

On 16 November 2019, the CPME Board adopted the 'CPME Policy on Novel Tobacco and Nicotine Products' (CPME 2019/074 FINAL).

# **CPME Policy on Novel Tobacco and Nicotine Products**

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Building on its previous policies on healthy living, CPME reaffirms its commitment to promoting healthy lifestyles and encourages all European doctors to act in this respect, both in their direct contacts with patients and through their national medical associations. CPME is highly concerned about the health risks of emerging novel tobacco and nicotine products, some of which fall into dangerous regulatory gaps. Currently, many European countries have tobacco legislation but not legislation that controls the sale of nicotine containing products.

### **Background**

Tobacco remains the single most lethal human product and the largest single avoidable cause of premature death and disability worldwide. Strong regulation of tobacco and nicotine products followed by meaningful surveillance of their manufacture, packaging, marketing, labelling and distribution is essential to establish comprehensive tobacco control strategies. Formalised supports for people who are trying to reduce or quit the use of tobacco and nicotine containing products are also important at this time to reduce the overall use of these lethal substances.

In recent years, industry has introduced a varied selection of novel products. **Electric nicotine delivery systems (ENDS)**, of which electronic cigarettes are the most popular, are devices that deliver aerosol by heating a liquid that the user inhales. The aerosol is commonly but inaccurately<sup>1</sup> called 'vapour', and, therefore, using an e-cigarette is known as 'vaping'. The main constituents of this solution, in addition to nicotine when present, are propylene glycol, with or without glycerol, and flavouring agents.<sup>2</sup> However, it does not contain tobacco. E-cigarette solutions and emissions contain also other chemicals, some of them considered to be toxic. Electronic non-nicotine delivery systems (ENNDS) are like ENDS but the heated solution does not generally contain nicotine. **Heated tobacco products (HTP)** produce aerosols containing nicotine and toxic chemicals upon heating of the tobacco or activation of

<sup>&</sup>lt;sup>1</sup> "Vapour refers to the gaseous state of a substance; in contrast, an aerosol is a suspension of fine particles of liquid, solid or both in a gas. Both the particulate and gas phases are mixtures of chemical substances in e-cigarette aerosols." <a href="Chemical evaluation of electronic cigarettes">Chemical evaluation of electronic cigarettes</a>. Cheng T. U.S. National Institutes of Health's National Library of Medicine, 2014.

<sup>&</sup>lt;sup>2</sup> <u>Electronic Nicotine Delivery Systems.</u> World Health Organization (WHO), 2014.



a device containing the tobacco. These aerosols are inhaled by the user during a process of sucking or smoking involving a device. Heated tobacco products contain nicotine, non-tobacco additives and they are often flavoured.<sup>3</sup>

These products are often promoted, especially to regulators, as conventional smoking cessation aids. However, there is limited evidence on the impact of their use on conventional smoking or on the relative harm of their use as compared to conventional cigarette smoking.<sup>4</sup>

Consumers' reasons to try new tobacco and nicotine products vary. Some try them to stop or reduce their use of tobacco, whereas some try them out of curiosity and find novel products attractive and fashionable.<sup>5</sup> <sup>6</sup> The product design, flavours, marketing, and perception of safety and acceptability have increased the appeal of new products particularly to young people who are susceptible to social and environmental influences to use tobacco and nicotine products.<sup>7</sup>

In recent years, there has been an upsurge in the use of e-cigarettes by young people. The developing brain is particularly susceptible to nicotine addiction.<sup>8</sup> There is also growing evidence that the use of e-cigarettes among children and teenagers serves as a gateway to conventional cigarette smoking.<sup>9</sup>

### **Health risks**

According to the World Health Organization (WHO), novel tobacco and nicotine products are not risk free although some of them have lower emissions than conventional cigarettes. Moreover, the long-term impact on health and mortality is as yet unknown. However, in the United States, deaths and lung injury cases associated with the use of e-cigarette or vaping products have been confirmed.<sup>10</sup>

The typical use of electronic cigarettes produces an aerosol that includes toxic substances that have known health effects resulting in a range of significant pathological changes. The amount and concentration of toxic substances inhaled while using e-cigarettes is on average lower than in traditional cigarette smoke. However, the levels of toxicants vary enormously depending on the brand and model, and can sometimes reach higher levels than in tobacco smoke. The aerosol in electronic cigarettes contains nicotine. In addition to the long-term risks of nicotine dependence, nicotine is known to have adverse effects on the development of the foetus during pregnancy and on the cardiovascular system.

<sup>&</sup>lt;sup>3</sup> WHO Report on the Global Tobacco Epidemic. World Health Organization (WHO), 2019.

<sup>&</sup>lt;sup>4</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> <u>Use of e-cigarettes among young people in Great Britain</u>. ASH UK, 2019.

<sup>&</sup>lt;sup>6</sup> Use of e-cigarettes (vaporisers) among adults in Great Britain. ASH UK, 2019.

<sup>&</sup>lt;sup>7</sup> <u>Electronic cigarette use in youths</u>. Forum of International Respiratory Societies, 2018.

<sup>8</sup> Ihid

<sup>&</sup>lt;sup>9</sup> WHO Report on the Global Tobacco Epidemic 2019. World Health Organization (WHO), 2019.

<sup>&</sup>lt;sup>10</sup> Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping. Centers for Disease Control and Prevention (CDC), 2019.

<sup>&</sup>lt;sup>11</sup> <u>Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)</u>. World Health Organization (WHO), 2016

<sup>12</sup> Visser W, et al. The health risks of using e-cigarettes. National Institute for Public Health and the Environment, 2015.

<sup>&</sup>lt;sup>13</sup> The Health Consequences of Smoking—50 Years of Progress. National Center for Chronic Disease Prevention and Health Promotion (US), Office on Smoking and Health, 2014.



The chemicals in second-hand aerosols may be inhaled by bystanders and may affect their health adversely. 14 15 Studies have shown that passive vaping results in short-term lung obstruction and increases cotinine. For ex-smokers and never smokers, use of e-cigarettes will increase the risk of harm to their health. Moreover, non-smokers who are passively exposed to e-cigarette vapour may absorb as much nicotine as when exposed to smoke from conventional cigarettes. Since the large majority of e-cigarette users continue to smoke conventional cigarettes as well, the health risks of this dual use must also be considered in any assessment of the harm of vaping. 16

The scientific evidence regarding the effectiveness of electronic cigarettes as a smoking cessation aid is limited, making it difficult to draw credible conclusions. Smokers and ex-smokers who have tried or used e-cigarettes most often say their tobacco smoking did not reduce as a result of using e-cigarettes.<sup>17</sup> Due to this lack of supporting evidence, e-cigarettes are not licensed and should not be promoted as smoking cessation aids. Doctors should support the use of approved, evidence-based aids to smoking cessation.

Also, the use of heated tobacco products has health risks as they contain tobacco, nicotine and produce toxic emissions. Nicotine and tar levels of heated tobacco products have been found to be nearly equal to conventional cigarettes.<sup>18</sup>

Further independent research is still needed to gather evidence regarding the risks and long-term effects of electronic cigarettes and heated tobacco products.

## **Current EU legislation**

<u>EU Tobacco Products Directive</u> (2014/40/EU) lays down rules governing the manufacture, presentation and sale of tobacco and related products. It applies also to heated tobacco products, particularly its Article 19 on novel tobacco products. Moreover, Article 20 lays down rules for electronic cigarettes sold as consumer products. Its key elements include:

- Safety and quality requirements for e-cigarettes: The Directive sets maximum nicotine concentrations and maximum volumes for cartridges, tanks and nicotine liquid containers as well as some other physical protection measurements. The ingredients must be of high purity and e-cigarettes should deliver the same amount of nicotine for puffs of the same strength and duration.
- Packaging and labelling rules for e-cigarettes: Health warnings for e-cigarettes are mandatory, advising consumers that e-cigarettes contain nicotine and should not be used by non-smokers. Packaging must include a list of all ingredients, including the product's nicotine

<sup>&</sup>lt;sup>14</sup> Exposure to aerosols from smoking-proxy electronic inhaling systems. World Health Organization (WHO), 2016.

<sup>&</sup>lt;sup>15</sup> Visser W, et al. <u>The Health Risks of Electronic Cigarette Use to Bystanders</u>. International Journal of Environmental Research and Public Health, 2019.

<sup>&</sup>lt;sup>16</sup> A systematic review of health effects of electronic cigarettes. World Health Organization (WHO), 2015.

<sup>&</sup>lt;sup>17</sup> Special Eurobarometer 429: Attitudes of Europeans towards tobacco and electronic cigarettes. European Union, 2015.

<sup>&</sup>lt;sup>18</sup> Li X, Luo Y, Jiang X, et al. <u>Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes</u>. Nicotine & Tobacco Research, 2018.

- content. Promotional elements are not allowed on e-cigarette packaging and cross-border advertising and promotion of e-cigarettes are prohibited.
- Monitoring and reporting of developments related to e-cigarettes: E-cigarette manufacturers must notify the EU member states of all products they place on the market and report annually to them on sales volumes, consumer preferences and trends.

The EU member state authorities must monitor the market for any evidence that e-cigarettes lead to nicotine addiction or to tobacco consumption, especially in young people and non-smokers. In 2021, the European Commission is supposed to submit a report on the application of the EU Tobacco Products Directive, including market developments concerning electronic cigarettes and novel tobacco products.

<u>EU Tobacco Excise Directive</u> (2011/64/EU) on the structure and rates of excise duty applied to manufactured tobacco does not cover electronic cigarettes and novel tobacco products. The EU member states have adopted different approaches towards the taxation of e-cigarettes and heated tobacco products.

#### **CPME Recommendations**

CPME calls on policy makers to:

- recognise that novel tobacco and nicotine products are harmful
- prohibit health claims for electronic cigarettes and heated tobacco products, including claims relating to their effectiveness as smoking cessation aids
- prohibit use of novel tobacco and nicotine products where smoking is banned
- prohibit cross-border advertising, promotion and sponsorship of e-cigarettes and heated tobacco products, and especially their marketing to children and non-smokers
- prohibit sale of e-cigarettes and heated tobacco products to minors and to eliminate vending machines for them
- ban flavourings in electronic nicotine delivery products and heated tobacco products
- support and encourage independent scientific research regarding the health risks and longterm effects of e-cigarettes and heated tobacco products
- ensure that the cost of novel tobacco and nicotine products is maintained at a high level similar to the cost of conventional cigarettes
- harmonise costs of novel tobacco and nicotine products between the EU member states
- establish an EU minimum excise duty rate for e-cigarettes and heated tobacco products
- continue to try to prevent young people starting smoking conventional cigarettes and novel products
- continue to try to reduce overall tobacco use by encouraging people to quit and supporting those who are trying to reduce or stop their use of tobacco and nicotine containing products

## CPME calls on European doctors to:

- follow the latest independent research on the health effects of novel tobacco and nicotine products
- inform their patients about the health risks associated with e-cigarettes and heated tobacco products
- encourage their patients to quit smoking and to promote healthy lifestyles
- influence central and local authorities to reduce accessibility to all tobacco and nicotine products, especially by young people
- not recommend novel tobacco or novel nicotine products as means to stop or reduce smoking