This side-by-side text advices WHO Member States in the Eastern Mediterranean Region on options to consider in relation to ENDS/ENNDS (e-cigarettes).

It is framed around the WHO FCTC Articles as these are a comprehensive to tobacco control. This text is necessary as ENDS/ENNDS (ecigarettes) are a new type of product and many Member States have request guidance in how best to proceed in relation to these products. It was developed with selected Member States from the region, WHO experts and external consultants at a regional consultation in WHO EMRO. This side-by-side text is not limited to Parties to the WHO FCTC and could be useful to WHO Member States in other WHO Regions.

Article FCTC	ENDS/ENNDS	Best practice
Article 1: Use of Terms	Although ENDS and ENNDS are not classified as tobacco products by WHO, Member	Georgia
	States may wish to opt for the regulatory option of treating ENDS/ENNDS (e-cigarettes)	South Africa
	as tobacco products for regulatory purposes. Some of the reasons for this option, in	Turkey
	addition to the COP recommendation, are listed below	
	a) ENDS and ENNDS contain or have been generally found to contain nicotine	In the USA
	which is a substance predominantly derived from tobacco.	ENDS/ENNDS are
	b) The use of ENDS and ENNDS mimic tobacco use in terms of physiological and	considered tobacco
	behavioral addiction and method of consumption.	products under the
	c) The evidence surrounding the claims that all ENDS and ENNDS carry reduced	FDA deeming rule,
	health risks are inconclusive and not agreed upon by the scientific and public	although the FDA has
	health community. There is also growing evidence and concern of the	not yet required
	negative health effects of these products	ENDS/ENNDS
	d) The claim that ENDS and ENNDS can be used as a cessation aid is heavily	companies to submit
	debated and not substantiated at population level.	their products or
	e) ENDS and ENNDS are attractive to youth; their use has been a gateway to	modified risk claims for
	initiation of tobacco use and dual/poly-use of tobacco products in some countries.	FDA evaluation
	f) ENDS and ENNDS are manufactured, distributed and sold by the well-known	
	multinational tobacco industry players, as well as other related industries.	
	g) The World Bank working note recommends that for taxation purposes all e-	
	products should be classified as "tobacco products" and covered by the 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".   h) ENNDS or both ENDS/ENNDS (e-cigarettes) should not be exempt from national tobacco control plans; exempting them will weaken the impact of tobacco control regulations.  It is worth noting that the use of the terms ENDS and ENNDS was considered unhelpful by some participants of the meeting because of the connotation that such products are 'ending the tobacco use epidemic'.  This means that ENDS and ENNDS can be considered as tobacco alike products; so 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-	
Article 2	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 countries from imposing more stringent requirements.	
Article 3	The objective to reduce continually and substantially the prevalence of tobacco use can be met by banning or strongly regulating ENDS/ENNDS (e-cigarettes) products.	
Article 5 : General Obligations	The relevant legislation, multi-sectoral committees and national action plans of tobacco control should cover tobacco, tobacco-related products and alternatives.  ENDS and ENNDS should all be included in this regardless of if Member States consider ENDS/ENNDS (e-cigarettes) to be tobacco products or alternative products.	

<sup>&</sup>lt;sup>1</sup> WORKING NOTE; E-CIGARETTES: USE AND TAXATION. WBG Global Tobacco Control Program Team

<sup>&</sup>lt;sup>2</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

Article 5 .3 : In setting	Member States can consider regulatory options such as	
and implementing their	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	
public health policies	OR	
with respect to tobacco	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with	
control,	the following provisions	
Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law.	<ul> <li>a) Applying guidelines for implementation of Article 5.3 and all COP decisions with a broader definition of tobacco industry to include "manufacturers, wholesale distributors and importers of tobacco products; tobacco, tobacco related products and alternatives industries."</li> <li>b) Data provided by the 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.<sup>3</sup></li> </ul>	
Article 6: Price and tax	Member States can consider regulatory options such as	South Korea
measures to reduce the	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	Bahrain
demand for tobacco	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 accordingly to the public health	
	objective of the Member State. Member states could consider applying excise tax to the devices and e-liquids collected at the manufacturer or importer level.	
	b) In Member States which consider ENDS/ENNDS (e-cigarettes) as a tobacco product then Member States could consider applying Article 6 comprehensively and aiming that >75% of retail price is tax or at least 70% of retail price is excited to the state of the state o	
	retail price is excise taxes. c) Member states should consider taxing ENDS/ENNDS at a level that makes them unaffordable to minor in order to deter its use in this age group- this will require an excise tax.	
	Issues likely to arise with ENDS/ENNDS (e-cigarettes) taxation and potential	
	approaches include :	

<sup>3</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

- a) State owned companies
  - o See Article 5.3
- b) Refills
  - Attempts to circumvent taxation
    - Develop a clear definition of the tax base, detectable upon importation. This may be volume of liquid, or nicotine concentration.
    - Only allow importation and/ or production for licensed operators
    - o Regulate the strength and volume of e-liquids
  - Different results from the same batch of products
    - Test products in government or independent laboratories which 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
    - Implement strong enforcement mechanisms such as licensing, record keeping, control of the supply chain (see the Protocol on the elimination of illicit trade in tobacco products and article 15 below)
- c) Device
  - Under-declaring the value of the device in order to pay less excise duties (ad valorem) and custom duties:
    - 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 could consider applying this higher rate of VAT also to ENDS/ENNDS (e-cigarette) devices.
  - Importation of separate parts and assembly after importation to avoid excise tax on the device
    - Only allowing manufacturing of devices to licensed operators.

Article 8 : Protection	Member States can consider regulatory options such as	Fifty-one member
from exposure to	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	states prohibit or
tobacco smoke	OR	restrict the use of e-
	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with	cigarettes in public
	the following provisions:	places. USA does not
	a) Emission of ENDS and ENNDS shall be considered as tobacco smoke alike and	allow ENDS on
	therefore included in work to comprehensively implement article 8 in line with the guidelines for implementation.	airplanes
	b) A sign for ENDS/ENNDS (e-cigarettes) should be developed and then all no	Use is prohibited in
	smoking signs should carry the signs of ENDS/ENNDS (e-cigarettes) to alert the public to them. <sup>4</sup>	vehicles with minors in Austria (18 years),
	c) All public places listed below completely smoke-free (or at least 90% of the population covered by complete subnational smoke-free legislation).  Designated Smoking Rooms are not allowed.  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 transports  Religious sites	Cyprus, (18 years), Finland (15 years), Malta (16 years), Moldova (18 years), Slovenia (18 years) and Tajikistan (16 years). Cyprus also prohibits use in personal vehicles with a pregnant woman.
	d) A comprehensive implementation plan should be drafted and enforced	
Article 9 : Regulation of	Member States can consider regulatory options such as	Thirty-two EU Member
the contents of tobacco	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	States regulate the
products	OR	amount
&	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) in line	(concentration/volume
Article 10 : Regulation of	with the guidelines for the implementation of Articles 9 and 10 and with the following	) of nicotine in e-liquids
tobacco product	additional considerations	— in the EU the
disclosures	Disclosures from industry to government	threshold
		concentration is

<sup>4</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

- 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 this 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) Require manufacturers to monitor and report adverse effects
- d) Toxicological data in line with Articles 9 and 10, as well as considering the range of potential concentrations possible and temperatures and not simply the advised concentration and temperature (reasonably foreseeable conditions).
- e) Information on nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
- f) Description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;
- g) 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.
- h) Development of a reporting template for product information and requiring electronic reporting of such information

## Disclosure from government to the public:

- 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.<sup>5</sup>
- b) Information must be comprehensible and descriptive

Monitoring and regulating contents of products

20mg/mL

Thirty-two 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 nicotinecontaining e-liquid.

Thirty-one member states regulate the quality of nicotine and other ingredients used to manufacture the eliquid; require products to pass safety and quality evaluation; or regulate flavors that can be used in e-liquids

Thirty-four member states have regulations that require manufacturers/retailer s to notify the competent authority prior to introducing ecigarettes to the market, as well as

<sup>&</sup>lt;sup>5</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

	a) Creating a 'negative list' of banned or restricted substances based on	submit an annual
	substances associated with ENDS/ENNDS (e-cigarettes) products which pose	report of sales and
	serious toxicological concern, such as diacetyl, acetyl propionyl,	other specified
	cinnamaldehydes or benzaldehyde	information.
	b) Ban all flavours or 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 flavored" that would be used for enforcement purposes of a flavor	
	ban.	
	d) If a total ban is not possible then create a 'positive list' of allowed flavours that	
	would be created by manufacturers applying for approval for specific flavors	
	rather than banning certain flavours. This will be more manageable to enforce	
	rather 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.	
	f) Setting limits such as 20mg/mL nicotine in e-liquids; and limits to the	
	concentration of aldehydes and heavy metals in emissions that are permitted.	
	g) Regulatory standards for e-cigarette devices, such as electrical and fire safety	
	standards which will regulate the power to below 25 Watts	
	h) The containers of e-liquids for refillable e-cigarettes should not exceed a	
	volume of 10ml and a volume of tank size not more than 2 ml for disposable e-	
	cigarettes and single use e-cartridges or pods.	
	i) Reducing the risk of accidental acute nicotine intoxication by	
	i) Requiring tamper evident/ child resistant packaging for e-liquids and leak-	
	proof containers for devices and e-liquids	
	ii) Limiting the nicotine concentration and total nicotine amount in devices and	
	e-liquids. <sup>6</sup>	
	Sanctions	
	a) Providing for the removal of products that do not comply with regulations	
Article 11 : Packaging	Member States can consider regulatory options such as	Georgia
and labelling of tobacco	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	South Korea
products	OR	

<sup>6</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

Article 12 : Education, communication, training and public awareness	Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)     OR     Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with
communication, training	
Autiala 40 : Educantiau	Member States can consider regulatory options such as
Article 12 : Education	same for ENDS/ENNDS (e-cigarettes) (devices & refills)  f) Prohibiting implicit or explicit claims about the comparative safety or addictiveness of ENDS/ENNDS (e-cigarettes) with respect to any product <sup>8</sup> g) Prohibiting implicit or explicit claims that ENDS/ENNDS (e-cigarettes) are harmless or that ENDS/ENNDS (e-cigarettes) are not addictive;  h) Prohibiting implicit or explicit claims that ENDS/ENNDS (e-cigarettes) are effectiveness as smoking cessation aids. Not a smoking cessation device unless regulated as a pharmaceutical product and approved as one.  i) Control the design of devices and accessories in terms of shapes & size (e.g. Turkey waterpipe device regulations), flavors, smell, colors  j) The use of cartoon characters or other attractive features to young people should be banned  Member States can consider regulatory options such as
	<ul> <li>2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions: <ul> <li>a) Enforce a law requiring mandated specific health warnings covering at least 50% of the inner and outer packaging of device and e-liquid bottles, e.g., packaging of midwakh in GCC</li> <li>b) Health warnings can cover nicotine addiction, cardio-vascular and pulmonary disease risks allowing for new health evidence to be included as more research is carried out.</li> <li>c) Health warnings should be in line with proven health risks<sup>7</sup></li> <li>d) The warnings should be large, clear, visible and legible (e.g. specific colors and font style and sizes are mandated), written in the principle language of the country and regularly rotated.</li> <li>e) Member States applying plain packaging for tobacco products should apply the</li> </ul> </li> </ul>

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	a) Comprehensively applying Article 12 in particular prohibiting implicit or explicit claims about	
	b) The effectiveness of ENDS/ENNDS (e-cigarettes) as smoking cessation aids	
	c) ENDS/ENNDS (e-cigarettes) being harmless or non-addictive;	
	d) the comparative safety or addictiveness of ENDS/ENNDS (e-cigarettes) with respect to any product <sup>9</sup>	
	e) If these products are planned to be categorized as drugs they should follow the same regulations as nicotine replacement therapy providing proof of safety, efficiency through clinical trials as with other drugs.	
	f) ENDS/ENDDS should be integrated into public education programs, specifically	
	to debunk myths about ENDS/ENDDS that are being promoted by manufacturers and sellers.	
	g) If there is a substantial illegal promotion for ENDS/ENNDS such as via the	
	internet, member states should include ENDS/ENNDS in educational programs	
	to counter this promotion if a judgement is made that doing so will reduce	
	rather than increase demand for these products.	
Article 13 : Tobacco	Member States can consider regulatory options such as	UK
advertising, promotion and sponsorship	Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)  OR	Canada
	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions:	
	a) Applying Article 13 comprehensively by applying a comprehensive ban on all forms of TAPS: direct or indirect. <sup>10</sup>	
	Direct advertising bans:	
	<ul> <li>National television and radio;</li> </ul>	
	<ul> <li>Local magazines and newspapers;</li> </ul>	
	<ul> <li>Billboards and outdoor advertising;</li> </ul>	
	<ul> <li>Point of sale- internet</li> </ul>	
	<ul> <li>Social media and mobile apps</li> </ul>	
	Indirect advertising bans:	

<sup>&</sup>lt;sup>9</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO <sup>10</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

	<ul> <li>Free distribution of tobacco products in the mail or through other means;</li> <li>Promotional discounts;</li> <li>Non-tobacco products identified with tobacco brand names (brand stretching);</li> <li>Brand names of non-tobacco products used for tobacco products (brand sharing);</li> <li>Appearance of tobacco brands (product placement) OR appearance of tobacco products, in television and/ or films;</li> <li>Sponsorship, including corporate social responsibility programmes</li> <li>Ban should include medical society and medical events; social media and mobile apps; internet videos and internet streaming adverts.</li> <li>As in Article 13 the indirect bans should include free distribution of devices or device refills products in the mail or through other means; as well as promotional discounts and home delivery and online purchasing.<sup>11</sup></li> </ul>	
Article 14 Demand	Member States can consider regulatory options such as	Several states in the
reduction measures concerning tobacco	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) OR	USA have educational programs on ENDS:
dependence and	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with	https://flavorshookkids
cessation	the following provisions:	.org and the FDA- Real
	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.	Cost campaign is an educational progamme for children.
Article 15 : Illicit trade in	Member States can consider regulatory options such as	
tobacco products	Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)  OR	
	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes)	
	subject to the provisions of the protocol of the illicit trade in tobacco products	
	considering ENDS/ENNDS (e-cigarettes) as tobacco products including: licensing,	

<sup>11</sup> Guidelines for implementation of the WHO FCTC Article 5.3 | Article 8 | Articles 9 and 10 | Article 11 | Article 12 | Article 13 | Article 14

	tracking and tracing and ban of duty-free sales. Member states are encouraged to	
	become parties of the Protocol, but in the meantime can use the protocol	
	documentation to inform national policy.	
Article 16 : Sales to and	Member States can consider regulatory options such as	South Africa
by minors	1. Banning the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) OR	Canada
	2. Allowing the importation, sale, and distribution of ENDS/ENNDS (e-cigarettes) with the following provisions:	Estonia, Germany and Lithuania prohibit use by minors under 18
	<ul> <li>a) Applying Article 16 comprehensively to ENDS/ENNDS (e-cigarettes), including</li> <li>Clear and prominent indicator at the point of sale about the</li> </ul>	years.
	prohibition of tobacco sales to minors	USA prohibits sales to
	Ban point of sale advertising	anyone under 18.
	<ul> <li>Prohibit the manufacture of any object in the form of a tobacco products which appeals to minors</li> </ul>	Several states and over 300 localities have
	Ban tobacco vending machines.	sales limits of 21. <sup>13</sup>
	<ul> <li>Prohibit the distribution of free tobacco products to the public, especially minors.</li> </ul>	
	<ul> <li>Prohibit sales of ENDS/ENNDS in small packets as these increase the affordability of the products to minors.</li> </ul>	
	<ul> <li>b) Banning the sale or distribution of ENDS/ENNDS (e-cigarettes) near/within educational facilities;</li> </ul>	
	c) Banning the sale and distribution of ENDS/ENNDS (e-cigarettes) by minors;	
	d) Regulating places, density and channels of sales. 12	
	e) Set the age limit for ENDS/ENNDS (e-cigarettes) use to 21.	
	<ul> <li>f) Establish an implementation and enforcement plan including penalties and confiscation of ENDS/ENNDS (e-cigarettes) devices.</li> </ul>	
Article 20: Research, surveillance and	a) Integrate ENDS/ENNDS (e-cigarettes) in ongoing national level surveys that cover all groups (adults and youth). National surveys should be at least every 5	
exchange of information	years and be representative of the national population. 14	

<sup>&</sup>lt;sup>12</sup> COP 7/11. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS (e-cigarettes)). Report by WHO

<sup>&</sup>lt;sup>13</sup> https://tobacco21.org

<sup>&</sup>lt;sup>14</sup> FCTC/COP/6/10 Rev.1 Electronic nicotine delivery systems Report by WHO

b)	surveillance and monitoring systems to monitor and report on scientific, regulatory, market and product use developments in ENDS/ENNDS (ecigarettes) use such as health effects, initiation, cessation, dual/poly-use, advertising and promotion by gender, age and socio-demographic groups. 15	
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<sup>15</sup> DECISION: FCTC/COP7/9 Electronic nicotine delivery systems and electronic non-nicotine delivery systems