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GEORGETOWN LAW



E-cigarette Regulation and Harm Reduction: The Case of Hong Kong

SHUE SING CHURK*

I. ABSTRACT

Harm reduction is an internationally recognized tobacco control strategy. E-cigarettes, being a less harmful alternative to smoking, have the potential to achieve harm reduction. Within this context, this article critiques Hong Kong's legal regime governing e-cigarettes and the proposed prohibition of the product. It is argued that the current law is uncertain and inadequate. Although a reform of laws relating to e-cigarettes is needed, it is argued that banning the product altogether as a means to reducing the harm of tobacco use is unsupported by evidence.

II. INTRODUCTION

An e-cigarette is a product that operates by applying heat to a liquid that may or may not contain nicotine, delivering a vapor to be inhaled by the user.¹ The product is mostly used as a substitute for conventional cigarettes,² but it does not involve burning tobacco. E-cigarettes have been commercialized since the early 2000s, and are rapidly gaining popularity around the world.³

As the health effects of e-cigarettes have become subject to increasingly intense investigations, a consensus is emerging from scientific research that e-cigarettes are overall, less harmful to health than conventional cigarettes (see section 4A below). Some experts are in favor of the use of e-cigarettes as a smoking cessation aid. Even the World Health Organization (WHO), which administers the stringent Framework

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¹ For a description and history of e-cigarettes, see John Britton & Ilze Bogdanovica, *Electronic Cigarettes: A Report Commissioned by Public Health England*, PUBLIC HEALTH ENGLAND § 2 (May 2014), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf.

² Donald S. Kenkel, *Healthy Innovation: Vaping, Smoking, and Public Policy*, 2 J. POL'Y ANALYSIS & MGMT. 473, 474–75 (2016).

³ Lauren Davidson, *Vaping Takes Off as E-Cigarette Sales Break Through \$6bn*, TELEGRAPH, Jun. 23, 2015, <http://www.telegraph.co.uk/finance/newsbysector/retailandconsumer/11692435/Vaping-takes-off-as-e-cigarette-sales-break-through-6bn.html>.

Convention on Tobacco Control (FCTC), does not rule out the public health opportunities that e-cigarettes may create.⁴

Different jurisdictions diverge as to their regulatory response to e-cigarettes, which range from treating them as normal consumer goods, to treating them as pharmaceutical products, through to imposing outright bans. However, in many cases the legislation affecting e-cigarettes is old and was developed long before these products were available.⁵ As will be shown below, the various statutes purported by the Hong Kong government to apply to e-cigarettes are such an example. While admittedly a need has arisen for new regulations addressing quality and other issues concerning e-cigarettes, often, as in the case of the twenty-five countries currently banning e-cigarettes, policymakers have been informed by the minimal-tolerance attitude toward tobacco products advocated by the WHO.⁶ If this purist approach is extended to a less harmful alternative, one might wonder how it is consistent with the harm reduction objective of most tobacco control regulation.

In Hong Kong, the current legal regime, including the Pharmacy and Poisons Ordinance and the Smoking (Public Health) Ordinance, does not directly address e-cigarettes, thus presenting a high degree of uncertainty when it is applied to the product. Recognizing the need for regulatory reform, the government recently submitted a paper to the legislative body stating its intention to prohibit the import, manufacture, sale, distribution, and advertising of e-cigarettes.⁷ Its rationales being that e-cigarettes are apparently harmful, that e-cigarettes may induce young people to turn to smoking, and that it is “the recommendation of the WHO.”⁸

This article first examines Hong Kong’s current regulatory framework relating to e-cigarettes. The government’s proposal to ban e-cigarettes and the justifications relied on by the government to put forward the proposal will then be scrutinized. It is concluded that in light of available evidence and the stated objective of reducing the harm of tobacco use, together with the availability of models of comprehensive e-cigarette regulations, the prohibition of e-cigarettes is not an appropriate regulatory response.

III. TOBACCO CONTROL AND E-CIGARETTE REGULATION: TRENDS AND OBJECTIVES

Regulation on e-cigarettes should be understood in the context of the broader regulatory environment of conventional tobacco products. Recognizing the harm caused by tobacco products, WHO is leading a global united front against tobacco use. Most prominently, it championed its Framework Convention on Tobacco Control

⁴ WORLD HEALTH ORG., *Electronic Nicotine Delivery Systems*, ¶ 2 (Sept. 1, 2014), http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1.

⁵ With the notable exceptions of FDA’s new rule on e-cigarettes and the recently amended European Union Tobacco Products Directive, to be discussed below.

⁶ This is best reflected in the WHO Framework Convention on Tobacco Control, to be discussed in section 2 below.

⁷ Legislative Council Panel on Health Serv., *Progress of Tobacco Control Measure*, LC Paper No. CB(2)1456/14-15(07) (2015), <http://www.legco.gov.hk/yr14-15/english/panels/hs/papers/hs20150518cb2-1456-7-e.pdf>.

⁸ *Id.* at 6–7.

(FCTC), adopted by 180 parties as of July 2016,⁹ as a “milestone in public health,”¹⁰ with “nearly 80% of Parties [having] adopted or strengthened” tobacco regulation following ratification.¹¹

Article 3 of the FCTC states that its objective is to protect people against “the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented.”¹² The FCTC introduces both price (e.g., duty on tobacco) and non-price measures (e.g., reducing second-hand smoke and health warning requirements) to reduce the demand for and supply of tobacco products.¹³ The FCTC emphasizes that it does not “prevent a Party from imposing stricter requirements” about tobacco control.¹⁴

With the introduction of “plain packaging” regulation¹⁵ and the subsequent defeat of tobacco companies in legal challenges against the same in Australia¹⁶ and in the United Kingdom,¹⁷ strict tobacco regulation has gained momentum. The WHO decried in the wake of these victories that “the tobacco industry is not a respectable player.”¹⁸ The FCTC also explicitly states that smoking control policies should be protected from “commercial and other vested interests of the tobacco industry,”¹⁹ and WHO has specifically made certain guidelines on this provision,²⁰ recommending, among other things, that the parties “limit interactions” with the industry.²¹

It is not inconceivable that this general hostility toward tobacco products and the tobacco industry may influence policymakers when they formulate regulation on e-cigarettes. Although the FCTC does not mention e-cigarettes, in 2012, the WHO

⁹ U.N. Treaty Collection, *WHO Framework Convention on Tobacco Control* (May 11, 2003), https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtsg_no=IX-4&chapter=9&clang=_en.

¹⁰ WORLD HEALTH ORG., *2014 Global Progress Report on Implementation of the WHO Framework Convention on Tobacco Control*, v (2014), <http://www.who.int/fctc/reporting/2014globalprogressreport.pdf?ua=1>.

¹¹ *Id.*

¹² World Health Organization Framework Convention on Tobacco Control art. 3, May 21, 2003, 2302 U.N.T.S. 166.

¹³ *Id.* art. 6–17.

¹⁴ *Id.* art. 2.1.

¹⁵ Plain packaging (or standardized packaging) regulation prohibits nearly all branding on cigarette packaging, and mandates the use of health warnings that occupy most of a cigarette pack. *See generally* Becky Freeman et al., *The Case for the Plain Packaging of Tobacco Products*, 103 ADDICTION 580 (2008).

¹⁶ *JT International SA v. Commonwealth*, [2012] HCA 43 (Austl.).

¹⁷ *British American Tobacco v. Secretary of State for Health* [2016] EWHC (Admin) 1169 (UK).

¹⁸ World Health Org., *EU, UK and India Victories Show That the Tobacco Industry is Not a Respectable Player*, <http://www.who.int/fctc/mediacentre/news/2016/legal-victories-against-tobacco-industry/en/>.

¹⁹ WHO Framework Convention on Tobacco Control, *supra* note 12, art. 5.3.

²⁰ World Health Org., *Guidelines for Implementation of Article 5.3* (2008), http://www.who.int/fctc/treaty_instruments/Guidelines_Article_5_3_English.pdf?ua=1.

²¹ *Id.* at 3.

expressed the view that various articles of the FCTC are applicable to e-cigarettes.²² The WHO's claims include: e-cigarettes "undermine the denormalization of tobacco use,"²³ that e-cigarettes "contribute to maintaining an addiction to nicotine,"²⁴ and, perhaps most unfortunately, that e-cigarette use, like tobacco advertisement, promotes smoking.²⁵

Harm reduction is apparently an approach endorsed by the FCTC.²⁶ Article 3 explicitly states that FCTC's objective is to protect people from the "devastating consequences" caused by tobacco use. To achieve this, it provides a framework for "tobacco control measures" to be implemented by parties, and the definition of the term "tobacco control measures" includes "harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke."²⁷

Given the relative harm of e-cigarettes compared to conventional cigarettes, as will be discussed in section 4A below, the WHO's attitude toward e-cigarettes is difficult to understand. Although it has fallen short of recommending a complete ban of e-cigarettes, and more recently it also recognized, however reluctantly, that e-cigarettes may bring about the "promise" of being "a pathway to the reduction of tobacco smoking,"²⁸ the relationship between the product and the FCTC's objective of reducing the harm of tobacco consumption has not been fully explored.²⁹ Its sweeping claims about how e-cigarettes would undermine the FCTC also appear to be a departure from the FCTC's stated "evidence-based" approach.³⁰

According to a 2015 WHO report, twenty-five countries (many in Middle and South America as well as the Middle East)³¹ had legislation banning e-cigarettes sales.³² Compared with many other countries with some form of e-cigarette regulations in place,³³ this number is still surprisingly high if indeed harm reduction is the objective. Some commentators do observe that "there has never been a serious discussion within the tobacco control community about what would constitute a final victory in tobacco

²² WORLD HEALTH ORG., *Electronic Nicotine Delivery Systems, Including Electronic Cigarettes: Report by the Convention Secretariat* (June 18, 2012), http://apps.who.int/eb/fctc/PDF/cop5/FCTC_COP5_13-en.pdf.

²³ *Id.* ¶ 33; cf. WHO Framework Convention on Tobacco Control, *supra* note 12, art. 12.

²⁴ World Health Org., *supra* note 22, ¶ 34; cf. WHO Framework Convention on Tobacco Control, *supra* note 12, art. 5.2(b).

²⁵ WORLD HEALTH ORG., *supra* note 22, ¶ 35.

²⁶ ROYAL COLL. OF PHYSICIANS, *Nicotine Without Smoke: Tobacco Harm Reduction* § 11.5 (2016), <https://www.rcplondon.ac.uk/file/3563/download?token=uV0R0Twz>.

²⁷ WHO Framework Convention on Tobacco Control *supra* note 12, art. 1(d).

²⁸ WORLD HEALTH ORG., *supra* note 4, ¶ 2.

²⁹ However, the issue surrounding e-cigarettes is expected to be discussed in the upcoming FCTC Conference of the Parties. See ROYAL COLL. OF PHYSICIANS, *supra* note 26.

³⁰ World Health Organization Framework Convention on Tobacco Control, *supra* note 12, v–vi.

³¹ See GLOBAL TOBACCO CONTROL COUNTRY COMPARISON DATABASE, <http://globaltobaccocontrol.org/e-cigarette/country-comparison-database>.

³² WORLD HEALTH ORG., *WHO Report on the Global Tobacco Epidemic, 2015: Raising Taxes on Tobacco* 88 (2015), http://www.who.int/entity/tobacco/global_report/2015/report/en/index.html.

³³ *Id.*

control,”³⁴ that is to say, the question of whether the tobacco “endgame” should entail the elimination of all forms of smoking. This debate could influence policymakers’ attitudes toward e-cigarettes, a product that may potentially perpetuate nicotine consumption. It is, however, not the intention of this article to contribute to this debate. Instead, it seeks to explore, using the example of Hong Kong, how the regulation of e-cigarettes may be relevant to the FCTC’s unambiguous objective to achieve harm reduction stated in Article 3.³⁵

Having said that, there may be a need for countries to update their local regulations as applied to a new product such as e-cigarettes, as will be demonstrated below using Hong Kong’s example. Zhu et al. reported that 30 to 50 percent of e-cigarette sales were conducted on the internet.³⁶ Hong Kong local media also reported the prevalence of e-cigarettes of questionable quality imported from unidentified sources through mainland Chinese e-commerce platforms.³⁷

However, quality issues and the need to fill the regulatory vacuum that exists for e-cigarettes should not be conflated with the question of whether the product should be legal. Based on current evidence, allowing technological innovation to make e-cigarettes a more satisfying alternative to smokers³⁸ along with robust quality control measures would appear to be more consistent with the harm reduction objective of tobacco regulation.

Models of comprehensive evidence-based e-cigarette regulation are already available. For example, the United States, while not a party to the FCTC³⁹ and while suffering setbacks in tobacco control due to successful legal challenges by the tobacco industry,⁴⁰ has recently made significant progress in e-cigarette regulation. In May 2016, the Food and Drug Administration (FDA) issued a deeming regulation which made e-cigarettes subject to the Federal Food, Drug, and Cosmetic Act.⁴¹ Certain requirements originally applicable to cigarettes have now been extended to e-cigarettes, including the requirement to submit ingredient lists, the registration requirement of product manufacturing establishments and of product listings, the prohibition against certain descriptors and the distribution of free samples, and pre-market review requirements.⁴² In addition, age restrictions and health warning

³⁴ Kenneth E. Warner, *An Endgame for Tobacco?*, 22 TOBACCO CONTROL i3 (2013).

³⁵ WHO Framework Convention on Tobacco Control, *supra* note 12.

³⁶ Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3 (2014).

³⁷ 【電子煙之害】加果味扮潮物 攻陷小學界, APPLE DAILY (Hong Kong), May 21, 2016, <http://hk.apple.nextmedia.com/realtime/breaking/20160521/55131469>.

³⁸ Terry F. Pechacek et al., *The Potential That Electronic Nicotine Delivery Systems Can be a Disruptive Technology: Results From a National Survey*, 00 NICOTINE & TOBACCO RES. 1, 1 (2016).

³⁹ United Nations Treaty Collection, *supra* note 9.

⁴⁰ See *RJ Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).

⁴¹ Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,973 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).

⁴² *Id.* at 28,976.

requirements will also be imposed on e-cigarette products.⁴³ FDA justified these rules with the risks posed by nicotine addiction,⁴⁴ but also noted that it “believes that the inhalation of nicotine (i.e., nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products.”⁴⁵ FDA also considered the relationship between the deeming regulation and tobacco control in general. It stated that the rules would afford “additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use,”⁴⁶ for example by allowing FDA to obtain information about health risks of tobacco products.⁴⁷

FDA’s regulation, together with the latest amendments to the European Union’s (EU’s) Tobacco Products Directive which now specifically covers e-cigarettes (to be discussed below), may serve as a model of rational policy making for countries currently contemplating an outright ban on e-cigarettes.

IV. THE CURRENT REGULATORY FRAMEWORK IN HONG KONG

Currently, Hong Kong’s government claims that legislation relating to pharmaceutical products and tobacco products applies to e-cigarettes. These statutes do not address e-cigarettes directly at all. As a result, there are no rules about e-cigarettes’ content, and no sales or advertising restrictions. Also, as will be demonstrated below, the application of the current legislation to e-cigarettes presents a high degree of legal uncertainty.

The following subsections discuss three pieces of legislation enforced by three different government agencies—the Pharmacy and Poisons Ordinance administered by the Pharmacy and Poisons Board, the Smoking (Public Health) Ordinance administered by the Tobacco Control Office, and the Consumer Goods Safety Ordinance administered by the Customs and Excise Department—all may or may not apply to e-cigarettes.

A. *E-cigarettes and Laws Governing Poisons and Medicines*

The first area of uncertainty is the application of the Pharmacy and Poisons Ordinance (Cap 138) to e-cigarettes. Depending on whether e-cigarettes should be classified as a “medicine” or a “pharmaceutical product” (the two terms bear the same meaning in the Ordinance),⁴⁸ different requirements may be applicable. Basically, nicotine, being a substance found in the Poisons List compiled by the Pharmacy and

⁴³ *Id.*

⁴⁴ *Id.* at 28,981.

⁴⁵ *Id.*

⁴⁶ *Id.* at 28,975.

⁴⁷ *Id.*

⁴⁸ Pharmacy and Poisons Ordinance, (2015) Cap. 138, 1, § 2(1) (H.K.).

Poisons Board⁴⁹ with the approval of the Secretary for Food and Health,⁵⁰ is categorized as a “poison”⁵¹ within the meaning of the law. Stringent restrictions normally apply to dealing with poisons, but these restrictions are relaxed to some extent if the particular poison is also a pharmaceutical product if marketed as such; but in the latter case, some additional requirements would apply. A medicine, or pharmaceutical product, must be registered with the Pharmacy and Poisons Board before it may be available for sale.⁵² The safety, efficacy, and quality of a product are the primary factors to be considered in an application for registration.⁵³

Except when used in certain ways in nicotine replacement therapy,⁵⁴ nicotine is classified as a Part 1 poison. According to the Ordinance, Part 1 poisons shall only be sold on premises of an authorized seller of poisons (i.e., pharmacies and dispensaries)⁵⁵ by a registered pharmacist or in their presence and under their supervision.⁵⁶ Possession of Part 1 poisons is prohibited “otherwise than in accordance with the provisions of this Ordinance.”⁵⁷ Part 1 poisons shall be labelled as “poison” upon sale.⁵⁸ Since nicotine is also a substance found in Schedule 1 (but not Schedule 3) of the Pharmacy and Poisons Regulations (Cap 138A),⁵⁹ section 22 of the Ordinance applies to the substance⁶⁰ and therefore it must therefore be sold by a fit and proper person;⁶¹ and the name, identity card number, and address of any purchaser shall be entered into a poisons book before sale.⁶²

However, the above restrictions applicable to Part 1 poison do not apply if the relevant Part 1 poison is a “medicine” supplied by a medical practitioner or an authorized seller of poisons under specified circumstances.⁶³

⁴⁹ The composition of the Pharmacy and Poisons Board is stipulated in Pharmacy and Poisons Ordinance, (2015) Cap. 138, 3, § 3(2) (H.K.). The board consists mostly of members with professional qualifications in medicine, pharmacology, or pharmacy.

⁵⁰ *Id.* at 3, § 29(1B)(a).

⁵¹ “Poison” is defined as a substance which is specified in the Poisons List. *Id.* at 3, § 2(1).

⁵² Pharmacy and Poisons Regulations (Cap 138A) Reg. 36(1).

⁵³ Pharmacy and Poisons Regulations (Cap 138A) Reg. 37(1).

⁵⁴ The exceptions are nicotine when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy. *Id.*

⁵⁵ The use of the terms “pharmacy” and “dispensary” is restricted only to the premises of an authorized seller of poisons. Pharmacy and Poisons Ordinance, (2015) Cap. 138, 14, § 20(3) (H.K.).

⁵⁶ *Id.* at 14, § 21.

⁵⁷ *Id.* at 15, § 23(1).

⁵⁸ *Id.* at 16, § 27.

⁵⁹ Except when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy. Pharmacy and Poisons Regulations (Cap 138A) Sch 1.

⁶⁰ Pharmacy and Poisons Regulations (Cap 138A) reg 3.

⁶¹ Pharmacy and Poisons Ordinance, (2015) Cap. 138, 15, § 22(1) (H.K.).

⁶² *Id.* at 15, § 22(3).

⁶³ *Id.* at 17, § 28(1).

It is highly debatable whether e-cigarettes are a “medicine” as defined in the Pharmacy and Poisons Ordinance. This definition was amended recently in February 2015⁶⁴ to accord with European law.⁶⁵ The new definition is as follows:⁶⁶

pharmaceutical product and medicine mean any substance or combination of substances—

- (a) presented as having properties for treating or preventing disease in human beings or animals; or
- (b) that may be used in, or administered to, human beings or animals, either with a view to—
 - (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
 - (ii) making a medical diagnosis

Products falling within the scope of the definition’s two prongs are referred to as medicinal products “by presentation” (i.e., part (a) of the definition) and “by function” (i.e., part (b) of the definition) respectively. As manufacturers seldom make claims that e-cigarettes have therapeutic properties,⁶⁷ the first prong is unlikely to apply.⁶⁸ Whether e-cigarettes are medicines by function is a more complicated question. However, as the definition in the Pharmacy and Poisons Ordinance is a word-for-word adoption of Directive 2001/83/EC,⁶⁹ European case law may be instrumental in its interpretation.

The European Court of Justice (ECJ) has held that in determining whether a product falls within the definition of a medicinal product by function, one must proceed on a case-by-case basis taking account of all the characteristics of the product.⁷⁰ A product may not be a medicinal product simply by virtue of its being capable of “modifying” physiological functions: it must also entail immediate or long-term beneficial effects

⁶⁴ Pharmacy and Poisons (Amendment) Ordinance, (2015) § 4(3) (H.K.).

⁶⁵ Food and Health Bureau, *Legislative Council Brief: Pharmacy and Poisons (Amendment) Bill 2014* ¶ 4 (March 19, 2014) http://www.legco.gov.hk/yr13-14/english/bills/brief/b201403211_brf.pdf.

⁶⁶ Pharmacy and Poisons Ordinance, (2015) Cap. 138, 1, § 2(1) (H.K.).

⁶⁷ But certain manufacturers are developing e-cigarettes claimed to be medicines for quitting smoking. See e.g., Ben Hirschler, *BAT’s novel e-cigarette rival wins UK medical approval*, Reuters (Sept. 12, 2014), <http://uk.reuters.com/article/uk-health-ecigarettes-brit-am-tobacco-idUKKBN0H70R220140912>; Nicovations, *Announcing Voke, a Safer Alternative to Smoking, Licensed by the Medicines and Healthcare Products Regulatory Agency*, (Sept. 12, 2014), <http://www.nicovations.com/announcing-voke-safer-alternative-smoking-licensed-medicines-and-healthcare-products-regulatory>.

⁶⁸ See also Clive Bates, *Are E-cigarettes Medicines?*, (Mar. 28, 2013), <http://www.clivebates.com/documents/areecigsmedicines.pdf>, for a discussion of the argument that e-cigarettes make “implicit” therapeutic claims.

⁶⁹ Cf. Council Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use [2001] O.J. (L 311) 1, 2.

⁷⁰ Joined Cases C-211/03, C-299/03, and C-316-03 to C-318/03 HLH Warenvertrieb and Orthica, 2005 E.C.R. I-5141, ¶ 30.

for human health.⁷¹ As a result, synthetic cannabinoids were not classified as a medicinal product despite being psychoactive.⁷²

Relying on ECJ case law, among other things, the German Federal Administrative Court held in 2014 that e-cigarettes are not medicinal products by function under Germany's local law which adopts Directive 2001/83/EC.⁷³ The court held that an overall assessment shows that liquids used in e-cigarettes are food products rather than medicinal products, despite nicotine's pharmaceutical effects.⁷⁴ The court noted that e-cigarettes closely resemble conventional cigarettes in a number of ways, come with a variety of flavors intended to taste good, and that the liquids only provide temporary relief from withdrawal symptoms, but do not have therapeutic purposes.⁷⁵

Despite the foregoing line of authority, the Hong Kong government appears to be of the view that e-cigarettes containing nicotine fall within the definition of "pharmaceutical product,"⁷⁶ presumably by function. It is unclear whether this view applies to e-liquids only, or any other component of an e-cigarette, or an e-cigarette in its entirety. But it is highly unlikely that the definition of "pharmaceutical product," properly interpreted, would extend to the non-chemical parts of an e-cigarette.⁷⁷ First, the term "substance" is defined in Directive 2001/83/EC (albeit not in the Pharmacy and Poisons Ordinance) to mean any matter of human, animal, vegetable, or chemical origin.⁷⁸ Second, Europe has enacted a separate Medical Devices Directive to regulate "instruments," "appliances," and other articles for medical use.⁷⁹ Clearly Directive 2001/83/EC is not intended to cover these.⁸⁰ It therefore appears that the definition of "pharmaceutical product" would, at most, only cover e-liquids containing nicotine, but not other components of an e-cigarette.

B. *E-cigarettes and Smoking Control Laws*

For the most part, Hong Kong's Smoking (Public Health) Ordinance (Cap 371) generally only applies to tobacco products. Hence, the health warning requirements, advertising restrictions, and the restrictions on sales to minors that are applicable to cigarettes and other tobacco products all do not apply to e-cigarettes.

⁷¹ Joined Cases C-358/13 and C-181/14 *Markus D and G* (Fourth Chamber, 10 July 2014) ¶ 33.

⁷² *Id.* ¶ 2.

⁷³ BVerwG 3 C 25.13, OVG 13 A 2448/12 (November 20, 2014).

⁷⁴ See Jenny Gesley, *Germany: Electronic Cigarettes 4*, The Law Library of Congress, (Jul. 2015), <https://www.loc.gov/law/help/electronic-cigarettes/germany-electronic-cigarettes.pdf>.

⁷⁵ *Id.*

⁷⁶ Panel on Health Services, *Minutes of Meeting Held on Monday, 18 May 2015, at 4:30 pm* ¶ 50, LC Paper No. CB(2)211/15-16, <http://www.legco.gov.hk/yr14-15/english/panels/hs/minutes/hs20150518.pdf>.

⁷⁷ Under the FDA regulatory regime, a product comprised of two or more regulated components, e.g., drug/device, is classified as a combination product. Federal Food, Drug, and Cosmetic Act, 21 CFR 3.2(e)(1) (2005). No similar concept exists in Hong Kong law.

⁷⁸ Council Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] O.J. (L 311) 1, 3.

⁷⁹ Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices [1993] O.J. (L 169) 1, 3.

⁸⁰ Note, however, that Hong Kong has no specific legislation that regulates medical devices. Medical Device Control Office, *Frequently Asked Questions*, <http://www.mdco.gov.hk/english/faq/faq.html#gen01>.

An exception may be the provisions on no smoking areas, where the definition of “smoking” comes into play. Specifically, section 3(2) of the Ordinance provides that “[n]o person shall smoke or carry a lighted cigarette, cigar or pipe in a no smoking area.”⁸¹

As defined in the Ordinance, the verb “smoke” means “inhaling and expelling the smoke of tobacco or other substance.”⁸² According to the Secretary for Food and Health, the definition means that “[the] smoking of [e-cigarettes] or similar products in a statutory no-smoking area constitutes an offence.”⁸³ This interpretation has two weaknesses.

First, the dictionary definition of the noun “smoke” (as is used in the statutory definition of the verb “smoke”) may not encompass vapor, which is what is inhaled and expelled by an e-cigarette smoker. For example, according to an online dictionary, “smoke” means “a visible suspension of carbon or other particles in air, typically one emitted from a burning substance.”⁸⁴ If the meaning of the noun “smoke” is taken more widely to include vapor, then it would lead to the absurd outcome that diners at a Chinese hotpot restaurant commit an offence by inhaling and expelling water vapor.

Second, it is unclear whether the word “smoke” in section 3(2) is used as a transitive or intransitive verb. If it is the former, to “smoke a lighted cigarette, cigar or pipe in a no smoking area,” rather than to “smoke in a no smoking area,” is made an offence. This is not an implausible interpretation as it neatly avoids the above absurd result. Also, as mentioned, all other parts of the Smoking (Public Health) Ordinance seek to regulate tobacco products. An interpretation of section 3(2) that makes it such that it creates an offence relating to the smoke of any “other substance” appears to be incongruent with the purpose of the legislation.

A limitation of the interpretation that treats the word “smoke” in section 3(2) as a transitive word is that this is not supported by the Chinese text of the law, which is equally authentic as the English text.⁸⁵ According to the Ordinance, the word “smoke” may correspond to either *xiyan* or *xiyong* in Chinese, the former being the intransitive and the latter being the transitive form, and the former is used in section 3(2). As the provisions in the two texts are presumed to have the same meaning,⁸⁶ the unambiguous meaning expressed by the Chinese text should prevail when there is ambiguity in the English text.⁸⁷

Nevertheless, if inhaling and expelling water vapor in a hotpot restaurant does not count as smoking, it is difficult to imagine the legislature intended in 1982 when the Smoking (Public Health) Ordinance was enacted that the definition of “smoking” should cover the use of a product which did not even exist. Because of the above omission in the drafting of the Chinese text, if e-cigarette users are prosecuted (for an

⁸¹ Smoking (Public Health) Ordinance, (2012) Cap 371, 1, § 3(2) (H.K.).

⁸² Smoking (Public Health) Ordinance, (2012) Cap 371, 1, § 2 (H.K.).

⁸³ Hong Kong Government Press Release, *LCQ5: Regulation of electronic cigarette*, (Oct. 22, 2014), <http://www.info.gov.hk/gia/general/201410/22/P201410220539.htm>.

⁸⁴ OXFORD DICTIONARIES, *Smoke*, <http://www.oxforddictionaries.com/definition/english/smoke>.

⁸⁵ Interpretation and General Clauses Ordinance, (1997) Cap. 1, 10, § 10B(1) (H.K.).

⁸⁶ Interpretation and General Clauses Ordinance, (1997) Cap. 1, 10, § 10B(2) (H.K.).

⁸⁷ See Department of Justice, *A Paper Discussing Cases Where the Two Language Texts of an Enactment are Alleged to be Different*, (May 1998), <http://www.legislation.gov.hk/blis/eng/inpr.html>.

offence that could result in a fine of around US\$640)⁸⁸ their liability will depend on the mercy of the judge, and how willing that judge is to depart from the literal meaning of the legislation in order to give effect to its purpose.⁸⁹

C. *E-cigarettes and Consumer Goods Laws*

The Consumer Goods Safety Ordinance (Cap 456) imposes a duty on manufacturers, importers, and suppliers of certain consumer goods to ensure that safety standards are met.⁹⁰ “Consumer goods” are defined to mean “goods which are ordinarily supplied for private use or consumption, not being goods set out in the Schedule.”⁹¹ The Schedule includes “pharmaceutical products, poisons and antibiotics”, and also includes “electrical products”. However, e-cigarettes fall outside of the definition of “electrical product” in the Electricity Ordinance (Cap 406), since e-cigarettes use “extra low voltage” as defined in that Ordinance.⁹²

As a result, the issue of whether e-cigarettes are pharmaceutical products again arises. While e-liquid containing nicotine is categorized as a “poison” under the Pharmacy and Poisons Ordinance, the Hong Kong government also expressed the view that “e-cigarettes” are pharmaceutical products, as discussed in subsection A above. The government’s position may make enforcement of the Consumer Goods Safety Ordinance in relation to e-cigarettes containing nicotine unlikely. E-cigarettes that do not contain nicotine, on the other hand, are definitely not covered by the Pharmacy and Poison Ordinance and would fall within the ambit of the Consumer Goods Safety Ordinance.

The Consumer Goods Safety Ordinance sets out a general safety requirement for consumer goods, such that the goods shall be reasonably safe having regard to all of the circumstances.⁹³ The Secretary for Commerce and Economic Development may by regulation approve a safety standard for goods,⁹⁴ the compliance with which shall be taken as complying with the general safety requirement.⁹⁵ In general, anyone who supplies, manufactures, or imports unsafe consumer goods commits an offence.⁹⁶

Other general laws may also apply. For example, the Trade Descriptions Ordinance (Cap 362) protects consumers against false, misleading, or incomplete trade descriptions. This is potentially another route to prosecute e-cigarette sellers who exaggerate the health effect of their product (other than invoking the Pharmacy and Poisons Ordinance).

⁸⁸ Smoking (Public Health) Ordinance, (2012) Cap. 371, 6, § 7(1) (H.K.).

⁸⁹ According to § 19 of the Interpretation and General Clauses Ordinance (Cap 1), “[a]n Ordinance shall be deemed to be remedial and shall receive such fair, large and liberal construction and interpretation as will best ensure the attainment of the object of the Ordinance according to its true intent, meaning and spirit.” See Interpretation and General Clauses Ordinance, (1997) Cap. 1, 12, § 19 (H.K.).

⁹⁰ Consumer Goods Safety Ordinance, (1997) Cap. 456 (H.K.).

⁹¹ *Id.* at 1, § 2 (H.K.).

⁹² Electricity Ordinance, (1999) Cap. 406, 2, § 2 (H.K.).

⁹³ Consumer Goods Safety Ordinance, (1997) Cap. 456, 2, § 4(1) (H.K.).

⁹⁴ *Id.* at 3, § 5. For specific standards applicable to consumer goods, see INNOVATION & TECH. COMM’N, *Consumer Goods*, <http://www.itc.gov.hk/en/quality/psis/src/consumergoods.htm>.

⁹⁵ Consumer Goods Safety Ordinance, (1997) Cap. 456, 3, § 4(2) (H.K.).

⁹⁶ *Id.* at 3, § 6; *Id.* at 8, § 22.

It is worth noting that previously a complete exemption was granted to “aerosol dispensers containing not more than 0.2% of nicotine” such that nothing in the Pharmacy and Poisons Ordinance applied to these products, unless the product otherwise fell within the meaning of a “pharmaceutical product”;⁹⁷ in which case certain requirements relating to manufacture, registration, and sale would continue to apply).⁹⁸ This exemption was revoked⁹⁹ by the statutory body Pharmacy and Poisons Board (a statutory body) in December 2015 in exercise of its power to amend certain lists of substances.¹⁰⁰ In the same amendment, nicotine contained in pharmaceutical products not exceeding 0.1 percent was also excluded from Part 2 of the Poisons List.¹⁰¹ The effect was that these products were no longer be able to enjoy certain relaxed conditions of sale compared to other poisons.¹⁰²

Although these exceptions previously applicable to e-cigarettes were also clouded by uncertainty (in terms of whether e-cigarettes should be classified as a pharmaceutical product), the revocation of these exceptions marked a clear departure from a more lenient approach towards e-cigarettes.

V. THE PROPOSED E-CIGARETTES BAN IN HONG KONG AND ITS JUSTIFICATIONS

In May 2015, the Food and Health Bureau submitted a paper to the Legislative Council putting forward a number of new smoking control measures.¹⁰³ Among these measures is the proposal to “prohibit import, manufacture, sale, distribution, and advertising of e-cigarettes.”¹⁰⁴ The government supported this proposal with three justifications(1) “the apparent health effect and hazards arising from the use of e-cigarettes, [(2)] the wider long-term impact to [youth] (e.g. inducing them to smoke), and [(3)] the recommendation of WHO.”¹⁰⁵ Each of these justifications will be examined in the subsections below.

A. *Health Effects of E-Cigarettes*

In its paper, the government put forward three adverse health effects of e-cigarettes.¹⁰⁶ First, it noted that “formaldehyde-releasing agents could be formed during vaporization of e-cigarette liquid”, implying that the use of e-cigarettes may

⁹⁷ Pharmacy and Poisons (Amendment) Regulation 1995, Reg. 8(1)(b); Sch. 2.

⁹⁸ *Id.* Reg. 8(2).

⁹⁹ Pharmacy and Poisons (Amendment) (No. 6) Regulation 2015 (LN 234 of 2015) § 2.

¹⁰⁰ This power is “subject to the approval of the Secretary for Food and Health.” Pharmacy and Poisons Ordinance, (2015) Cap. 138, 20, § 29(1B)(b)(ii) (H.K.).

¹⁰¹ Pharmacy and Poisons (Amendment) (No. 6) Regulation 2015 (LN 234 of 2015) § 3.

¹⁰² Part 2 poisons may be sold by listed sellers of poisons. Pharmacy and Poisons Ordinance, (2015) Cap. 138, 16, § 26 (H.K.). See section 3A above for conditions of sale of Part 1 poisons.

¹⁰³ Legislative Council Panel on Health Serv., *supra* note 7.

¹⁰⁴ *Id.* ¶ 30.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* ¶ 24.

cause cancer.¹⁰⁷ Second, it noted that e-cigarettes contain propylene glycol which is a known irritant, the inhalation of which “may induce airway disorders such as asthma and other inflammatory respiratory diseases.”¹⁰⁸ Lastly, “e-cigarettes also give rise to exposure to nicotine and other toxicants from passive smoking.”¹⁰⁹

Public Health England (PHE), an executive agency of the United Kingdom Department of Health, published the latest evidence review on e-cigarettes in August 2015, reviewing 185 publications.¹¹⁰ The report was written by Ann McNeil, Professor of Tobacco Addiction at King’s College London and Peter Hajek, Professor of Clinical Psychology at Queen Mary University of London, among others. The conclusions of the report have received support from reputable groups such as the Action on Smoking and Health, the Royal College of Physicians, the British Lung Foundation, and Cancer Research UK.¹¹¹ More recently, the Royal College of Physicians (RCP) also published a 200-page report supporting using e-cigarettes in harm reduction.¹¹²

All of the health concerns mentioned by the Hong Kong government have been addressed in the PHE and RCP reports. Commenting on the study cited by the Food and Health Bureau about formaldehyde,¹¹³ the PHE report noted that “[i]n this study, negligible levels of formaldehyde were released at lower EC [e-cigarette] settings” and that high levels of formaldehyde were only released under unrealistic experimental conditions, or specifically during “dry puffs.”¹¹⁴ The report concluded after reviewing a number of other studies that “[a]lthough e-liquid can be heated to a temperature which leads to a release of aldehydes, the resulting aerosol is aversive to vapers and so poses no health risk.”¹¹⁵

Confirming PHE’s conclusion about formaldehyde, a recent study found a 750-fold difference in aldehyde yield between tested devices, but noted that high levels of aldehyde formation were observed only when overheating was likely to have occurred; otherwise, the devices produced less aldehydes than combustible cigarettes.¹¹⁶

As to the claim that e-cigarettes contain irritants and cause asthma, the PHE report recognized that “local irritation and dry mouth” are adverse effects of using e-cigarettes,¹¹⁷ but also noted that “[a] study that monitored asthma patients who

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ A. McNeill et al., *E-cigarettes: An Evidence Update* (2015) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

¹¹¹ E-CIGARETTES: AN EMERGING PUBLIC HEALTH CONSENSUS (2015), <https://www.gov.uk/government/news/e-cigarettes-an-emerging-public-health-consensus>.

¹¹² ROYAL COLL. OF PHYSICIANS, *supra* note 26, at 136.

¹¹³ R. Paul Jensen et al., *Hidden Formaldehyde in E-Cigarette Aerosols*, 372 NEW ENG. J. MED. 392 (2015).

¹¹⁴ McNeill et al., *supra* note 109, at 77.

¹¹⁵ *Id.* at 78.

¹¹⁶ I.G. Gillman et al., *Effect of Variable Power Levels on the Yield of Total Aerosol Mass and Formation of Aldehydes in E-cigarette Aerosols*, 75 REG. TOXICOLOGY & PHARMACOLOGY 58, 63–64 (2016).

¹¹⁷ McNeill, *supra* note 109, at 79.

switched from smoking to vaping found significant improvements in symptoms and in respiratory function.”¹¹⁸

Finally, the PHE report noted that “[EC] release negligible levels of nicotine into ambient air with no identified health risks to bystanders.”¹¹⁹ The report cited a study with the conclusion that “EC aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of EC use are unknown but compared with cigarettes, EC are likely to be much less, if at all, harmful to users or bystanders.”¹²⁰ The PHE report identified an earlier report¹²¹ that had been interpreted as showing that e-cigarettes may be dangerous to bystanders, but noted that the researchers of the relevant study discredited such an interpretation “because their findings did not concern any health risks. It is the content of the particles rather than their presence or size which has health implications.”¹²²

Overall, the PHE report concluded that “[w]hile vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger,”¹²³ and that it is a “reasonable estimate” that e-cigarettes are “around 95% safer than smoking.”¹²⁴ While the 95 percent figure has been subject to some dispute,¹²⁵ this does not change the ultimate conclusion: e-cigarettes are substantially less harmful than smoking.¹²⁶

B. Do E-cigarettes Induce Young People to Smoke?

The Hong Kong Food and Health Bureau claimed that e-cigarettes “have a potential to significantly undermine our tobacco control measures if not controlled effectively from the start” as they “tend to target at the young generation as their designs and marketing tactics suggest.”¹²⁷ It also expressed concern about e-cigarettes’ “gateway” (i.e., according to the government, the possibility that children will switch to cigarette smoking once addicted to nicotine through e-cigarettes) and “renormalization” effects.¹²⁸ Emphasizing the prevalence of e-cigarettes among the youth, the government cited a survey conducted between 2014 and 2015 showing that 2.6 percent

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 65.

¹²⁰ *Id.* at 76; Peter Hajek et al., *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801, 1801 (2014).

¹²¹ Ingrid Torjesen, *E-Cigarette Vapour Could Damage Health of Non-Smokers*, 349 BRIT. MED. J. g6882 (2014).

¹²² McNeill et al., *supra* note 109, at 79; Gordon B. McFiggans & Roy Harrison, *Re: E-cigarette Vapour Could Damage Health of Non-smokers*, (2014), <http://www.bmj.com/content/349/bmj.g6882/rr/780389>.

¹²³ McNeill et al., *supra* note 109 at 12.

¹²⁴ *Id.*

¹²⁵ *E-cigarettes: Public Health England’s Evidence-Based Confusion*, 386 LANCET 829 (2015); Martin McKee and Simon Capewell, *Electronic Cigarettes: We Need Evidence, Not Opinions*, 386 LANCET 829, 829 (2015).

¹²⁶ John Britton, *E-cigarettes, Public Health England, and common sense*, 386 LANCET 1238, 1238 (2015).

¹²⁷ Legislative Council Panel on Health Serv., *supra* note 7, ¶ 24.

¹²⁸ *Id.* ¶ 25.

of Primary four to six students and 9 percent of secondary students were ever e-cigarette users, while 1.3 percent of secondary students were current e-cigarette users.¹²⁹

While the Hong Kong government did not expressly claim that banning e-cigarettes will contribute to lower smoking rates, implicit in the “renormalization” and “gateway” argument is the notion that e-cigarettes will overall lead to more tobacco consumption overall.

As mentioned above, it has been WHO’s view for a few years that e-cigarettes may disrupt the denormalization of smoking.¹³⁰ Some tobacco control advocates prefer an abstinence-only approach to tobacco control and reject the value of e-cigarettes in harm reduction, claiming that “dual use” of e-cigarette and conventional tobacco products may perpetuate the habit of smoking.¹³¹ When making this argument, however, proponents should be clear whether they base their view on practical effects or merely moral considerations.¹³² The former view especially does not appear to be supported by evidence outlined below.

According to the PHE report, the percentage of young current e-cigarette users (2.4 percent)¹³³ in England is higher than in Hong Kong. The English statistics also indicate a strong association between e-cigarette use and smoking status: only 0.3 percent of never smokers use e-cigarettes at least once a month, while the figures for ever smokers and current smokers are 10.0 percent and 19.1 percent respectively.¹³⁴ A separate study by the Office for National Statistics also found that 53 percent of vapers in Great Britain used e-cigarettes as an aid to quit smoking.¹³⁵

The PHE report is opposed to the use of the term “gateway” since there is no good way of testing the theory.¹³⁶ It took the view that e-cigarettes do not “renormalize” smoking because “[s]ince [e-cigarettes] arrived on the market in England, smoking prevalence has continued to decline among both adults and youth.”¹³⁷

Perhaps more importantly, recent evidence indicates that e-cigarettes can help smokers quit smoking. The relevant evidence has been documented in detail in the PHE report¹³⁸ and the RCP report.¹³⁹ It is noted, for example, in the PHE report that some smoking cessation services and practitioners in England support using e-

¹²⁹ Hong Kong Government Press Release, *Latest Cigarette Smoking Prevalence Rate Announced* (Feb. 4, 2016), <http://www.info.gov.hk/gia/general/201602/04/P201602040963.htm>.

¹³⁰ WORLD HEALTH ORG., *supra* note 22.

¹³¹ Amy Fairchild et al., *The Renormalization of Smoking? E-Cigarettes and the Tobacco “Endgame”*, 370 NEW ENG. J. MED. 293, 294 (2014).

¹³² Fairchild et al. contrasted abstinence-only advocates holding the latter view and those advocating harm reduction as two competing schools of thoughts. *Id.* at 295.

¹³³ McNeill et al., *supra* note 109, at 31.

¹³⁴ *Id.* at 32.

¹³⁵ OFFICE FOR NAT’L STATISTICS, *Adult smoking habits in Great Britain: 2014*, <http://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adult-smokinghabitsingreatbritain/2014/pdf>.

¹³⁶ McNeill et al., *supra* note 109, at 38.

¹³⁷ *Id.* at 36.

¹³⁸ *Id.* at 45–52.

¹³⁹ ROYAL COLL. OF PHYSICIANS, *supra* note 26, § 6.

cigarettes to quit smoking.¹⁴⁰ PHE has also recommended employing a combination of e-cigarette use and behavioral support to help smokers to quit, and has issued a guidance note for stop smoking services.¹⁴¹

Given that e-cigarettes are likely to be substantially safer than smoking (see subsection A above), and also that most e-cigarette users are also smokers, to completely ban e-cigarettes would deprive smokers of a safe alternative to smoking, and probably even an opportunity to quit. This can indirectly *increase* tobacco consumption.¹⁴²

The RCP report contains a detailed analysis of the potential problem of “dual use.” While cautioning that tobacco companies may use e-cigarettes as an opportunity to sustain tobacco smoking,¹⁴³ it recognized that using e-cigarettes is likely to increase the chance of successful quitting.¹⁴⁴ As to the overall effect of e-cigarettes, the RCP report concluded that “[u]ptake [of e-cigarettes] has been rapid among adults and limited almost entirely to smokers, and has contributed to a continued downward trend in UK smoking prevalence,”¹⁴⁵ and also that e-cigarettes “within the context of a regulatory environment designed to discourage use among youth and never-smokers, are likely to benefit public health.”¹⁴⁶

C. World Health Organization’s Recommendation

WHO published a report on e-cigarettes in 2014.¹⁴⁷ While the general tone of the report is cautious, noting that e-cigarette use poses health risks and may interfere with the implementation of the FCTC, the report also recognized the public health opportunities brought by e-cigarettes (referred to in the report as “electronic nicotine delivery systems” or ENDS):

ENDS are the subject of a public health dispute among bona fide tobacco-control advocates that has become more divisive as their use has increased. Whereas some experts welcome ENDS as a pathway to the reduction of tobacco smoking, others characterize them as products that could undermine efforts to denormalize tobacco use. ENDS, therefore, represent an evolving frontier, filled with promise and threat for tobacco control. Whether ENDS fulfils the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS

¹⁴⁰ McNeill et al., *supra* note 109, at 45, 48.

¹⁴¹ PUB. HEALTH ENG., *Electronic Cigarettes: A Briefing for Stop Smoking Services* (2016) <http://www.ncsct.co.uk/usr/pub/Electronic%20cigarettes.%20A%20briefing%20for%20stop%20smoking%20services.pdf>.

¹⁴² Similar conclusions have been reached by the Action on Smoking and Health. See Action on Smoking and Health, *Electronic Cigarettes (also known as vapourisers)*, (Feb. 2016), http://www.ash.org.uk/files/documents/ASH_715.pdf.

¹⁴³ ROYAL COLL. OF PHYSICIANS, *supra* note 26, § 9.

¹⁴⁴ *Id.* § 8.5.3.

¹⁴⁵ *Id.* § 8.5.4.

¹⁴⁶ *Id.*

¹⁴⁷ WORLD HEALTH ORG., *supra* note 4.

(independent makers and tobacco companies), consumers, regulators, policymakers, practitioners, scientists, and advocates.¹⁴⁸

The report laid out a number of specific regulatory options, addressing each of the concerns about the risks of e-cigarettes. None of the recommendations involved banning the product altogether. The Hong Kong government claimed that “WHO has recently recommended that measures should be considered to *prohibit* or regulate e-cigarettes products” (emphasis added) to achieve certain objectives.¹⁴⁹ This claim is simply false. The objectives quoted by the government were extracted from the WHO report on e-cigarettes, and are merely considerations to be borne in mind “[w]hen designing a regulatory strategy.”¹⁵⁰

A complete ban of e-cigarettes, for the reasons given in the previous section, is contrary to the theme of the FCTC and the WHO report, one that advocates regulatory actions in response to emerging scientific evidence¹⁵¹ and one that aims at reducing “the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke.”¹⁵² A prohibitory approach also fails to maximize the possible public health benefits of e-cigarettes, and eliminates the likelihood of the product to fulfil its promise in relation to harm reduction.

D. Negative Media Campaign Against E-Cigarettes

The proposal to ban e-cigarettes was accompanied by a fierce, government-sponsored media campaign against e-cigarettes. The Hong Kong Council on Smoking and Health (COSH), a statutory body¹⁵³ almost fully funded by the Hong Kong government,¹⁵⁴ was among the most prominent players in this campaign. The statutory purposes of COSH include: education on tobacco dependence and use,¹⁵⁵ tobacco-related research,¹⁵⁶ and to giving advice to the government about tobacco dependence.¹⁵⁷

Before the submission by the Food and Health Bureau of the amendment proposals¹⁵⁸ to the Legislative Council, COSH began publicly declaring its support for a total ban on e-cigarettes.¹⁵⁹ COSH’s reasons for supporting a ban are largely reflected in the government’s proposals. COSH emphasized the situation of e-cigarette

¹⁴⁸ *Id.* ¶ 2.

¹⁴⁹ Legislative Council Panel on Health Serv., *supra* note 7, ¶ 25.

¹⁵⁰ WORLD HEALTH ORG., *supra* note 4, ¶ 36.

¹⁵¹ *Id.* ¶ 37.

¹⁵² WHO Framework Convention on Tobacco Control, *supra* note 12, at 1.

¹⁵³ Hong Kong Council on Smoking and Health Ordinance, (1997) Cap. 389, 1, § 3(1).

¹⁵⁴ H.K. Council on Smoking and Health, *Annual Report 2014-2015* 110, [http://www.smokefree.hk/UserFiles/resources/about_us/annual_r Hong Kong Council on Smoking and Health Ordinance \(Cap 389\) s 3.eports/COSH_Annual_Report_2014_2015.pdf](http://www.smokefree.hk/UserFiles/resources/about_us/annual_r%20Hong%20Council%20on%20Smoking%20and%20Health%20Ordinance%20(Cap%20389)%203.eports/COSH_Annual_Report_2014_2015.pdf).

¹⁵⁵ Hong Kong Council on Smoking and Health Ordinance, (1997) Cap. 389, 1, § 3(2)(a), (c).

¹⁵⁶ *Id.* § 3(2)(b).

¹⁵⁷ *Id.* § 3(2)(d).

¹⁵⁸ Legislative Council Panel on Health Serv., *supra* note 7.

¹⁵⁹ H.K. Council on Smoking & Health, *Support a Total Ban on Electronic Cigarettes*, (Mar. 30, 2015), <http://smokefree.hk/en/content/web.do?page=news20150330>.

use by youth, claiming that e-cigarette use may both normalize smoking and be harmful to health.¹⁶⁰ Recently, COSH commissioned a local university to study the emissions of e-cigarettes.¹⁶¹ Despite criticisms over the methodology of the study,¹⁶² COSH claims the study showed that e-cigarettes contain one million times more polycyclic aromatic hydrocarbons (PAHs, a class of substances produced by combustion) than roadside air. This study caught the attention of local¹⁶³ and international media¹⁶⁴ alike. COSH's narrative regarding youth access to e-cigarettes appears to have been adopted even by media known for their anti-establishment stance.¹⁶⁵

Misleading messages about e-cigarettes are also directly by the Hong Kong government. In April 2016, it launched a TV commercial titled "Say No to Cigarettes and Electronic Cigarettes," strongly implying that the two products are just the same.¹⁶⁶

E. Potential Benefits of E-Cigarettes

The Food and Health Bureau dismissed the relevance of any potential benefits of e-cigarettes. It simply stated that "[t]here are claims that e-cigarettes are less harmful than traditional tobacco products and that e-cigarettes could help smokers to quit. However, such evidence is considered limited and inconclusive up to now."¹⁶⁷ The paper went on to suggest that "[i]f there is such scientific proof later that e-cigarettes may be used for smoking cessation purpose, we can consider regulating it as pharmaceutical product for such purpose [sic]."¹⁶⁸

Apparently, two completely different standards have been applied by the Hong Kong government in evaluating the evidence about e-cigarettes harm of on the one hand, and the benefits on the other. If the evidence showing that e-cigarettes are less

¹⁶⁰ *Id.*; H.K. Council on Smoking & Health, *Adolescents Using E-cigarettes are More Likely to Smoke Other Tobacco Products*, (Aug. 25, 2015), <http://smokefree.hk/en/content/web.do?page=news20150825>.

¹⁶¹ Hong Kong Council on Smoking & Health, *Enact Total Ban on E-cigarettes Promptly*, (Feb. 29, 2016), <http://smokefree.hk/en/content/web.do?page=news20160229>.

¹⁶² Konstantinos Farsalinos, *Hong Kong Biology Professor Cannot Understand the Difference Between mLs of E-liquid and mLs of Breathing Air*, E-CIGARETTE RESEARCH (Feb. 29, 2016), <http://www.ecigarette-research.org/research/index.php/whats-new/whatsnew-2015/238-h-k>.

¹⁶³ See e.g., Elizabeth Cheung, *A Million Times More Harmful Than Outdoor Air: Hong Kong Study Raises E-cigarette Cancer Alarm*, SOUTH CHINA MORNING POST, (Mar. 1, 2016), <http://www.scmp.com/news/hong-kong/health-environment/article/1918571/million-times-more-harmful-outdoor-air-hong-kong>.

¹⁶⁴ See e.g., Lizzie Parry, *Could E-cigarettes Cause INFERTILITY? Devices 'Contain More Toxins Than Polluted Air'*, *Daily Mail*, (Mar. 1, 2016), <http://www.dailymail.co.uk/health/article-3470372/Could-e-cigarettes-leave-INFERTILE-Devices-contain-flame-retardants-cancer-causing-toxins-disrupt-fertility.html>.

¹⁶⁵ The *Apple Daily* published a series of articles on e-cigarettes which target the youth in May 2016 under the theme "the harm of e-cigarettes." See e.g., 電子煙之害】加果味扮潮物 攻陷小學界, *supra* note 37.

¹⁶⁶ HONG KONG GOV'T INFO. SERVS. DEP'T, *Say No to Cigarettes and Electronic Cigarettes*, http://www.isd.gov.hk/eng/tvapi/16_md275.html.

¹⁶⁷ Legislative Council Panel on Health Serv., *supra* note 7, ¶ 30.

¹⁶⁸ *Id.*

harmful than conventional cigarettes is considered “inconclusive,” then it is difficult to imagine how the evidence showing the negative effects—which, as discussed above, has been questioned even by reputable public health authorities—may be conclusive enough to justify a complete ban on the product.

VI. PROHIBITION AS A REGULATORY OPTION

The analysis in section 3 above shows that the current legal regime in Hong Kong is ill-fitted to regulate e-cigarettes which incongruously occupy the gray areas of several pieces of legislation. Further, no regulation is in place to address issues specific to e-cigarettes; and even using the most liberal interpretation of the current law, e-cigarettes that do not contain nicotine are not regulated under any specific law.¹⁶⁹ Indeed a case can be made for regulatory reform.

The Hong Kong government, however, has not provided evidence to show that a complete ban of the product would be an appropriate response to the current deficiencies in the law, nor has it explained how the proposed ban may contribute to the objective of harm reduction. In a society where “economic freedom” is championed¹⁷⁰ and where the freedom of movement of goods is constitutionally guaranteed,¹⁷¹ all products should be legal and regulated by default, unless prohibiting specific products can be established with solid evidence.

A. A Precautionary Approach?

Saitta et al. discusses the application of the “precautionary principle” to e-cigarettes.¹⁷² The principle states that something which may potentially have dangerous effects should be subject to restrictive regulations even before the harm can be determined with sufficient certainty.¹⁷³ The authors reviewed European jurisprudence on the subject, and observed that risk assessment of specific actions is required to invoke the principle; therefore, the harm caused by those actions to consumers, including the harm of “perpetuating exposure to substances in smoke” must be taken into account.¹⁷⁴

Even if every claim the Hong Kong government made about the harm of e-cigarettes turned out to be true, a complete ban on e-cigarettes may still not be warranted. Saitta et al.’s cogent argument explains that eliminating the potential benefits of e-cigarettes is potential harm for current smokers. Deciding whether to ban e-cigarettes therefore involves balancing two kinds of potential harm: that caused by using the product versus the harm caused by the deprivation of a useful harm reduction tool. Thus, it is

¹⁶⁹ Except for general laws such as the Consumer Goods Safety Ordinance and the Trade Descriptions Ordinance discussed above.

¹⁷⁰ Hong Kong Government Press Release, *Government welcomes Heritage Foundation ranking of Hong Kong as world’s freest economy*, (Jan. 28, 2015), <http://www.info.gov.hk/gia/general/201501/28/P201501280027.htm>.

¹⁷¹ Xianggang Jiben Fa art. 115 (H.K.).

¹⁷² Daniela Saitta et al., *Achieving appropriate regulations for electronic cigarettes*, 5 THERAPEUTIC ADVANCES CHRONIC DISEASE 50 (2014).

¹⁷³ *Id.* at 51.

¹⁷⁴ *Id.* at 52–53.

very difficult to use “precaution” as a justification for applying two different standards in assessing the costs and benefits of e-cigarettes (see section 4E above).

If the government is seeking to overhaul the legislative framework surrounding e-cigarettes to the extent of a total ban on the availability and sale of this product, then it is proper that a comprehensive assessment of the available research is conducted including the PHE’s conclusion that e-cigarettes are 95 percent less harmful than the conventional cigarettes. Enacting a ban without conducting a proper cost–benefit analysis (as FDA, for example, did in support of the deeming rule on e-cigarettes¹⁷⁵) would be seen as an example of a prioritization of convenience over rational deliberation when it comes to e-cigarette regulation.¹⁷⁶

The RCP report raised certain moral and ethical considerations of harm reduction strategies. It states that “these strategies include a duty to ensure that options to reduce harm are made available to smokers, and provision of a substitute for tobacco to smokers, particularly those on low incomes, to protect them from the hardship that might otherwise arise from applying tax increases to provide a stronger fiscal disincentive to smoke”.¹⁷⁷ This statement very well summarizes the shortcomings of a so-called precautionary approach in regulating e-cigarettes very well.

B. Relative Harm and Harm Perception

Despite the government’s stated policy of creating a “smoke-free Hong Kong,”¹⁷⁸ tobacco products are legal in Hong Kong, albeit subject to strict regulations. If one considers relative harm, it would seem that no more stringent regulations should be applicable to a product that is likely to be substantially safer than tobacco, such as e-cigarettes. Even though the government has not admitted that e-cigarettes can help smokers to quit,¹⁷⁹ the differential treatment of the two products as such may lead to an increased consumption of the more harmful product, as e-cigarettes and conventional cigarettes are substitutes.¹⁸⁰

WHO states that regulation of e-cigarettes is a necessary precondition for ensuring that “the public has current, reliable information as to the potential risks and benefits” of e-cigarettes.¹⁸¹ The proposed differential treatment of tobacco products and e-cigarettes, with the former being subject to more lenient regulations, distorts the public’s risk perceptions about the two products, and therefore works against the supposed objective of e-cigarette regulation.

¹⁷⁵ See 81 Fed. Reg. 28,980 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140 & 1143) (Summary).

¹⁷⁶ For example, Feldman discussed the extension of laws prohibiting smoking in public places to e-cigarettes in the United States, noting that legislators “do not appear troubled by the lack of evidence-based policy, and have instead widened their tobacco laws without providing an explicit justification for doing so.” He also noted that countries like Singapore “avoided the need to make fine-grained regulatory decisions by banning all e-cigarettes.” See Eric Feldman, *Layers of Law: The Case of E-Cigarettes*, 10 FIU L. REV. 101, 110–6 (2015).

¹⁷⁷ ROYAL COLL. OF PHYSICIANS, *supra* note 26, § 12.1.

¹⁷⁸ See e.g., Legislative Council Panel on Health Serv., *supra* note 7, ¶ 7.

¹⁷⁹ *Id.* ¶ 30.

¹⁸⁰ Kenkel, *supra* note 2, at 474–75.

¹⁸¹ WORLD HEALTH ORG., *supra* note 4, ¶ 35.

The PHE report discussed the issue of harm perceptions. It noted that in Great Britain, the perceptions about the relative harmfulness of e-cigarettes has become “less accurate”, with increasingly many people perceiving e-cigarettes to be at least as harmful as smoking.¹⁸² The report hypothesized that negative media reports about e-cigarettes may be having a significant impact on public perception of the safety of e-cigarettes.¹⁸³ Further, it is recommended that e-cigarettes be regulated no more strictly than conventional cigarettes so that they can “improve their competitiveness against cigarettes.”¹⁸⁴

Hertogen and Killeen¹⁸⁵ criticized New Zealand’s legal regime which creates “the paradoxical situation in which e-cigarettes are treated more harshly than tobacco products that are known to be very harmful.”¹⁸⁶ They considered e-cigarettes to be “the lesser of two evils”, and that “a market for less harmful alternatives needs to be supported” as a step towards the smoke-free endgame.¹⁸⁷

While the Hong Kong government has correctly identified a gap in the current regulatory framework, the proposal to ban e-cigarettes altogether is one that does not pay sufficient regard to the comparative harm of existing products, or to the fact that the proposal may work against the stated regulatory objective by depriving smokers of a safer alternative to smoking and thus inadvertently increasing their consumption of conventional cigarettes. The problem will likely be exacerbated by the recent negative media campaign against e-cigarettes.¹⁸⁸

C. Prohibition in General

More fundamentally, assuming again that e-cigarettes and conventional cigarettes cause comparable degrees of harm, the government has not yet established that prohibition as a strategy can lead to harm reduction regarding harm directly arising from e-cigarette use. Economist Mark Thornton argued against prohibition as a regulatory approach generally.¹⁸⁹ Among other things, he pointed out that prohibition stifles the discovery process, including by discouraging new technological developments and safety features.¹⁹⁰ This will suppress the market’s ability to solve social problems.¹⁹¹ He also observed that prohibition causes the potency of the prohibited drug to increase and quality to decrease, and the cost of these effects outweighs the benefit of the decrease in quantity.¹⁹²

¹⁸² McNeill et al., *supra* note 110, at 58.

¹⁸³ *Id.* at 79.

¹⁸⁴ *Id.* at 75.

¹⁸⁵ An Hertogen & Anita Killeen, *The Burning Issue of Combustible Tobacco: The Inconvenient Truth*, 2014 N.Z. L. REV. 239, 239–62 (2014).

¹⁸⁶ *Id.* at 262.

¹⁸⁷ *Id.* at 258.

¹⁸⁸ *See supra* Section 00.

¹⁸⁹ Mark Thornton, *The Economics of Prohibition* (1991).

¹⁹⁰ *Id.* at 82.

¹⁹¹ *Id.* at 83.

¹⁹² *Id.* at 142.

The prohibition of dangerous drugs in the United States sets the background of Thornton's thesis. It appears to be arguable that the unintended consequences in the case of the prohibition of e-cigarettes are even more worrying because a more harmful and legal substitute (conventional cigarettes) is currently readily available.

VII. OTHER REGULATORY OPTIONS

The Hong Kong government's proposed ban is neither justified nor substantiated given that models of comprehensive e-cigarette regulations already exist, most notably in the United States as discussed in section 2 above, and in the EU. The EU Tobacco Products Directive revised in 2014 provides for detailed requirements about refill containers, e-liquids, health warnings, advertising restrictions, etc.¹⁹³ WHO and other commentators have recommended other forms of regulation such as age restrictions.¹⁹⁴ It appears natural to first examine the feasibility of these less restrictive measures before moving on to enact a complete ban. However, the Hong Kong government has failed to do so.

The goal of any regulatory reform on e-cigarettes should be to reduce adverse public health consequences, or more specifically the harm caused by the tobacco epidemic. To this end, the spirit of WHO's statement on e-cigarettes should be borne in mind: regulation on e-cigarettes should be conducive to achieving the outcome of reducing tobacco use, or at the very least, should not actively hinder such an outcome.¹⁹⁵

As a first step, the Hong Kong government may consider whether it is necessary to regulate e-cigarettes containing nicotine under the legal regime governing pharmaceutical products in the Pharmacy and Poisons Ordinance. The stringent registration requirements and sales restrictions deter e-cigarette manufacturers from entering the market, as there had been no nicotine-containing e-cigarette products registered as pharmaceutical products as of 2014.¹⁹⁶ If manufacturers are unwilling to incur the cost of regulatory compliance, the current legal regime would be in practice equivalent to a prohibition against nicotine-containing e-cigarettes. In this case, the proposed complete ban on e-cigarettes appears to be a disproportionate means to achieve the intended health objective.

An apparent solution is to reverse the revocation of the exemption previously applicable in Hong Kong to e-liquids containing not more than 0.2 percent of nicotine¹⁹⁷ (or arrive at another level of nicotine concentration on a sound scientific basis). It is also important for the government to clarify that e-cigarettes do not in

¹⁹³ Directive 2014/40/EU, of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Council Directive 2001/37/EC, 2014 O.J. (L 127) 1, 1.

¹⁹⁴ See WORLD HEALTH ORG., *supra* note 4; Saitta et al., *supra* note 172; Marilyn Krawitz, *We Didn't Start This Fireless Vapour: E-cigarette Legislation in Australia*, 22 J. L. & Med. 462, 462–81 (2014).

¹⁹⁵ WORLD HEALTH ORG., *supra* note 4, at 23.

¹⁹⁶ See Hong Kong Government Press Release, *supra* note 83. Note however that at that time, an exemption from complying with the Pharmacy and Poisons Ordinance was granted for "aerosol dispensers containing not more than 0.2% of nicotine" except when the substance is a pharmaceutical product. The exemption was revoked in 2015.

¹⁹⁷ See *supra* section 0.

general fall within the definition of pharmaceutical products by function, as argued in section 3A above. On the other hand, e-cigarettes claiming to have therapeutic effects may continue to be regulated under the Pharmacy and Poisons Ordinance as pharmaceutical products by presentation.

This approach has been adopted in the United Kingdom. E-cigarettes containing nicotine not more than the concentration of 20 mg/ml¹⁹⁸ have been regulated by the EU Tobacco Products Directive from May 2016. Those exceeding the potency limit and those claiming to have therapeutic effects will have to go through the licensing process of the Medicines and Healthcare products Regulatory Agency (MHRA).¹⁹⁹

Exempting e-cigarettes from the Pharmacy and Poisons Ordinance also produces an additional advantage in that the Consumer Goods Safety Ordinance may then be invoked (see section 3C above). Standards in relation to the safety of e-cigarettes may be set. The EU Tobacco Products Directive may again be used as a model for such standards.²⁰⁰ The Directive requires among other things that e-liquids do not contain certain additives,²⁰¹ that ingredients shall be of high purity,²⁰² that e-cigarettes and refill containers shall be child- and tamper proof and protected against leakage and,²⁰³ that packets shall include leaflets with instructions for use and warnings.²⁰⁴

As to the government's concern that e-cigarette use may initiate smoking by non-smokers, certain regulatory options seeking to directly address the problem may be considered. For example, the EU Tobacco Products Directive requires that e-cigarette packages must carry health warnings communicating that nicotine is highly addictive and is not recommended for use by non-smokers.²⁰⁵ Advertising and promotion restrictions,²⁰⁶ age restrictions,²⁰⁷ and restrictions on flavorings were also introduced.²⁰⁸ These targeted measures may be better positioned to address specific concerns about e-cigarettes, but can also minimize the costs and disproportionality created by Hong Kong's total ban.

VIII. CONCLUSION

The current law on e-cigarettes in Hong Kong is in a state of confusion. The government claims that e-cigarettes which contain nicotine are within the ambit of the Pharmacy and Poisons Ordinance (Cap 138), and that the use of e-cigarettes in public is an act governed by the Smoking (Public Health) Ordinance (Cap 371). An analysis of the legislative provisions shows that these claims may not be accurate. In any event,

¹⁹⁸ Tobacco Products Directive, *supra* note 193, at art. 20(3)(b).

¹⁹⁹ See Action on Smoking and Health, *supra* note 142.

²⁰⁰ Note that a European Council Directive is directly adopted as a standard applicable to facial cream. See INNOVATION & TECH. COMM'N, *supra* note 94.

²⁰¹ Tobacco Products Directive, *supra* note 193, art. 20(3)(c).

²⁰² *Id.* art. 20(3)(d).

²⁰³ *Id.* art. 20(3)(g).

²⁰⁴ *Id.* art. 20(4)(a).

²⁰⁵ *Id.* art. 20(4)(b).

²⁰⁶ *Id.* art. 20(5).

²⁰⁷ Cf. Smoking (Public Health) Ordinance, (2006) Cap. 371, 11, § 15A(1) (H.K.).

²⁰⁸ WORLD HEALTH ORG., *supra* note 4, ¶ 48(f).

Hong Kong's law is unable to address issues presented by e-cigarettes as a new type of nicotine delivery device. There are no requirements about their content, no advertising and promotion restrictions, and no restrictions on sale to minors. Some form of new regulations addressing these issues may be justified.

The government's response, however, is to simply propose to impose a complete ban on e-cigarettes. While this is a convenient option, it fails to recognize that according to available evidence e-cigarettes are substantially safer than conventional cigarettes. Since most e-cigarette users are also smokers, a complete ban on e-cigarettes will deprive smokers of a safer alternative to smoking. The other concerns of the government, namely that e-cigarettes induce young people to smoke and that passive inhalation of e-cigarette vapor causes harm, so far lack evidential basis. Given the potential public health benefits of e-cigarettes, even assuming that these concerns are in some way substantiated, new regulations that specifically address them appear to be more justifiable and proportionate than a complete ban.