



ELECTRONIC NICOTINE AND NON-NICOTINE DELIVERY SYSTEMS

A BRIEF



**World Health
Organization**

REGIONAL OFFICE FOR **Europe**

Abstract

Electronic nicotine and non-nicotine delivery systems (EN&NNDS) are a heterogeneous class of products that use an electrically powered coil to heat and turn a liquid into an aerosol, which is inhaled by the user. EN&NNDS are not harmless. Although the consequences for long-term effects on morbidity and mortality have not yet been studied sufficiently, EN&NNDS are not safe for young people, pregnant women and adults who have never smoked. While it is expected that use of EN&NNDS in these groups might increase their health risks, non-pregnant adult smokers who completely and promptly switch from combustible tobacco cigarettes to use of unadulterated and appropriately regulated EN&NNDS alone might reduce their health risks. Member States that decide to regulate EN&NNDS may consider, inter alia: regulating EN&NNDS that make health claims as medicinal products and therapeutic devices; banning or restricting advertising, promotion and sponsorship of EN&NNDS; minimizing health risks to non-users by outlawing the use of EN&NNDS in all indoor spaces or where smoking is prohibited; and limiting the level and number of specific flavours allowed in EN&NNDS to reduce initiation by young people.

Keywords

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Electronic nicotine and non-nicotine delivery systems

Electronic nicotine and non-nicotine delivery systems (EN&NNDS)¹ are a heterogeneous class of products that use an electrically powered coil to heat and turn a liquid into an aerosol, which is inhaled by the user.

The generation and composition of aerosol during EN&NNDS use or so-called vaping and the subsequent exposure to aerosol substances is determined by four factors:

- 1_ the e-liquid composition
- 2_ the materials used in manufacturing the device
- 3_ the electrical power or wattage used during operation to heat the e-liquid
- 4_ the puffing topography or inhaling characteristics of the user while using EN&NNDS.

E-liquids always contain carrier liquids (humectants) which comprise 80–90% of the volume of the liquid, some water (10–20% of the volume) and, generally, nicotine and flavours. Propylene glycol and glycerol, the principal carriers used in e-liquids, undergo partial decomposition in contact with the atomizer heating coil, forming several toxicants, including carbonyls. E-liquids may also contain nicotine, a highly addictive substance, that may adversely affect fetal and adolescent brain development.

Heating elements or coils in EN&NNDS are usually made of resistance wires of various metals, such as nickel, or metal alloys, including nichrome (chrome and nickel). Metal parts of the device are sometimes soldered with lead.

To heat and aerosolize the e-liquid, an electrical current from a battery is run through the coil when the EN&NNDS is activated. The temperature reached depends on the electrical power generated, which in turn depends on the amount of energy provided by the battery and the resistance of the coil. The lower the resistance, the more electricity flows through it, and the more heat is generated at the coil. Under normal operation conditions, the e-liquid reaches a temperature of between 100–350 °C.

The inhaling behaviour or puffing topography of users has the following variables: puff volume, depth of inhalation, rate of puffing, and intensity of puffing. These variables determine the amount of aerosol inhaled and how deep it is carried into the respiratory system.

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¹ This brief follows the terminology of the Conference of the Parties of the WHO Framework Convention on Tobacco Control by referring to electronic nicotine delivery systems (ENDS) for products in which the e-liquid contains nicotine and electronic non-nicotine delivery systems (ENNDS) for those in which it does not. These systems are referred to collectively as electronic nicotine and non-nicotine delivery systems (EN&NNDS). They are popularly known as electronic cigarettes or e-cigarettes. Other sources refer to ENDS as alternative nicotine delivery systems (ANDS).

EN&NNDS use among the population

Proportion of the adult population using EN&NNDS regularly

The proportion of adults who currently (defined as at least once in the last month) used EN&NNDS in the two main world markets for these products, the United States of America and the European Union (EU), was 3.2% in 2018 (1) and 2% in 2017 (2) respectively. Highest prevalence of use among EU countries in 2018 was in the United Kingdom (England), at 6.2% (3). In New Zealand, 3.8% of adults currently used EN&NNDS in 2017–2018 (4). Additional data from nine countries indicate that in most, no more than 4% of adults used EN&NNDS regularly between 2017 and 2018 (5).

Very few countries have trend data. The proportion of current adult users of EN&NNDS in the United States has remained stable since 2014 (at 3.7%) (1) and in the EU since 2015 (2%) (6). In Canada, past 30-day use and daily use of EN&NNDS among adults remained stable in the period between 2013 and 2017 (7). Only New Zealand shows a clear increase of use of EN&NNDS among adults, from 1.4% in 2015–2016 to 3.8% in 2017–2018 and 4.7% in 2018–2019 (4). Most EN&NNDS users are or were smokers.

Proportion of young people using EN&NNDS regularly

Data on the current use of EN&NNDS among young people aged 13–15 years from 22 countries indicate that the proportion using EN&NNDS regularly is higher than among their adult counterparts. Figures for young people ranged from 0.7% in Japan to 18.4% in Ukraine between 2017 and 2019, with a median country value of 8.1% (8).

Between 2008 and 2015, ever using EN&NNDS among young people increased in Poland, New Zealand, the Republic of Korea and the United States, decreased in Canada and Italy, and remained stable in the United Kingdom (9). Current use of EN&NNDS among 11–18-year-olds in the United States increased from 2017 to 2018 (10) while remaining stable in the United Kingdom. In 2019, 1.6% of 11–18-year-olds in the United Kingdom used EN&NNDS more than once a week, compared to 1.7% in 2018 (11). In Canada, past 30-day use of EN&NNDS among young people in grades 7–9 was 5.4% in 2016–2017, which was not significantly different from use in 2014–2015 (12). A recent study comparing the change in EN&NNDS use among 16–19-year-olds in Canada, the United Kingdom (England) and the United States between 2017 and 2018

confirmed the increase of EN&NNDS use in Canada and the United States and the stability in the United Kingdom (England) for use during the past 30 days and past week (Table 1) (13).

EN&NNDS use during:	Canada		United States		United Kingdom (England)	
	2017 (%)	2018 (%)	2017 (%)	2018 (%)	2017 (%)	2018 (%)
past 30 days	8.4	14.6	11.1	16.2	8.7	8.9
past week	5.2	9.3	6.4	10.6	4.6	4.6

Source: Hammond et al. (13).

TABLE 1. Prevalence change of current EN&NNDS use among 16–19-year-olds between 2017 and 2018 in three countries

EN&NNDS current use among non-smoking young people

Data from the United States show that in 2017, 0.8% of all 11–18-year-olds who had never smoked a cigarette before were using EN&NNDS regularly (at least once in the last 10 days). In 2018, the proportion increased to 2.4% (14). In the United Kingdom (England), however, 0.8% of young people aged 11–18 years who had never smoked were currently using EN&NNDS (3). Weekly use of EN&NNDS among never-smokers aged 17 and 18 years was 0% in 2016 and 2017 (15) and 0.2% in 2018 (3). The recent study comparing the change in EN&NNDS use among 16–19-year-olds in Canada, the United Kingdom (England) and the United States between 2017 and 2018 confirmed the increasing number of never-smokers using EN&NNDS during the past 30 days and the past week in Canada and the United States, while the figure did not change in the United Kingdom (England) (Table 2) (13).

EN&NNDS use during:	Canada		United States		United Kingdom (England)	
	2017 (%)	2018 (%)	2017 (%)	2018 (%)	2017 (%)	2018 (%)
past 30 days	2.3	5.0	2.4	5.9	1.6	1.9
past week	0.8	2.7	1.1	3.0	0.5	0.4

Source: Hammond et al. (13).

TABLE 2. Prevalence change of current EN&NNDS use among 16–19-year-old never-smokers between 2017 and 2018 in three countries



EN&NNDS contents and health effects

EN&NNDS aerosol contents

The aerosol users breathe from EN&NNDS contains numerous potentially toxic substances, in addition to nicotine when included in the e-liquid. The number, quantity and characteristics of potentially toxic substances in the aerosol emitted by EN&NNDS are highly variable and depend on product characteristics (including device and e-liquid features) and how the device is operated by the user. Under typical conditions of use, however, the number and concentrations of potentially toxic substances emitted from unadulterated EN&NNDS are lower than in tobacco smoke, except for some metals.

The main substances in the aerosol that raise health concern are **metals**, such as chromium, nickel, and lead, and **carbonyls**, such as formaldehyde, acetaldehyde, acrolein and glyoxal.

The types and concentrations of **metals** depend on the product features and inhaling patterns of use. Exposure to certain levels of some metals may cause serious health effects, such as diseases of the nervous, cardiovascular and respiratory systems. The number of metals in the aerosol could be greater than in combustible tobacco cigarettes, and in some cases is found at higher concentrations than in cigarette smoke. It is suspected that metals come mostly from the metallic coil used to heat the e-liquid and soldered joints of the device. Metal emissions can largely be prevented through appropriate engineering of devices.

Carbonyl compounds are potentially hazardous to users. Formaldehyde is a human carcinogen, acetaldehyde is possibly carcinogenic to humans, acrolein is a strong irritant of the respiratory system and glyoxal shows mutagenicity. Most carbonyls come from the thermal decomposition of humectants, propylene glycol and glycerol. The number and levels of carbonyls detected in the aerosol are lower than in smoke from combustible tobacco, but even these levels raise health concerns.

Other substances in the aerosol of possible health concern are **particulate matter** and some **flavourings**.

The **particle** count and size in EN&NNDS aerosols do not differ greatly from those found in mainstream combustible tobacco smoke. The composition of the particles nevertheless is dissimilar and likely to have a different health impact. Aerosol particulates from EN&NNDS consist mostly of a mix of aqueous and humectant droplets, whereas particles in combustible tobacco smoke are mostly complex organic constituents that contain known or suspected carcinogens.

Although of health concern, particles from EN&NNDS are therefore expected to have smaller health risks than particles in tobacco smoke.

Certain **flavourings**, such as diacetyl, cinnamaldehyde and benzaldehyde, have been cited as a source of health concerns when heated and inhaled.

When the e-liquid contains **nicotine**, the aerosol contains nicotine. The amount of nicotine inhaled by ENDS users is highly variable and depends on product characteristics (including device and e-liquid characteristics) and how the device is operated. There is substantial evidence that nicotine intake from ENDS among experienced adult ENDS users can be comparable to that from combustible tobacco cigarettes.

Health effects of using EN&NNDS

Scientists are still learning about the long-term health effects of EN&NNDS. Currently, there is insufficient research to determine with certainty whether unadulterated and appropriately regulated EN&NNDS use is associated with cardiovascular, lung or cancer diseases.

The following section describes what currently is known by strength of evidence,² as assessed by the National Academies of Sciences, Engineering and Medicine (NASEM) in 2018 (16).

There is **conclusive evidence** that:

- ▶ completely substituting EN&NNDS for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes;
- ▶ EN&NNDS devices can explode and cause burns and projectile injuries when batteries are of poor quality, stored improperly or modified by users; and
- ▶ intentional or accidental exposure to e-liquids (from drinking, eye contact or dermal contact) can result in adverse health effects, sometimes fatal.

There is **substantial evidence** that:

- ▶ ENDS use results in symptoms of nicotine dependence – the risk and severity of nicotine dependence are influenced by the ENDS product characteristics (nicotine concentration, flavouring, device type and brand), but the risk and severity of dependence seem lower for ENDS than from combustible tobacco cigarettes;

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² Only conclusions for which the NASEM deems there to be conclusive, substantial and moderate evidence are presented, not evidence with limited, insufficient or no available proof. Conclusive, substantial and moderate scientific evidence allows firm conclusions, firm conclusions with minor limitations, and a general conclusion with limitations, respectively. Strength of evidence refers to the certainty of an association but not necessarily to its magnitude. The strength of using reliable literature reviews, such as the one from NASEM, is that their conclusions are based on the systematic and methodical overview of consolidated evidence at the moment of the review, 2018 in this case. Research on EN&NNDS is developing rapidly, however, which means that some new studies may contradict the conclusions of systematic reviews. Findings of new studies not yet included in reliable systematic reviews are not discussed here, unless they present overwhelming and undisputed evidence.

- EN&NNDS aerosol can cause some human cells to malfunction – it is not clear what this means in terms of the long-term consequences of chronic use of EN&NNDS, but it is possible that it could increase the risk of some diseases, such as cardiovascular disease, cancer and adverse reproductive outcomes, although the risk is probably lower than from combustible tobacco cigarette smoke; and
- completely switching from regular use of combustible tobacco cigarettes to EN&NNDS results in reduced short-term adverse health outcomes in several organ systems.

There is **moderate evidence** that:

- EN&NNDS use increases cough and wheeze in adolescents and is associated with an increase in asthma exacerbations; and
- the positive and negative health impacts of EN&NNDS use is applicable to the employment of these products in the absence of simultaneous consumption of tobacco products, but a significant proportion of EN&NNDS users, referred to as dual- or poly-users, also smoke tobacco products.

The question is – do EN&NNDS users who continue to smoke have any reduction in health risk? The NASEM review concluded that there is no available evidence on whether long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes. Recent evidence, however, suggests that dual users have a greater level of oxidative stress than smokers (17) and that adding use of EN&NNDS to smoking may contribute to cardiopulmonary health risks, particularly involving the respiratory system (18).

A note on the cases of lung problems linked to EN&NNDS use in the United States

During the drafting of this brief, the Centers for Disease Control and Prevention (CDC) of the United States reported an outbreak of lung disorders associated with the use of e-cigarettes and vaping (19). As of 7 January 2020, more than 2500 cases had been reported to CDC from 50 states. Almost 60 deaths had been confirmed in 27 states.

CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product-use associated lung injury (EVALI). CDC laboratory testing of fluid samples collected from the lungs of 29 patients with EVALI submitted from 10 states found vitamin E acetate in all of the samples. Vitamin E acetate is used as an additive, most notably as a thickening agent in tetrahydrocannabinol-containing e-cigarette, or vaping, products.

Another study concludes that dual users are not reducing exposure to harmful toxicants compared to exclusive cigarette smokers due to their continued smoking (20). A possible explanation is that dual users include a great variety of tobacco- and EN&NNDS-use behaviours, each with different motivations (21). Dual use may not represent only a transitional phase to reduce or quit smoking; this category may also include EN&NNDS users who still rely on smoking to manage their dissatisfaction with the EN&NNDS experience, to circumvent smoke-free policies or simply to comply with social group norms and manage the stigma associated with smoking (22).

Second-hand exposure to EN&NNDS aerosol

EN&NNDS users inhale the aerosol directly from the device and partly exhale it back into the air, which bystanders may then breathe in. As a result, **EN&NNDS use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels** (16). Some studies indicate that some volatile organic compounds are also exhaled into the environment during EN&NNDS use. The concentration of these substances in the air increases with the number of users in confined spaces. **Second-hand exposure to nicotine and particulates is lower from EN&NNDS aerosol compared with combustible tobacco cigarettes** (16) but are higher than the smoke-free level recommended by the WHO Framework Convention on Tobacco Control (WHO FCTC) (23).

Health effects of exposure to exhaled aerosol

No available studies have evaluated the health effects of second-hand EN&NNDS exposure, so the risks to health of exposure to exhaled aerosol remain unknown. It is expected, however, to present some health risks for bystanders, although at lower levels than from exposure to second-hand tobacco smoke.

EN&NNDS' role in smoking cessation and initiation

EN&NNDS' role in smoking cessation among adults

The NASEM review concluded that there is insufficient evidence from randomized controlled trials about the effectiveness of ENDS as cessation aids compared with no treatment or approved smoking-cessation treatments (16), although it did not include a recent trial whose results depart from this conclusion (24). Moderate evidence, however, shows that some smokers may successfully quit tobacco by using some types of ENDS frequently or intensively (16), while others experience no difference or are even prevented from quitting (25).

EN&NNDS' role in smoking initiation among young people

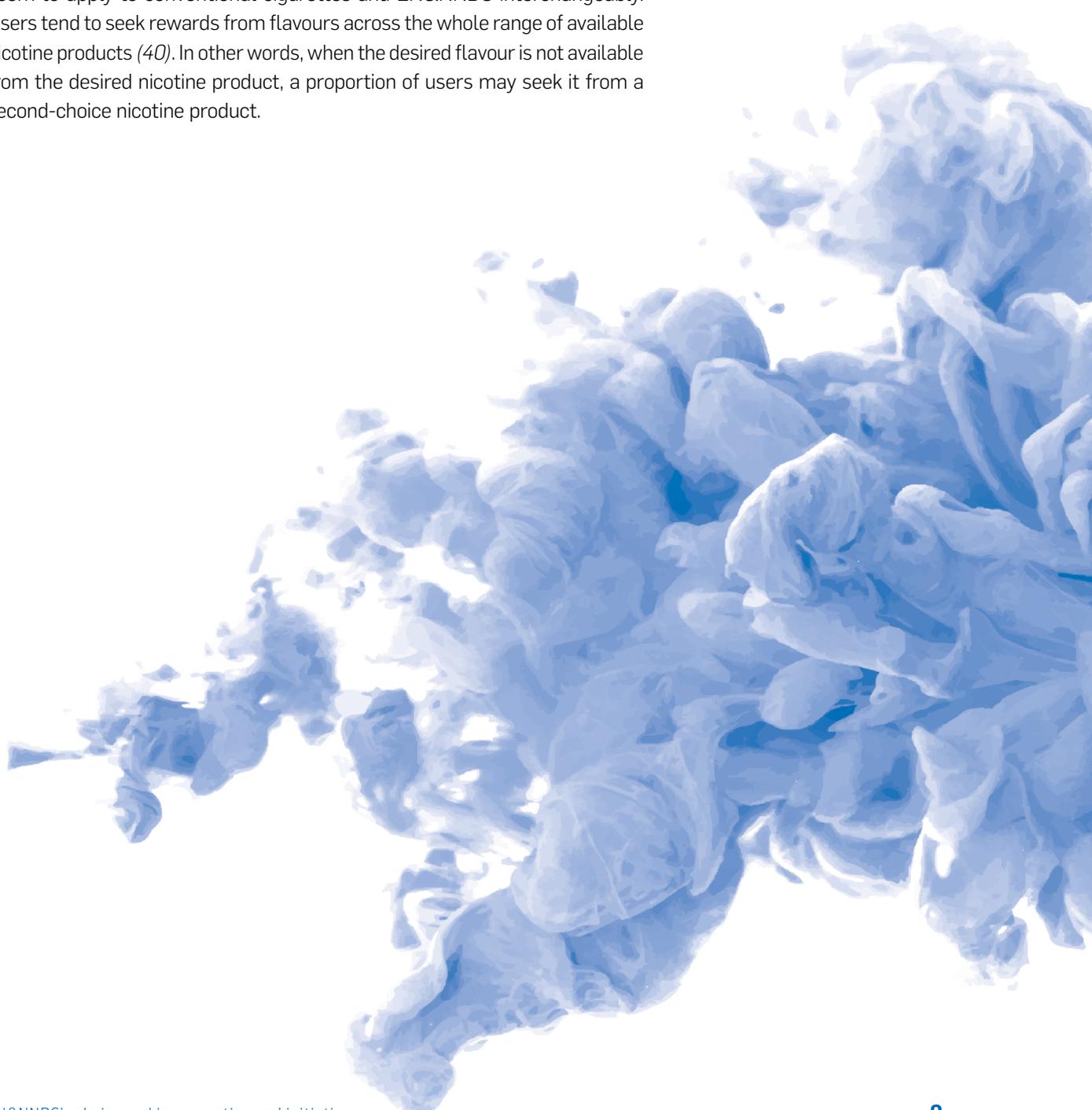
There is moderate evidence that young never-smokers who experiment with EN&NNDS are at least twice more likely to experiment with smoking later (16). The data available so far do not, however, prove that this evident association is causal. While some authors believe that ENDS use and smoking are initiated independently of each other as the result of a common latent propensity to risky behaviour, others think that the similarity between ENDS use and smoking facilitates the trajectory from one product to the other within a social learning framework.

The role of flavours in EN&NNDS initiation and use

E-liquids for EN&NNDS are marketed in more than 15 000 unique flavours (26,27). Flavours are classified in two big groups: tobacco flavours, and those that impart a strong non-tobacco smell or taste. The latter are considered so-called characterizing flavours, the main categories of which are menthol/mint, nuts, spices, coffee/tea, alcohol, other beverages, fruit, candy and other sweets (28).

Flavours are one of the most appealing features of EN&NNDS and have been described as the major motivation for ENDS use by young people. They can alter expectations and reward from EN&NNDS, including nicotine effects (29,30). Advertisements on e-liquid containers and vendor websites frequently contain images and descriptions of flavours that convey appealing product sensations (31).

Flavours seem to play a part in promoting the switch from combustible tobacco products to EN&NNDS (32–34). They also play an important role in increasing uptake of EN&NNDS among young people (35–37), noticeably more significantly than among adults (38). The use of flavoured e-liquids is generally higher among young people and young adults than in older adults. It is also more frequent among non-smokers than conventional cigarette smokers (39). The preferences and demand for flavoured nicotine products seem to apply to conventional cigarettes and EN&NNDS interchangeably. Users tend to seek rewards from flavours across the whole range of available nicotine products (40). In other words, when the desired flavour is not available from the desired nicotine product, a proportion of users may seek it from a second-choice nicotine product.



Key messages and conclusions

EN&NNDS are not harmless. Although the consequences for long-term effects on morbidity and mortality have not yet been studied sufficiently, EN&NNDS are not safe for young people, pregnant women and adults who have never smoked. While it is expected that use of EN&NNDS in these groups might increase their health risks, non-pregnant adult smokers who completely switch from combustible tobacco cigarettes to use of unadulterated and appropriately regulated EN&NNDS alone might reduce their health risks. This potential has been recognized by WHO (41), NASEM (16) and the CDC (42).

As indicated by WHO (41), the key to any policy on EN&NNDS is 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”, as well as “avoiding nicotine initiation among non-smokers and particularly youth while maximizing potential benefits for smokers”. To strike such a regulatory balance is challenging in view of the existing scientific evidence and the fact that not all countries will have the required regulatory and surveillance capacity (43). WHO Members States that decide to regulate EN&NNDS may consider the options below to attain the policy objectives set by the Conference of the Parties (COP) of the WHO FCTC, which are to (44):

- › prevent the initiation of EN&NNDS by non-smokers and young people, with special attention to vulnerable groups;
- › minimize as far as possible potential health risks to EN&NNDS users and protect non-users from exposure to their emissions;
- › prevent unproven health claims from being made about EN&NNDS; and
- › protect tobacco-control activities from all commercial and other vested interests related to EN&NNDS, including interests of the tobacco industry.

Countries that decide to regulate EN&NNDS should consider:

- › being mindful of the unintended consequences of any regulatory measure in swaying the market towards any specific type of EN&NNDS product;
- › regulating EN&NNDS that make health claims as medicinal products and therapeutic devices and authorizing their marketing once such claims have been verified scientifically;
- › banning or restricting advertising, promotion and sponsorship of EN&NNDS, regulating sales channels (including online sales) and strongly enforcing laws on minimum age of purchase, while recognizing that restricting access to tobacco products for minors and adults to make it difficult to transition to cigarettes when using EN&NNDS is paramount;
- › minimizing health risks to EN&NNDS users by standardizing:
 - the manufacture of devices and EN&NNDS components under effective electrical equipment safety regulations, including waste and safe disposal of electrical and electronic equipment;

- the content of e-liquids, to limit the amount of nicotine available per cartridge or bottle and avoid some ingredients, such as carcinogens, mutagens or reprotoxins, those that facilitate inhalation or nicotine uptake and additives such as amino acids, caffeine, colouring agents, essential fatty acids, glucuronolactone, probiotics, taurine, vitamins and mineral nutrients – the existing evidence is insufficient to recommend banning (or not banning) certain flavours that may be attractive to children; and
- the packaging of e-liquids by requiring child-proof containers and labelling ENDS to inform users of the addictive nature of the product;
- › minimizing health risks to non-users by outlawing the use of EN&NNDS in all indoor spaces or where smoking is prohibited until it is proven that the second-hand aerosol poses no health risks to bystanders;
- › limiting the levels and number of specific flavours allowed in EN&NNDS to reduce initiation by young people; and
- › setting surveillance systems to monitor the evolution in patterns of EN&NNDS consumption and detect health or safety incidents involving EN&NNDS – given the current state of knowledge about market dynamics, it is extremely important for countries to start monitoring EN&NNDS products in the market and evaluate the impact of regulation on prices and consumption (this includes surveillance of population patterns of EN&NNDS use by use intensity, type of device, the content of e-liquid and reason for use, and by demographic characteristics and smoking status); as the market is rapidly evolving, adjustments to taxation approaches may be needed over time.

In addition, countries that decide to impose an excise tax should consider:

- › adopting the best tax structure that the level of national tax administration, product regulation and tobacco-control policies determine – for example, countries with strong tax administration and strong product regulation may find the option of specific excise taxation advantageous, while those with strong tax administration and weak product regulation may find an ad valorem system is an option;
- › setting product characteristics to improve the effectiveness of any taxation structure, regardless of context; and
- › collecting tax in the same way as for tobacco products in the country (in most countries, the collection is made at the source – the manufacturing/importing point).

Some types of ENDS help some smokers quit under certain circumstances, but the evidence is insufficient to issue a blanket recommendation to use any type of EN&NNDS as a cessation aid for all smokers.

A final and important caveat regarding any EN&NNDS policy, of whatever nature, is that such a policy would benefit extraordinarily from the simultaneous implementation of a very strong tobacco-control policy to curtail any potential trajectory from EN&NNDS use to smoking.

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