its devolved entities have chosen to go further than the required minimums. These laws are likely to remain after Brexit, including prohibitions on advertising, promotion, and sponsorship; excise duties, standards for packaging and labelling of tobacco products (Action on Smoking and Health, 2016).

Harm Reduction and Cessation Aid Potential

HNB products were first sold in the UK in 2016. At present, however, knowledge and usage of HNB products has remained relatively low. According to a 2017 YouGov survey on behalf of Action on Smoking and Health (ASH) involving 12,696 participants, 9.3% reported awareness of HNB products and 1.7% had tried or were using the products. Among those who had ever tried HNB products, 38.7% had tried it once or twice and 12.7% had been using it daily. However, survey participants were asked about HNB products prior to answering about e-cigarettes, which is likely to have led to overestimations of awareness and use of heated tobacco products (Brose, Simonavicius, and Cheeseman, 2018). The hypothesis that data from ASH is likely to be an overestimation is strongly supported by the most recent Smoking Toolkit Study (STS), which found a very low usage of HNB products among their sample (<1%). Between January and July 2017, nearly 12,000 respondents were surveyed. The STS did not ask about awareness of the product, only about use. Last-year smokers (n=2,185) were asked about use of HNB products in recent quit attempts (n=4 reported use), to help cut down the amount smoked (n=6), in situations where not allowed to smoke (n=1) or for any other reason (n=0). Among never and long-term ex-smokers (n=9,777), n=5 said they were using HNB products (McNeill, Brose, Calder, Bauld and Robson, 2018).

With a diverse and mature e-cigarettes market in the UK, it is currently not clear whether these products provide any advantage as an additional potential harm reduction and smoking cessation product. Nevertheless, this is likely to change in the future as these products become more commonplace in the market.

3.3. United States of America

Cigarette smoking among American adults has reached an all-time low of 13.7% in 2018. With the number of tobacco users on the decline, smoking cessation rate increased from 6.3% in 2009 to 7.5% in 2018, according to the National Health Interview Survey. Among the smoking population in 2018, 3.2% of them were e-cigarette users while 2.4% were smokeless tobacco users (Centers for Disease Control and Prevention, 2019).

The FDA regulates all tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). At the federal level, the Tobacco Control Act legislates the minimum age of legal access to all tobacco products to be 18. Usage of reduced-harm products is also subject to additional state legislation which varies widely across localities (U.S. Food and Drug Administration, 2009).

Regulation

In 2016, the FDA finalized a rule to subsume reduced harm products under its regulatory purview and therefore subject to the Federal Food, Drug and Cosmetic (FD&C) Act with an uptake trend of these products and uncertainty over their health implications. Under the FD&C act, there are two major legal constraints for manufacturers of reduced harm products in the US.

The first legal constraint refers to the legal marketing of new reduced-harm products. Section 910 of the FD&C Act requires that manufacturers must receive FDA's permission to market new reduced harm products in the US. The provision applies to all tobacco products covered by the FD&C Act that were commercially marketed in the US as of February 15, 2007, or have been modified since that date. Manufactures of these products may seek permission to market under one of three pathways: Premarket Tobacco Application (PMTA), Substantial Equivalence (SE) and SE exemption. The manufacturer may submit a PMTA, which is an application that requires the manufacturer to provide information about the product, including ingredients, additives, properties, manufacture, processing, labeling, and health risks, among other things. The FDA will grant permission to market the new product if the PMTA shows that it would be appropriate for the protection of public health. FDA will consider the risks and benefits, including the relative health risks of the product and the likelihood of changes in tobacco initiation and cessation rates. These considerations will allow for an evaluation of the impact of the new tobacco product on morbidity and mortality for the population as a whole.

Under the SE pathway, manufacturers may apply for permission to market new tobacco products that the FDA deems to have the same characteristics as ones already legally available on the market, or different characteristics but do not raise new questions of public health. As for the SE exemption pathway, it applies for manufacturers introducing minor modifications to their product already legally marketed under the FD&C Act, and through which manufacturers would be exempted from demonstrating their product's substantial equivalence.

Overall, these premarket pathways not only ensure that the new reduced harm products entering the market will maintain a consistently high standard, but also limits market access for risky products, thereby forcing tobacco manufacturers to create products that pose less risk to human health.

The second legal constraint concerns the manufacturer's claims that their product offers a lower risk of tobacco-related disease. Under the FD&C, there is a separated category for tobacco products that may be sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. This product category is defined as modified-risk tobacco product (MRTP). Manufactures must submit an MRTP application under section 911 and receive an FDA order to legally market an MRTP. In their applications, manufacturers must provide research findings to substantiate their products' harm-reduction potential. Besides, they are required to conduct mandatory post-market surveillance on consumers' perceptions, behaviour and health regarding their product on an annual basis. Research findings from successful MRTP applications as well

as post-market surveillance data will also be made available to the public (U.S. Food and Drug Administration, 2016).

PMI submitted two separate applications to the FDA, one is PMTA to obtain market permission for its new HNB product IQOS, another is an MRTP application to market it as being less harmful than cigarettes. Following a rigorous science-based review through the PMTA pathway, the FDA authorized PMI to market and sell IQOS in the United States on April 30, 2019. The FDA determined that the authorization is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes. In addition, IQOS is categorized as noncombustible e-cigarettes and would be subject to the same regulations as other new tobacco products under its jurisdiction, including packaging and labeling requirements, ingredient reporting requirements, and advertising requirements. FDA also requires post-market surveillance of IQOS sales, use, and advertising so as to prevent youth access and exposure. As for MRTP application, FDA has not yet made a decision (U.S. Food and Drug Administration, 2019).

Harm Reduction and Cessation Aid Potential

At this point in time, the US has yet to conduct a nationwide survey of IQOS usage and perceptions since the product has not been officially on the market for a long time. Nevertheless, HNB products are not entirely new to the U.S. A study in 2017 found that 0.7% of American adults surveyed reported ever use of HNB products and a total of 5.2% of U.S. adults were aware of the product. Most of these adults who reported use and awareness of HNB products were current cigarette smokers (Marynak, Wang, King, Agaku, Reimels and Graffunder, 2018).

3.4. Singapore

Smoking rate in Singapore continues to decline due to the country's stringent tobacco control policies. Singapore has implemented tobacco control policies since the 1970s, and under the National Smoking Control Program launched in 1986, it aims to become 'a nation of non-smokers'. In 2005, Singapore became a party to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), the first evidence-based global health treaty. Singapore was among the first 40 countries to ratify the FCTC before the treaty came into force (World Health Organization, 2005). With massive efforts on tobacco control, the smoking prevalence rate in Singapore decreased from 20% in 1984 to 12% in 2017, which is one of the lowest in the world. Even so, the government of Singapore still aims to lower smoking prevalence rates to 12 per cent by 2020 through a comprehensive strategy composed of preventing initiation among the youth, public education and specific programs for target groups, and providing more support and access to smoking cessation programs (Singapore Health Promotion Board, 2019).

A ban on emerging tobacco products

In 2015, the Singapore government imposed a ban on emerging tobacco products, including e-cigarettes and vaporisers, despite opposition even from international tobacco control advocates. According to the Ministry of Health, the ban was a pre-emptive measure to

protect public health against the known and potential harms, and was part of ongoing enhancements to existing tobacco control efforts in Singapore (Stimson and Bates, 2015). Under the Tobacco (Control of Advertisement and Sale) Act, import, distribution, sale, purchase, use and possession of emerging tobacco products are prohibited. In 2018, the complete ban extended to cover HNB products. Anyone found buying, possessing or using HNB products will be subject to a fine of no more than S\$2,000. Any person who breaks the law for importing, selling or distributing prohibited tobacco products including HNB products will be liable to a fine of not more than S\$10,000 or to imprisonment for not more than six months (Singapore Ministry of Health, 2018).

Unintended Consequence of The Ban

The outright ban, however, brings unintended consequences. The black market is booming in Singapore with serious smuggling problems. Despite stringent scrutiny, resourceful individuals can still procure successfully their own e-cigarettes or refills from underground dealers at physical shops using the code word such as 'cartridges' or 'juices', or just at home, online. Even though many of these concealment methods have been discovered by the Health Sciences Authority (HSA), under-the-table deals haven't stopped and the number of arrests is increasing. Since the ban took effect in February 2018, over 465 people have been caught selling and possessing e-cigarettes and electronic vaporizers (Janice Lim, 2019). The stiffest penalty imposed was \$99,000 against a 35-year-old who illegally peddled e-cigarettes online (Prisca Ang, 2019).

The black market not only feeds a criminal network but also affects the follow up of vapers. It is inferred that a significant number of Singaporeans are using vapes and other alternative tobacco products of dubious origin. The Straits Times conducted a poll of 200 people and found that around 14% were vape users, with 10% saying they vape often (at least once a week). Those who vape said they got the vapes through illegal channels (Cheryl Teh, 2019). This means that even in a relatively small sample size of 200 people, 28 still vape despite vaping and other alternative tobacco products being illegal, and black market is their main source. Since sellers have no legal or moral obligation to ensure product quality, authenticity and safety of the products are difficult to verify. Hence, the market is flooded with substandard and dangerous products, which could be the probable cause of the mystery vaping-related illnesses among vapers. This is particularly the case in the United States. In 2019, an outbreak of vaping-related illness involving more than 2,000 lung injuries and 54 deaths occurred in the country. The Centers for Disease Control (CDC) then confirmed that the outbreak was linked to the use black market THC vaping products that contain vitamin E acetate (Bryan Llenas, 2019).

Even though such illness has not been found in Singapore, actions are demanded to regulate black market so as to prevent possible negative effects on public health. This is necessary because it would become difficult for authorities to evaluate the dynamics of this market if a substantial part occurred unofficially and beyond any governmental control (Cheryl Teh, 2019).

	Japan	United Kingdom	The United States	Singapore
Regulation on market permit	Wholesalers and importers of HNB products must obtain a license from the Ministry of Finance.	Public Health England must be notified before any HNB product is put on the market.	Before being permitted to market a new tobacco product in the USA, manufacturers must first receive premarket authorisation from FDA through a premarket tobacco product application (PMTA), a 'substantial equivalence' (SE) order or an exemption from SE ¹ .	HNB tobacco products, e-cigarettes and vaporisers are considered emerging tobacco products and their importation, distribution, sale, purchase, use and possession are prohibited under the Tobacco (Control of Advertisement and Sale) Act.
Product classification	Pipe Tobacco Products	Novel tobacco products	Non-combusted cigarette	
Access	Age of sale 20	Age of sale 18	Age of sale 21	
Availability	Devices of HNB products can be sold anywhere in Japan as long as they are not supplied with an actual tobacco product.	<ul style="list-style-type: none"> - Prohibition of vending machine sales. - Sales currently limited by manufacturer to IQOS stores, some vape shops for IQOS and C-stores for Heets. 	<ul style="list-style-type: none"> - Prohibition of vending machine sales. - IQOS devices can only be sold at their flagship store and pop-up kiosks, but the heatsticks are available at different tobacco retailers. - IQOS can be purchased online but only reserved for store pickup. 	
Packaging and labelling	Text-only warnings are required on 30% of the front and back of packaging (two messages in Japanese, one on front and one on back of packs) ² .	<ul style="list-style-type: none"> - The package must carry the health warning 'This tobacco product damages your health and is addictive'. - The format of health warning is required to cover 30% of the packaging. 	All package labels and advertisements for these products include a warning about the addictiveness of nicotine, in addition to other warnings required for cigarettes, to prevent consumer misperceptions about the relative addiction risk of using IQOS compared to combusted cigarettes.	
Advertising, promotion and sponsorship	Advertising, promotion, and sponsorship of tobacco products in Japan are largely left to industry self-regulation.	All forms of tobacco advertising, promotion or sponsorship are prohibited.	Advertising on television and radio are prohibited.	

¹ The less rigorous SE pathway is not available to the current generation of HTPs because no HTPs with similar characteristics were marketed in the USA before 15 February 2007

² In December 2018, the Ministry of Finance announced plans to increase the size of text-only health warnings to cover at least 50% of the front and back of both cigarette and HTP packs before the 2020 Summer Olympics and Paralympic Games in Tokyo.

Tax	Tax rate is lower than regular tobacco.	<ul style="list-style-type: none"> - Attract both excise duty and VAT. - The excise duty is currently calculated based on the weight of the tobacco inside the product. - A separate category has been defined for heated tobacco products, so this allows for risk-based differentiation in future. 	IQOS would be categorized as cigarettes under the current definition of cigarettes in the federal tax code, and therefore would be subject to the federal excise tax for cigarettes.	
Smoking free place	Smoking is completely banned in Type A facilities: schools, hospitals, children's facilities, government facilities, passenger cars and planes. However, in practice, use of HNB products is allowed in Type B facilities (i.e. other public places including restaurants and passenger ships and trains).	<ul style="list-style-type: none"> - No specific laws in place banning using HNB products outdoors. - HNB does not fall under the indoor smoking ban, because the tobacco is heated but not burned as it is in conventional tobacco products such as cigarettes and cigars. 	IQOS is included in smoke-free policies.	

Figure 1: Regulatory frameworks for HNB products in Japan, United Kingdom, the United States and Singapore.

Section 4 - Policy Discussion

From the case studies, it is observed that Singapore is keeping an increasingly harsh attitude toward tobacco control in order to establish their smoke-free environment. However, as it has been explained in Section 2, a total ban might not be the most appropriate approach to deal with HNB products. Therefore, this section would put more effort into the discussion of regulatory approaches of the other three regions in order to provide a policy package for the HNB control.

Based on the information from Section 3, we identified the following domains of regulation including product prohibitions or restrictions related to HNB: (1) market permits, (2) sales regulations (distribution and minimum age), (3) packaging and labelling, advertising and promotion, (4) taxation and (5) usage regulation. We would discuss three regions' approaches with respect to each domain of regulation.

4.1. Regulation product safety (market permit)

This domain of regulation relates to the market entry of HNB products as well as the manufacturing standards, which could be categorized as product safety requirements. Safety requirements can be implemented with or without product notification and/or pre-market approval requirements.

A robust notification system is being implemented in the UK for novel tobacco products including HNB products, in accordance with the European Union's Tobacco Product Directive. The advantage of notification as a minimum requirement is that the regulator knows what products are on the market and who is responsible if any action is required, for example, to remedy a breach of the rules or to recall an unsafe product. However, there would be a cost to industry. The cost would depend on how robust the overall requirements associated with notification were.

A pre-market approval system would require the importer or manufacturer to notify products to the regulator via a web-based system, prior to marketing, which is implemented by the US. For Japan, the case would be looser in which only wholesalers and importers are required to obtain the licenses from the Ministry of Finance as other normal products. As it has been emphasized in the previous section, the product safety is particularly significant for reduced-harm products so that we would not consider the approach applied by Japan.

Alternatives	Alternative 1: without product notification (pre-market approval system by US)	Alternative 2: with product notification (a notification system by UK)
Pros	<ul style="list-style-type: none"> a. Risks to health mitigated b. Smokers have access to locally-sold products they can have confidence in, which may encourage them to switch c. Ministry of Health is government agency with the best understanding of regulating products to reduce risks to health (e.g., medicines, natural health products, psychoactive substances) 	Apart from the pros for Alternative 1, <ul style="list-style-type: none"> d. Enforcement would be proactive e. Self-certification would facilitate compliance f. Notification would facilitate regulator to take action against any breaches
Cons	<ul style="list-style-type: none"> a. Costs to industry to implement (depends on specific controls), which may be passed on to consumers b. Costs to government and industry to implement and enforce c. May reduce consumer choice if some products are removed from the market d. Difficulty in identifying international best standards to adopt e. Consumers may continue to access poor quality products over the Internet f. Enforcement is passive, in response to complaints and product failures g. Regulator wouldn't know what products are on the market, whether they comply or who is responsible for compliance h. Enforcement would be in response to complaints and product failures/harm to health 	As for Alternative 1, <ul style="list-style-type: none"> i. Greater cost to industry regarding to notification

In conclusion, although making regulations or guidelines with notification would result in more costs to administrative departments within government and more costs to HNB industry, it is more proactive compared with the pre-market approach. In addition, notification would facilitate the regulator more power to deal with any breaches and guarantee compliance of the whole industry.

4.2. Sales regulation

The domain of regulation on sales contains the places in which HNB products could be sold and what age group of people could access HNB products. In terms of consumer age, three regions seem to reach a consensus that they all ban the sales to people under 18. However, Japan and the US set a higher age standard, which are 20 and 21. According to the current studies, there is little evidence showing what specific age would be the most appropriate for novel tobacco products. However, all the evidence insists that we should set a minimum age to protect the young people from harms and risks.

More importantly, three regions implement different approaches regarding the sales place. The question relies on whether HNB products should be sold in self-served channels, vendor machines and the Internet. Based on the case studies, the study team provide the following alternatives:

Alternative s	Alternative 1: no restriction (Japan)	Alternative 2: restrict vendor machine and e-shop and require manual operation by salesperson	Alternative 3: prohibit sales on vendor machine (UK) but online sales are allowed (US)
Pros	a. Increases smokers' access to HNB products	Limits potential risks to health from long-term HNB use, including addiction Limits potential risk of renormalization of smoking-like behavior among young people Allows access by minors who smoke, e.g., via parents in a private place	As for Alternative 2 a. Less costly to monitoring and supervision b. Save the cost of salespersons
Cons	a. Increases young peoples' access to HNB products	a. Reduce smokers' access to reduced harm products b. Limits size of market and potential for business growth c. More cost to industry	As for Alternative 2 (a., b.)

In conclusion, the study team would recommend the alternative 3. Considering the young people who are more frequently use the internet and vendor machine, opening these two sales channels would increase their access to HNB products. Although Alternative 2 provides a more open approach which allows access by smokers and setting the salespersons as the burden line for restriction, it would be harder for the regulator to monitor and for those salespeople to identify the qualified products and consumers.

4.3. Regulation on advertising, promotion and sponsorship

There is little evidence proving that advertising and promotion would affect smokers' decision-making on tobacco products. However, a randomized trial studying the effect of advertising on young people in the United States found that exposure to e-cigarette advertisements may enhance curiosity and limited trial of e-cigarettes in those who have never used them (Vilanti et al, 2015)

Based on regulations of three regions, the study team summarized three alternatives regarding advertising and promotion, which is illustrated as below:

Alternative s	Alternative 1: no restriction/ industry self-regulated (Japan)	Alternative 2: Prohibit all promotion and advertising, including sponsorship (UK)	Alternative 3: Exemption for physical store promotion, e.g. in-store display, free samples, rewards, discounts and co-packaging, and window displays (US)

Pros	<ul style="list-style-type: none"> a. Increases smokers' awareness of HNB products as a safer alternative to smoking b. Promotes potential for market growth and/or businesses to grow their market share 	<ul style="list-style-type: none"> a. Minimizes potential for HNB products to be seen as 'normal' consumer products b. Limits potential for downplay of risks to non-smokers c. Minimizes uptake by non-smokers d. Limits potential for long-term health risks e. Minimizes risk of renormalization of smoking-like behavior 	<ul style="list-style-type: none"> a. May encourage smokers to try new products which may be safer or more effective b. Minimizes potential for HNB products to be seen as a normal consumer product c. Increases potential for market growth and/or businesses to grow their market share
Cons	<ul style="list-style-type: none"> a. May downplay risks of HNB products for non-smokers b. May increase risk of uptake by non-smokers c. May increase risk of renormalization of smoking-like behavior d. May increase the likelihood of people continuing to smoke 	<ul style="list-style-type: none"> a. Limits smokers' awareness of less harmful alternative to smoking b. Restricts potential for market growth c. Restricts freedom of expression in relation to commercial activity 	<ul style="list-style-type: none"> a. May increase likelihood of non-smokers trying HNB products b. Potential difficulty defining 'specialist vape shop' c. Restricts freedom of expression in relation to commercial activity

In conclusion, rather using industry self-regulation which would likely make young people and non-smokers under the risk of getting addiction to smoking, it is necessary to implement restrictions on promotion of HNB products. Comparing the two approaches used by the UK and US, the study team recommended alternative 3. In particular, alternative 3 allows the flexibility of industry growth. At the same time of minimizing the risk of exposure to non-smokers and young people, alternative 3 allows the smokers to get acknowledgement of low-risk products as HNB.

4.4. Taxation

So far, there are very few studies on the responsiveness of novel tobacco product demand to price changes. However, surely, taxation would set a certain degree of pressure on the manufacture and consumption of traditional tobacco products. However, design and implementation of taxation are likely to be highly complex. Any duties would need to be set at a level that does not disincentivize smokers to switch, or increase inequalities in smoking prevalence and smoking-related disease.

Considering this issue simply, the alternatives might be whether the tax level on HNB products is lower than, or the same as traditional tobacco products.

Alternatives	Alternative 1: Lower than traditional tobacco products (Japan, UK)	Alternative 2: The same as traditional tobacco products (US)
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Pros	<ul style="list-style-type: none"> a. Encourage smokers to switch to HNB products b. Promote potential for market growth and/or businesses to grow their market share c. Reflect less risk of HNB than traditional cigarettes 	<ul style="list-style-type: none"> a. Make the non-smokers and the youth treat HNB the same as tobacco b. Less costly to administrative department if taking HNB the same as cigarette regarding tax
Cons	<ul style="list-style-type: none"> a. Increase inequality of fair trade between traditional tobacco and novel products b. Less tax revenues for the government 	<ul style="list-style-type: none"> a. Less incentive to smokers to switch to reduced harm products b. Less space for HNB industry growth

In conclusion, so far, the current information is not enough to support whether imposing duty and tax on cigarettes would help to reduce harm to the public health, or what taxation standards are set up specific to HNB products. However, the study team would recommend the alternative 1, setting a lower tax level than traditional tobacco. As HNB products at least are proved to be less harmful than the traditional tobacco, the government should give some degree of incentive for smokers to switch.

4.5. Usage regulation

As it has been argued that it is not reasonable to ban the supply of HNB while leaving the usage of HNB products free, it is necessary to discuss the approaches that other regions take regarding this regulation domain. The usage regulation covers for what group of people and at what place that the products can be used. As the group of people has been mentioned in the sales regulation, this section would put more effort into discussing the place of smoking.

Referring to the three cases that we choose, United Kingdom governments have not legislated to prohibit using HNB products in smoke-free areas. Public Health England has issued guidelines to assist employers, businesses and local authorities to decide their own environmental smoking policies.

In Japan, the government distinguishes HNB products and traditional tobacco regarding smoking place. Type A facilities, such as school and hospital are completely prohibited for smoking. However, the use of HNB products is allowed in Type B facilities, including restaurants, passenger ships and trains.

Different from Japan and UK, US takes a stricter approach regarding the smoke-free places for HNB products. As Section 3 mentions, HNB products like IQOS are treated the same as traditional tobacco regarding in what place they can be used. Therefore, based on those approaches, we formulate three options for this regulation domains, whose cost and benefits analysis are demonstrated as below:

Alternatives	Alternative 1: no restrictions on using HNB in legislated smoke-free areas (UK)	Alternative 2: enable a distinction to be drawn between HNB and tobacco products (Japan)	Alternative 3: Include HNB in smoke-free place policies (US)
Pros	<ul style="list-style-type: none"> a. May provide incentive for smokers to switch if they can vape where they can't smoke b. Businesses able to tailor policies to suit customer preferences/target market c. No costs on business to implement d. No cost to government to implement or enforce 	<ul style="list-style-type: none"> As for option 1 e. May reduce costs to business and local authorities by providing information to support decision-making, including clarity on the legal position. 	<ul style="list-style-type: none"> a. Employees and bystanders are not exposed to HNB emissions
Cons	<ul style="list-style-type: none"> a. May encourage 'dual use' – smokers smoke where they can, but otherwise use HNB, reducing incentives to quit b. May provide a trigger for ex-smokers to return to smoking or take up HNB c. Constrains business owners' choices on best use of their premises d. May be some cost to businesses to determine own policies, particularly if consultation required e. May appear inconsistent and confusing if using HNB is allowed in some places but not others, including outdoor areas which fall under local authorities' smoke-free policies f. Employees and bystanders exposed to HNB emissions g. Potential to renormalize smoking-like behavior 	<ul style="list-style-type: none"> As for option 1(e, f, g) 	<ul style="list-style-type: none"> a. May expose HNB users to second-hand smoke if required to use HNB outside alongside smokers b. May reduce incentives on smokers to switch to low-risk products like HNB c. Constrains business owners' and employers' choices on the best uses of their premises

In conclusion, our team recommend the Alternative 2, issue a distinction between HNB and tobacco products. Although in some cases, allowing using HNB in places that do not allow smoke traditional tobacco products would rise the potential to renormalize smoking-like behavior, and make people confused whether the place they can use HNB, it reduce the cost to business and local authorities by providing information to support their decision-making. In addition, the distinction also put an incentive to smokers to switch to HNB.

Section 5 - Recommendations to HNB Product Control

There has been a strong aversion from the government against the idea of HNB products and other reduced-risk tobacco products, but the analysis in this paper has brought us to a conclusion that in the government's pursuit of a perfectly safe solution, they may end up with a doctrinaire policy that does not hit the target of bringing the optimal value to society. This paper evaluated different regulatory approaches across different countries, and the observed policy outcomes in these jurisdictions tell us a paternalistic outright ban is not the answer. Now the question becomes what policies should be introduced to allow the products in the market, at the same time do enough to curb unintended consumption.

In this section, we present a set of recommendations to be executed by related stakeholders, including the Hong Kong government and players in the tobacco industry. Recommendations 1 to 3 are made in the perspective of regulators, which could be included in PMI's counterproposal to the government's current plan of a total ban. Point 4 identifies necessary changes in the tobacco industry's attitude towards corporate social responsibilities.

The government should bear the major responsibility in tobacco control and promotion of public health as the regulator, but the private sector's participation is equally important. Although there is a conflict of interest between the traditional nature of the tobacco industry and public health policies, emerging product innovation and industry transformation show us a common ground where reduced-risk tobacco products manufacturers and policymakers can agree on. The ultimate objective in the collaboration of government and HNB producers is to transform the society into a smokeless environment, by helping cigarette smokers quit, which switching to HNB products is empirically shown as a promising assisting tool. The industry's effort in providing less harmful alternatives with true social responsibility at heart is an integral part in creating a sustainable reduced-risk future. Each strategy is further broken down into actionable items, which stakeholders should evaluate further and commence in implementation.

5.1. HNB tobacco control as a subset in the current tobacco regulatory practice

Comparing with the international practices as summarized in our case study, Hong Kong's traditional tobacco control lies somewhat in the middle of the spectrum between light and heavy regulations. Although HNB products are still relatively new to the consumers in Hong Kong, we can reasonably predict a good acceptability for a similar level of control for HNB products, given that the health risks posed by traditional tobacco are even higher. The current tobacco control framework is largely still suitable to be used on HNB products, to restrict access and limit consumption:

Distribution channel control.

Only registered distribution channels are allowed to sell, to limit accessibility of the products. HNB products could be distributed through the same restricted outlets that are currently

selling traditional cigarettes. Sale of HNB products from a vending machine is also prohibited.

Ban on advertising, promotion and sponsorship; restrictions in branding.

Advertising and marketing restriction will remain a major component of the framework, in an effort to reduce appeal and exposure to youth. Current laws strictly prohibit advertisements and promotions of tobacco, which can be implemented on HNB products in the same manner to sufficiently control exposure to consumers. A different set of health warnings shall be created to suit the health concerns of HNB products, which must cover at least 85% of the surface area of packaging. Consumer information on the packaging needs to be accurate and without misleading branding that implies health benefits.

Statutory no-smoking areas.

HNB products will still fall under the *Fixed Penalty (Smoking Offences) Ordinance*, which its consumption will be prohibited in statutory no-smoking areas. This aims to minimise any effects to non-users, at the same time make it less convenient for consumption. Same as traditional tobacco smoking, any violation will be given a penalty of HKD 1,500.

Tax.

According to the *Dutiable Commodities Ordinance (Cap. 109)*, traditional tobacco is currently subject to tax which is reflected in market prices. HNB products shall be taxed, which remains a way to discourage end-user consumption as prices are kept high. Tax revenue, which would otherwise be lost under a total ban, could be injected back into the ecosystem to fund tobacco control activities and research. As presented in section 4, how much we should tax HNB products remains in question as not many studies have explored the quantifiable effects of taxation in tobacco. How heavy the products are taxed should correspond to the health risks that they present (House of Commons, Science and Technology Committee, 2018), to discourage harmful consumption. Applying this logic, HNB products should be taxed, but at a lower rate than traditional cigarettes, to help smokers switch from conventional combustible cigarettes to HNB products. Further economic analysis should be conducted to examine this proposal before implementation.

To strengthen the framework for effective gatekeeping to ensure product safety, the following items, which were not applied on traditional tobacco control, shall be included to the HNB products regulations:

Stringent premarket reviews.

Before the products can be released to the market, science-based approval will be needed for authorization with key considerations such as the product must produce fewer or lower levels of toxins than traditional combustible cigarettes, and that the electric heating devices are safe to use. Legislation should grant the government authority to require manufacturers to provide a complete list of ingredients, additives, and demonstrate that each ingredient is safe in quantity under conditions of intended use. The government should also have the authority to publicise this information in a manner that does not disclose legitimate trade secrets, as consumers have the rights to know what substances they are consuming.

Strict monitoring on product compliance.

After the products are released to the market, regular product inspections shall be performed to ensure all guidelines are strictly followed. The government will retain the rights to take down certain products if any violation is found. While the government can require manufacturers to conduct mandatory post-market surveillance on consumer' behavior, product uptake and health like what the United States is currently doing, we recommend the government conduct their own market surveillance to prevent questions on the validity of observation due to potential conflict of interest.

5.2. Introducing HNB products as a tool in smoking cessation services

In a comparative research published in 2019, a randomized trial showed that e-cigarettes are almost twice as effective as traditional nicotine-replacement therapies (i.e. patch, gum, nasal spray, mouth spray, mouth strip, and microtabs) in helping individuals quit smoking (Hajek, Phillips-Waller, Dunja, et al., 2019). Behavioral scientists hypothesize that, the way reduced-risk smoking products mimic the gesture of traditional smoking, including HNB products and e-cigarettes as demonstrated in the comparative study, would aid smoking cessation, as part of the addiction is about the physical habit of holding and consuming cigarette sticks. As discussed in the previous sections, most current HNB product users are smokers who want to quit. Although so far there is limited research on the psychology and behavioral science of how reduced-risk products impact smoking cessation, existing empirical evidence still justifies a cautious trial to give smoking cessation advisers, addiction specialists and doctors the option to offer HNB products to patients who find nicotine replacement products ineffective and struggle to quit cigarette smoking. Given that the products are prescribed by medical or behavioral sciences professionals with close monitoring of the patients, the risk of potential product abuse is low. This will also allow collection of local data and insights for further research to determine the effectiveness in achieving complete cessation.

5.3. Continuous research to support evidence-based policymaking and nurture a base of experts to cope with emerging issues

As suggested in the literature review section, regulators' fear for HNB products, or in fact alternative smoking products in general, stem from the feelings of uncertainty, often leads to cognitive biases that impair effective policymaking. More research on HNB products is necessary to provide evidence to develop better measurement of the constituents and impact of HNB products to draw better public health implications. It should be a priority for the government to support research on the long-term health effects of HNB products consumption, impact of HNB products on population-level overall smoking rates and nicotine dependence, and the likelihood of dual-use of HNB and traditional tobacco products. However, an internal constraint is that the capacity within the government may not be adequate to understand technical aspects of tobacco products. Therefore we highly recommend the government to establish a collaborative relationship with research institutes and universities, formulate teams of experts of different disciplines, fully support and fund continuous research on reduced-risk tobacco/smoking products to inform future policymaking.

Since HNB and reduced-risk smoking products are still relatively new, there could be more issues emerging. Even if the government capacity and expertise is sufficient to design and launch a new regulatory process, it may require a broader base of experts and scientists to cope with future challenges. Therefore the government must nurture a larger base of expert assistance to maintain sustainable governance.

5.4. PMI: a strategy to move towards a better reputation and higher acceptability

The interests of the tobacco industry are inherently in conflict with public health. Scepticism over the industry's involvement and role in harm reduction would create tensions between the scientific, industry and political communities on the issue of related products. As a result, even though PMI and the tobacco industry have much valuable knowledge from their R&D to share, acceptability has been low as people remain skeptical to the reality behind how the industry frames the image of HNB products. However if the government is to adopt our first recommended policy, a stringent pre-market review with strict safety and quality standards although sets a higher barrier from market entry, the scrutiny itself is a credible recognition of IQOS, proving to consumers PMI's reliability and innovative value. This could be an opportunity rather than an obstacle.

On the other hand, instead of aggressively advocating the use of HNB products under the "harm reduction" moniker to lobby for lenient tobacco control and product uptake, PMI can better rehabilitate their reputations by devoting effort to convey the message of how they further improve the quality and safety of these new products. Instead of trying to prove people's first impression wrong by publishing almost one-sided arguments for the benefits of HNB products, more focus could be put into emphasising product safety and the high transparency PMI exercises over its robust quality control.

Conclusions

While there is yet to be a consensus whether HNB and reduced-risk smoking products in general facilitate or jeopardize existing tobacco control and prevention efforts, our research has come to the conclusion that the Hong Kong government should refrain from adopting an approach on the extremely paternalistic end of the policy spectrum. This paper provided a dissection of factors behind different attitudes towards HNB products, a comparative evaluation of international policies through case studies, and a policy package which the Hong Kong government shall begin to implement. Three concluding remarks are as follow:

First and most importantly, to bring the greatest positive impact to society, a well planned and strictly enforced control policies and regulations is far more effective than an outright ban. A ban is weakly supported by existing evidence and international practices. Given the potential negative consequences, prominently the emergence of unregulated illicit markets, disruption to economic value chains, uncaptured tax revenue, and restriction of consumer choices, a total ban is not justified for the objectives to optimize social benefits and safeguard public health.

Second, as motivated as the government is in combating smoking, a hard ban on HNB products is unlikely to solve the problem from its root based on behavioural sciences. Except for the addictiveness of nicotine, smokers are unconsciously attached to the gesture of smoking, and the social aspect of the habit. While it is much harder to totally quit smoking than opting for a less harmful type of tobacco, smokers who are trying to quit or at least to cut down on cigarette consumption would switch to the less harmful HNB product. If HNB products are eliminated from the market, it would in turn have HNB product users fall back to their old habit of smoking combustible cigarettes, which are even more harmful to public health. Therefore, banning HNB products as a way to reduce smoking is simply not justified.

Last but not least, given the cultural and political context of Hong Kong, it is doubtful that a hard ban will ever be successful in its implementation. Public trust in the Hong Kong government has been decreasing, we should take into consideration how likely people will comply with a harsh law that takes away freedom and rights to choose. Furthermore, the border between Hong Kong and China is highly porous that it would be very challenging to prevent and tackle illicit market transactions. Consumers' safety could be compromised if faulty or poor-quality products are sold under the counter.

Despite the government and some advocating groups' effort in promoting a total ban, they should take into consideration different aspects of policy consequences. An outright ban might be the most straightforward, but it would be a short-sighted approach that only tackles the surface of a problem. Potential pros and cons of a decision should be evaluated comprehensively to anticipate side effects associated with policy actions. Further research shall be conducted to support the design of HNB products and/or reduced-risk tobacco control framework to the specific details.

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