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**Electronic nicotine delivery systems,
including electronic cigarettes****Report by the Convention Secretariat****INTRODUCTION**

1. This document was prepared in response to the request made by the Conference of the Parties (COP) at its fourth session (Punta del Este, Uruguay, 15–20 November 2010) to the Convention Secretariat to prepare jointly with WHO's Tobacco Free Initiative a comprehensive report based on the experience of Parties on the matter of electronic nicotine delivery systems (ENDS) including electronic cigarettes for consideration at the fifth session of the COP.¹

2. ENDS are designed to deliver nicotine to the respiratory system. The term encompasses products that contain tobacco-derived substances, but in which tobacco is not necessary for operation.² They are battery-powered devices that provide inhaled doses of nicotine by delivering a vaporized propylene glycol/nicotine mixture. ENDS are marketed under a variety of brand names and descriptors, of which the terms “electronic cigarettes” or “e-cigs” are the most common.

3. It appears that electronic cigarettes that are capable of providing inhaled doses of nicotine, but that do not contain nicotine are also available in some Parties. In addition, and separately, vials of various nicotine concentrations are for sale. These vials can be added to the electronic cigarettes (the consumer can determine the dosage of nicotine).

4. Recent studies and publications point out that more research on ENDS must be conducted, especially with regard to their safety and the marketing claims made by the manufacturers (such as

¹ See decision FCTC/COP4(14).

² Report on the scientific basis of tobacco product regulation. Third report of a WHO Study Group. Geneva, World Health Organization, 2009 (WHO Technical Report Series, No. 955).

“alternative to smoking” or “helps smokers quit”). It is consistently noted that the popularity of ENDS is growing and that a thorough examination of these products is needed.¹

5. The report submitted by the Convention Secretariat to the fourth session of the COP² provided an explanation of ENDS as well as an overview of recommendations made by the WHO Study Group on Tobacco Product Regulation and the outcome of a regulatory consultation convened by WHO. In a further effort to gather and analyse information on ENDS, the Convention Secretariat sent a questionnaire on ENDS to all Parties in November 2011. The survey included questions on availability, regulatory framework, sales volume and scientific studies on ENDS. A total of 33 Parties responded to the survey.³

6. In addition, the reports by Parties on implementation of the WHO Framework Convention on Tobacco Control (WHO FCTC) were reviewed with regard to comments on ENDS. Three Parties, two of which had also responded to the questionnaire, referred to ENDS in their implementation reports.

AVAILABILITY OF ENDS

7. When asked in the questionnaire if ENDS, such as electronic cigarettes, were available for sale in their country, the response choices were “yes”, “no”, and “do not know”.

8. Of the 33 Parties that replied, 16 stated that ENDS are available in their country, 13 stated that these products are not available, and 4 stated that they did not know whether or not ENDS are available. All 16 Parties in which ENDS are available are upper-middle-income or high-income countries. Since the price of a single electronic cigarette kit may be 10 or more times the price of a packet of “regular” cigarettes, it appears that the marketing of ENDS is targeted at countries with a sub-population with a relatively high disposable income.

9. In all 16 Parties in which ENDS are available, electronic cigarettes are the most common form of ENDS, followed by e-cigars, sold in 6 countries, and e-pipes, sold in 4 countries.

10. Parties in which ENDS are available reported that they are sold in pharmacies (4 Parties), supermarkets (6 Parties), kiosks (5 Parties), via the Internet (14 Parties) and other (9 Parties). Parties replied that “other” places include retail shops, kiosks, supermarkets, specialized shops, markets/market stalls, on the street, and bars and pubs and leisure venues such as casinos and bingo halls.

¹ Recent publications include: Vansickel AR, Eissenberg T. Electronic cigarettes: effective nicotine delivery after acute administration. *Nicotine & Tobacco Research*, 2012; Etter J-F et al. Electronic nicotine delivery systems: a research agenda. *Tobacco Control*, 2011, 20:243–248; Vansickel AR et al. A clinical laboratory model for evaluating the acute effects of electronic “cigarettes”: nicotine delivery profile and cardiovascular and subjective effects. *Cancer Epidemiology, Biomarkers & Prevention*, 2010, 19:1945–1953; Eissenberg T. Electronic “cigarettes”: ineffective nicotine delivery and craving suppression after acute administration. *Tobacco Control*, 2010, 19:87–88.

² Document FCTC/COP/4/12.

³ Australia, Belgium, Bhutan, Brazil, Bulgaria, Canada, China, Germany, Ghana, Hungary, Ireland, Japan, Kuwait, Lesotho, Lithuania, Malaysia, Mauritania, New Zealand, Norway, Portugal, Republic of Korea, Romania, Rwanda, San Marino, Serbia, Seychelles, Singapore, South Africa, Trinidad & Tobago, Turkey, Uganda, United Kingdom of Great Britain and Northern Ireland, and Uruguay.

11. Electronic cigarettes are available via the Internet in 14 of the 16 Parties. In terms of Internet sales, the survey did not attempt to determine where the Internet-based ENDS providers are located or the country of origin of the shipment.

12. Very few Parties, whether or not they regulate ENDS, indicated that they are able to monitor sales levels of ENDS or historical trends. Of the 16 Parties in which ENDS are available, only 2 (Malaysia and Republic of Korea) provided any numerical data. With regard to historical trends, only 2 Parties (Bulgaria and Republic of Korea) provided data suggesting an increase in sales over time.

SCIENTIFIC ANALYSIS OF ENDS INCLUDING ON CONTENTS, EMISSIONS OR HEALTH EFFECTS

13. In the questionnaire, Parties were asked if they or a delegated entity had conducted any scientific analyses of ENDS, including on contents, emissions or health effects. If yes, Parties were asked to state the conclusions and summary of the outcome of such analyses.

14. Based on the replies received, only 4 of the 16 Parties in which ENDS are available have carried out any scientific studies on ENDS. In addition, in its most recent WHO FCTC implementation report, Australia reported with regard to the progress made in implementation of Article 20 (*Research, surveillance and exchange of information*) that its Department of Health and Ageing was currently commissioning research in a number of areas to inform future consideration of further regulatory options, including research on options for further regulation of ENDS and smokeless tobacco products.

15. The Republic of Korea performed a liquid chromatography-tandem mass spectrometry and gas chromatography-mass spectrometry to identify and quantify contaminants and additives in electronic cigarettes. Preliminary results suggest that 10 toxicants can be identified and quantified and that there may be inconsistencies in nicotine content labeling and the actual values of nicotine. Bulgaria and Malaysia undertook studies to determine if the actual nicotine content was equal to what had been declared.

16. In Brazil, where electronic cigarettes have been banned since 2009, a preliminary laboratory study showed that the chemical fingerprint points to the fact that the liquid found in electronic cigarette cartridges contains tobacco extracts. Brazil reported that the results of the study will be shared once finalized.

17. None of the above studies addresses the claims made regarding the quality, safety, and efficacy of ENDS. It should be noted in this regard that the WHO Study Group on Tobacco Product Regulation (TobReg) submitted a report on ENDS to the 126th session of the WHO Executive Board in January 2010.¹

18. In that report, TobReg concluded that the safety and extent of nicotine uptake had not been established; that the products were marketed as smoking cessation aids, but that not enough scientific evidence existed to validate this claim; and that delivery to the lung might be dangerous and, independent of the effects of nicotine, it was of global importance to address lung delivery in scientific

¹ Document EB 126/37.

studies. TobReg also concluded that ENDS designed for the purpose of direct nicotine delivery to the respiratory system fall into a regulatory gap in most countries, escaping regulation as drugs and avoiding the controls applicable to tobacco products. There is also insufficient evidence currently to assess whether ENDS may be used to aid cessation, whether they create or sustain addiction, and whether they deliver constituents other than nicotine to smokers.

19. TobReg recommended that clinical trials, behavioural and psychological studies, and post-marketing studies at individual and population levels are needed to answer these questions. Claims that these products have health benefits, reduce harm, or can be used to aid smoking cessation should be prohibited until they are scientifically proven. They should be regulated as nicotine delivery devices, and where this regulation is not possible under tobacco-control laws, should be subject to regulation of contents and labelling, prohibitions against use in public places, and restrictions on advertising, promotion, and sponsorship.

20. Furthermore, participants of a Regulatory Consultation on the Safety of ENDS convened by WHO in May 2010 expressed the concern that the quality and safety of ENDS have not been established. They urged regulators of medical and tobacco products to collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) ENDS to protect public health. They also recommended that in instances where health and/or therapeutic claims are being made or implied, quality, safety and efficacy data substantiating those claims should be presented to the appropriate national regulatory body.¹

REGULATORY STRATEGIES UNDERTAKEN BY PARTIES

21. Of the 13 Parties that stated that ENDS are not available for sale in their jurisdictions, only 4 – Brazil, the Seychelles, Singapore and Uruguay – have laws banning the manufacturing, importation, distribution, and sale of ENDS. The strategy taken by the Seychelles and Singapore² is to consider ENDS as a tobacco imitation product, regardless of accompanying health claims and the presence or absence of tobacco or nicotine extracts. Article 11 of Seychelles' Tobacco Control Act of 2009 states that “a person shall not manufacture, import, supply, display, distribute or sell any sweets, snacks, toys or other non-tobacco products resembling a tobacco product” (emphasis added). Singapore's Tobacco Act, section 16, states that “No person shall import, distribute, sell or offer for sale any confectionery or other food product or any toy or other article that is designed to resemble a tobacco product or the packaging of which is designed to resemble the packaging commonly associated with tobacco products” (emphasis added).

22. Eight Parties reported that they regulate ENDS marketed with health claims and containing nicotine, but that ENDS are not available. It can be concluded that market authorization for ENDS has not been requested, or that it has been requested, but not granted.

¹ See document FCTC/COP/4/12 for details of this meeting.

² While Brazil and Uruguay also banned ENDS, their survey responses did not provide information on whether ENDS are regarded as an imitation tobacco product or whether they are banned on another basis.

23. Of the 16 Parties in which ENDS are available, 9 do not regulate ENDS.¹ The remaining 7 Parties regulate ENDS in different ways, covering either only their sale, or only their production, or covering their sale, distribution, advertisement, and promotion. One Party replied that ENDS are available and regulated as a pharmaceutical product. This would mean that ENDS have been given market authorization; however, that Party also stated that no scientific analysis had been conducted.

24. A table showing the availability of ENDS in Parties, and whether or not and how ENDS are regulated is attached as Annex 1.

25. It can be concluded from the survey that there are four types of ENDS that could be regulated, each with and without health claim(s): ENDS with tobacco extracts, ENDS with nicotine and tobacco extracts, ENDS with nicotine, and ENDS with neither nicotine nor tobacco. Annex 2 indicates the scope of regulation of the different types of ENDS in Parties.

26. As indicated in Annex 2, some Parties stated that they regulate nicotine-containing ENDS if health claims are made. Based on the replies, it can be concluded that ENDS containing nicotine and that make health claims could only be sold in these countries with prior market approval by a competent national regulatory authority. On the other hand, several Parties in which ENDS are available do not regulate nicotine-containing ENDS, even if health-claims are made.

27. It appears from the survey responses that ENDS are being regulated by Parties under both tobacco and medicines regulation. The survey also shows that some Parties have taken a more radical approach by banning ENDS regardless of whether or not they contain tobacco extracts or nicotine or make health claims. Concurrently, under a Party's medicines framework, ENDS that make health claims could undergo regulatory scrutiny and pre-market approval by a competent national regulatory body to verify the claims made regarding quality, safety and efficacy. This two-pronged approach would prevent a situation in which ENDS are available and unregulated simply because no health claims are made.

28. In addition, Hungary indicated in its most recent WHO FCTC implementation report that since a stricter smoking ban had been put in place, demand for ENDS had increased. As nicotine was a pharmaceutical active ingredient, the marketing of electronic cigarettes interfered with pharmaceutical rules. It was necessary to make internationally coordinated efforts in the field of combating illicit tobacco replacement products.

OTHER DEVELOPMENTS

29. Parties are invited to note some recent developments. First, disposable electronic cigarettes have appeared on the market. These products are aimed at consumers who prefer not to charge batteries or who do not have enough money to buy electronic cigarettes for long-term use. The price of "regular" electronic cigarettes ranges from US\$ 50 to US\$ 150 depending on the brand, with a lifespan of up to three years. In contrast, the price for a disposable electronic cigarette ranges from US\$ 2 to US\$ 13, depending on the number of puffs it can provide. It is also possible to buy a pack of individual cigarettes or disposable nicotine atomizers only. Some companies are only selling disposable nicotine atomizers, which are very easy to use. Electronic cigarettes (including accessories such as fruit and

¹ In addition, Latvia in its WHO FCTC implementation report noted that electronic cigarettes were not subject to regulation, and that existing legislation had to be amended.

confectionery flavourings) are also widely advertised on the Internet, and a study monitoring Internet search engine queries from January 2008 to September 2012 reported that online interest in electronic cigarettes had surpassed that of oral tobacco (snus) and nicotine replacement therapies.¹

30. Secondly, one prominent tobacco manufacturer in the United States recently purchased an electronic cigarette company, making it the first major tobacco firm to buy or invest in electronic cigarettes.² In 2009, a European company that produces a range of products that it describes as being for nicotine replacement therapy was purchased by another large United States tobacco manufacturer, and a producer of nicotine delivery systems has agreed a marketing and distribution agreement with a company within the corporate group of yet another major tobacco manufacturer.³ These developments demonstrate that traditional cigarette companies are taking notice of the emerging products.

31. In addition, recent estimates indicate that the electronic cigarette market is growing rapidly in the European Union, and that the total value of the market in 2011 was €400–500 million.⁴ Additional statistics confirm that the use of electronic cigarettes has grown markedly in recent years: 7% of citizens of the European Union have reported that they have at least tried electronic cigarettes,⁵ and in the United Kingdom of Great Britain and Northern Ireland, the number of electronic cigarette owners is expected to rise from a small number in 2006 to over 1 million by 2013.⁴

32. Finally, a recent press release⁶ by a market analyst⁷ announcing its global report on the projected tobacco industry in 2050 predicted that “the concept of reduced harm tobacco products is expected to pick up pace as innovation in non-combustible, cigarette mimicking nicotine delivery devices are developed by cigarette companies. The e-cigarette and the (non-e) nicotine aerosol cigarette will lead the nicotine delivery market over the long-term ... By 2050, ... [the market analyst] expects the novel nicotine delivery device (NNDD) market (including e-cigarettes) to be equal in value size to the whole other tobacco products (OTP) market”.⁸

¹ Ayers JW, Ribisl KM, Brownstein J. Tracking the rise in popularity of electronic nicotine delivery systems (electronic cigarettes) using search query surveillance, *American Journal of Preventive Medicine*, 2011, 40:448–453.

² See: <http://online.wsj.com/article/SB10001424052702304723304577365723851497152.html>.

³ See: <http://www.euroinvestor.no/nyheter/2009/12/09/reynolds-american-inc-completes-acquisition-of-niconovum-ab/10780721>; <http://www.bloomberg.com/news/2011-04-05/bat-establishes-non-tobacco-nicotine-product-unit-ft-reports.html>.

⁴ Information provided by the European Commission’s Directorate General for Health and Consumers from its own data gathering.

⁵ *Special Eurobarometer 385: Attitudes of Europeans towards tobacco*. European Commission, 2012. Available from: http://ec.europa.eu/health/eurobarometers/index_en.htm.

⁶ The press release may be found at: <http://www.marketwatch.com/story/the-future-of-the-global-tobacco-industry-1-billion-smokers-in-2050-reports-euromonitor-2012-05-15>. It was published by MarketWatch, which is published by Dow Jones & Co., and is part of The Wall Street Digital Network, which includes WSJ.com and Barrons.com.

⁷ Euromonitor International, which describes itself as “the world’s leading provider for global business intelligence and strategic market analysis”. It is headquartered in London, with regional offices in Chicago, Singapore, Shanghai, Vilnius, Santiago, Dubai, Cape Town, Tokyo, Sydney and Bangalore, and has a network of over 800 analysts worldwide.

⁸ Details of the Euromonitor International report, “The Future of Tobacco” may be found at: www.euromonitor.com/the-future-of-tobacco/report.

ENDS AND THE WHO FCTC

33. It should be noted that ENDS are products resembling cigarettes and could therefore undermine the denormalization of tobacco use upheld by the WHO FCTC. One of the guiding principles of the guidelines for implementation of Article 12 (*Education, communication, training and public awareness*) is *Norm change*. It stipulates that it is “essential to change social, environmental and cultural norms and perceptions regarding the acceptability of the consumption of tobacco products, exposure to tobacco smoke ...”.¹ Parties are therefore invited to consider that a ban of ENDS as already undertaken by some Parties would contribute to changing the social norms regarding the consumption of tobacco products.

34. Another aspect to consider is that if ENDS are regarded as imitation tobacco products and banned, all ENDS would be covered, regardless of whether or not they contain nicotine, tobacco extracts, or make health claims. Parties may wish to consider that strong measures to prevent further spread of ENDS could be considered under a number of provisions of the WHO FCTC, including Article 5.2(b) which requires Parties to “adopt and implement effective ... measures ... for preventing and reducing ... nicotine addiction ...”. Most ENDS contain nicotine, and would therefore contribute to maintaining an addiction to nicotine.

35. Furthermore, under Article 13.2, Parties have an obligation to undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. “Tobacco advertising and promotion” is defined in Article 1(c) as “any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly”. Therefore, Parties may also wish to consider whether the sale, advertising, and even the use of electronic cigarettes can be considered as promoting tobacco use, either directly or indirectly. Regardless of whether or not ENDS contain nicotine or tobacco extracts, they are used to mimic smoking, which could be considered as a (direct or indirect) promotion of tobacco use. Article 16.1(c) could also be relevant since it requires Parties to prohibit “the manufacture and sale of ... any other objects in the form of tobacco products which appeal to minors”.

36. Additionally, the use of ENDS could hamper the implementation of Article 8 (*Protection from exposure to tobacco smoke*) as ENDS users in public places may claim that their electronic cigarette does not contain tobacco and/or does not produce second-hand tobacco smoke. Parties may also wish to note that Article 14 (*Demand reduction measures concerning tobacco dependence and cessation*) and its guidelines for implementation refer to evidence-based treatment for tobacco dependence and tobacco cessation, and to making available medications that have been clearly shown by scientific evidence to increase the chances of tobacco cessation.

37. If ENDS are not banned, a two-pronged strategy – regulating ENDS as both a tobacco and a medical product – could close potential loopholes in their regulation. However, Parties may again wish to consider the desirability of allowing the sale of new products that may have the capacity to maintain a nicotine addiction.

38. If a Party decided to categorize and regulate ENDS as tobacco products, all provisions of the WHO FCTC would also apply to ENDS. However, Parties may wish to consider that as ENDS are

¹ The *Guidelines for implementation of Article 12 of the WHO Framework Convention on Tobacco Control* are available at: http://www.who.int/fctc/protocol/guidelines/adopted/article_12/en/index.html.

new products resembling tobacco products that would maintain a nicotine addiction, regulating them rather than banning them could grant these new products a level of legitimacy in terms of market access, even though they may be subject to the provisions of the WHO FCTC or to regulation as medical products. Parties may wish to consider that admitting such new products would not support the objective of the WHO FCTC as stated in Article 3, which is to "... reduce continually and substantially the prevalence of tobacco use ...".

39. Regulating ENDS as medical products would most likely be the case for ENDS that are marketed with health or therapeutic claims. In this case, ENDS would be subject to the Party's relevant regulations, most notably the requirement to provide data substantiating those claims in order to obtain market authorization.

40. In summary, ENDS are a new type of product entering the market with or without regulation by Parties. Specific complexities as derived from the review above could be summarized as follows:

- (a) there are many different product categories (with or without tobacco, with or without nicotine, with cartridge or single use, battery driven or chargeable);
- (b) the market for ENDS has increased significantly;
- (c) Parties regulate ENDS differently, resulting in legal complexity, possible uncertainty and a regulatory gap in most countries;
- (d) health and safety concerns have not been resolved;
- (e) products may be subject to heavy marketing, including promotion to young people and use of flavourings;
- (f) the role of ENDS is not clearly established: they are perceived in some quarters as smoking cessation aids, and in others as a starter or dual-use (to maintain nicotine addiction) product.

41. The review expected by the COP at its fifth session would represent an important step in addressing developments, challenges and future action in relation to ENDS.

ACTION BY THE CONFERENCE OF THE PARTIES

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

ANNEX 1

AVAILABILITY AND REGULATION OF ENDS IN PARTIES¹

	Regulated (including banned)			Unregulated		
	<i>As a tobacco product</i>	<i>As a product with health/therapeutic claims</i>		<i>Regardless of whether or not contain nicotine or make health/therapeutic claims</i>	<i>Only if do <u>not</u> contain nicotine and/or <u>no</u> health/therapeutic claims are made</i>	
		<i>Contains nicotine</i>	<i>Does not contain nicotine</i>	<i>Regardless of whether or not contain nicotine</i>		
Available	Belgium, Republic of Korea	Hungary		United Kingdom of Great Britain and Northern Ireland ²	Bulgaria, Ireland, Lithuania, Malaysia, Portugal, Romania, Serbia, South Africa, Trinidad and Tobago	Australia, ³ Belgium, Canada, Germany, ⁴ Hungary, New Zealand, United Kingdom of Great Britain and Northern Ireland
Not available	Bhutan, Brazil, ⁵ Norway, Seychelles, ⁵ Singapore, ⁵ Uruguay ⁵	Australia, ³ Belgium, Canada, Germany, ⁶ New Zealand, Norway, Turkey		Japan, Uruguay	Ghana, Kuwait, Lesotho, Mauritania, Rwanda	Australia, ³ Germany ⁴

¹ Based on the replies received from Parties.

² These products are regulated as medicines only if they are promoted as a smoking cessation aid (if promoted as an alternative to smoking, they are not regulated as medicines).

³ ENDS implements are available for retail sale, but the retail sale of nicotine in the form used in ENDS is illegal. Electronic cigarettes making claims of therapeutic benefits may be available, although they are required by law to have therapeutic claims approved; electronic cigarettes have not been approved as a therapeutic device.

⁴ According to the survey response, ENDS in this form are unregulated and may or may not be available.

⁵ This Party has banned ENDS.

⁶ The distribution, sale and advertisement of these products would require market authorization. To date, no such authorization has been granted.

ANNEX 2

SCOPE OF REGULATION OF ENDS¹

		ENDS with tobacco-extracts	ENDS with nicotine and tobacco-extracts	ENDS with nicotine	ENDS with neither nicotine nor tobacco
Health/therapeutic claims	<i>Regulated</i>	Bhutan, Brazil, ² Seychelles, ² Singapore, ² Uruguay ²	Bhutan, Brazil, ² Seychelles, ² Singapore, ² Uruguay ²	Australia, Belgium, Bhutan, Brazil, ² Canada, Germany, Hungary, Japan, Norway, New Zealand, Seychelles, ² Singapore, ² Turkey, United Kingdom of Great Britain and Northern Ireland, Uruguay ²	Brazil, ² Seychelles, ² Singapore, ² Uruguay ²
	<i>Unregulated</i>			Bulgaria, Ghana, Ireland, Kuwait, Lesotho, Lithuania, Malaysia, Mauritania, Portugal, Romania, Rwanda, Serbia, South Africa, Trinidad and Tobago	

¹ Based on the replies received from Parties.

² This Party has banned ENDS.

		ENDS with tobacco-extracts	ENDS with nicotine and tobacco-extracts	ENDS with nicotine	ENDS with neither nicotine nor tobacco
No health/therapeutic claims made	<i>Regulated</i>	Belgium, Bhutan, Brazil, ² Seychelles, ² Singapore, ² Uruguay ²	Bhutan, Brazil, ² Seychelles, ² Singapore, ² Uruguay ²	Bhutan, Brazil, ² Republic of Korea, Seychelles, ² Singapore, ² Uruguay ²	Brazil, ² Seychelles, ² Singapore, ² Uruguay ²
	<i>Unregulated</i>			Bulgaria, Ghana, Ireland, Kuwait, Lesotho, Lithuania, Malaysia, Mauritania, Norway, Portugal, Romania, Rwanda, Serbia, South Africa, Trinidad and Tobago, Turkey, United Kingdom of Great Britain and Northern Ireland	Australia, Belgium, Canada, Germany, Hungary, New Zealand

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