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Electronic nicotine delivery systems

Report by WHO

INTRODUCTION

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fifth session (Seoul, Republic of Korea, 12–17 November 2012) to the Convention Secretariat to invite WHO to examine emerging evidence on the health impacts of electronic nicotine delivery systems (ENDS) use and to identify options for their prevention and control, for consideration at the sixth session of the COP.¹ This report incorporates the December 2013 deliberations and scientific recommendations on ENDS by the WHO Study Group on Tobacco Product Regulation (TobReg), and analysis from a recent WHO survey on tobacco products.²

2. 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

¹ See decision FCTC/COP5(10).

² The WHO tobacco products survey on smokeless, electronic nicotine delivery systems, reduced ignition propensity cigarettes, and novel tobacco products was sent to all WHO Member States. A total of 90 WHO Member States, including 86 Parties to the WHO FCTC, had responded to the survey as at 9 April 2014. These countries are: Australia, Austria, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Bhutan, Bolivia (Plurinational State of), Botswana, Brazil, Brunei Darussalam, Cambodia, Canada, Chile, China, Colombia, Congo, Costa Rica, Croatia, Czech Republic, Djibouti, Dominica, Ecuador, Egypt, Estonia, Fiji, Finland, France, Gabon, Georgia, Ghana, Guatemala, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Jamaica, Japan, Jordan, Kenya, Kuwait, Lao People's Democratic Republic, Latvia, Lebanon, Lithuania, Malaysia, Maldives, Mali, Mauritania, Mongolia, Morocco, Myanmar, Netherlands, New Zealand, Nicaragua, Norway, Oman, Pakistan, Palau, Panama, Paraguay, Peru, Philippines, Poland, Qatar, Republic of Korea, Russian Federation, Slovakia, South Sudan, Spain, Sudan, Suriname, Sweden, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, Tuvalu, United Arab Emirates, United States of America, Uruguay, Uzbekistan, Viet Nam, and Zambia.

with promise and threat for tobacco control. Whether ENDS fulfil the promise or the threat depends on a complex and dynamic interplay among the industries marketing ENDS (independent makers and tobacco companies), consumers, regulators, policy-makers, practitioners, scientists, and advocates. The evidence and recommendations presented in this report are therefore subject to rapid change.

PRODUCT DESIGN AND CONTENTS

3. ENDS, of which electronic cigarettes are the most common prototype, deliver an aerosol by heating a solution that users inhale. The main constituents of the solution by volume, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents.

4. Although some ENDS are shaped to look like their conventional tobacco counterparts (e.g. cigarettes, cigars, cigarillos, pipes, or hookahs), they also take the form of everyday items such as pens, USB memory sticks, and larger cylindrical or rectangular devices.

5. Battery voltage and unit circuitry differences can result in considerable variability in the products' ability to heat the solution to an aerosol and, consequently, may affect delivery of nicotine and other constituents, and may contribute to the formation of toxicants in the emissions.

6. User behaviour may affect nicotine absorption – length of puffs, depth of inhalation and frequency of use may be factors. However, while a faster, deeper puff increases nicotine delivery from a conventional cigarette, it might diminish it from ENDS due to cooling of the heating element.

7. In addition to manufacturer differences, some users modify products at home to alter delivery of nicotine and/or other drugs. Products vary widely in the ease with which they can be modified and the ease with which they can be filled with substances other than nicotine solutions.

THE ENDS MARKET

8. The use of ENDS is apparently booming. It is estimated that in 2014 there were 466 brands¹ and that in 2013 US\$ 3 billion was spent on ENDS globally. Sales are forecasted to increase by a factor of 17 by 2030.² Despite this projection, transnational tobacco companies are divided about the prospects of the growth of ENDS sales and some companies have reported a slowdown in sales in some markets.^{3,4,5} There are no data on ENDS use at the global level and for many countries. However, data mainly from North America, the European Union (EU) and Republic of Korea indicate that ENDS use at least doubled among both adults and adolescents from 2008 to 2012.⁶ In 2012, 7% of EU citizens aged 15 years and over had tried electronic cigarettes. However, only 1% of the total population used them regularly.⁷ In 2013, 47% of smokers and ex-smokers in the United States of

¹ Zhu S-H, Sun JY, Bonnevie E, Cummins SE, Gamst A, Yin L, Lee M. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control*. 2014;23:iii3–iii9. doi:10.1136/tobaccocontrol-2014-051670.

² The tobacco industry at a crossroads: cigarettes growth falters as focus falls on alternatives. *Euromonitor international*. July 2013

³ Evans P. E-cigarettes are the future? Not so fast, says BAT's boss. *Wall Street Journal*. 30 July 2014 (<http://blogs.wsj.com/corporate-intelligence/2014/07/30/e-cigs-are-the-future-not-so-fast-says-bats-boss/>)

⁴ Prior A. Lorillard profit down as e-cigarette sales drop: electronic cigarette sales tumble 35%, offsetting slight increase in traditional cigarettes. *Wall Street Journal*. 30 July 2014 (<http://online.wsj.com/articles/lorillard-profit-down-as-e-cigarette-sales-drop-1406720447>).

⁵ Wile R. Citi e-cigarettes: the e-cigarette boom is over. *Business Insider*. 15 May 2014 (<http://www.businessinsider.com/citi-ecigarette-growth-slows-2014-5>).

⁶ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

⁷ Attitudes of Europeans towards tobacco (Special Eurobarometer 385). *European Commission*, May 2012.

America had tried e-cigarettes, but prevalence of established use was 4% in this group.¹ Users report that the main reasons for using ENDS are to reduce or stop smoking and because they can be used in smoke-free places.²

9. According to the recent WHO survey, ENDS availability is widespread. Slightly over half of the world's population live in 62 countries that report the availability of ENDS in their jurisdictions, 4% live in countries reporting that ENDS are not available, while the rest live in countries that did not respond concerning the availability of ENDS.

10. Recently, the transnational tobacco companies have entered the ENDS market. Some of them are aggressively competing with the independent companies to gain market share. Given the economic power of the tobacco industry, recent moves to sue other companies alleging patent infringement may be an indicator of how difficult it will be for ENDS to remain a business niche dominated by independent companies.

QUESTIONS RELATED THE USE OF ENDS

11. Questions have been articulated in three groups:

- (a) health risks to users and non-users;
- (b) efficacy in helping smokers to quit smoking and ultimately nicotine dependence; and
- (c) interference with existing tobacco-control efforts and implementation of the WHO FCTC.

Health risks to users and non-users

12. Most ENDS products have not been tested by independent scientists but the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions.

13. Health risks from nicotine inhalation are affected by several factors.

- (a) The capacity of ENDS to deliver nicotine to the user varies widely, ranging from very low to levels similar to that of cigarettes, depending on product characteristics, user puffing behaviour and nicotine solution concentration.
- (b) Nicotine is the addictive component of tobacco. It can have adverse effects during pregnancy and may contribute to cardiovascular disease. Although nicotine itself is not a carcinogen, it may function as a "tumour promoter".³ Nicotine seems involved in fundamental aspects of the biology of malignant diseases, as well as of neurodegeneration.

¹ Giovenco DP, Lewis MJ, Delnevo CD. Factors associated with e-cigarette use. *American Journal of Preventive Medicine*. Published online, 27 May 2014. doi: <http://dx.doi.org/10.1016/j.amepre.2014.04.009>.

² Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

³ Nicotine alters essential biological processes like regulation of cell proliferation, apoptosis, migration, invasion, angiogenesis, inflammation and cell-mediated immunity in a wide variety of cells including fetal, embryonic and adult stem cells, adult tissues as well as cancer cells.

(c) The evidence is sufficient to caution children and adolescents, pregnant women, and women of reproductive age about ENDS use because of the potential for fetal and adolescent nicotine exposure to have long-term consequences for brain development.¹

14. The main health risk from nicotine exposure other than through inhalation is nicotine overdose by ingestion or through dermal contact. Since most countries do not monitor these incidents the information is very scarce. Reports from the United States and the United Kingdom nonetheless indicate that the number of reported incidents involving nicotine poisoning has risen substantially as the use of ENDS has increased. The actual number of cases is probably much higher than those reported.

15. Evidence concerning the health risks resulting from chronic inhalation of toxicants in aerosol to ENDS users are described below.

(a) Short-term effects of ENDS use include eye and respiratory irritation caused by exposure to propylene glycol. Serious short-term health problems may occur but are very rare.

(b) Given the relatively recent entry of ENDS into the market and the lengthy lag time for onset of many diseases of interest,² such as cancer, conclusive evidence about the association of ENDS use with such diseases will not be available for years or even decades.

(c) However, evidence based on the assessment of the chemical compounds in the liquids used in and aerosol produced by ENDS indicate:

- (i) potential cytotoxicity of some solutions that have raised concerns about pregnant women who use ENDS or are exposed to second-hand ENDS aerosol.³ Cytotoxicity was related to the concentration and number of flavourings used in the e-liquid;
- (ii) the aerosol usually contains some carcinogenic compounds and other toxicants found in tobacco smoke at average levels of 1–2 orders of magnitude lower than in tobacco smoke, but higher than in a nicotine inhaler. For some brands, the level of some of these cancer causing agents, such as formaldehyde and other toxicants like acrolein have been found to be as high as in the smoke produced by some cigarettes;⁴
- (iii) the range of size of particles delivered by ENDS is similar to that of conventional cigarettes, with most particles in the ultrafine range (modes around 100–200 nm) compared to the bigger size found in cigarette smoke. However, ENDS generate lower level of particles than cigarettes.⁵

(d) Therefore, it is very likely that average ENDS use produces lower exposures to toxicants that combustible products.

16. Evidence concerning the health risks resulting from inhalation of second-hand ENDS aerosol by non-users are described below.

¹ The health consequences of smoking – 50 years of progress. A report of the Surgeon General. Rockville (MD); US Department of Health and Human Services: 2014 (p.126).

² Including the lack of agreed early biomarker changes to assess potential harms.

³ Bahl V, Lin S, Xu N, Davis B, Wang Y. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reproductive Toxicology*. 2012;34:529–37.

⁴ Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control*. 2014;23(2):133–139. doi:10.1136/tobaccocontrol-2012-050859.

⁵ Schripp T., D. Markewitz, E. Uhde, and T. Salthammer. Does e-cigarette consumption cause passive vaping? *Indoor Air*. 2013;23(1):25–31.

(a) Bystanders are exposed to the aerosol exhaled by ENDS users, which increases the background level of some toxicants,^{1,2} nicotine³ as well as fine and ultrafine particles in the air. Nevertheless the level of toxicants, nicotine and particles emitted from one ENDS is lower than that of conventional cigarette emissions.⁴ It is not clear if these lower levels in exhaled aerosol translate into lower exposure, as demonstrated in the case of nicotine. Despite having a lower levels of nicotine than in second-hand smoke, the exhaled ENDS aerosol results in similar uptake as shown by similar serum cotinine levels.⁵

(b) It is unknown if the increased exposure to toxicants and particles in exhaled aerosol will lead to an increased risk of disease and death among bystanders as does the exposure to tobacco smoke. However, epidemiological evidence from environmental studies shows adverse effects of particulate matter from any source following both short-term and long-term exposures. The low end of the range of concentrations at which adverse health effects has been demonstrated is not greatly above the background concentration, which for particles smaller than 2.5 µm has been estimated to be 3–5 µg/m³ and increases with dose, which means that there is no threshold for harm and that public health measures should aim at achieving the lowest concentrations possible.⁶

17. In summary, the existing evidence shows that ENDS aerosol is not merely “water vapour” as is often claimed in the marketing for these products. ENDS use poses serious threats to adolescents and fetuses. In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants. Nevertheless, the reduced exposure to toxicants of well-regulated ENDS used by established adult smokers as a complete substitution for cigarettes is likely to be less toxic for the smoker than conventional cigarettes or other combusted tobacco products. The amount of risk reduction, however, is presently unknown. The 2014 Surgeon General’s Report concluded that non-combustible products such as ENDS are much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced.⁷

Efficacy in helping smokers to quit smoking and ultimately nicotine dependence

18. Although anecdotal reports indicate that an undetermined proportion of ENDS users have quit smoking using these products their efficacy has not been systematically evaluated yet. Only a few studies have examined whether the use of ENDS is an effective method for quitting tobacco smoking.

¹ Under near real-use conditions, e-cigarettes increased indoor air levels of polycyclic aromatic hydrocarbons, 1,2-propanediol, 1,2,3-propanetriol, glycerine, and aluminium.

² Schober W, Szendrei K, Matzen W, Osiander-Fuchs H, Heitmann D, Schettgen T et al. Use of electronic cigarettes (e-cigarettes) impairs indoor air quality and increases FeNO levels of e-cigarette consumers. *International Journal of Hygiene and Environmental Health*. 2014;217(6):628–37. doi:10.1016/j.ijheh.2013.11.003.

³ Czogala J1, Goniewicz ML, Fidelus B, Zielinska-Danch W, Travers MJ, Sobczak A. Secondhand exposure to vapors from electronic cigarettes. *Nicotine and Tobacco Research*. 2014;16(6):655–62. doi: 10.1093/ntr/ntt203.

⁴ McAuley TR, Hopke PK, Zhao J, Babaian S. Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation Toxicology*. 2012;24(12):850-7.

⁵ Flouris AD, Chorti MS, Poulianiti KP, Jamurtas AZ, Kostikas K, Tzatzarakis MN et al. Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function. *Inhalation Toxicology*. 2013;25(2):91–101. doi: 10.3109/08958378.2012.758197.

⁶ WHO air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide: summary of risk assessment. Geneva: World Health Organization; 2006.

⁷ The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014 (p. 874).

19. The evidence for the effectiveness of ENDS as a method for quitting tobacco smoking is limited and does not allow conclusions to be reached. However, the results of the only randomized control trial that compared use of ENDS, with or without nicotine, to use of nicotine patches without medical assistance in the general population, showed similar, although low, efficacy for quitting smoking.¹ A recent study also shows some, although limited, effectiveness in real-world conditions.²

20. At this level of efficacy, the use of ENDS is likely to help some smokers to switch completely from cigarettes to ENDS. However, for a sizeable number of smokers ENDS use will result in the reduction of cigarette use rather than in quitting. This will lead to dual use of ENDS and cigarettes. Given the likely greater importance of duration of smoking (number of years smoking) over intensity (number of cigarettes smoked per day) in generating negative health consequences, dual use will have much smaller beneficial effects on overall survival compared with quitting smoking completely.³

21. No ENDS product has yet been evaluated and approved for smoking cessation by a governmental agency, although the United Kingdom's Medicines and Healthcare Products Regulatory Agency is in the process of reviewing some of these products.

22. In considering ENDS as a potential cessation aid, smokers should first be encouraged to quit smoking and nicotine addiction using a combination of already approved treatments. However, at the individual level, experts suggest that in some smokers who have failed treatment, have been intolerant to it or who refuse to use conventional smoking cessation medication, the use of appropriately-regulated ENDS may have a role to play in supporting attempts to quit.^{4,5}

Impact on existing tobacco-control efforts

23. Although ENDS present a range of potential benefits to smokers, there is an extensive and often heated debate about whether ENDS will prove to have a positive or negative impact on population health and particularly tobacco control. Areas of legitimate concern include avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers. Such concerns are referred to as the gateway and renormalization effects.

24. Gateway and renormalization concerns.

(a) The gateway effect refers to two potential circumstances:

- (i) the possibility that children (and generally non-smokers) will initiate nicotine use with ENDS at a rate greater than expected if ENDS did not exist;⁶ and
- (ii) the possibility that once addicted to nicotine through ENDS children will switch to cigarette smoking.

¹ Bullen CB, Howe C, Laugesen M, McRobbie H, Parag V, Williman J et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*. 2013;382(9905):1629–37.

² Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. *Addiction*. Published online, 20 May 2014. doi:10.1111/add.12623.

³ The health consequences of smoking – 50 years of progress: a report of the Surgeon General. Atlanta (GA): US Department of Health and Human Services; 2014.

⁴ Fiore MC, Schroeder SA, Baker TB. Smoke, the chief killer – strategies for targeting combustible tobacco use. *New England Journal of Medicine*. 2014;370(4):297–9. doi: 10.1056/NEJMp1314942.

⁵ Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation*. 2014;129: e490–e492. doi:10.1161/CIRCULATIONAHA.114.008545.

⁶ this This does not mean that use of ENDS by children is not a concern in itself.

(b) The renormalization effect refers to the possibility that everything that makes ENDS attractive to smokers may enhance the attractiveness of smoking itself and perpetuate the smoking epidemic. ENDS mimic the personal experience and public performance of smoking and their market growth requires marketing that is challenging commercial communication barriers erected to prevent the promotion of tobacco products.

(c) The likelihood and significance of these two effects occurring will be the result of a complex interplay of individual, market and regulatory factors and is difficult to predict. They can only be assessed with empirical data, which at present are virtually non-existent.

(d) The limited existing survey data from a handful of countries show that experimentation with ENDS is increasing rapidly among adolescents and that in itself is of great concern even if most of the young ENDS users also smoke. In fact, except in one case, the surveys show that there are few exclusive ENDS users who have never smoked (mostly around 1% of the population).^{1,2,3} These data do not allow the conclusions to be drawn as to whether this is a sign of adolescent smokers switching to ENDS, an established pattern of dual use, or a temporary experimentation fashion. Therefore, in the absence of longitudinal data, existing evidence does not allow an affirmation or rejection of the role of ENDS in increasing nicotine addiction among adolescents above existing uptake rates, much less as to whether ENDS lead to smoking in these countries. Among adults the pattern of dual use seems also the predominant one, resulting in a reduction of smoked cigarettes and with few never smokers starting to use ENDS (below 1% of the population).^{4,5}

(e) There are also very limited data from very few countries about the evolution of the smoking epidemic in the presence of the ENDS boom. In one country (United Kingdom), where tobacco-control measures are very strong and ENDS use is popular and growing, it seems that smoking prevalence, cigarette consumption as well as overall nicotine use continues to decrease gradually.⁶ Whether these contrasting trends are causally related cannot be concluded from these data. At least for the United Kingdom, renormalization as measured by prevalence of smoking is not occurring currently. Whether this would be the case for other countries cannot be generalized from the existing data and needs to be proven empirically.

25. More specific public health questions related to the interaction between ENDS and tobacco-control efforts are discussed below.

26. Positioning the tobacco-control message: The entry of ENDS in the market has created challenges to the core message of tobacco control, which until now has been that tobacco use should

¹ Calculations based on Centers for Disease Control and Prevention reported data from the United States National Youth Tobacco Survey, contained in: Corey C, Wang B, Johnson SE, Apelberg B, Husten C, King BA et al. Notes from the field: electronic cigarette use among middle and high school students – United States, 2011–2012. *Morbidity and Mortality Weekly Report*;62(35):729–30.

² Lee S, Grana RA, Glantz SA, Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking. *Journal of Adolescent Health*. Published online, 22 November 2013. doi: <http://dx.doi.org/10.1016/j.jadohealth.2013.11.003>.

³ Lukasz Goniewicz M, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. *Pediatrics*. Published online, 17 September 2012. doi:10.1542/peds.2011-3448.

⁴ Sutfina EL, McCoy TP, Morrell HER, Hoepfner BB, Wolfson M. Electronic cigarette use by college students. *Drug and Alcohol Dependence*. 2013;131(3):214–221. <http://dx.doi.org/10.1016/j.drugalcdep.2013.05.001>.

⁵ ASH UK fact sheet. Use of electronic cigarettes in Great Britain. April 2014. Available from: http://www.ash.org.uk/files/documents/ASH_891.pdf.

⁶ West R, Brown J, Beard E. Smoking toolkit study. Trends in electronic cigarette use in England. Updated 4th April 2014. Available from: <http://www.smokinginengland.info/latest-statistics/>.

not be started and if started it should be stopped.¹ The promotion of ENDS comes with at least one of the following messages or a combination of them: (a) try to quit smoking and if everything fails use ENDS as the last resort; (b) you do not need to quit nicotine addiction, just smoking; and (c) you do not need to quit smoking, use ENDS where you cannot smoke. Some of these messages are difficult to harmonize with the core tobacco-control message and others are simply incompatible.

27. The role of the tobacco industry: The future role of ENDS is strongly determined by the commercial interests of the industry that manufactures and sells ENDS. While there are “independent” ENDS companies that have reported no interest in perpetuating tobacco use, the tobacco industry involved in the production and sale of ENDS certainly is.

(a) The ENDS market, initially dominated by companies with no links to the tobacco industry, is increasingly owned by the tobacco industry. All main transnational tobacco companies sell ENDS and one of them is launching legal proceedings over patents against its rivals as they become increasingly aggressive in the battle for the fast-growing e-cigarette market. The increasing concentration of the ENDS market in the hands of the transnational tobacco companies is of grave concern in light of the history of the corporations that dominate that industry.

(b) It is unclear yet what this means for the ENDS market. However, if prior interest of the tobacco industry in reduced-risk products serves as a precedent, their interest lies in maintaining the status quo in favour of cigarettes for as long as possible, while simultaneously providing a longer-term source of profit should the cigarette model prove unsustainable. In addition, selling these products is intended to bring reputational benefits to these companies, as they can pretend to be part of the solution to the smoking epidemic.² ENDS may follow the trend of smokeless tobacco wherein the industry’s historic interest in smokeless tobacco products outside some Nordic countries was both because they could be used in smoke-free environments and because they could be promoted to young, non-tobacco users to create a new form of tobacco use.³

28. Potential interference with smoke-free policies.

(a) Smoke-free policies are designed not only to protect non-smokers from second-hand smoke, but also to provide incentives to quit smoking and to denormalize smoking as adolescents are particularly vulnerable to visual cues and social norms.⁴

(b) The use of ENDS in places where smoking is not allowed

- (i) increases the exposure to exhaled aerosol toxicants of potential harm to bystanders,
- (ii) reduces quitting incentives, and
- (iii) may conflict with the smoking denormalizing effect.

(c) Many ENDS look like smoking products and even if they do not resemble them, the exhaled vapour looks like tobacco smoke. ENDS are marketed to be used where smoking is

¹ de Andrade M, Hastings G, Angus K, Dixon D, Purves R. The marketing of electronic cigarettes in the UK. London: Cancer Research UK; November 2013.

² Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry’s use of the term tobacco harm reduction in order to inform public health policy. Tobacco Control. Published online, 22 January 2014. doi:10.1136/tobaccocontrol-2013-051502.

³ Mejia AB, Ling PM. Tobacco industry consumer research on smokeless tobacco users and product development. American Journal of Public Health. 2010;100(1):78–87. doi: 10.2105/AJPH.2008.152603.

⁴ Preventing tobacco use among youth and young adults. A report of the Surgeon General. Rockville (MD); US Department of Health and Human Services: 2012.

prohibited and given the resemblance to tobacco products it is likely that their use where smoking is banned will make enforcing smoke-free policies more difficult.

(d) The fact that ENDS exhaled aerosol contains on average lower levels of toxicants than the emissions from combusted tobacco does not mean that these levels are acceptable to involuntarily exposed bystanders. In fact, exhaled aerosol is likely to increase above background levels the risk of disease to bystanders, especially in the case of some ENDS that produce toxicant levels in the range of that produced by some cigarettes.

29. The role of ENDS marketing (which falls into two categories: consumer marketing aimed at the general public, and stakeholder marketing aimed at policy-makers and public health bodies):

(a) ENDS are being marketed to consumers in many media and forms, including television commercials, sports and cultural sponsorship, celebrity endorsement, social networking, online advertising, point-of-sale displays, pricing strategies, and product innovation. Some marketing clearly emulates the very successful tobacco advertising asserting an independent identity and a lifestyle choice, aligning oneself with celebrities, fashionable and youthful places and activities. Some ENDS are marketed not only as socially acceptable but as socially superior. Unsubstantiated or overstated claims of safety and cessation are frequent marketing themes aimed at smokers. Some ENDS marketing also promotes long-term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned. ENDS marketing activities have the potential to glamorize smoking and attracting children and non-smokers even if those are unintentional results. However, no empirical studies have been conducted to show whether the negative prospects of ENDS marketing are actually directly associated with attitudinal and behavioural changes among children and non-smokers consistent with the realization of such potential. Concerns have also been raised over the use of flavours in the marketing of ENDS. One recent study indicates that ENDS are marketed in 7764 unique flavours.³ Although the role of ENDS flavours potential attractiveness has not been studied yet, expert opinion indicates that candy-like flavours could entice youths to experiment with ENDS and could also facilitate the development of tobacco dependence by enhancing the sensory rewards of ENDS use.¹ The tobacco industry’s internal documents suggest that flavouring agents have played an important role in the industry’s targeting of children and youth, and there is a concern that they could play the same role in the uptake of ENDS in these age groups.

(b) The marketing message to tobacco-control stakeholders is one of alignment of industry and public health interests based on the harm reduction potential of ENDS. This leads to a proposal of partnership between government and industry because industry claims a meaningful seat at the table in the so-called harm reduction debate.

CURRENT REGULATION AND POLICY: RESULTS OF THE WHO SURVEY

30. **Table 1** reflects the results of the 2014 WHO survey, showing the distribution of countries according to the regulatory approach taken to ENDS.

Type of ENDS	ENDS regulated as					Not regulated or unknown
	consumer product	therapeutic product	tobacco product	other	total	
With nicotine	14 (27%)*	12 (6%)	22 (10%)	11 (6%)	59 (49%)	135 (51%)
Without nicotine	23 (35%)	0 (0%)	18 (7%)	12 (2%)	53 (44%)	141 (56%)

¹ The scientific basis of tobacco product regulation: a WHO Study Group on Tobacco Product Regulation report. Candy-flavoured tobacco products: research needs and regulatory recommendations. Geneva; World Health Organization: 2007 (WHO Technical Report Series 945).

* The figure in parentheses after the number of countries indicates the percentage of the world population living in these countries.

31. The sale of ENDS with nicotine is banned in 13 of the 59 countries that regulate them. However, the majority of these 13 countries report that ENDS are available to the public, probably through illicit trade and cross-border Internet sales.

32. The survey also shows that:

- (a) comprehensive advertising, promotion and sponsorship bans on ENDS are in place in 39 countries (in which 31% of the world's population live);
- (b) use of ENDS in enclosed public places is banned in 30 countries (35%);
- (c) premarket review is required by 19 countries (5%);
- (d) vendor licences are required by nine countries (4%);
- (e) policies on ENDS sales to minors were confirmed by 29 countries (8%). Where specified, minimum required age for purchase ranged from 18 to 21 years.

GENERAL CONSIDERATIONS

33. Smokers will obtain the maximum health benefit if they completely quit both tobacco and nicotine use. In fact, Article 5.2(b) of the Convention commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also to preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not.

34. The rapid growth of ENDS use globally can neither be dismissed nor accepted without efforts to appropriately regulate these products, so as to minimize consequences that may contribute to the tobacco epidemic and to optimize the potential benefits to public health. Thus it is important to identify public health concerns and to consider these concerns when undertaking regulation and surveillance.

35. Regulation of ENDS is a necessary precondition for establishing a scientific basis on which to judge the effects of their use, and for ensuring that adequate research is conducted, that the public has current, reliable information as to the potential risks and benefits of ENDS, and that the health of the public is protected. Public health authorities need to prioritize research and invest adequately to elucidate evidentiary uncertainties as soon as possible. However, the greater responsibility to prove claims about ENDS scientifically should remain with the industry.

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

- (a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;
- (b) minimize potential health risks to ENDS users and non-users;
- (c) prohibit unproven health claims from being made about ENDS; and
- (d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.

37. Because the product, the market and the associated scientific evidence surrounding ENDS are all evolving rapidly, all legislation and regulations related to ENDS should be adaptable in response to

new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates.

38. Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realized.

SPECIFIC REGULATORY OPTIONS

39. In order to achieve the general regulatory objectives mentioned above, Parties that have not banned the sale of ENDS could consider the following non-exhaustive list of regulatory options, on the understanding that the advisability and feasibility at country level of each of these options will depend on a complex set of country-specific factors, including the existing regulatory frameworks and the legal exigencies of the regulatory process.

40. **Health claims.** Prohibit manufacturers and third parties from making health claims for ENDS, including that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval. The regulatory standard for cessation claims and approval as cessation aids should remain an appropriate body of evidence, based on well-controlled clinical trials. For ENDS products to be approved for smoking cessation by the suitable regulatory agency, the appropriate balance should be reached between providing accurate scientific information to the public about the risks of ENDS use and its potential benefits as compared with smoking. This balance can only be determined through scientifically tested audience messaging.

41. **Use of ENDS in public places.** Since the reasonable expectation of bystanders is not a diminished risk in comparison to exposure to second-hand smoke but no risk increase from any product in the air they breathe, ENDS users should be legally requested not to use ENDS indoors, especially where smoking is banned until exhaled vapour is proven to be not harmful to bystanders and reasonable evidence exists that smoke-free policy enforcement is not undermined. If smoke-free legislation is not fully developed according to Article 8 of the WHO FCTC and the guidelines for its implementation, this should be done as soon as possible.

42. **Advertising, promotion and sponsorship.** Given that the same promotional elements that make ENDS attractive to adult smokers could also make them attractive to children and non-smokers, Parties should contemplate putting in place an effective restriction on ENDS advertising, promotion and sponsorship. Some forms of ENDS promotion, however, may be considered acceptable by Parties if empirical evidence shows that ENDS might play a role in helping some smokers to quit without leading to increased ENDS use by minors and non-smokers who otherwise would not have used nicotine.

43. Any form of ENDS advertising, promotion and sponsorship must be regulated by an appropriate governmental body. If this is not possible, an outright ban on ENDS advertising, promotion and sponsorship is preferable to the implementation of voluntary codes on ENDS marketing, given the overwhelming evidence that similar codes for tobacco and alcohol products have failed to protect young people from such advertising.

44. Advertising, promotion and sponsorship of ENDS with or without nicotine, must, at a minimum:

- (a) state clearly whether the product contains nicotine or may be used with nicotine solutions;
- (b) not make them appealing to or target, either explicitly or implicitly, non-smokers or non-nicotine users, and must therefore indicate that ENDS are not suitable for use by people who do not currently consume tobacco products;

- (c) not make them appealing to or target, either explicitly or implicitly, minors, including through the selection of media, location or the context in which they appear or through imagery that promotes sexual or sporting prowess;
- (d) never promote ENDS for non-smokers, and their use should not be portrayed as a desirable activity in its own right;
- (e) encourage smoking cessation and provide a quitline number if one exists;
- (f) contain nothing that could reasonably be expected to promote the use of tobacco products, such as:
 - (i) the appearance or/and use of tobacco products;
 - (ii) the use of any brand name, design, colour, emblem, trademark, logo or trade insignia or any other distinctive feature that might be associated by the audience with a tobacco product;
 - (iii) the use of the words e-cigarette, electronic cigarette, or any other descriptor that might reasonably be expected to create confusion with the promotion of cigarettes and other combustible tobacco products;
 - (iv) showing ENDS products in ways that could reasonably be expected to promote tobacco products, including images of tobacco-like products;
- (g) not contain health or medicinal claims, unless the product is licensed for those purposes by the appropriate regulatory agency. Electronic cigarettes and other nicotine-containing products should be presented only as an alternative to tobacco, and should include warnings that dual use will not substantially reduce the dangers of smoking;
- (h) not undermine any tobacco-control measure, including by not promoting the use of ENDS in places where smoking is banned;
- (i) include factual information about product ingredients other than nicotine and in a way that does not distort evidence of risks;
- (j) not link these products with gambling, alcohol, illicit drugs or with activities or locations in which using them would be unsafe or unwise.

45. Advertising, promotion and sponsorship of ENDS that contain nicotine or may be used with nicotine solutions must:

- (a) clearly state the addictive nature of nicotine and that these products are intended to deliver nicotine;
- (b) Prohibit suggestions that ENDS have positive qualities as a consequence of the addictive nature of the product.

46. All authorized forms of ENDS advertising, promotion and sponsorship must be cleared by the appropriate authority prior to publication/transmission in order to proactively prevent inappropriate marketing, and then be monitored to assess compliance.

47. **Protection from vested commercial interests.** Transparency should be required from ENDS and tobacco companies advocating for and against legislation and regulation, both directly and through third parties. No matter what role the tobacco industry plays in the production, distribution and sale of ENDS, this industry, its allies and front-groups can never be considered to be a legitimate public health partner or stakeholder while it continues to profit from tobacco and its products or represents the interests of the industry. Article 5.3 of the WHO FCTC should be respected when developing and implementing ENDS legislation and regulations.

48. **Product design and information.** ENDS should be regulated to:
- (a) minimize content and emissions of toxicants;
 - (b) ensure use of nicotine of pharmacological quality, when nicotine use is intended;
 - (c) standardize nicotine delivery at levels known to the consumers;
 - (d) minimize acute nicotine toxicity;
 - (e) impede product alteration to use of other drugs;
 - (f) ban ENDS solutions with fruit, candy-like and alcohol-drinks flavours until empirical evidence shows that they are not attractive to minors;
 - (g) require manufacturers and importers to disclose to governmental authorities information about the contents and emissions of ENDS; and
 - (h) require registration of manufacturers and importers with governmental authorities.
49. **Health warnings.** ENDS health warnings should be commensurate with proven health risks. In this regard, the following risk warnings could be considered: potential nicotine addiction; potential respiratory, eyes, nose and throat irritant effect; potential adverse effect on pregnancy (due to nicotine exposure).
50. **Surveillance and monitoring.** Governments are recommended to use or strengthen their existing tobacco surveillance and monitoring systems to assess developments in ENDS and nicotine use by sex and age.
51. **Sale to minors.** Retailers should be prohibited from selling ENDS products to minors, and vending machines should be eliminated in almost all locations.

REGULATORY FRAMEWORK

52. In order to implement the suggested general regulatory objectives as well as the specific regulatory options, Parties will need to consider the available national regulatory frameworks that could best provide solid regulatory grounds. Nevertheless, it is likely that a two-pronged regulatory strategy – regulating ENDS as both a tobacco product, in accordance with the provisions of the WHO FCTC, and as a medical product – would be necessary.
53. The applicability of many of the WHO FCTC provisions to the regulation of ENDS was reviewed in a report by the Convention Secretariat on this topic¹ presented at the fifth session of the COP.

ACTION BY THE CONFERENCE OF THE PARTIES

54. The COP is invited to note this report and to provide further guidance.

¹ Document FCTC/COP/5/13 (available at www.who.int/fctc/publications).