

Novel and emerging nicotine and tobacco products

Health effects, research needs and provisional recommended actions for regulators

Report on a regional consultation

Cairo, Egypt
3–4 July 2019



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Experts

Dr Stella Bialous, Dr Matus Ferech, Professor Stanton Glantz, Dr Derrick Heng, Ms Lily Joung-eun Lee, Dr Sungkyu Lee, Mr Mohammed Madbouly, Dr Aya Mostafa Kamal Eldin, Mr Austin Rowan, Dr Lorenzo Spizzichino, Dr Reinskje Talhout and Professor Ghazi Zaatari (as head of the WHO Study Group on Tobacco Product Regulation [TobReg] and nominated representative of the WHO FCTC Secretariat).

Member States

Bahrain, Egypt, Jordan, Kuwait, Oman, Qatar, Saudi Arabia, Sudan and United Arab Emirates.

Nongovernmental organizations

Dr Wael Safwat, representative of the Framework Convention Alliance.

WHO headquarters

Ms Annerie Bouw, Dr Ranti Fayokun and Dr Vinayak Prasad.

WHO FCTC Secretariat

Represented by Professor Ghazi Zaatari.

WHO Regional Office for the Eastern Mediterranean

Dr Ahmed Al-Mandhari, Dr Fatimah El-Awa, Dr Heba Fouad, Mr Charles Fraser, Ms Miriam Gordon, Dr Asmus Hammerich, Dr Mahmoud Ismail and Dr Slim Slama.

WHO country offices

Dr Randa Abou Elnaga (Egypt), Ms Hala Boukerdenna (Jordan) and Dr Doa'a Saleh (Egypt).

1. INTRODUCTION

The global tobacco market is rapidly changing as more people begin and continue to use novel and emerging nicotine, non-nicotine and tobacco products. These products include: electronic nicotine delivery systems (ENDS), of which e-cigarettes are the most common type; electronic non-nicotine delivery systems (ENNDS); and newer products, including heated tobacco products (HTPs). In response to shifting attitudes towards conventional cigarettes, the tobacco industry aggressively markets these products as “reduced risk” products to be used instead of conventional cigarettes and claims that using some of them provides an effective route to smoking cessation.

These novel nicotine, non-nicotine and tobacco products are a major investment strategy for the tobacco industry. Despite this, their central “reduced risk” claim is as yet unsubstantiated at a population level for HTPs, and even the industry’s own data have not provided sufficient evidence to support it. This data gap, however, is exploited by the tobacco and related industries to push sales of their products. Ultimately their objective is to sustain use of these products and increase their market share.

The industry’s novel products are diverse, have unconventional features and are made to be attractive to different segments of the population, especially the young and non-smokers. Products are sold in a wide array of sizes, colours and flavours. In addition, pricing strategies are used to “hook” customers; for example, a HTP base and charger are subsidized, but refills are expensive. Such strategies, as well as the lack of regulation for packaging, advertising, pricing and use in public places, allow the tobacco industry to be effective in encouraging the use of these products.

The WHO has issued guidance on the regulation of ENDS/ENNDS and HTPs. In a 2014 technical report on ENDS to the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), WHO advised that Parties should consider either banning the sale of ENDS or pursuing certain specific regulations regarding the sale and use of ENDS and ENDS advertising and health warnings (1). Accordingly, the COP recommended that Parties to the WHO FCTC adopt comprehensive regulations for these products (2). A second report by WHO to the COP in 2016 provides further specific policy recommendations for ENDS and ENNDS (3). A recent COP decision on novel and emerging tobacco products, including HTPs, recommends that such products be treated and regulated as tobacco products, reminds Parties of their commitments under the WHO FCTC in this regard, and requests further work to clarify the classification of HTPs to support regulatory efforts (4). In 2018, WHO’s information sheet on HTPs advised that all forms of tobacco use are harmful, including HTPs, and that tobacco is inherently toxic and contains carcinogens even in its natural form (5). It recommended, therefore, that HTPs be subject to the policy and regulatory measures applied to all other tobacco products, in line with the WHO FCTC.

The situation presents a unique set of challenges to regulators, who are grappling with a range of issues in relation to these products. The Eastern Mediterranean Region continues to see high rates of tobacco use among men and, increasingly, among male and female youth. The high prevalence of tobacco use, paired with increasing measures to combat the use of traditional

tobacco products, could drive a market move to these newer nicotine, non-nicotine and tobacco products. The use of ENDS among youth in the Eastern Mediterranean Region is already worryingly high, with some Member States finding that over 17% of their youth use such products. In 2016, ENDS were banned in 30 WHO Member States globally, 11 of which were in the Eastern Mediterranean Region.

As HTPs are introduced in the Region, and following an emerging trend of WHO Member States in the Region legalizing e-cigarettes, it is crucial that policy dialogue and action takes place. For this reason, a regional consultation on regulating e-cigarettes and new tobacco products (ENDS, ENNDS and HTPs) was held by the WHO Regional Office for the Eastern Mediterranean on 3–4 July 2019 in Cairo, Egypt, to equip countries with regulatory or policy options to regulate these products (see Annex 1 for the programme).

The objectives of the consultation were to:

- review the global and regional status of regulation on e-cigarettes and newer tobacco products;
- examine best practice regulations for e-cigarettes and newer tobacco products; and
- review and develop recommendations for Member States on how to regulate e-cigarettes and newer tobacco products.

The consultation aimed to be a platform for sharing recommendations for the regulation of these products, alongside national and regional experiences of regulating ENDS, ENNDS and HTPs. The consultation was inaugurated by Dr Ahmed Al-Mandhari, WHO Regional Director for the Eastern Mediterranean, who emphasized the importance of the consultation and its expected outcomes, and encouraged participants to produce clear guidance to Member States to advance the regulation of novel nicotine, non-nicotine and tobacco products.

During the consultation, participants, including representatives from Member States, international experts and WHO staff, worked in five working groups to develop two “side-by-side” texts, one for ENDS/ENNDS and one for HTPs. These texts, included in this report, provide preliminary regulatory options for novel nicotine, non-nicotine and tobacco products alongside the relevant articles of the WHO FCTC.

This report presents the findings and recommendations of the regional consultation on novel nicotine, non-nicotine and tobacco products. The side-by-side texts will be developed further in a WHO global consultation to be held in early 2020 to formulate authoritative global guidance, based on available evidence and country experience, for WHO Member States on ENDS/ENNDS and HTP regulation.

2. WHAT ARE ENDS, ENNDS AND HTPS?

2.1 ENDS/ENNDS

ENDS, of which e-cigarettes are the most common type, make use of a device to heat a solution (e-liquid) that contains nicotine and flavourants, usually dissolved in propylene glycol and/or

glycerin, to create an aerosol which is then inhaled by the user. ENNDS are similar products for which the e-liquid does not contain nicotine (3). There are also e-liquids that contain a nicotine base and a weak organic acid that form a nicotine salt (6). This allows vaping at lower temperatures and with very high levels of nicotine. E-cigarettes can also be used to deliver marijuana and other drugs (7). Although generally considered a single product class, these products constitute a diverse group with potentially significant differences in the production of toxicants and delivery of nicotine (3).

There are several types of device on the market. First-generation e-cigarettes (known as “cigalikes”) look like traditional cigarettes. The device has a battery, compartment for the liquid product (e-juice) and an atomizer to aerosolize the liquid for inhalation. Devices can be single use, or can be reused with a new e-liquid cartridge. In second generation e-cigarettes, the tank and battery are separate allowing them to be refilled, making it possible for users to choose the flavour and nicotine concentration of the e-liquid. Third generation e-cigarettes, including “mechanical mods” (unregulated devices without a circuit board that run directly off a battery), do not look like traditional tobacco products and come with improved atomizers, which allow for voltage alterations. Fourth generation e-cigarettes have coils with lower resistance (sub-ohm tanks) and temperature control devices (7).

There is a huge number of e-cigarette flavours available on the market.

2.2 HTPs

According to WHO: “Heated tobacco products are tobacco products that produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. They contain the highly addictive substance, nicotine (contained in the tobacco), which makes HTPs addictive. They also contain non-tobacco additives, and are often flavoured. HTPs mimic the behaviour of smoking conventional cigarettes, and some make use of specially designed cigarettes to contain the tobacco for heating” (5). The heated tobacco units (units that contain tobacco) are heated by a device that requires charging, and the user draws on the mouthpiece at intervals to inhale volumes of the aerosol through the mouth, which is then taken into the body (5). There are different types of HTPs, which vary in the style of the heating device and the form of the tobacco heated (stick or loose). Recent developments carry worrying technology to record user information via the device (8).

3. THE TOBACCO INDUSTRY AND THE MARKET FOR ENDS/ENNDS AND HTPS

3.1 The tobacco industry

As stated in the WHO FCTC, the “tobacco industry” means tobacco manufacturers, wholesale distributors and importers of tobacco products. While major international companies such as British America Tobacco (BAT), Philip Morris International (PMI) and Japan Tobacco International (JTI) hold large market shares globally and have significant lobbying power, it is important to also consider national tobacco companies and other members of the tobacco industry.

Shifts in the tobacco market due to awareness of tobacco risks, implementation of WHO FCTC provisions and tightening of regulations have resulted in declining sales of cigarettes in high-income economies. The tobacco industry has responded by promoting what they claim to be, among other things, “cleaner” or “reduced risk” “alternative products” including ENDS, of which e-cigarettes are the most common type, ENNDS and other newer tobacco products, such as new generation HTPs. Currently, HTPs are available in at least 40 WHO Member States and they are spreading to Member States of all incomes. The evolution of these products over time and the interchangeability of the component parts of some of these products have posed a unique challenge to their monitoring, surveillance, classification and regulation.

PMI leaked documents show that the company views what they term “reduced risk products” (RRP) as “the pathway for [...] future growth” and aims to establish the “legitimacy of tobacco companies to be part of the regulatory debate on RRP (‘part of solution’)” (9). This approach is widely seen across the major tobacco industry players. The concept of “reduced risk” or “smoke-free” products is perceived with scepticism by the public health community and is not supported by WHO. These products have not been proven to reduce risk or to aid cessation. Further, the idea that smokers cannot quit and need a “reduced risk” product is not supported by evidence. The observed youth and non-smoker initiation of use of these products is highly concerning.

Products are sold in a wide array of sizes, colours and flavours. Pricing strategies are used to “hook” customers on new nicotine and tobacco products; for example, a HTP base and charger are subsidized, but refills are expensive. Such strategies, as well as the lack of regulation for packaging, advertising, pricing and use in public places, allow the tobacco industry to be effective in encouraging the use of these products.

3.2 The ENDS/ENNDS market

ENDS sales worldwide are increasing. Global sales of ENDS reached US\$ 2.76 billion in 2014, US\$ 8.61 billion in 2016 and are expected to reach US\$ 26.84 billion by 2023 (10).

Initially, the growth of the ENDS/ENNDS market was driven by companies that were independent from the traditional transnational tobacco companies. However, these companies are rapidly increasing their share of what is so far a generally under or unregulated market. The engagement of transnational tobacco companies in the marketing of ENDS/ENNDS is a major threat to tobacco control. A growing concern is the extent to which research on the topic has links to commercial and other vested interests of the ENDS/ENNDS industry, including the tobacco industry and its allies. A systematic review of 175 studies on the health effects of e-cigarettes found that for 34% of authors a conflict of interest existed, with this mostly being due to the study receiving funding or other support from ENDS/ENNDS interests – including the tobacco industry (11).

There have been recent successful steps against the ENDS industry in the United States of America. It was ruled in court that there would be a 10-month deadline for e-cigarette manufacturers (until 12 May 2020) to submit their products for public health review to the United States Food and Drug Administration (FDA) or else remove their products from the

market. The FDA will have one year to review the products (12). San Francisco has banned the sale of e-cigarettes until products have FDA authorization (13).

3.3 The HTP market

Global sales for HTPs are projected to reach US\$ 17.9 billion by 2021. Currently, HTPs are available in about 40 Member States of WHO. The market may also change, since the tobacco industry is developing or has bought nicotine inhaler technology that does not require a heating mechanism (3).

In December 2014, PMI became the first company to hold a large-scale launch of a HTP, to promote its IQOS product. Both non-smokers and former smokers have been found to use the product. In Japan, IQOS quickly gained a significant market share, reaching 10% of the tobacco market in less than a year (14). Similarly, in the Republic of Korea, IQOS (introduced in June 2017) and other HTPs gained a 6.1% share of the tobacco market in less than six months (15). In 2017, JTI and Korea Tobacco & Ginseng Corporation (KT&G) responded with the launch of Ploom TECH and Lil, respectively, followed by BAT's GLO. These transnational companies are aiming to increase the number of WHO Member States in which their products are available (14) and are employing diverse strategies to make this a reality, especially in low- and middle-income countries.

PMI has used the fact that the FDA authorized the sale of IQOS to advertise the product internationally, including in Member States of the WHO Eastern Mediterranean Region. This FDA authorization, widely criticized by the United States health community, is not equivalent to FDA approval of the product as "reduced risk" and does not mean the product is considered safer than conventional cigarettes. Using the lack of awareness regarding the differences between these two FDA decisions, PMI has inflated and warped the FDA authorization of IQOS to suggest that the FDA has identified it as a reduced risk product (16). PMI has an application to explicitly market IQOS as a reduced risk product pending with the FDA; the FDA has not yet ruled on this application.

4. HEALTH EFFECTS OF ENDS/ENNDS AND HTPS

4.1 Are ENDS/ENNDS and HTPs harm-reduced products?

It is important to recognize that, unlike cigarettes which have been on the market and studied for decades, ENDS/ENNDS and HTPs are relatively new products. As such, knowledge of their associated health effects is developing rapidly. An increasing number of harmful health effects for these products are being uncovered.

ENDS/ENNDS and HTPs are marketed as harm-reduced products. This is a scientifically unsubstantiated claim given current research. Indeed, there is an ever-growing literature base on the health risks associated with the use of these products. There is also increasing evidence that dual use of ENDS/ENNDS and HTPs with traditional cigarettes increases the health risks beyond those associated with smoking cigarettes alone.

One rationale given by the tobacco industry in support of harm-reduced products is that there are smokers unable to quit, who will benefit from reduced risk products rather than using conventional cigarettes. However, evidence points to the fact that tobacco control policies reduce both the prevalence of smoking and the number of smokers who are reluctant or unable to quit. So, the existence of a “core” group of “hard” smokers is not a reality borne out by the data (17). Indeed, in several Member States, as smoking prevalence has fallen, remaining smokers tend to smoke less and quit more, a so-called “softening” of the “hard core” smoking population.

4.2 ENDS/ENNDS

4.2.1 Health effects on users

There is not enough research to quantify the relative risk of ENDS/ENNDS in comparison to combustible products. Quantifying the health effects of ENDS/ENNDS is difficult as the concentration, “puffing” topology and battery power vastly change the emissions of these products.

However, there is already peer-reviewed evidence that ENDS/ENNDS use increases the risk of chronic obstructive pulmonary disease, other lung diseases and cardiovascular disease (3).

The evidence presented below demonstrates the link between e-cigarette use and myocardial infarction, angina and coronary heart disease (Tables 1 and 2). The odds ratio describes the increased risk of suffering certain health outcomes compared to a baseline group. It also implies that dual use of traditional cigarettes and e-cigarettes worsens health outcomes. This a major concern given the frequency of dual use, and means that research considering e-cigarettes alone will likely underreport the health risks of these products.

Table 1. Link between e-cigarette use and myocardial infarction (18)

	Baseline	Odds ratio of myocardial infarction
Every-day e-cigarette use	Never cigarette smoker who never used e-cigarettes	2.25
Some-day e-cigarette use		1.99
Daily use of e-cigarettes and cigarettes		6.64

Table 2. Link between e-cigarette use and myocardial infarction, angina and coronary heart disease (19)

	Baseline	Disease	Odds ratio
Ever e-cigarette use	Non-users of e-cigarettes	Myocardial infarction	1.71
		Angina	1.59
		Coronary heart disease	1.4

4.2.2 ENDS/ENNDS aerosols

Examining the components of ENDS/ENNDS aerosols allows for the health risks to be better understood.

Nicotine

ENDS aerosol contains nicotine, the addictive component of tobacco and nicotine products. In addition to dependence, nicotine can have adverse effects on the development of the fetus during pregnancy and may contribute to cardiovascular disease. Although nicotine itself is not a carcinogen, it may function as a “tumour promoter” and seems to be involved in the biology of malignant diseases, as well as of neurodegeneration. Fetal and adolescent nicotine exposure may have long-term consequences for brain development, potentially leading to learning and anxiety disorders. The evidence is sufficient to warn children and adolescents, pregnant women and women of reproductive age against ENDS use and exposure to nicotine (3).

The development of nicotine salt e-liquids allows delivery of much higher nicotine concentrations per puff than previously seen in cigarettes and older ENDS that use freebase nicotine. This is a cause for concern.

Toxicants

The levels of toxicants in ENDS/ENNDS can vary enormously across and within brands, and sometimes reach higher levels than in tobacco smoke (3).

Carcinogens

Of special concern are compounds that are classified by the International Agency for Research on Cancer (IARC) as carcinogens. Formaldehyde, which is an IARC group 1 carcinogen, is a chemical product of heating propylene glycol in the presence of oxygen to temperatures reached by commercially available e-cigarettes (7). An e-cigarette user vaping at a rate of 3 mL per day would inhale 14.4 mg (\pm 3.3 mg) of formaldehyde per day, while tobacco cigarettes produce 3 mg per pack of 20 cigarettes (20). Another compound detected is acrolein, which is toxic and an irritant to skin, eyes and nasal passages. Table 3 outlines research comparing levels of selected carcinogens and toxicants in vapour from e-cigarettes to levels from conventional cigarettes and nicotine inhalers (21).

Altering the power settings of the device can more than double the amount of formaldehyde and acetaldehyde in the aerosol of an e-cigarette (22). Increasing ENDS power from 4.1 to 8.8 watts tripled volatile aldehyde emissions, while increasing it from 6 to 13 watts increased benzene emissions 100-fold and increasing it from 4.3 to 10.8 watts doubled furan emissions. To date, most studies on the toxicant profile of ENDS aerosols have been limited to devices powered at less than 25 watts.

Table 3. Levels of carcinogens and toxicants in vapour from e-cigarettes compared to conventional cigarettes and nicotine inhalers

Toxins	E-cigarette	Conventional cigarette	Nicotine inhaler
Formaldehyde (µg)	0.20–5.61	1.6–52.0	0.20
Acetaldehyde (µg)	0.11–1.36	52.0–140.0	0.11
Acrolein (µg)	0.07–4.19	2.4–62.0	ND
o-methylbenzaldehyde (µg)	0.13–0.71	–	0.07
Toluene (µg)	ND–0.63	8.3–70.0	ND
p,m-xylene (µg)	ND–0.2	–	ND
NNN (ng)	ND–0.00043	0.0005–0.19	ND
NNK (ng)	ND–0.00283	0.012–0.11	ND
Cadmium (ng)	ND–0.022	–	0.003
Nickel (ng)	0.01–0.03	–	0.019
Lead (ng)	0.003–0.057	–	0.004

ND = not detected; -- = not reported; NNN = N'-nitrosornicotine; NNK = 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.

Data from Goniewicz et al. 2014 (21), using lowest and highest values reported for 15 puffs of each product.

Flavours

Close to 8000 unique e-liquid flavours have been reported (23). The health effects of the heated and inhaled flavourants used in the e-liquids have not been fully studied. The limited literature on the topic indicates that most flavourants may pose appreciable health risks with long-term use, especially those that are sweet. Many are irritants, which may increase airway inflammation. Some are more cytotoxic than unflavoured aerosol, although less so than tobacco smoke. Some also increase the susceptibility of airway cells to viral infection after direct contact with e-liquid, although the relevance of direct effects of contact with e-liquid, as opposed to aerosol, is unclear (3).

Metals

A number of metals – including lead, chromium and nickel – have been detected in the aerosol of some ENDS/ENNDS at concentrations equal to or greater than traditional cigarettes under normal experimental conditions of use (3). These elements appear to come from the metal components of the device (7).

Fine/ultrafine particles

Research on the number and size spread of particles in the aerosol from ENDS/ENNDS devices has found that the particles are smaller, and the span of particle size wider, compared to the particles in conventional cigarette smoke (24). The particles of the e-cigarette vapour are smaller than 1 µm and some of them are in the ultrafine particle range (smaller than 0.1 µm), making them able to penetrate deep into the human respiratory system (25). Fine particles (less than 2.5 µm) can pass into the deeper lung, while ultrafine particles can pass into the circulatory system. The small size of the particles also means that the amount delivered into the respiratory system,

and likely transferred into the blood stream, is much greater. In addition, the number of particles increases with an increase in the voltage of the battery of the ENDS/ENNDS device (24).

Battery explosion

This is rare, but such explosions pose a serious health risk to users (26).

4.2.3 Health effects on non-users

Nicotine exposure

There is a potentially lethal dose of nicotine in many e-liquid products. There is a high risk to children from inadvertently consuming the liquid orally, resulting in serious harmful consequences. The attractive packaging of e-liquids and the variety of flavours, including candy and fruit, heightens this risk (7).

Second-hand aerosol

A recent systematic review of the health risks from passive exposure to exhaled aerosol from ENDS/ENNDS users – or second-hand aerosol – concluded that “the absolute impact from passive exposure to electronic cigarette vapour has the potential to lead to adverse health effects” (27).

A WHO-commissioned review found that, while there are a limited number of studies on second-hand aerosol, it can be concluded that second-hand aerosol is a new air contamination source for particulate matter (PM), including fine and ultrafine particles, as well as 1,2-propanediol, some volatile organic compounds, some heavy metals and nicotine (3).

The levels of some metals – such as nickel and chromium – are higher in second-hand aerosol from ENDS than in second-hand smoke, and certainly than in background air (3).

PM_{1.0} (particles less than 1.0 µm in diameter) and PM_{2.5} (particles less than 2.5 µm in diameter) in second-hand aerosol are between 14 and 40 times higher, and 6 and 86 times higher, respectively, than levels in background air. In addition, nicotine in second-hand aerosol has been found to be between 10 and 115 times higher than in background air levels, acetaldehyde between 2 and 8 times higher, and formaldehyde about 20% higher (3).

It is reasonable to assume that the increased concentration of toxicants from second-hand aerosol over background levels poses an increased risk for the health of all bystanders (3). Children, pregnant women, the elderly and patients with cardiorespiratory diseases may be at special risk (28).

4.3 HTPs

Research has compared the chemical composition of smoke breathed in from tobacco products with that from HTPs (29). Although some substances are reduced in HTPs, such as tar, it is noticeable that the devices contain higher amounts of other potentially harmful chemicals.

Focusing on the reduction in certain components, as the tobacco industry describes, does not allow the health risks of the increased amount of other products to be discussed (29). Health assessments of HTPs should consider possible toxicities beyond those of traditional cigarettes (30).

Despite delivering lower levels of some toxins than conventional cigarettes, even PMI's own data fail to show that its HTP, IQOS, presents lower risks of harm for humans than conventional cigarettes (31). IQOS is associated with significant pulmonary and immunomodulatory toxicities, with no detectable differences between conventional cigarette smokers and those who switched to IQOS, even in PMI's own studies (32).

5. THE EFFECT OF ENDS/ENNDS ON THE PREVALENCE OF SMOKING

5.1 ENDS/ENNDS and smoking cessation

ENDS/ENNDS are often marketed as a tool for cessation. This is despite the fact that among the population as a whole smokers who use ENDS are *less* (not more) likely to quit smoking than smokers who do not use ENDS (33). Further, there is evidence that at a population level, e-cigarettes may increase the number of cigarette smokers. A population study of the United States, which made optimistic assumptions about the value of ENDS for smoking cessation, found that for every cigarette smoker that quits, there are 80 youth that will become regular cigarette smokers as a result of use of e-cigarettes (34). In light of this evidence, use of ENDS/ENNDS should not be considered a cessation tool.

A WHO-commissioned review found that the quality of evidence from randomized control trials was low (35). Longitudinal studies are more abundant and better reflect "real world" conditions of use than randomized control trials, but present more methodological concerns. Two reviews of these studies suggest that the use of ENDS may reduce the chances of quitting smoking (35,36). However, the evidence is of very low certainty. Most longitudinal studies have found that use of ENDS made it less likely that a smoker would quit (3). Furthermore, it is of relevance whether users continue to use e-cigarettes, not only whether they stop using combustible cigarettes. A recent study showed that, although e-cigarettes may lead to higher sustained absence from combustible cigarettes than nicotine replacement therapy, the nicotine-free abstinence rate was lower as many smokers continued to use e-cigarettes. There was also very high dual use of e-cigarettes and traditional cigarettes among those that failed to quit (37). Continued use of ENDS also brings elevated risks of cardiovascular and pulmonary disease, which may offset the benefits of quitting cigarettes.

Certain studies have examined the extent and pattern of dual use (use of conventional cigarettes and e-cigarettes). In fact, most adult e-cigarette users do not stop smoking cigarettes, but instead utilize both products (7). The health risk of dual use is higher than of single use of e-cigarettes or cigarettes. This means that if users begin to dual use, rather than completely stopping traditional cigarette use, the health risks will actually increase. On average, dual users do not smoke fewer combustible tobacco cigarettes than those who smoke only combustible tobacco cigarettes (28).

An examination of the results of 27 studies conducted to record a quantitative estimate of the link between e-cigarette use and smoking cessation found that the odds of quitting cigarettes were 27% lower in those who used e-cigarettes compared with those who did not use e-cigarettes (odds ratio = 0.73; 95% CI 0.59–0.92) (33). The overall conclusion is that use of e-cigarettes in fact makes people less likely to stop smoking conventional cigarettes.

5.2 Recruitment of minors and non-smokers

WHO commissioned a review of data on the prevalence and trends of ENDS/ENNDS use among people of 20 years of age or less (38). The trend data show that there are two groups of WHO Member States. In one group, the prevalence of ENDS/ENNDS use is low and is not increasing significantly; in the other group, prevalence is rapidly increasing. There is considerable debate about whether for the latter Member States the increase in ENDS/ENNDS use among young non-smokers is a precursor to smoking. Existing longitudinal studies indicate that ENDS/ENNDS use by minors who have never smoked at least doubles their chance of starting to smoke. It is not clear whether the association of ENDS/ENNDS use and smoking is because their use leads to smoking, or because young ENDS/ENNDS users and smokers share similar social and behavioural characteristics, rendering them susceptible to the use of nicotine (3).

Among youth in the United States of America, a longitudinal study found that compared with no prior tobacco use, prior e-cigarette use was associated with more than four times the odds of ever cigarette use (odds ratio = 4.09) and nearly three times the odds of current cigarette use (odds ratio = 2.75) (39).

Among youth in Canada, a longitudinal study found that past 30-day e-cigarette use was strongly associated with smoking status and smoking susceptibility. Past 30-day use of e-cigarettes at baseline was associated with initiation of smoking a whole cigarette (adjusted odds ratio = 2.12) and with initiation of daily smoking (adjusted odds ratio = 1.79) at follow-up (40).

Among cigarette-naïve youth in Taiwan, those with e-cigarette experience at baseline exhibited higher odds of smoking initiation at follow-up (odds ratio = 2.14) (41).

The results of nine longitudinal studies quantifying the effect of starting tobacco use with e-cigarettes on subsequent progression to smoking conventional cigarettes indicate that once demographic, psychosocial and behavioural risks factors for cigarette smoking are taken into account, the odds of subsequent cigarette smoking after using e-cigarettes were quadrupled relative to the baseline (33).

6. THE USE OF ENDS, ENNDS AND HTPS

6.1 ENDS/ENNDS

E-cigarettes are a product aimed at, and consumed by, youth.

Youth experiment with ENDS. In 2017, among young people in Europe aged 15–24 years, 25% had tried or used e-cigarettes. By comparison, only 6% of respondents aged 55 or over had done so (42).

More youth develop nicotine addiction through e-cigarettes than among adults. A higher percentage (40%) of current youth e-cigarette users have never smoked a cigarette than among adult current e-cigarette users (1.3%) (43).

The marketing and product development of e-cigarettes is aimed at youth. Among e-cigarette users aged over 40 years, more than 60% prefer e-cigarettes with tobacco flavour, while among users aged 15–24 years, 77% prefer non-tobacco flavours (fruit, candy, alcohol or mint) (7). With over 8000 flavours on the market, this diversification captures youth consumers.

There is considerable heterogeneity in ENDS use among youth globally, with countries of the WHO Eastern Mediterranean Region showing particularly high prevalence for this demographic (see Table 4). Unfortunately, there are no data for national adult ENDS use in the Region.

6.2 HTPs

Research in Italy has shown that of those who have tried IQOS, a HTP produced by PMI, over 30% were non-smokers (45).

Some research suggests that, contrary to the assumption that the tobacco industry's reduced harm claim plays a significant role in increasing interest in and use of HTPs, HTP users typically use such products for other reasons. In December 2017, the Korean National Tobacco Control Center conducted a focus group interview with conventional cigarette users, HTP users and non-smokers. Participants tended to reserve judgement on the potential harm from HTP use, citing insufficient evidence. Instead, the most common reason for using HTPs was to avoid the odour from smoking conventional cigarettes. Non-smokers acknowledged this reduced odour, and also reported that this affected their perception of the harm of second-hand smoke/vapour from HTPs.

Table 4. ENDS use among 13–15 year olds, WHO Global Youth Tobacco Survey (GYTS) (44)

Country	Year	Prevalence (%)
Italy	2018	17.5
UNRWA – Jordan	2014	17.4
Qatar (unpublished)	2018	17.1
Russian Federation – Moscow	2012–2015	14.5
Yemen	2014	14.5
UNRWA – Gaza Strip	2014	13.4
Georgia	2018	13.2
UNRWA – Lebanon	2014	11.6
Iraq	2014	11.2
Bulgaria	2012–2015	10.8
Latvia	2014	10.0
Russian Federation – Novosibirsk	2012–2015	9.8
San Marino	2018	8.9
Russian Federation – Pskov	2012–2015	8.5
Romania	2017	8.2
Sudan	2014	7.8
Seychelles	2012–2015	7.3
Belize	2012–2015	6.5
Albania	2012–2015	5.8
Russian Federation – Khabarovsk	2012–2015	5.7
Guatemala	2012–2015	5.6
Nicaragua	2012–2015	5.4
Morocco	2016	5.3
Oman	2016	5.3
Finland	2012–2015	5.0
Tunisia	2017	4.9
Russian Federation – Cheboksary	2012–2015	4.1
Paraguay	2012–2015	3.7
Thailand	2015	3.3
Greece	2012–2015	2.8
China–Macau	2012–2015	2.6
Peru	2012–2015	2.4
Kazakhstan	2012–2015	1.6

UNWRA = United Nations Relief and Works Agency for Palestine Refugees in the Near East

7. THE REGULATION OF ENDS, ENNDS AND HTPS

7.1 ENDS/ENNDS

This report and side-by-side text builds on the following reports by WHO and the WHO FCTC Secretariat and decisions made by the COP regarding ENDS and ENNDS.

- Report of the Convention Secretariat to COP4 in 2010 on the Control and prevention of smokeless tobacco products and electronic cigarettes (FCTC/COP/4/12). The report provided information on ENDS, as well as an overview of the recommendations made by the WHO Study Group on Tobacco Product Regulation (TobReg) and the outcome of a regulatory consultation convened by WHO. The report noted that there was a growing global concern about the quality and safety of, and “regulatory gap” for, these emerging products as they continue to penetrate new markets.
- Report of the Convention Secretariat to COP5 in 2012 on Electronic nicotine delivery systems, including electronic cigarettes (FCTC/COP/5/13). The report included the results of a questionnaire sent by the Convention Secretariat on ENDS to all the Parties in November 2011. The survey included questions on availability, regulatory framework, sales volume and scientific studies on ENDS. The regulatory strategies undertaken by the Parties, as well as the policy domains that need to be considered, were included in the report.
- Report of WHO to COP6 in 2014 on Electronic nicotine delivery systems (FCTC/COP/6/10 Rev.1), which included the deliberations and scientific recommendations on ENDS made by TobReg and the analysis from a WHO survey on tobacco products for which 90 WHO Member States, of which 86 were Parties to the WHO FCTC, responded. The survey showed that more than 50% of the Parties did not regulate ENDS, which prompted in the same report a proposal for a regulatory framework for ENDS.
- Report of WHO to COP7 in 2016 on Electronic nicotine delivery systems and electronic non-nicotine delivery systems (FCTC/COP/7/11) updating the evidence on the health impact of ENDS/ENNDS, their potential role in tobacco cessation and their impact on tobacco control efforts, as well as an assessment of regulatory options.
- Decision FCTC/COP7(9) by COP7 in 2016 inviting WHO to report on the development of methods by regional and international standards development organizations for the testing and measuring of the contents and emissions of these products, at either the eighth or the ninth session of the COP, as applicable.

7.2 HTPs

The WHO FCTC recognizes that HTPs are tobacco products and subject to the Convention, despite the difficulties in comprehensively applying the Convention to these products. This report and side-by-side text builds on the following reports by WHO and the WHO FCTC Secretariat and decisions made by the COP regarding HTPs.

- Report of WHO to COP6 in 2014 (FCTC/COP/6/14) on the evolution of new tobacco products and related marketing strategies, which also provided conclusions and recommendations including on the toxicity, addictive potential, perception and potential impact on public health of new tobacco products.
 - Decision FCTC/COP7(14) adopted by COP7 in 2016 inviting WHO to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as “heat-not-burn” tobacco products, and to report progress to future sessions of the COP.
 - Report of WHO to COP8 in 2016 on technical matters related to Articles 9 and 10 of the WHO FCTC, which covers market developments of HTPs (FCTC/COP/8/8).
 - Decision FCTC/COP8(22) on novel and emerging tobacco products, which included the following commitments.
- WHO will:
1. provide a report to COP9 on research and evidence on novel and emerging tobacco products, in particular HTPs, regarding their health impacts including on non-users, their addictive potential, perception and use, attractiveness, potential role in initiating and quitting smoking, marketing including promotional strategies and impacts, claims of reduced harm, variability of products, regulatory experience and monitoring of Parties, impact on tobacco control efforts and research gaps, and to subsequently propose potential policy options;
 2. examine the chemical and physical processes these products are undergoing during use, including the characterization of emissions;
 3. assess whether the available standard operating procedures for contents and emissions are applicable or adaptable to HTPs;
 4. advise, as appropriate, on suitable methods to measure the contents and emissions of these products.
- The Convention Secretariat will:
1. examine possible challenges that these products are posing for the comprehensive application of the WHO FCTC and, in particular, those articles and guidelines referring to definitions/terminology and to tobacco smoke, while considering the need to adapt these guidelines;
 2. advise, as appropriate, on the adequate classification of novel and emerging tobacco products such as HTPs to support regulatory efforts and the need to define new product categories.
- The Parties, Convention Secretariat and WHO will comprehensively monitor market developments and the use of novel and emerging tobacco products, including the relevant questions in all appropriate surveys and reports, such as from the WHO FCTC reporting instrument, and to report on it at regular intervals.

7.3 Cases studies

7.3.1 European Union (EU) Tobacco Products Directive

The European Tobacco Products Directive binds EU Member States to impose limits on the sale and merchandising of tobacco and related products (46). Restrictions for ENDS include:

- packaging must include a list of ingredients contained in the product, information on the product's nicotine content, and a leaflet with instructions for use and information on adverse effects, risk groups, addictiveness and toxicity;
- e-cigarette packaging must not feature promotional elements;
- maximum nicotine concentration and volume for cartridges, tanks and nicotine liquid containers are to be as follows:
 - the concentration of nicotine should be less than 20 mg/mL;
 - the nicotine-containing liquid should only be placed on the market in dedicated refill containers not exceeding a volume of 10 mL, in disposable e-cigarettes or in single use cartridges, where such cartridges or tanks do not exceed a volume of 2 mL;
- e-cigarettes should be child-resistant, tamper-evident and have a mechanism that allows refilling without spillage to protect consumers;
- e-cigarette ingredients must be of high purity;
- e-cigarettes should consistently deliver the same amount of nicotine when puffed at the same strength for the same duration;
- manufacturers and importers must notify all products they place on the EU market through a standardized electronic format.

7.3.2 Canada

Canada has regulatory measures to reduce youth use of both ENDS and ENNDS products, including:

- prohibiting the manufacture and sale of vaping products with certain flavours and/or prohibiting the promotion of certain flavours;
- restricting the concentration and/or delivery of nicotine in vaping products;
- regulating design features;
- restricting online retail access;
- restricting product packaging;
- increasing regulatory transparency and openness (47,48).

7.3.3 Republic of Korea

When IQOS was introduced in the Korean market, it was initially taxed at a much lower rate than conventional cigarettes. Due to rising concerns among politicians and the Ministry of Health and Welfare about the rapid increase in HTP sales, in January 2018 the Korean National Assembly passed an amendment to raise the tax rate of HTPs to about 90% of the tax rate for conventional cigarettes.

Table 5. Comparison of taxation on cigarettes and HTPs, based on 20 cigarettes or tobacco heat sticks, Republic of Korea

Tax	Cigarette (4500 Korean won)	HTP, before tax increase (4300 Korean won)	HTP, after tax increase (4500 Korean won)
Tobacco excise tax	1 007	528	897
Local education tax	443	232.2	395
Individual consumption tax	594	126	529
Tobacco farming support fund	5	–	–
Health Promotion Fund	841	438	750
Waste management charge	24.4	24.4	24.4
Value-added tax (VAT) <i>*10% of retail price excluding VAT</i>	409	391	391
Total tax	3 323.4	1 739	2 986

In June 2018, the Ministry of Food and Drug Safety conducted an analysis of mainstream smoke emissions from HTPs and found the following health risks:

- HTPs are not recommended for tobacco cessation as they contain a comparable amount of nicotine. Nicotine by itself is addictive;
- HTPs may contain other harmful constituents which are not present in conventional cigarettes. Higher levels of tar were detected from the two brands of HTP than the average tar level of conventional cigarettes;
- HTPs can cause cancer and/or other diseases. Carcinogens, such as benzo[a]pyrene and benzene were detected in HTP emissions.

These findings supported the implementation of stronger HTP health warnings on packs, including the addition of messages on carcinogens. The Republic of Korea was one of the first WHO Member States to mandate public health warnings on the packaging for ENDS and HTPs. The country developed new, evidence-based warnings on the risk of exposure to carcinogens, in addition to warnings on the risks of nicotine addiction. Pictorial warnings were also developed to better communicate these changes.

7.3.4 Italy

Italy has faced complexities regarding the control of HTPs. First, PMI began to construct a heat sticks factory in Italy at the same time as the registration of the product in the country. This has been used as a marketing strategy by PMI to suggest that they are a company that contributes to the Italian economy and to shift focus away from the health burden of PMI products in Italy.

Secondly, a new law introducing a category of tobacco product for “inhalation without combustion” was passed in the Italy on 23 December 2014. Products in this category have an excise equal to 50% of the excise on traditional cigarettes. On 24 December 2014, PMI applied for IQOS to be authorized as such a product; authorization was given on the same day. In Italy, more than 77% of conventional cigarette retail price is tax, but, as a result of this law, only 33–43% of the retail price of HTPs is tax.

Thirdly, use of HTPs is permitted in public places, whereas use of traditional cigarettes is not. Cigarettes have 42 different combined health warnings (pictures and text) which are rotated, cover 65% of the pack and include a quit line number. In contrast, HTPs have only one textual health warning that covers 30% of the pack and no quit line number. There is a total ban on advertising, sponsorship and promotion of cigarettes, but HTPs are excluded from this ban and face no limitations in advertising, promotion and sponsorship.

7.3.5 Singapore

Singapore maintains a ban on ENDS, ENNDS and HTPs. In tobacco control laws, the term “tobacco product” includes traditional tobacco products as well tobacco derivatives, substitutes and mixtures containing any form of tobacco/tobacco derivative/tobacco substitute. Therapeutic products registered under the Health Products Act are excluded from this derivation.

7.4 Illicit trade

There is already an illicit trade in ENDS/ENNDS and HTPs, with these products currently available in WHO Member States that have banned their sale. There is, however, no concrete evidence on the size of the problem. Due to a lack of regulation and harmonized taxation levels in different Member States, there is a serious possibility of a significant illicit market in these products in the future. It should be borne in mind that ENDS/ENNDS and HTPs are continuing to make considerable inroads into the conventional cigarette market, which is anticipated to significantly reduce tax revenue from conventional cigarettes collected by Member States. In addition, there are other circumstances to consider that could lead to a considerable increase in the illicit trade in these products. Significantly, some WHO Member States impose the same taxation level on ENDS and HTPs as that imposed on conventional cigarettes, while others impose low or zero taxes on these products. Other WHO Member States have decided to prohibit these products entirely. Accordingly, it is possible for a Member State to have neighbours with high, low or zero taxation in place, or even a prohibition on ENDS and HTPs. Such circumstances create a high chance of significant illicit trade in these products.

In light of the above, the following is recommended:

- In order to counter future illicit trade in ENDS/ENNDS and HTPs, it is necessary for WHO Member States to plan and address such potential problems.
- Serious consideration should be given to implementation of the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products with respect to ENDS/ENNDS and HTPs.
- Law enforcement bodies should seek to utilize the chance to be proactive rather than reactive when addressing the problem.
- WHO Member States should take advantage of the knowledge and intelligence acquired in the fight against the illicit trade in conventional cigarettes over several decades.
- WHO Member States should work to harmonize their regulatory approaches, particularly within subregional groups and cooperative blocs.

7.5 Regulation of ENDS/ENNDs and HTPs in the WHO Eastern Mediterranean Region

7.5.1 ENDS

By 2016, the WHO Eastern Mediterranean Region accounted for 11 of the 30 WHO Member States that had banned ENDS globally. This included: Bahrain, Egypt, Islamic Republic of Iran, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syrian Arab Republic and United Arab Emirates. In this way, the Region led the world in taking a firm stance against these products and has maintained banning ENDS as an option in COP decisions. However, national legislation banning these products in the Region has begun to be weakened and reversed, mainly due to pressure from the tobacco industry, which has employed a range of strategies to get governments to lift the ban on these products.

7.5.2 HTPs

The regulatory situation of HTPs is different to that of ENDS/ENNDs in the WHO Eastern Mediterranean Region. Member States of the Region are less clear on their official position regarding HTPs, and there are no clear bans on products or authorization in many countries. Across the Region, many WHO Member States are basing their official position on customs, trade or finance considerations and not on health concerns. Some countries, however, do consider HTPs to be tobacco products and are applying tobacco control legislation. More clarity on the regulatory status of these products is needed.

8. SIDE-BY-SIDE TEXTS FOR IMPLEMENTATION OF THE WHO FCTC GUIDELINES

During the consultation, experts, Member States and WHO regional and headquarters staff divided into working groups, based on expertise, and developed the following side-by-side texts based on the WHO FCTC and COP decisions. Following the consultation, the WHO Regional Office for the Eastern Mediterranean introduced changes to the side-by-side texts based on the outcomes of the working groups, before sharing with all participants by email. Final feedback was gathered, and the side-by-side texts finalized. For more information about the working groups, see the Introduction.

8.1 Side-by-side text for ENDS/ENNDS

<p>This side-by-side text advises Member States of the Eastern Mediterranean Region on options to consider in relation to ENDS/ENNDS (e-cigarettes).</p> <p>It is framed around the articles of the WHO FCTC as a comprehensive approach to tobacco control. This text is necessary as ENDS/ENNDS (e-cigarettes) are categories of products with unconventional characteristics, and many Member States have requested guidance on how best to proceed in relation to regulating these products. It was developed with selected Member States of the Eastern Mediterranean Region, WHO experts and external consultants at a regional consultation. This side-by-side text is not limited to Parties to the WHO FCTC, and could be useful to Member States in other WHO regions.</p>		
WHO FCTC Article	ENDS/ENNDS	Good practice
<p>Article 1: Use of terms</p>	<p>Member States may wish to opt for the regulatory option of treating ENDS/ENNDS (e-cigarettes) as tobacco products for regulatory purposes, as noted in decision FCTC/COP6(9) (2). Some of the reasons for this option are listed below.</p> <ul style="list-style-type: none"> a) ENDS/ENNDS (e-cigarettes) contain, or, in the case of ENNDS, have been often found to contain, nicotine, which is a substance predominantly derived from tobacco. b) The use of ENDS/ENNDS (e-cigarettes) mimic tobacco use in terms of physiological and behavioural addiction and method of consumption. c) The evidence surrounding the claims that all ENDS/ENNDS (e-cigarettes) carry reduced health risks are inconclusive and not agreed upon by the scientific and public health community. There is also growing evidence and concern about the negative health effects of these products. d) The claim that ENDS/ENNDS (e-cigarettes) can be used as a cessation aid is heavily debated and not substantiated at population level. e) ENDS/ENNDS (e-cigarettes) are attractive to youth; their use has been a gateway to initiation of tobacco use and dual/poly-use of tobacco products in some Member States. f) ENDS/ENNDS (e-cigarettes) are manufactured, distributed and sold by the well-known multinational tobacco industry players, as well as other related industries. g) The 2019 World Bank working note recommends that for taxation purposes all ENDS/ENNDS (e-cigarettes) should be classified as “tobacco products” and covered by the Harmonized System (HS) Code 2403: e-cigarette devices should be classified as “manufactured tobacco substitutes” and liquids for e-cigarettes (regardless of nicotine content) as “tobacco extracts and essences” (7). h) ENDS/ENNDS (e-cigarettes) should not be exempt from national tobacco control plans; exempting these devices will weaken the impact of tobacco control regulations. <p>This means that ENDS/ENNDS (e-cigarettes) can be considered as tobacco-like products. As such, all tobacco control measures must include reducing the use of ENDS and ENNDS; the rules and regulations of dealing with the tobacco industry must also cover ENDS/ENNDS (e-cigarettes) manufacturers, wholesale distributors and importers; and the rules and standards applied to tobacco products should also be applied to ENDS/ENNDS (e-cigarettes) (3).</p> <p>Note: the use of the terms ENDS and ENNDS was considered unhelpful by some participants of the consultation, because of the connotation that such products are “ending the tobacco use epidemic”.</p>	<p>Georgia</p> <p>South Africa</p> <p>Turkey</p> <p>In the United States of America, ENDS/ENNDS are considered tobacco products according to the FDA. The FDA requires all ENDS/ENNDS companies to submit their products for evaluation by May 2020.</p>

Article 2: Relationship between this Convention and other agreements and legal instruments	To better protect human health, Member States are urged to implement measures and good practice beyond the regulatory options specified in this document and for Parties to the WHO FCTC, beyond those required by the WHO FCTC and its protocols. Therefore, nothing in the document shall prevent Member States from imposing more stringent requirements.	
Article 3: Objective	The objective to reduce continually and substantially the prevalence of tobacco use can be assisted by banning or strongly regulating ENDS/ENNDS (e-cigarettes).	
Article 5: General obligations	The relevant legislation, national action plans and multisectoral committees for tobacco control should cover tobacco, tobacco-related products and alternatives. ENDS and ENNDS should be included in this regardless of whether Member States consider ENDS/ENNDS (e-cigarettes) to be tobacco products or alternative products.	
Article 5.3: In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.	Member States can consider regulatory options such as: 1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes); OR 2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions. a) Applying the guidelines for implementation of Article 5.3 and all COP decisions with a broader definition of the tobacco industry to include “manufacturers, wholesale distributors and importers of tobacco products; tobacco, tobacco-related products and tobacco alternatives”. b) Data provided by the tobacco industry must be validated using internationally approved methods by scientists with no conflict of interest with the industry – WHO TobLabNet methods are strongly recommended, where applicable. These laboratories shall not be owned or controlled directly or indirectly by the tobacco industry (3).	
Article 6: Price and tax measures to reduce the demand for tobacco	Member States can consider regulatory options such as: 1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes); OR 2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions. a) ENDS/ENNDS (e-cigarettes) should be taxed according to the public health objectives of the Member State. Member States should consider applying excise tax to the devices and e-liquids, collected at the manufacturer or importer level. b) Member States that consider ENDS/ENNDS (e-cigarettes) as tobacco products should consider comprehensively applying Article 6 and aiming for more than 75% of retail price to be tax or at least 70% of retail price to be excise tax. c) Member States should consider taxing ENDS/ENNDS (e-cigarettes) at a level that makes them unaffordable to minors in order to deter their use in this age group; this will require an excise tax.	Bahrain Republic of Korea

	<p>Issues likely to arise with ENDS/ENNDS (e-cigarettes) taxation, and potential approaches to address these issues</p> <p>a) State-owned companies</p> <ul style="list-style-type: none"> • See Article 5.3. <p>b) Refills</p> <ul style="list-style-type: none"> • Attempts to circumvent taxation: <ul style="list-style-type: none"> – develop a clear definition of the tax base, detectable upon importation. This may be volume of e-liquid, or nicotine concentration; – only allow importation and/or production for licensed operators; – regulate the strength and volume of e-liquids. • Different results from the same batch of products: <ul style="list-style-type: none"> – test products in government or independent laboratories that are accredited. Impose sanctions for high variation in product contents and emissions. • Non-nicotine containing liquids are used in multiple industries and for non-tobacco related items: <ul style="list-style-type: none"> – implement strong enforcement mechanisms such as licensing, record keeping and control of the supply chain (see the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products and Article 15 below). <p>c) Devices</p> <ul style="list-style-type: none"> • Under-declaring the value of the device in order to pay lower excise duties (ad valorem) and custom duties: <ul style="list-style-type: none"> – establish a list of prices of comparable products on the market and actively correct prices; – apply a specific excise duty or establish a minimum value (minimum tax base); – Member States that apply a higher rate of VAT on tobacco products than on general products should consider applying this higher VAT rate to ENDS/ENNDS (e-cigarettes). • Importation of separate parts and assembly after importation to avoid excise tax on the device: <ul style="list-style-type: none"> – only allow manufacturing of devices to licensed operators. 	
<p>Article 8: Protection from exposure to tobacco smoke</p>	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes); <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions. <ol style="list-style-type: none"> a) Emissions of ENDS/ENNDS (e-cigarettes) shall be considered as tobacco smoke; therefore, national laws regarding cigarette smoking in public places should apply to ENDS/ENNDS (e-cigarettes), and ENDS/ENNDS (e-cigarettes) should be included in work to comprehensively implement Article 8 in line with the guidelines for implementation. b) A standard symbol for ENDS/ENNDS (e-cigarettes) should be developed or agreed on, and all no smoking signs should carry this symbol to alert the public. c) All public places listed below should be completely smoke-free and emission-free (or at least 90% of the population covered by complete 	<p>51 WHO Member States prohibit or restrict the use of e-cigarettes in public places.</p> <p>Use is prohibited in vehicles with minors in Austria (18 years), Cyprus, (18 years), Finland (15 years), Malta (16 years), Republic of</p>

	<p>subnational smoke-free legislation). Designated smoking rooms are not allowed, as these do not work and are difficult to enforce.</p> <ul style="list-style-type: none"> • Health-care facilities • Educational facilities other than universities • Universities • Government facilities • Indoor offices and workplaces not considered in any other category • Restaurants or facilities that serve mostly food • Cafés, pubs and bars, or facilities that serve mostly beverages • Public transport • Religious sites. <p>d) A comprehensive implementation plan should be drafted and enforced.</p>	<p>Moldova (18 years), Slovenia (18 years) and Tajikistan (16 years). Cyprus also prohibits use in personal vehicles with a pregnant woman.</p>
<p>Article 9: Regulation of the contents of tobacco products and Article 10: Regulation of tobacco product disclosures</p>	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes); <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) in line with the guidelines for the implementation of Articles 9 and 10, and with the following additional considerations. <p>Regulating contents of products</p> <ol style="list-style-type: none"> a) Create a “negative list” of banned or restricted substances, based on substances associated with ENDS/ENNDS (e-cigarettes) that pose serious toxicological concern such as diacetyl, acetyl propionyl, cinnamaldehydes, benzaldehyde or high concentrations of heavy metals. b) Ban all flavours and components such as packages, capsules or any technical features allowing modification of smell and taste of the product. c) Allow manufacturers and retailers to submit specific products to be confirmed as “not flavoured” to be used for enforcement purposes of a flavour ban. d) If a total ban is not possible due to the volume of flavours for analysis, create a “positive list” of permitted flavours, rather than banning certain flavours. Manufacturers can then apply for the approval of specific flavours. This would be more manageable to enforce than having to monitor the market and ban new products as they arise. e) Fruity, sweet flavours and other flavours that appeal to children should be banned in all scenarios. A flavour ban for ENDS/ENNDS (e-cigarettes) should be accompanied with a corresponding ban on flavours in other tobacco products to prevent users switching to other products. f) Set limits of 20 mg/mL nicotine for e-liquids, and limits for the permissible concentration of aldehydes and heavy metals in emissions. g) Develop regulatory standards for e-cigarette devices, such as electrical and fire safety standards that regulate the power to below 25 watts. h) Containers of e-liquids for refillable e-cigarettes should not exceed a volume of 10 mL, and the tank size for disposable e-cigarettes and single use e-cartridges or pods should not exceed a volume of more than 2 mL. 	<p>28 EU Member States regulate the amount (concentration/ volume) of nicotine in e-liquids – in the EU the threshold concentration is 20 mg/mL.</p> <p>28 EU Member States do not permit the use of ingredients (other than nicotine) that pose a risk to human health in heated or unheated form in nicotine-containing e-liquid.</p> <p>28 EU Member States regulate the quality of nicotine and other ingredients used to manufacture the e-liquid; require products to pass safety and quality evaluation; or regulate flavours that</p>

	<p>i) Reduce the risk of accidental acute nicotine intoxication by:</p> <ul style="list-style-type: none"> • requiring tamper-evident/child-resistant packaging for e-liquids and leak-proof containers for devices and e-liquids; • limiting the nicotine concentration and total nicotine amount in devices and e-liquids (3). <p>j) Declaration that the manufacturer and importer bear full legal liability for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.</p> <p>Disclosures from industry to government</p> <p>a) Collecting data via devices (including directly or indirectly from the devices via electronic communication with the device itself) on user preferences and use patterns should be banned. If a ban is not in place, then data collected on devices regarding user preferences and use of device should be shared with governments.</p> <p>b) Manufacturers and third parties should be prohibited from using data on use patterns from devices to feedback to the devices to control the performance of the device, such as controlling puff patterns and intensity or recommending changes in liquid or tobacco plugs.</p> <p>c) Require manufacturers to monitor and report adverse effects.</p> <p>d) Toxicological data in line with Articles 9 and 10, as well as considering the range of potential concentrations and temperatures and not simply the advised concentration and temperature (reasonably foreseeable conditions).</p> <p>e) Information on nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions.</p> <p>f) Description of the components of the product including, where applicable, the opening and refill mechanism of the e-cigarette or refill containers.</p> <p>g) Development of a reporting template for product information and requiring electronic reporting of such information.</p> <p>Disclosure from government to the public</p> <p>a) Public disclosures of information about the toxic constituents of the products and the emissions that they may produce must take into account all reasonable foreseeable conditions (3).</p> <p>b) Information must be comprehensible and descriptive, with no numerical information.</p> <p>Sanctions</p> <p>a) Provide for the removal of products that do not comply with regulations.</p>	<p>can be used in e-liquids.</p> <p>28 EU Member States have regulations that require manufacturers/r etailers to notify the competent authority prior to introducing e-cigarettes to the market, as well as submit an annual report of sales and other specified information.</p>
<p>Article 11: Packaging and labelling of tobacco products</p>	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p> <p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions.</p> <p>a) Enforce a law requiring mandated specific health warnings covering at least 50% of the inner and outer packaging of devices and e-liquid containers (like packaging of midwakh in Gulf Cooperation Council countries).</p> <p>b) Health warnings can cover nicotine addiction, cardiovascular and pulmonary disease risks, allowing for new health evidence to be included as more research is carried out.</p>	<p>Georgia</p> <p>Republic of Korea</p>

	<p>c) Health warnings should be in line with proven health risks (1).</p> <p>d) The warnings should be large, clear, visible and legible (e.g. specific colours and font style and sizes are mandated), written in the principle language of the Member State and regularly rotated.</p> <p>e) Member States applying plain packaging for tobacco products should apply the same for ENDS/ENNDS (e-cigarettes) (devices and refills).</p> <p>f) Prohibiting implicit or explicit claims about the comparative safety or addictiveness of ENDS/ENNDS (e-cigarettes) with respect to any product (3).</p> <p>g) Prohibiting implicit or explicit claims that ENDS/ENNDS (e-cigarettes) are harmless or that ENDS/ENNDS (e-cigarettes) are not addictive.</p> <p>h) Prohibiting implicit or explicit claims that ENDS/ENNDS (e-cigarettes) are effective as smoking cessation aids. They are not a smoking cessation device unless regulated as a pharmaceutical product and approved as such.</p> <p>i) Controlling the design of devices and accessories in terms of shapes and size (e.g. Turkey waterpipe device regulations), flavours, smell and colours.</p> <p>j) The use of cartoon characters or other attractive features to young people should be banned.</p>	
<p>Article 12: Education, communication, training and public awareness</p>	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p> <p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions.</p> <p>a) Comprehensively applying Article 12; in particular, prohibiting implicit or explicit claims about:</p> <ul style="list-style-type: none"> • the effectiveness of ENDS/ENNDS (e-cigarettes) as smoking cessation aids; • ENDS/ENNDS (e-cigarettes) being harmless or non-addictive; • the comparative safety or addictiveness of ENDS/ENNDS (e-cigarettes) with respect to any product (3). <p>b) If ENDS/ENNDS (e-cigarettes) are planned to be categorized as pharmaceutical products they should follow the same regulations as nicotine replacement therapy and other medicines, providing proof of safety and efficiency through clinical trials.</p> <p>c) ENDS/ENNDS (e-cigarettes) should be integrated into public education programmes, specifically to debunk myths about ENDS/ENNDS that are being promoted by manufacturers and sellers, and to share information about the negative health effects of using ENDS/ENNDS.</p> <p>d) If there is a substantial illegal promotion for ENDS/ENNDS (e-cigarettes), such as via the internet, Member States should include ENDS/ENNDS in educational programmes to counter this promotion, provided a judgement is made that doing so will reduce rather than increase demand for these products.</p>	<p>Several states in the United States of America have educational programmes for children on ENDS: https://flavorshookids.org and the FDA Real Cost campaign.</p>
<p>Article 13: Tobacco advertising, promotion and</p>	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p>	<p>Canada</p> <p>United Kingdom of</p>

sponsorship (TAPS)	<p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions.</p> <p>a) Comprehensively applying Article 13 by implementing a comprehensive ban on all forms of TAPS, direct or indirect (3).</p> <ul style="list-style-type: none"> • Direct advertising bans: <ul style="list-style-type: none"> – national television and radio; – local magazines and newspapers; – billboards and outdoor advertising; – point-of-sale advertising and display; – internet, social media and mobile apps. • Indirect advertising bans: <ul style="list-style-type: none"> – free distribution of tobacco products in the mail or through other means; – promotional discounts; – non-tobacco products identified with tobacco brand names (brand stretching); – brand names of non-tobacco products used for tobacco products (brand sharing); – appearance of tobacco brands (product placement), and appearance of tobacco products, in television and/or films; – sponsorship, including corporate social responsibility programmes. <p>b) Ban should include medical and public health events, social media and mobile apps, and internet videos and streaming.</p> <p>c) As in Article 13, indirect bans should include free distribution of devices or device refill products in the mail or through other means, as well as promotional discounts and home delivery and online purchasing (49).</p>	Great Britain and Northern Ireland
Article 14: Demand reduction measures concerning tobacco dependence and cessation	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p> <p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions.</p> <p>a) ENDS/ENNDS (e-cigarettes) should not carry any health claims or be marketed as a cessation product unless there is robust, independent evidence of safety and efficiency, and approval by the medicines regulatory agency of the Member State.</p> <p>b) Treatment of ENDS/ENNDS addiction should be incorporated into existing cessation programmes or included in the design of future cessation programmes.</p>	
Article 15: Illicit trade in tobacco products	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p> <p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) subject to the provisions of the Protocol to Eliminate Illicit Trade in Tobacco Products, considering ENDS/ENNDS (e-cigarettes) as tobacco products including licensing, tracking and tracing, and ban of duty-free sales. Member States are encouraged to</p>	

	become Parties to the Protocol, but in the meantime can use the Protocol documentation to inform national policy.	
Article 16: Sales to and by minors	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of ENDS/ENNDS (e-cigarettes);</p> <p>OR</p> <p>2. Allowing the importation, sale and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions.</p> <p>c) Comprehensively applying Article 16 to ENDS/ENNDS (e-cigarettes), including:</p> <ul style="list-style-type: none"> • requiring a clear and prominent indicator at the point of sale about the prohibition of sales of ENDS/ENNDS (e-cigarettes) to minors; • banning point-of-sale advertising and displays; • prohibiting the manufacture of any object in the form of tobacco products that appeal to minors; • banning ENDS/ENNDS (e-cigarettes) vending machines; • prohibiting the distribution of free ENDS/ENNDS (e-cigarettes) products to the public, especially minors; • prohibiting sales of ENDS/ENNDS in small packets as these increase the affordability of the products to minors. <p>d) Banning the sale or distribution of ENDS/ENNDS (e-cigarettes) near/within educational facilities.</p> <p>e) Banning the sale and distribution of ENDS/ENNDS (e-cigarettes) to minors.</p> <p>f) Regulating places, density and channels of sales (3).</p> <p>g) Setting the age limit for ENDS/ENNDS (e-cigarettes) sales to 21 years.</p> <p>h) Establishing an implementation and enforcement plan including penalties and confiscation of ENDS/ENNDS (e-cigarettes).</p>	<p>Canada</p> <p>Estonia, Germany and Lithuania prohibit use by minors under 18 years old.</p> <p>South Africa</p> <p>The United States of America prohibits sales to anyone under 18 years old. Several states and over 300 localities have age limits of 21 years for sales (50).</p>
Article 20: Research, surveillance and exchange of information	<p>a) Integrating ENDS/ENNDS (e-cigarettes) in ongoing national level surveys that cover all groups (adults and youth). National surveys should be at least every 5 years and be representative of the national population (1).</p> <p>b) It is suggested that Member States use or strengthen their existing tobacco surveillance and monitoring systems to monitor and report on scientific, regulatory, market and product use developments in ENDS/ENNDS (e-cigarettes) use, such as health effects, initiation, cessation, dual/poly-use, advertising and promotion by gender, age and sociodemographic group (51).</p> <p>c) Ensuring that the right questions are included in national surveys to capture these products in order for the results to accurately reflect the country situation.</p>	

8.2 Side-by-side text for HTPs

<p>This side-by-side text advises Member States of the Eastern Mediterranean Region on options to consider in relation to HTPs.</p> <p>It is framed around the articles of the WHO FCTC as a comprehensive approach to tobacco control. This text is necessary as HTPs are a category of product with unconventional characteristics, and many Member States have requested guidance on how best to proceed in relation to these products. It was developed with selected Member States of the Eastern Mediterranean Region, WHO experts and external consultants at a regional consultation.</p> <p>This side-by-side text is not limited to Parties to the WHO FCTC, and could be useful to Member States in other WHO regions.</p>		
WHO FCTC Article	HTPs	Good practice
Article 1: Use of terms	HTPs are tobacco products and Member States should treat and regulate them as such. <i>“HTPs should be subject to the same policy and regulatory measures applied to all other tobacco products, in line with the WHO Framework Convention on Tobacco Control (WHO FCTC)” (5).</i>	
Article 2: Relationship between this Convention and other agreements and legal instruments	To better protect human health, Member States are urged to implement measures and good practice beyond the regulatory options specified in this document and for Parties to the WHO FCTC, beyond those required by the WHO FCTC and its protocols. Therefore, nothing in the document shall prevent Member States from imposing more stringent requirements.	
Article 3: Objective	The objective to reduce continually and substantially the prevalence of tobacco use can be assisted by banning or strongly regulating these products. Member States have banned these products while the evidence is examined and research is conducted.	
Article 5: General obligations	The relevant legislation, national action plans and multisectoral committees related to tobacco control should cover all tobacco products.	
Article 5.3: In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.	Member States can consider regulatory options, such as: 1. Banning the importation, sale and distribution of HTPs; OR 2. Allowing the importation, sale and distribution of HTPs with the following provisions. a) Comprehensively applying Article 5.3 and all COP decisions to HTPs, as HTPs are classified as a tobacco product. b) Data provided by the tobacco industry must be validated using internationally approved methods by scientists with no conflict of interest with the industry. These laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.	
Article 6: Price and tax measures to reduce the demand for tobacco	Member States can consider regulatory options such as: 1. Banning the importation, sale and distribution of HTPs; OR 2. Allowing the importation, sale and distribution of HTPs with the following provisions.	Georgia taxes HTPs, tobacco heat sticks, pods and plugs at the same rate as cigarettes.

	<p>a) Comprehensively applying Article 6 to HTPs as they are tobacco products, aiming to contribute to the public health objective to reduce tobacco consumption and preventing HTPs becoming affordable. No duty-free sales of these products should be allowed.</p> <p>With regards to tobacco sticks, pods or plugs</p> <p>a) Member States should consider applying the same tax rate as applied to the most commonly used premium tobacco product (e.g. some countries apply the same tax rate to HTP sticks, pods and plugs as they apply to cigarettes). WHO recommends that more than 75% of the retail price of a pack of cigarettes should be tax or at least 70% of retail price be excise tax.</p> <p>With regards to the device</p> <p>a) Member States should consider applying excise tax to the device, collected at the manufacturer or importer level; either an ad valorem excise tax with a possible minimum specific floor, or an excise specific tax.</p> <p>b) Member States should consider preventing under-declaring the value of the device in order to pay lower excise duties (ad valorem) and custom duties by establishing a list of prices of comparable products on the market and actively correct prices, and applying a specific excise duty or establishing a minimum value (minimum tax base).</p> <p>c) Member States that apply a higher rate of VAT on tobacco products than on general products should consider applying this higher VAT rate to HTPs.</p> <p>d) Control the importation of separate parts and assembly after importation to avoid excise tax on the device by only allowing manufacturing of devices to licensed operators.</p>	
<p>Article 8: Protection from exposure to tobacco smoke</p>	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs with the following provisions. <p>a) Emissions of HTPs constitute tobacco smoke; therefore, national laws regarding cigarette smoking in public places should apply to HTPs and HTPs should be included in work to comprehensively implement Article 8 in line with the guidelines for implementation.</p> <p>b) A symbol for HTPs should be developed or agreed on, and all no smoking signs should carry the HTP symbol to alert the public.</p> <p>c) All public places listed below should be completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation). Designated smoking rooms should not be allowed, as these do not work and are difficult to enforce.</p> <ul style="list-style-type: none"> • Health-care facilities • Educational facilities other than universities • Universities • Government facilities • Indoor offices and workplaces not considered in any other category • Restaurants or facilities that serve mostly food • Cafés, pubs and bars, or facilities that serve mostly beverages • Public transport • Religious sites. 	<p>Ban on HTP use in enclosed public spaces as per other smoked tobacco products: Austria, Belgium, France, Monaco, Poland, Republic of Korea, Spain, Sweden</p>

	d) A comprehensive implementation plan should be developed and enforced.	
Article 9: Regulation of the contents of tobacco products and Article 10: Regulation of tobacco product disclosures	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs with the following provisions. <ol style="list-style-type: none"> a) Comprehensively apply Articles 9 and 10 to HTPs, as they are tobacco products. <p>Regulating contents of products</p> <ol style="list-style-type: none"> a) In addition to applying the Partial Guidelines for implementation of Articles 9 and 10, safety measures should be developed for HTPs, including considerations about the power of devices (limited to 25 watts) and other measures. b) The design of devices, ingredients and accessories should be regulated in terms of shape and size (e.g. waterpipe device regulations in Turkey), flavours, smell and colours, in line with the Partial Guidelines, in order to prevent these products being perceived as attractive. c) Ban all flavours and components such as packages, capsules or any technical features allowing modification of smell and taste of the product. A flavour ban for HTPs should be accompanied with a corresponding ban on flavours in other tobacco products to prevent users switching to other flavoured products. d) Declaration that the manufacturer and importer bear full legal liability for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions. <p>Disclosures from industry to government</p> <ol style="list-style-type: none"> a) Collecting data via devices, including directly or indirectly from the devices via electronic communication with the device itself, on user preferences and use patterns should be banned. If a ban is not in place, then data collected on devices regarding user preferences and use of device should be shared with governments. b) Manufacturers and third parties should be prohibited from using data on use patterns from devices to feedback to the devices to control the performance of the device, such as controlling puff patterns and intensity or recommending changes in liquid or tobacco plugs. c) Development of a reporting template for product information and requiring electronic reporting of such information. <p>Sanctions</p> <ol style="list-style-type: none"> a) Provide for the removal of products that do not comply with regulations. 	EU
Article 11: Packaging and labelling of tobacco products	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs with the following provisions. <ol style="list-style-type: none"> a) As HTPs are tobacco products, comprehensively applying Article 11 including enforcing a law requiring mandated specific graphic health warnings covering at least 50% of the inner and outer packaging of all devices and tobacco heat sticks, pods or plugs (like packaging of midwakh in Gulf Cooperation Council 	Republic of Korea

	<p>countries). The warnings should be large, clear, visible and legible (i.e. specific colours, font style and sizes are mandated), written in the principle language of the Member State and regularly rotated.</p> <p>b) Consider all lateral sides of packs and of devices to be main display areas.</p> <p>c) Member States applying plain packaging for tobacco products should apply the same for HTPs (including both devices and tobacco heat sticks, pods or plugs).</p>	
Article 12: Education, communication, training and public awareness	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of HTPs; OR</p> <p>2. Allowing the importation, sale and distribution of HTPs with the following provisions.</p> <p>a) Comprehensively applying Article 12 as HTPs are tobacco products.</p> <p>b) Educating people that HTPs are not vaping products.</p> <p>c) HTPs should be integrated into public education programmes, specifically to debunk myths about HTPs that are being promoted by manufacturers and sellers.</p> <p>d) If there is a substantial illegal promotion for HTPs, such as via the internet, Member States should include HTPs in educational programmes to counter this promotion, provided a judgement is made that doing so will reduce rather than increase demand for these products.</p>	
Article 13: Tobacco advertising, promotion and sponsorship (TAPS)	<p>Member States can consider regulatory options such as:</p> <p>1. Banning the importation, sale and distribution of HTPs; OR</p> <p>2. Allowing the importation, sale and distribution of HTPs with the following provisions.</p> <p>a) Comprehensively applying Article 13 by implementing a comprehensive ban on all forms of TAPS, direct or indirect, as HTPs are tobacco products.</p> <p>b) As in Article 13, indirect bans should include the free distribution of devices or tobacco heat sticks, pods or plugs in the mail or through other means, as well as promotional discounts, home delivery and online purchasing (49).</p> <p>c) Banning all form of direct and indirect advertising.</p> <ul style="list-style-type: none"> • Direct advertising bans: <ul style="list-style-type: none"> – national television and radio; – local magazines and newspapers; – billboards and outdoor advertising; – point-of-sale advertising and display; – internet, social media and mobile apps. • Indirect advertising (promotion and sponsorship) bans: <ul style="list-style-type: none"> – free distribution of tobacco products in the mail or through other means; – promotional discounts; – non-tobacco products identified with tobacco brand names (brand stretching); – brand names of non-tobacco products used for tobacco products (brand sharing); 	<p>Banned as per other smoked tobacco products: Austria; Belgium; Japan Lithuania; Netherlands; Norway; Poland; Republic of Korea; Spain Sweden; Switzerland; Ukraine; United Kingdom of Great Britain and Northern Ireland</p>

	<ul style="list-style-type: none"> – appearance of tobacco brands (product placement), and appearance of tobacco products, in television and/or films; – sponsorship, including corporate social responsibility programmes. <p>d) The ban should include medical and public health events, social media and mobile apps, and internet videos and streaming.</p>	
Article 14: Demand reduction measures concerning tobacco dependence and cessation	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs with the following provisions. <ol style="list-style-type: none"> a) HTPs are not to be considered a cessation product. b) Comprehensively applying Article 14, as HTPs are tobacco products. 	
Article 15: Illicit trade in tobacco products	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs, subject to the provisions of the Protocol to Eliminate Illicit Trade in Tobacco Products, considering HTPs as tobacco products. This includes licensing, tracking and tracing, and ban of duty-free sales. Member States are encouraged to become Parties to the Protocol, but in the meantime can use the Protocol documentation to inform national policy. 	
Article 16: Sales to and by minors	<p>Member States can consider regulatory options such as:</p> <ol style="list-style-type: none"> 1. Banning the importation, sale and distribution of HTPs; <p>OR</p> <ol style="list-style-type: none"> 2. Allowing the importation, sale and distribution of HTPs with the following provisions. <ol style="list-style-type: none"> a) Applying Article 16 comprehensively to HTPs, as they are tobacco products, including: <ul style="list-style-type: none"> • requiring clear and prominent indicators at the point of sale about the prohibition of HTP sales to minors; • banning point-of-sale advertising and displays; • prohibiting the manufacture of any object in the form of tobacco products that appeal to minors; • banning HTP vending machines; • prohibiting the distribution of free HTPs to the public, especially minors; • prohibiting sale of HTPs and tobacco heat sticks, pods or plugs as single units, as these increase the affordability of the products to minors. b) Banning the sale or distribution of HTPs near/within educational facilities. c) Banning the sale and distribution of HTPs by minors. d) Regulating places, density and channels of sales (3). e) Setting the age limit for HTPs use to 21 years. f) Establishing an implementation and enforcement plan, including penalties and confiscation of HTP devices. 	<p>Austria; Belgium; Canada; Czech Republic; France; Israel; Japan; Lithuania; Monaco; Netherlands Norway; Poland; Portugal; Republic of Korea; Spain Sweden; Ukraine</p>

	<ul style="list-style-type: none"> g) Banning the sale of single units. h) Banning internet sales and requiring age verification to access HTP manufacturers' websites. 	
Article 20: Research, surveillance and exchange of information	<p>HTPs are tobacco products and so Article 20 should be comprehensively applied. HTPs should be part of the tobacco use indicator and the tobacco reduction target.</p> <ul style="list-style-type: none"> a) Integrate HTPs in ongoing national level surveys that cover all groups (adults and youth). National surveys should be at least every 5 years and be representative of the national population (1). b) It is suggested that Member States use or strengthen their existing tobacco surveillance and monitoring systems to monitor and report on scientific, regulatory, market and product use developments in HTP use, such as health effects, initiation, cessation, dual/poly-use, advertising and promotion by gender, age and sociodemographic group (47). c) Ensure that the right questions are included to capture these products in order for the results to accurately reflect the country situation. 	

9. NEXT STEPS

It was agreed by participants that the side-by-side texts produced during the regional consultation provide a set of provisional recommended actions for regulators and are intended to feed into a global WHO consultation to be held in early 2020 that will provide regulatory options for Member States based on WHO FCTC commitments and international best practices. WHO will continue to monitor emerging science, country experience and market developments and will update these options, as necessary, based on new knowledge.

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Annex 1**PROGRAMME****Wednesday, 3 July 2019**

- 09:00–09:30 Opening Session
- Regional Director’s welcome
 - Introduction
Dr Asmus Hammerich, Director, Noncommunicable Diseases and Mental Health, WHO Regional Office for the Eastern Mediterranean
 - Introduction to participants
 - Introduction to the challenge
Dr Fatimah El-Awa, Regional Advisor, Tobacco Free Initiative, WHO Regional Office for the Eastern Mediterranean
 - Review of the programme
- 09:30–10:00 The overarching scientific evidence on ENDS, ENNDS and HTPs
Dr Ghazi Zaatari, Professor, Department of Pathology and Laboratory Medicine, Faculty of Medicine, American University of Beirut, Lebanon
- 10:30–11:00 Identifying the problem: ENDS and HTPs
- What are the unique challenges associated with ENDS?
 - What are the unique challenges associated with HTPs?
 - What are the common challenges associated with these products?
 - What are the regulatory implications?
- Open discussion on challenges and country views
Dr Slim Slama, Regional Advisor, Noncommunicable Diseases Prevention, WHO Regional Office for the Eastern Mediterranean (Moderator)
- 11:00–11:30 ENDS, ENNDS and HTPs prevalence in the Region
Dr Heba Fouad, Regional Surveillance Officer, Noncommunicable Diseases Surveillance, WHO Regional Office for the Eastern Mediterranean
- 11:30–12:30 Global recommendations (WHO FCTC/WHO) on ENDS and HTPs and the relevant Articles of the WHO FCTC
Dr Ranti Fayokun, National Capacity Scientist, WHO headquarters
- 12:30–13:30
- ENDS and HTPs
 - ENDS Taxation
Ms Annerie Bouw, Consultant, WHO headquarters
 - Policy considerations and approaches towards regulating ENDS and HTPs (with a focus on Protecting users and non-users and Preventing unproven health claims)
Dr Derrick Heng, Group Director, Public Health Group, Ministry of Health, Singapore

- 14:30–15:30
- ENDS and HTPs
 - European perspective on policies to control ENDS and HTPs
Dr Matus Ferech, Tobacco Control Team, European Commission (in a personal capacity)
 - Preventing youth initiation
Dr Ranti Fayokun, National Capacity Scientist, WHO headquarters
 - Protecting tobacco control policies from vested interest
Ms Lily Joung-eun Lee, Technical Officer, Korea Health Promotion Institute, Seoul, Republic of Korea
- 16:00–16:30 Overview of the tobacco industry (traditional and emerging products),
Remote presentation by Professor Stanton Glantz, Director, Center for Tobacco Research Control & Education, University of California San Francisco, United States of America
- 16:30–17:00 Summary of day one and plan for next day
Dr Fatimah El-Awa, Regional Advisor, Tobacco Free Initiative, WHO Regional Office for the Eastern Mediterranean

Day Two: Thursday, 4 July 2019

- 09:00–09:30 Illicit tobacco trade in ENDS/ENNDS and HTPs,
Mr Austin Rowan, Member of the Expert Panel on the Protocol
- 09:30–10:00 Countries' experiences in establishing strong policies to control ENDS and HTPs:
- Flavour regulation in the EU
Remote presentation by Dr Reinskje Talhout, Senior Scientific Advisor Tobacco Regulatory Science, National Institute for Public Health and the Environment, Netherlands
- 10:15–11:30 Countries' experiences in establishing strong policies to control ENDS and HTPs:
- Singapore's experience
Dr Derrick Heng, Group Director, Public Health Group, Ministry of Health of Singapore
 - Italian experience of regulating HTPs
Dr Lorenzo Spizzichino, Statistical Officer, General Directorate for Prevention, Ministry of Health, Italy
 - TAPS prohibition, country examples, *Several countries*
 - GHW implementation on ENDS and HTPs, *Several countries*
- 11:30–13:00
- Working groups: Implementation of Global Recommendations on ENDS/ENNDS
 - Agreeing on the elements in the side-by-side text for implementation of the WHO FCTC on ENDS and ENNDS
 - Groups will be divided as follows:
 - Group 1: Articles 6 & 15
 - Group 2: Articles 11, 13 & 16
 - Group 3: Articles 8 & 14

- Group 4: Articles 5, 12 & 20
- Group 5: Articles 9 & 10

14:00–15:30	Working groups: Implementation of Global Recommendations (HTPs)
15:30–16:00	Reports to the plenary
16:00–16:30	Open discussion on the next steps from WHO, WHO FCTC, and Member States
16:30–16:45	Closure

