

Position statement on electronic cigarettes or electronic nicotine delivery systems

An official statement of the E-cigarette Working Group of the International Union Against Tuberculosis and Lung Disease*

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KEY MESSAGES

- The International Union Against Tuberculosis and Lung Disease (The Union) has issued this position statement based on a careful review of the scientific evidence; the position statement will be reviewed by mid-2015.
- The safety of electronic cigarettes (ECs) or electronic nicotine delivery systems (ENDS) has *not* been scientifically demonstrated.
- Adverse health effects for third parties exposed (second-hand exposure) cannot be excluded because the use of electronic cigarettes leads to emission of fine and ultrafine inhalable liquid particles, nicotine and cancer-causing substances into indoor air.
- The benefits of e-cigarettes have not been scientifically proven. To date, very few studies have assessed ECs/ENDS as a harm reduction and cessation aid, with conflicting findings.
- The Union is concerned that the marketing, awareness and use of ECs or ENDS is growing rapidly.
- A range of current and proposed legislative and regulatory options exists; some countries (such as Brazil, Norway, and Singapore) have banned ECs/ENDS completely.
- ENDS could undermine the implementation of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) Article 12 (denormalisation of tobacco use); use of ENDS could also 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.
- The Union strongly supports the regulation of the manufacture, marketing and sale of electronic cigarettes or ENDS; the preferred option is to regulate ECs or ENDS as medicines.
- If regulation as medicines is not feasible, the following measures should be considered, pending the availability of reliable evidence:
 - a comprehensive ban on all advertising, promotion and sponsorship;
 - promotion of ECs/ENDS for tobacco cessation to be prohibited;
 - display of ECs/ENDS in retail stores to be prohibited;
 - sale to minors (persons under the age of full legal responsibility) to be prohibited;
 - ECs/ENDS and their refills should not be sold in flavours that are appealing to children;
 - packaging and labelling of EC/ENDS cartridges and disposable ECs/ENDS should include a list of all ingredients, stipulate the quantity of nicotine and include appropriate warning labels;
 - ECs/ENDS should not be used in public places, workplaces or on public transportation;
 - consumer safety standards for EC cartridges should be established, including ensuring manufacturing consistency and regulating the maximum quantity/dosage of nicotine they may contain.

POSITION STATEMENT

- 1 Electronic cigarettes (ECs) or electronic nicotine delivery systems (ENDS) may be defined as devices whose function is to vaporise and deliver to the lungs of the user a chemical mixture typically composed of nicotine, propylene glycol and other

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chemicals, although some products claim to contain no nicotine. Each device contains an electronic vaporisation system, rechargeable batteries, electronic controls and cartridges of the liquid that is vaporised. These products are not currently regulated or monitored, so the contents may vary between different e-cigarettes and may not be known to the consumer. ENDS initially emerged in China in 2003 and have since become widely available globally, particularly over the Internet.

- 2 **The safety of ECs or ENDS has *not* been scientifically demonstrated.** The potential risks they pose for the health of users remain undetermined. Furthermore, scientific testing indicates that the products vary widely in the amount of nicotine and other chemicals they deliver, and there is no way for consumers to find out what is actually delivered by the product they have purchased. As ENDS do not generate the smoke that is associated with the combustion of tobacco, their use is commonly believed by consumers to be safer than smoking tobacco. This illusive 'safety' of ENDS can be enticing to consumers; however, the chemicals used in electronic cigarettes have not been fully disclosed, and there are no adequate data on their emissions. Adverse health effects for exposed third parties (second-hand exposure) cannot be excluded because the use of electronic cigarettes leads to emission of fine and ultrafine inhalable liquid particles, nicotine and cancer-causing substances into indoor air.
- 3 **Awareness and use of ECs or ENDS is growing rapidly.** Population-based estimates of awareness (among current and former smokers) for the year 2010 are in the range of 32.2–40.9% for the United States; for the year 2011 estimates for the United States are 57.9–73.4%, for the United Kingdom 54.4%, for Canada 39.5%, for Australia 20% and for Indonesia 10.9%. Use of ENDS among current and former tobacco users in 2010–2011 was estimated at 6% for the United States, 4% for the United Kingdom, and 1% for both Canada and Australia, and use of ENDS among Indonesian men is 0.5%. However a recent report by the UK Medicines and Healthcare Products Regulatory Agency found that a tenth of UK smokers now use e-cigarettes; the number of UK users has risen to around 1.3 million in 2013, up from 700 000 in the previous year. A recent study by the US Centers for Disease Control and Prevention showed that e-cigarette experimentation and recent use doubled among US middle and high school students during 2011–2012, resulting in an estimated 1.78 million students ever having used e-cigarettes as of 2012. This is of serious concern because the overall impact of e-cigarette use on public health remains uncertain. In youths, concerns include the potential negative impact of nicotine on adolescent brain development as well as the risk of nicotine addiction and initiation of the use of conventional cigarettes or other tobacco products.
- 4 **The benefits of e-cigarettes have not been scientifically proven.** To date, few studies have assessed ECs/ENDS as a harm reduction or cessation aid, with conflicting findings. For example, one study, with positive findings, was based on a very small prospective study that monitored possible modifications in the smoking habits of 40 regular smokers; another with equivocal findings was based on a sample of 5939 current and former smokers across four countries. The all-important 'bottom line' from the 'four-country' study was that ENDS users were not more likely to quit smoking than non-users (further waves of research in this longitudinal study will yield important insights into this important question). More recently, a randomised controlled trial conducted in New Zealand found that e-cigarettes, with or without nicotine, were modestly effective at helping smokers to quit, with similar achievement of abstinence as with nicotine patches, and few adverse events.
- 5 **A range of proposals for legislative and regulatory approaches to ENDS currently exist.** Electronic cigarettes and other electronic products containing nicotine are to be regulated as medicines in the United Kingdom from 2016, to ensure their quality and safety. The United Kingdom's plans are aligned with forthcoming European legislation, so e-cigarettes would not be required to obtain a medicines licence until the European Commission's Tobacco Products Directive is agreed and becomes UK law in 2016. The United Kingdom's decision contrasts with those of some countries that have introduced restrictions on the sale and use of e-cigarettes and other countries that have banned them completely, such as Brazil, Norway and Singapore. In the United States, e-cigarettes that are marketed for therapeutic purposes are regulated by the US Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). The FDA Center for Tobacco Products (CTP) currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. The FDA has stated its intention to issue a proposed rule that would extend the FDA's tobacco product authorities to products that meet the statutory definition of 'tobacco product'. The Food and Drug Monitoring Agency in Indonesia has warned the Indonesian people that electronic cigarettes could be more dangerous than regular cigarettes. ECs are illegal in Indonesia.
- 6 **ENDS could undermine the implementation of the WHO Framework Convention on Tobacco Control Article 12 (denormalisation of tobacco use); use of ENDS could also 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. The WHO FCTC Secretariat has produced a report entitled 'Electronic nicotine delivery systems, including electronic cigarettes'.*

7 The Union strongly supports the regulation of the manufacture, marketing and sale of electronic cigarettes or electronic nicotine delivery systems. The preferred option is to regulate ECs or ENDS as medicines.

8 If regulation as medicines is not feasible, the following measures should be considered, pending the availability of reliable evidence:

- a comprehensive ban on all advertising, promotion and sponsorship;
- promotion of ECs/ENDS for tobacco cessation to be prohibited;

- display of ECs/ENDS in retail stores to be prohibited;
- sale to minors (persons under the age of full legal responsibility) should be prohibited;
- ECs/ENDS and their refills should not be sold in flavours that are appealing to children;
- packaging and labelling of EC/ENDS cartridges and disposable ECs/ENDS should include a list of all ingredients, stipulate the quantity of nicotine and include appropriate warning labels;
- ECs/ENDS should not be used in public places, workplaces or on public transportation;
- consumer safety standards for EC cartridges should be established, including ensuring manufacturing consistency and regulating the maximum quantity/dosage of nicotine they may contain.

* An excerpt from the report is featured in online Appendix A.